

NHS: ISB – DRAFT OPERATIONAL INFORMATION STANDARD SUBMISSION

NAME OF DRAFT STANDARD

Common Data Set for Sexual Health

DEVELOPER

Department of Health – Sexual Health team

David Helson	David.Helson@aeat.co.uk
Scott Hanchett	Scott.Hanchett@aeat.co.uk
Mike Catchpole	Mike.Catchpole@hpa.org.uk
Alan Lodwick	Alan.Lodwick@dh.gsi.gov.uk

There will be an overall sexual health standard with three sub classifications for the following areas:

- GUM Clinics/Integrated services
- CCS (Community Contraceptive Services)
- GP (General Practice)

SPONSOR

The sponsor is:

Department of Health
Sexual Health team
Wellington House
London
SE1 8UG

Contact: Alan.Lodwick@dh.gsi.gov.uk

A letter of sponsorship from Department of Health (Andrea Duncan: Programme Manager, Sexual Health) is attached within **Appendix 1** of this submission. This updates an earlier letter provided with Version 1.1 of the REQUIREMENT submission in 29-4-05, signed by Cathy Hamlyn the then Head of Sexual Health and Substance Misuse at the Department of Health

Government approval and/or policy

The main DH policy documents supporting the development and use of this Standard are:

- The National Strategy for Sexual Health and HIV (July 2001),
- 'Recommended standards for Sexual Health Services', March 2005, (nearest equivalent to an NSF for sexual health) Author: Medical Foundation for AIDS and Sexual Health (MedFASH)
- Choosing Health (White Paper: November 2005),

How the Standard is intended to relate to the National Programme for IT

With regard to the relation of the Standard to the National Programme for IT, a new letter from Jeremy Thorp (Technology Office) was requested on 17-8-06. The requirement is for a letter confirming awareness of CDSSH, how it will fit with NHS Connecting for Health etc. A recent response dated 6th November can be seen in Appendix 1. The previous response and endorsement from Jeremy Thorp (dated 14-9-05) was enclosed with version 1.2 of the REQUIREMENT submission. A further copy is also contained within Appendix 1.

The CDSSH defines a set of information to support various secondary uses that NPfIT electronic patient record systems and associated reporting and data "warehouse" systems will need to be able to support.

For secondary uses, the expectation is that the dataset information (from GP / GU / CCS settings) will be forwarded initially to the central 'Data Warehouse' run by the BT national contract. Relevant anonymised data can then be made available via the Secondary User Service SUS to external organisations (Health Protection Agency – Centre for Information or individual clinical sites) for analysis. It is important to link the common data set into the SUS specification (ie within the BT national contract). Our recent understanding (November 2006) from discussion with Jeremy Thorp is that the NASP contract with BT, responsible for delivering SUS, is currently limited to collection of summary level data only (e.g. QMAS) from primary care. In the light of this recent information, the Developers will need to investigate and consider alternative options for collecting CDSSH data from GPs (see also sub-section within 'Scope' under the title of 'Envisaged data flow from GP systems').

It is envisaged that the sexual health data set will be handled as part of the secondary uses service of NHS Connecting for Health, with mandated data being transferred through the spine to the relevant data repository.

Interim solutions, involving transfer of pseudonymised data from GUM services to HPA are also described, as a fall back position should NHS CfH not be able to deliver the required EPR and reporting systems within the tolerances of DH's timescales for this.

It is acknowledged and intended that the data set will eventually migrate to being derived from a SNOMED CT-compatible data set. The CDSSH developers are engaged in ongoing correspondence with the NHS CfH technology service to ensure compliance with SNOMED CT coding where it already exists – and to create new codes to support CDSSH items where SNOMED CT codes do not yet exist

Dependency on NPfIT

The Developers' premise is that the CDSSH will be derived from and is therefore reliant upon the EPR that is central to the NPfIT OBS. The CDSSH project seeks only to provide appropriate definitions and guidance material to enable a standardised data set to be derived from clinical settings providing sexual health services i.e. specialist GUM clinics, community contraceptive and family planning services, and general practice.

The degree and nature of reliance upon NPfIT solutions varies by setting as follows:

- **GP setting**

In the GP setting, full implementation is dependent on NPfIT solutions. Without functioning EPR, spine and SUS (provided by NPfIT), CDSSH will not be deliverable in the 'standard' GP setting. As mentioned previously, there may be alternative options for the Developers to consider such as a focus on the relatively small number of GP sites offering enhanced sexual health services, currently estimated by DH to be approximately 50).

- **CCS setting**

CCS sites are currently very poorly provided with IT infrastructure, typically lacking suitable PCs, local networking and software for recording clinical data. Without these prerequisites, it will not be possible for CCS to collect EPR. The CDSSH Developers had previously assumed that these costs would be part of the core NPfIT/LSP contract, but are advised that these costs would in fact fall to PCT/SHA. CDSSH is therefore reliant upon PCTs to fund the necessary local IT infrastructure – and, we assume, upon NPfIT to provide the necessary EPR capability and data transfer systems for collation of data within SUS (as a minimum this will be required for SUS to be able to support the central return requirements, KT31, from CCS) as a prerequisite to derive CDSSH from the CCS setting.

- **GUM setting (including Integrated Sexual Health Services)**

The majority (at least 90%) of GU clinics have IT systems. These are typically provided by one of three main IT suppliers. These systems are technically capable of recording the majority of patient record data although currently they are rarely used to the full extent of this capability. The NPfIT solution may (it is not yet known) allow for some or all of these legacy systems. In the absence of NPfIT-provided solutions for EPR etc, it should be technically feasible to modify these existing systems to derive CDSSH data for output to a central data warehouse (such as HPA). The Developers prefer to await the NPfIT solution in order to implement CDSSH. Subject to the requested response from the NPfIT Technology Office on availability of necessary NPfIT functionality, it may be appropriate to consider modification of the existing IT supplier systems as a Phase 1 for implementing the CDSSH within the GU setting.

CUSTOMER NEED

The main need is to achieve a sustainable improvement in sexual health, which the current status of available data does not readily support e.g. it is currently not possible to include gonorrhoea incidence data in the local health profiles that have been developed by the DH Public Health Information and Intelligence Task Force.

During the past decade, the rates of sexually transmitted infections (STIs) including human immunodeficiency virus (HIV) have escalated at an alarming rate in the

United Kingdom. Unintended pregnancies also continue at a high rate. England currently has one of the highest teenage birth rates in Western Europe. Evidence of increased risk taking and, often, poor control of infections, have all helped to raise the level of concern among health professionals, the Government and the public.

The NHS provides a comprehensive range of sexual health services – including GUM clinics, community contraceptive services (CCS) clinics and services in primary care – but analysis undertaken in developing the National Strategy for Sexual Health and HIV has indicated that ‘too often [services] are fragmented, poorly advertised and too narrowly focused. Access is a problem in most parts of the country. Information on sexual health is often out of date or simply not available’.

The National Strategy for Sexual Health and the more recent ‘Choosing Health’ White Paper set out a programme that begins to put things right. This strengthens existing programmes that prevent sexual health problems, and sets out important new measures for improving people’s understanding of the issues, for better planning of services and for better provision of treatment. The Choosing Health White Paper announced the intention to set a goal that, by 2008, everyone referred to a GUM clinic should be able to have an appointment within 48 hours. It also signals the establishment of a Health Information and Intelligence Task Force to lead action to develop and implement a comprehensive public health information and intelligence strategy. This includes working with the Health Protection Agency to develop effective systems in Sexual Health.

To support the implementation and monitoring of the National Strategy, the Department of Health is seeking to develop a Common Data Set for Sexual Health (CDSSH). The Common Data Set is intended to provide a single, standard structure for collecting data on sexual health within the National Health Service. It will apply to each of the main settings providing sexual health services i.e. Genito-Urinary Medicine (GUM) clinics, integrated sexual health services, contraceptive services and primary care.

The main goal for implementing a common data set is to obtain common disaggregate data from different settings that will enable the Department of Health and the Health Protection Agency Centre for Infection to improve surveillance of sexually transmitted infections and other sexual behaviour related health issues as well as to improve its ability to monitor and implement the sexual health strategy. The data set will also provide improved information for service planning and monitoring (e.g. 48hr waiting times) by PCTs and acute and community trusts.

REQUIREMENT STAGE

The following table sets out the response to the ISB feedback from the Requirement submission, addressing points raised and detailing actions taken as a result.

Each feedback item was addressed within the revised Requirement document, version 1.2, submitted to ISB on 30-9-05

ISB feedback / points raised	Developer response / actions taken
1. Finally clarify the purpose of the standard and indicate sponsor sign off to the revised version of the submission.	Addressed within the revised Requirement document, version 1.2, submitted to ISB on 30-9-05. Also clarified within this submission.
2. Explicitly state whether an interim position for implementation is intended by the sponsor in advance of CfH supplied systems in a revised version of the submission and how this will be operationalised and funded.	Addressed within the revised Requirement document, version 1.2, submitted to ISB on 30-9-05. Also clarified within this submission (see 'Implementation')
3. Revise the timescale included in the submission to give realistic achievement dates for all activities up to and including implementation.	Addressed within the revised Requirement document, version 1.2, submitted to ISB on 30-9-05. Further changes are included with this submission....see 'Implementation'.
4. Explicitly state in a revised version of the submission the mechanism for securing ROCR participation and agreement in this development.	Copy of original email dated 21 st July from Steve Webster (ROCR) to ISB and Department of Health was attached with revised Requirement submission to ISB on 30-9-05. A further copy is attached with this submission (within Appendix 1)
5. Secure an explicit reference from CfH Technical Office supporting this development. Note: ISB expect this will to include acknowledgement of DH intentions and timescales.	Supplied by email from Jeremy Thorp to ISB on 14-9-06. A further copy is attached with this submission (within Appendix 1)
6. Secure an explicit reference from PIAG supporting this development and its intentions for patient confidentiality.	A letter from Karen Thomson, (Head of Operations at the Patient Information Advisory Group) was attached with our email to ISB dated 30-9-05. A further copy is attached with this submission (within Appendix 1)
7. Describe plans on how the issues of Patient identification are to be resolved for information to flow through SUS	Addressed within the revised Requirement document, version 1.2, submitted to ISB on 30-9-05. Also see additional comment within 'Issues of patient identification' beneath this table.
8. Explicitly state in a revised version of	The Developers have provided detail of

<p>the submission how the support of key nursing stakeholder groups will be gained. Also do this for the National Midwifery Council.</p>	<p>the CDSSH and sought feedback from the Royal College of Nurses (RCN), the National association of Nurses for contraception and sexual health (NANCSH) and the Nursing & Midwifery Council (NMC). The majority of feedback to date has been from RCN via three separate adviser groups for sexual health, practice nurses/nurse practitioners and midwives. This confirms support for CDSSH, subject to satisfactory measures to ensure patient confidentiality. Also subject to feasibility, to be proven through pilot testing.</p> <p>Dialogue with the Nursing and Midwifery Council revealed that they had no representational role for nurses or midwives, so was not progressed as the Developers felt this was already adequately covered by RCN.</p>
--	---

Issues of patient identification

The CDSSH as shown in Appendix 2 will be recorded within primary patient records and also used in pseudonymised form within SUS. Two issues have been identified by the CDSSH Project Board, to which ISB and NHS CfH attention is drawn.

The first issue is that patients seen in GUM and CCS settings currently can choose to remain anonymous. Consultation with clinical stakeholders has indicated that they would not wish to see this ability for patients to remain effectively anonymous within the context of their clinic episode eroded, and therefore NPfIT systems must be designed to cope with patients for whom NHS number may not be available.

The second issue is that although it is understood that data can flow to SUS without NHS number, record linkage between data from different services may not be possible and the overall number of individuals seeking sexual health services may therefore not be definable. These issues do not prevent the CDSSH from meeting its broad secondary use purposes as long as NHS CfH can give assurances that the data can be recorded where identity is not disclosed. Recent discussion with NHS CfH Technology Office (see Appendix 1, Email from Jeremy Thorp of 6th November 2006, sub-section ‘Anonymity’) confirms that patient data can flow to SUS without NHS number or any other identifiers beyond a clinic-generated patient ID number. All that is lost in such instances is longitudinal linkage across episodes relating to the same patient. For secondary use, this remains useful and usable data lacking only in ability to achieve record linkage within SUS

PURPOSE

The data is being collected for one main purpose:

The monitoring of sexual health as observed and treated in a range of settings in order to describe and investigate trends in the incidence of sexually transmitted infections (STIs) and other sexual health problems and in the provision of

'treatments' (including contraceptive services) including analyses of sub-groups in the population including groups at particular risk. This information will be used:

- To inform public health response and policy formulation
- To monitor the effectiveness of the policies introduced as part of the National Strategy for Sexual Health and HIV
- For performance management at PCT, SHA and national level to ensure delivery of the national PSA target on sexual health
- For better planning and management of services at local level, and
- To adapt and refine interventions, as appropriate
- To further support the improvement of sexual health care services by:
 - Providing appropriate definitions and guidance material to enable a standardised data set to be derived from clinical settings providing sexual health services
 - Providing a core data set for clinical audit

One of the overall aims on the public health agenda is to achieve a sustainable improvement in sexual health. The main agenda of the Department of Health (DH) for this project is to obtain better collection of sexual health data to enable it to improve its ability to monitor and implement the National Strategy for sexual health and to improve surveillance of rates of sexually transmitted infections and other key sexual health performance indicators. In addition, it needs to implement the sexual health strategy to improve the access and level of clinical care provided to people with sexual health needs across a range of settings. The ability to derive a standardised set of data from different services will support improved integration of patient care between settings and enable better monitoring of performance of the NHS in delivering the strategy and will allow PCT level indicators on sexual health to be included within the NHS Performance Management Framework. This will provide an incentive for PCTs to devote more effort and resources to improving sexual health services.

In order to achieve this, the DH encouraged the development of the Common Data Set for Sexual Health. Historically, this started in approximately 1999 with the objective of enabling the collection of disaggregate data from GU clinics, the main clinical setting for providing care and treatment of STIs. The main purpose was to provide better data for surveillance purposes.

With the publication of the National Strategy for Sexual Health and HIV in July 2001, which emphasised the importance of integrated sexual health service, the CDSSH project and expanded this data recording and collection process to include the two other main settings (Community Contraceptive clinics and GP practices) using one mutually acceptable, common and disaggregate data set. The strategy's emphasis on integrated sexual health services reflects the fact that many of those seeking contraceptive services will be those at risk from STIs. At this point, a second core purpose of the CDSSH was suggested, to improve the effectiveness of clinical care at patient management level.

This second purpose was included within the Requirement submission but, as a result of subsequent review assisted by the pilot process, has now been reduced in this submission to that of a by-product of the single, core purpose to be able to derive consistent data in order to improve surveillance of sexual health and monitoring of the National strategy.

The above text therefore differs to that provided at the Requirement stage by now qualifying 'Purpose' as one the main objective and by providing additional historical

background to explain how the previous 'second purpose' had originated

SCOPE

- ***Where it will be used***

The dataset will be used in the three main clinical settings providing sexual health services throughout England (i.e. Genitourinary Medicine/GUM clinics, Community Contraceptive clinics, and if feasible General Practice), and in PCTs, Acute and Community Trusts, and the HPA.

- ***Who will use it***

Sexual Health clinicians i.e. doctors, practice nurses, and administrative staff within the three main clinical settings (see above), and by epidemiologists, service managers and policy makers in the HPA, NHS and DH

- ***How it will be used in routine practice***

The data set is intended to be a mandatory standard.

- **CDSSH items to be collected by setting**

The full data set at the time of Phase 1 pilot, August 2005, contained 23 main data items. The project board has subsequently revised the data set (see **Appendix 2**) to contain 22 main data items.

The number of data items to be collected within the Common Data Set varies according to the sexual health service setting. Appendix 2 shows the intended collection differences between the settings:

A) At the time of the Phase 1 pilot testing and

B) The current and amended data set as at August 2006.

The majority of requested data items would already be recorded as part of the normal patient record within each clinical setting

NB. It should be noted that the recent GP pilots have given rise to a review of data expectations for the GP-standard setting which intends to limit extracted data from that setting to that which is routinely collected and no more.

- **When to collect**

Scenario 1: GUM service, CCS and Integrated Sexual Health Services. It is envisaged that these clinics will typically collect the CDSSH for ALL patients*. A new patient is referred to the clinic. The clinic will create and progressively inhabit a patient record in the normal way (identification information, date of attendance, investigations undertaken, diagnosis, treatment provided etc). The initial analysis undertaken for this project, and the results of the phase 1 pilot, have shown that recording of the range of data items required to support clinical decision-making in this setting, that will also allow the reporting of information currently collected through the KC60 and KT31 returns, is acceptable and possible but will only be

practicable on a long term basis through appropriately designed electronic patient record systems.

(* There may be exceptions to this general rule such as when, in the interests of achieving targeted access times, clinics may operate a fast-track clinic for asymptomatic attendees in which urine/blood etc samples are collected for testing. Exceptions are to be confirmed via Phase 2 pilot tests)

Scenario 2: GP practice. It is envisaged that GP practice will collect the CDSSH only for those patients presenting with a qualifying Sexual Health-related issue*. This will include issues related to either sexually transmitted infection (the incidence of which presenting in a GP setting is relatively low) or issues related to first time or new contraception/fertility consultations (more common). As summarised in Appendix 2 and in further detail in Appendix 5 and 5a (Phase 1 pilot reports), there is a distinction in data collection expectation between GPs providing sexual health services at Level 2 or 3 (i.e. 'enhanced' services) and 'standard' GPs where sexual health service is up to Level 1. In the latter category, as summarised in Appendix 2, several of the data items have been made optional and are collectable at the discretion of the practice according to the nature of the sexual health issue. NHS Connecting for Health will eventually ensure that the majority of the data items (within the GP setting) are routinely collectable as part of the EPR. Those items which fall outside current EPR requirements will become part of GP contract negotiations.

(*This is further defined in the Guidance documentation. See Appendix 5a, sub-appendix S2, section 2.1)

- **Means, methodology of data collection**

The means and methodology by which the data will be captured within each setting will be a function of their current data capture systemisation and practice:

Each clinical setting (GUM clinics, CCS clinics, Integrated Sexual Health Services, GP practices) currently captures core elements of the patient record (including the majority of those items requested by the CDSSH) by a mixture of handwritten and electronically recorded means. The goal is that CDSSH is derived from the EPR which NPfIT/NHS CFH functionality will provide. This in turn anticipates that much of the clinical data that will be utilised to derive the CDSSH will be recorded during the clinical consultation, a practice that will evolve according to availability of suitable systems, resources and commitment to implement.

For further details, please see the section on 'Implementation'

- ***What it will be used for***

To support and deliver the objectives outlined in the previous section entitled 'Purpose'

The intention is that the CDSSH will be approved as a mandatory standard – to be derived in full or in part (according to the particular clinical setting) from information recorded as part of the clinical consultation and associated administrative processes, and as the source of disaggregated data to be submitted to a central (NHS Connecting for Health) data warehouse on a

regular basis.

As noted previously, the Developers' premise in the case of GU and CCS settings, is that the CDSSH will be derived from and is therefore reliant upon the EPR that is central to the NPfIT OBS. This assumption also extends to the mechanisms whereby SHAs, PCTs and other authorised organisations will obtain access to data for analysis through SUS. The envisaged 'data flow' will therefore be entirely that laid out in proposals for the delivery of SUS. At the moment, the developers are unclear as to whether Connecting for Health have defined precisely whether data will be routed to SUS only through PSIS, or whether other routes will be invoked. The only departure from this proposal based on analysis through access to SUS, would be if either:

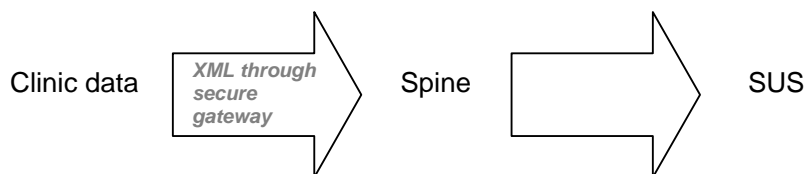
- (a) it was deemed that SUS should not contain sexual health data (which the developers have no reason to believe is the case), or
- (b) the timescales for implementation of EPR systems within GU services, according to the NPfIT OBS, and the implementation of sufficient SUS functionality, are beyond DH tolerances for improved sexual health data provision (for GP and CCS services it is likely that NHS CfH timescales will be accepted).

Should either (a) or (b) transpire to be the case, then the most likely alternative would be for anonymised, disaggregate data to be forwarded directly from GU clinics to the HPA (as currently occurs for aggregated KC60 data flows, and for anonymised disaggregated data flows in Scotland – the latter is only mentioned here to demonstrate that there is precedent within the UK), and that HPA would then make suitable summary data available to SHAs, PCTs, etc (again, as is currently the case for KC60 data).

Further indication of the process and timescales associated with a potential interim solution in the GU setting can be found in the section on 'Implementation'.

- **Envisaged data flow from GP systems**

It had initially been thought that data from GP systems would be transmitted onto the spine from which it could then be extracted to SUS (in common with data for GU and CCS data).



A recent discussion (3-11-06) with Jeremy Thorp informs that the NASP contract with BT, responsible for delivering SUS, is currently limited to collection of summary level data only (e.g. QMAS) from primary care. In the light of this recent information, the Developers will need to investigate and consider alternative options for collecting CDSSH data from GPs. One of the options could be to delay CDSSH data collection from the 99% of GP 'standard' sites until such time as the NPfIT/Connecting for Health system includes collection of high level patient data within primary care and to focus instead on the relatively small number of GP sites providing 'enhanced' sexual health services (currently estimated by DH to be approximately 50).

GP Systems would need to create 'event applications' in the form of XML

schema messages. Each developed event is triggered by a certain set of criteria, for example Qflu (part of the Qresearch system) has an event triggered by any GP consultation that activates Flu keywords on their systems. The event packages up the data and sends it via an XML schema through the secure document gateway to another device. This same process is in operation for prescriptions. It is therefore envisaged that the same process, using sexual health keywords and/or codes would be applied for CDSSH.

- ***List of high level risks the standard is hoping to ameliorate or eradicate***

The incidence of both sexually transmitted disease and teenage pregnancy in England is extremely high relative to most other European countries and has been worsening. To reverse this trend requires timely and relevant information about the incidence of disease, and distribution by geographic, demographic and other risk factors, at a local level which will inform national strategy and efficient planning and allocation of resources. The only sexual health data currently available at regional and national level is aggregate (as opposed to disaggregate) data. For STI, it collects incidence of disease, diagnosis and treatment but lacks additional information to enable proper targeting of resources. The STI data is reported quarterly (as part of the KC60 return). For example, additional information about age, gender and ethnic group could identify an emerging issue in a particular social group that could be quickly addressed through a specific awareness campaign.

- ***What it is outside of CDSSH scope***

In relation to the ongoing treatment for HIV-related conditions, the capture and transmission of data unrelated to the investigation, diagnosis and treatment of conditions other than HIV, other STI, or other sexual health 'problems/issues' is considered to be outside of CDSSH scope

Patients who are out of scope are, of course, all patients seen in general practice who do not have any sexual health problem/issue. This would include patients attending for the purpose of repeat contraceptive prescription. For these, the exclusion process will operate at the EPR (clinical consultation recording) level (if certain CDSSH prompts – e.g. sexual partners – are only to be made if a SH problem/issue is recorded) or at the extraction or analysis (e.g. SUS) level (if no such prompts are to be invoked).

Additionally, for any patient with a sexual health problem/issue, in any setting, all investigations, diagnoses and treatments that are not related to sexual health problems/issues are 'excluded' from the data set (in exactly the same way as for HIV cases with ongoing treatment of HIV-related (non-SH) conditions level). The process of 'excluding' such data will then occur in the context of full EPR/SUS implementation at the analysis or data extraction (from SUS) phase.

The Developers acknowledge the possibility, in light of the recent discussion (3-11-06) with CfH Technology Office, that the collection of CDSSH from the GP setting (with the possible exception of those providing 'enhanced' sexual health services) may be deemed to be outside CDSSH scope for the short-medium term future.

ADVERSE EVENTS / INTEROPERABILITY ISSUES

Within most GU and CCS settings, current practice is for a majority of clinical data to be recorded in handwritten clinician notes. It is anticipated that the initial transition process towards EPR will involve additional staff time taken in recording clinical information, although this needs to be seen against the benefits in terms of availability of information for service planning, clinical audit and patient referral, and in reduced effort required to produce central returns based on these data. It is anticipated that administrative staff may be involved in extracting and inputting clinical data from clinical notes in the early stages of implementation. The CDSSH project seeks only to provide appropriate definitions and guidance material to enable a standardised data set to be derived from clinical settings providing sexual health services.

Harmonisation of data requirements with other sexual health policy initiatives and data sets (i.e. National Chlamydia Screening Programme, SOPHID, and planned HRG/PBR data set and 48-hour access data set) has been agreed within the Health Protection Agency and with the BASHH/GUM IT Group chairman.

IMPLEMENTATION

Details of the Draft Standard

Supporting documentation providing greater detail of the data set and its specification for this Draft Standard can be found at:

Appendix 2: A brief summary of the CDSSH data items and the settings in which each item is expected to be collected

Appendix 4: CDSSH: Description, Rationale and Outputs

Appendix 5: Report of Phase 1 pilot tests (i.e. conformance tests to date)

Appendix 5a: Supplementary report on additional GP pilot tests (Phase 1).

Please note: This supplementary report also contains:

- Details of Guidance material provided*
- Details of the data extract specification provided to the IT suppliers

* It is planned within Phase 2 pilots that the human guidance material will be reviewed and strengthened as to who would collect which data items and how to ask questions ie which data items collected by clinician and which administration staff.

- **Phase 1 pilot exceptions**

The pilot tests to date have focused on demonstrating CDSSH acceptability and feasibility within each setting. Neither of the two Phase 1 elements has tested the analysis of the data collected or its clinical usefulness or clinical suitability. The

intention is that the Phase 2 pilots will involve more detailed epidemiological analysis

The outputs section given in the Rationale Document (Appendix 4) gives a detailed insight into the types of analyses that we are intending to do using the CDSSH. The utility and importance of these types of analyses to health service planning and public health intervention at a local and national level has been demonstrated by many groups including the HPA, UCL and the University of Bristol. We have included a pdf of one of these papers with this response

- **Phase 2 pilot intentions**

The content of the Common Data Set is indicated in Appendix 2. It is acknowledged that this specification is currently under review and may be subject to some alteration. In particular, it is recognised from phase 1 piloting that a number of terms included in the data set to describe clinical examination and/or clinical findings lack utility. Further tests will seek to incorporate any required changes.

It is intended that Phase 2 pilots to be conducted and submitted for Full Operational Information Standard will include:

- Greater detail of conformance tests
- All necessary changes to the codes used to collect data = DERIVATION FROM RECORD
- Evidence of end-to-end piloting in all required settings
- Evidence of assurances from all current providers of systems which will be used to implement the Data Set. These assurances should clearly support the implementability of the standard
- Assessment of impact upon the service as a consequence of collecting/extracting the CDSSH, including a comparison against the existing central returns; KC60 in GU clinics, KT31 in CCS*

(* It is considered that CDSSH will deliver a significant improvement in data quality versus the current KC60 and KT31 returns with consequent benefit as described in the section on 'Purpose'

- **Additional activity in support of submission for Full Operational Information Standard**

- Provide detailed statements about the maintenance and updating of the Data Set, and of any risks associated with it
- Provide a sponsorship letter which explicitly refers to the maintenance process
- Give details of the approach taken to conformance testing e.g. using statistical process control measures – measuring conformance by users and the service, and covering the collection and analysis of data, and the clinical usefulness (for Clinical Audit purposes)
- Set out the potential safety risks that could be associated with this standard, and the approach taken to them (how risks have been

eliminated, reduced, transferred etc). This would also detail any reporting that need to put in place at FULL standard.

Implementation Plan

Extent of the implementation

The intention is that CDSSH is implemented in each of the three main clinical settings in England as soon as is practicable.

Recent discussion with CfH Technology Office (see Appendix 1, Email from Jeremy Thorp of 6th November 2006, sub-section LSP obligations) indicates that LSP functionality to support CDSSH implementation, particularly provision for patient confidentiality issues around sexual health, is unlikely to be available within the next 2-3 years.

Therefore CfH suggest that until approximately 2009 at the earliest, the Developers will be dependent on EXISTING IT SYSTEMS to generate the data. In turn, this recommends the development of an INTERIM SOLUTION where applicable

Table 1

Clinical setting	Number of sites in England	Availability of EXISTING IT SYSTEMS capable of adaptation to CDSSH	Proposed phasing
GUM clinics	200	YES	2007: First CDSSH priority
Integrated Sexual Health clinics (typically clinics combining GU/CCS)	50*	YES (at least in 2 clinics. Seeking confirmation regarding remainder)	2007: First CDSSH priority
CCS clinics	200	NO	As PCTs confirm availability of IT capability (i.e. PCs, laptops + associated software such as RIO/London)
GPs providing 'enhanced' sexual health services (i.e. at Level 2 or 3)	50 (at present)*	YES**	2007: TBC
GPs 'standard'	8,522	YES**	TBC

* DH estimate

** Recent information from CfH reveals that current plans include only summary GP data to be sent to the spine. The Developers need to investigate whether such data includes items

relevant to CDSSH

Phasing of the implementation

Each of the three main clinical settings has its different attributes in terms of need and preparedness for progressing toward implementation of the CDSSH. For example, CCS settings typically lack basic IT capability (e.g. PCs, laptops, software to capture patient records etc) at this stage and require that these are provided either through implementation of NPfIT or through separate PCT resourcing before CDSSH can be implemented. For this reason it is proposed that implementation of the data set will be phased, starting with implementation in GUM clinics, since that is the setting for which the policy and professional drivers are strongest. Implementation with respect to other clinical settings will then proceed in the light of any lessons learned from GUM implementation and as roll out of electronic patient record systems and behavioural guidance in those other settings allows. The submission for Full Standard will reflect this phased approach.

Timings

Estimated timings are provided in the table below. A more detailed plan will be produced taking account of results and recommendations arising from the Phase 2 pilot test.

As indicated above, an area of possible risk associated with the implementation is the availability of relevant NPfIT/CfH functionality to correspond with the estimated CDSSH implementation timings. Key functionality includes availability of :

- CfH provision of data security, protection of patient confidentiality
- CfH provision of Secondary Use Service (SUS) to serve as Central data Warehouse and provision of pseudonymised data to secondary users
- LSP-provided systems to collect the data set

Milestone	Proposed date related to INTERIM SOLUTION for GUM clinics and integrated SH clinics	Proposed date related to other SHS settings**
Submission for Draft Operational Information Standard Completion including report of Phase 1 pilot tests plus supplementary report of additional GP pilot testing.	August 2006	August 2006
Draft Operational Information Standard approval obtained	November 2006	November 2006
Phase 2 pilot test Common data set successfully piloted in up to 10 locations** and report of this produced including endorsement by relevant user community body (e.g. BASHH, FFPRH, Joint GP-IT Group)	January 2007*	January 2007*
Project Plan for implementation of the rollout phases prepared including details of the organisations to be involved and linkages to NPfIT	January 2007	January 2007

Milestone	Proposed date related to INTERIM SOLUTION for GUM clinics and integrated SH clinics	Proposed date for implementation within other SHS settings**
Documentation for Full Operational Information Standard for each setting (GUM, CCS, GP) prepared and approvals obtained	February/March 2007	TBA
ROCR approval – for each setting (GUM, CCS, GP)	February 2007	TBA
Seek approval as mandatory standard	March 2007	TBA
Data Set Change Notice notification obtained	March 2007	TBA
<p>Communication campaign to clinical community, SHAs, PCTs etc advising of DSCN, ministerial mandation, sources of additional support material and intended training provision. Also to include examples of output, best practice.</p> <p>All key reference material to be available on established CDSSH website www.cdssexualhealth.org.uk</p> <p>Phase 1: Notification and preparation to implement, including regional training events for key systems</p> <p>Phase 2: Support for implementation</p> <p>A proposed CDSSH helpline will supplement the communication campaign</p>	<p>March – July 2007</p> <p>July 2007 – July 2008</p>	TBA
IT suppliers (Proprietary) to amend systems to ensure ability to collect and report CDSSH	By July 2007	TBA
Establish central data warehouse for receipt of CDSSH data (e.g. HPA)	By July 2007	TBA
Implementation of Interim approach within GUM clinics and integrated SH clinics	From January 2008	Not applicable
Implementation via Npfit/CfH		
The CDSSH is intended to be implemented, make full use of, and be in line with the rollout of relevant NPfIT/CfH functionality.	TBA (as determined by availability of NPfIT/CfH functionality***)	TBA (as determined by availability of NPfIT/CfH functionality***)

* Subject to ISB recommendations

** 2 x GU clinics, 2 x Integrated SH clinics, 2 x CCS, 2 x GP 'standard', 2 x GP 'enhanced'

*** Recent discussion with NHS CfH Technology Office (see Appendix 1, Email from Jeremy Thorp of 6th November 2006, sub-section LSP obligations) indicates that LSP functionality to support CDSSH implementation, particularly provision for patient confidentiality issues around sexual health, is unlikely to be available within the next 2-3 years. The Developers will maintain regular contact with NHS CfH to ascertain when more specific dates for availability of relevant functionality are known

Possible merger with other standards

There are two other associated Sexual Health standards in development at present, namely the 48-hour target standard and Payment by Results both of which apply to the GU setting. Either or both of these may at some future point be accommodated within the existing CDSSH structure. Indeed, detailed discussions between the chairs of the CDSSH Project Board and BASHH/GUM IT Group have identified that the 48hr waiting time indicator and the Payment by Results indicators that have been developed by the latter group should be capable of later accommodation within CDSSH, perhaps simply by adding one or two new terms as valid entries for the relevant CDSSH data items

The current 48-hour/access times project is currently being progressed as a separate entity in recognition of the pressing deadline for GU clinics to be able to supply this specific data by April 2007, a date which is clearly not achievable for the currently envisaged CDSSH implementation. In the event that the awaited response from Connecting for Health regarding available functionality to support CDSSH implementation leads to a DH decision to pursue an interim solution, the potential merging will be actively explored. Such a merger is considered impracticable before April 2007 as the current 48-hour/access times project will require full focus to achieve this without the additional complexity or potential 'drag' of the CDSSH.

CDSSH interim solution within the GU setting and integrated SH clinic setting

In view of the recent NHS CfH indication that relevant NHS CfH functionality to facilitate CDSSH implementation will not be available within the next 2-3 years, the interim means to generate and collect the CDSSH data will be via modification of the existing IT supplier systems as a First Phase for implementing the CDSSH within the GU and integrated SH clinic settings.

An interim solution would follow a similar approach to that envisaged for the currently planned Phase 2 pilot tests to follow approval at Draft Operational Information Standard i.e. it would focus on co-development with the 3 main IT-system suppliers to the GU setting (Blithe Computer Systems Limited, Mill Systems Ltd, Clinisys Solutions Ltd) who cover a minimum of 90% of the 200 GU clinics in England. Discussion with each of these suppliers confirms that modification of their current systems to enable collection and extract of CDSSH data is achievable within the suggested timescales. The early stages of Phase 2 pilot testing also confirm that the clinics can collect the data in this way. Phase 2 pilots will identify and assess all associated issues

The interim approach will involve a more detailed development.

The steering group and development team would need to include BASHH/GUM IT Group, Health Protection Agency, Department of Health, and the aforementioned 3 main IT suppliers

to GU settings.

The development process would include:

- a full technical specification, including construction and testing of a scaleable database, schema etc
- system modification/development for each supplier, including each significant legacy system where applicable
- system testing at suppliers
- initial testing with senior users
- First phase testing with pilot sites (ensuing modifications as appropriate)
- Second phase testing with pilot sites
- Production of guidance material and reports of test results on conformance, interoperability etc

It is estimated that the process would require **12 months** from the point of DH decision to proceed to the availability of fully tested systems to implement. The starting point would also be subject to available resources from the key stakeholder groups mentioned above.

Possible CDSSH interim solutions in non-GU settings

It is currently considered that no similarly comprehensive interim solution would be applicable for CCS or GP settings

Handling of sensitive personal information in non-NHS CFH environments

A central premise of CDSSH is that patient data will always be anonymised/pseudonymised before it is available to secondary users, whether within a NHS CFH environment or (in the case of a potential interim GU solution) a non-NHS CFH environment. Any instance of sensitive personal information reaching a non-NHS CFH environment would be considered a gross failure. This eventuality will be avoided by stringent schema conditions, whether in a NHS CFH environment or potential 'interim solution/ non-NHS CFH environment, which will determine what data is to be sent and will thus specifically exclude sensitive personal information

Implementation: Details of funding

Appendix 6 contains a spreadsheet estimating the funding and appropriate source associated with CDSSH implementation in each of the main Sexual Health Service settings. These costs are compiled with an NPfIT/NHS CfH solution in mind, but because they separate cost by setting can also be used to assess the costs associated with the GU interim solution

Please note the following assumptions or exceptions to Appendix 6:

- Costs associated with providing the necessary IT infrastructure for EPR, etc within each setting are not attributable to CDSSH. The only area where we are aware that this is specifically needed is CCS which is why we had not included this within our costings.
- The eventual DSCN will require IT system providers to modify their system to accommodate CDSSH. That cost or investment falls to the IT system providers and is therefore not included within our costings.
- The cost of staff time at clinic is currently left blank on the premise that CDSSH seeks to collect data from each setting which is consistent with existing best practice. As such, it should not give rise to additional staff time at the clinic.
It is accepted that the envisaged EPR, upon which CDSSH is dependent, represents a significant change to current data collection practice within each of the settings (less so

in GPs) and one which will undoubtedly impact upon staff time as they adjust to new processes. These costs should not be attributed to CDSSH. If subsequent evidence (e.g. from piloting) suggests that specific CDSSH data items do give rise to additional staff time for reasons other than adjustment to an environment of electronic data capture, CDSSH costings and/or the continuing inclusion of those items within the CDSSH will be reviewed

Risk assessment

- **Partial implementation in GP setting**

The Developers recognise that implementation of the CDSSH within the GP setting will be challenging and, at least in the earlier stages, partial and sketchy. It may also be that, following further investigation as a result of recent NHS CfH information regarding the limitations of data collection from primary care, that CDSSH expectations will be significantly reduced. Nevertheless, it is necessary to make a start in collecting information in this setting. For STIs it is known that an increasing amount of work is being done by GPs and the people involved would like recognition for it - which the CDS will help to provide. In the area of contraception, GPs are very important providers.

It is accepted that, if feasible within the current NPfIT/NHS CfH contractual arrangements, CDSSH implementation in general practice is likely to be gradual with data likely to be provided initially by the enhanced services and the others being encouraged to provide as much as they can (even it at just at a minimum level). It is not considered that this calls into question the benefits arising from the proposed £8m expenditure - which is phased over an 8 year period

- **Investment required to enable CDSSH implementation**

Investment is necessary within the CCS setting to provide the necessary IT infrastructure to enable implementation of EPR and subsequently CDSSH. We are advised that this funding has to come from PCTs/SHAs. Our understanding is that all PCTs are aware of the lack of IT resource and that CCS will be unable to participate in NPfIT/NHS CfH or CDSSH until sufficient funding is allocated.

As regards possible investment/modification of existing and/or NPfIT-provided data systems to enable CDSSH implementation, it has been assumed that the eventual DSCN for CDSSH will address any required modification by IT suppliers

- **Resolution of Phase 1 pilot issues**

It is acknowledged that piloting done to date encountered a number of issues that would need resolution before implementation. These issues arose primarily in GU and CCS settings where existing systems were, for the most part, unmodified (see Appendix 5).

Consequently, data extraction often required a degree of manual effort at the clinics and were submitted in a variety of formats, with limited compliance to NHS standard coding, which caused subsequent problems for collation and analysis.

Later piloting in the GP setting (see Appendix 5a of the submission) shows how these issues have been addressed and resolved. As mentioned previously, following a subsequent review of the data expectations for the GP-standard setting, it is now intended to limit extracted data from that setting to that which is routinely collected and no more.

- **Additional staff time required to implement CDSSH**

Clerical staff may be involved in extracting and inputting clinical data in early stages of implementation. The likelihood of such involvement will very much depend on the details

and timing of implementation of NHS CfH EPR systems in the settings that will record the CDSSH. This response can hopefully be more meaningfully informed by the awaited response from the NHS CfH Technology Office

Assessments

The Developers have undertaken assessments to ensure the Draft Standard as follows:

The project board for development of the Common Data Set for Sexual Health includes representation by Data Standards (Nicholas Oughtibridge/Gillian Foley). This will ensure compliance with NHS Data Standards.

See also comments in 'Dependencies' below.

The chairman, and other members of the project board, have been involved in the recent consultation on the revision of the VD Regulations that cover the use and disclosure of data on sexual health issues, in order to ensure that proposals on the secondary uses of the CDSSH data are in compliance with current legislation and any likely future changes.

A description of the purpose and pilot implementation of the CDSSH was submitted to PIAG, which has indicated its support for the recording and collation of the data within the context of Section 60 support provided for processing of patient data for the control and prevention of infectious disease and other threats to health. PIAG support for implementation of the Standard within the context of the development of the Care Record Service and the Secondary Uses Service is also being sought. (see Appendix 1 for copy of relevant PIAG correspondence)

Dependencies

The following provides detail of known or envisaged interactions and/or dependency with existing or planned standards within the NHS architectures:

For details of 'Dependency on NPfIT', please see comment under this title within the SPONSOR section at the start of this submission

KC60 and KT31 returns will be replaced (and improved upon) by the Common Dataset for Sexual Health

There is an additional dependency with CfH Terminology Service on the mapping of the 'clinical terms' within item 15 to SNOMED. The terminology service has already undertaken extensive work with the Developers to map KC60 and KT31 data items to SNOMED, identifying where any gaps currently exist.

There are related activities associated with:

- a) An HRG initiative to establish PBR within the GU clinics
- b) An interim process to monitor patient access times within the GU clinics ('48 hour access').

The Developers, via HPA who is common to CDSSH and the 2 standards identified in a) and b) above, have ensured and will continue to ensure harmonisation of common data items between the three standards.

There was an interdependency with the newly 'Do Once & Share' STI group, formed October 2005 and which reported its conclusions March 2006. Meetings between DoaS and CDSSH took place in November 2005, January, February and March 2006. DoaS Project Manager

attended CDSSH board meeting 30-11-05.

There is a dependency with Data Standards which are being developed with /Nicholas Oughtibridge/Gillian Foley of NHS CfH which will also be submitted to ISB for approval. Each of the data items to date have been checked against the NHS Data Dictionaries by Michelle Cambridge, Barbara Fogarty formerly of NHSIA (as seen in Section S1, pages 10-21 inclusive of Appendix 5a 'Supplementary report Appendices').

Regarding ROCR: The CDSSH is intended to replace the KC60 and KT31 returns. The developers have informed the ROCR secretariat about the work to develop the dataset and will make a formal application when it is ready to be rolled out nationally. This was detailed in an email from Steve Webster dated 21-7-05 and subsequently forwarded to ISB in connection with the REQUIREMENT submission. A further copy is provided with this submission (within Appendix 1).

USERS

A list of staff groups who will use the Draft Standard is provided below:

Clinical setting	List of staff groups who will use the standard
GU clinics	GU consultant Nursing staff (occasional) Administrative support staff (e.g. receptionist etc)
CCS	CCS consultant Nursing staff (occasional) Administrative support staff (e.g.receptionist etc)
GP	GP practitioner Nursing staff (occasional) Administrative support staff (e.g. receptionist, Practice Manager etc)

CONSULTATION AND EVALUATION

- **Consultation**

The CDSSH Project Board contains representatives of all main stakeholder groups. Having discussed and agreed within the Project Board, a proposal for the content and structure of the CDSSH, the Developers sought comments via stakeholder consultation prior to embarking on Phase 1 pilot testing. As concluded within the eventual report'The overall impression from this feedback is that the CDSSH in its current form, as agreed by the SHSDG, is ready to proceed to Phase 1 pilots. Amendments, as required, can be made for the Phase 2 pilots

For further details of the consultation and associated report, please see **Appendix 3: 'Report: Stakeholder consultation pre-pilot Phase 1'**

Details of support supplied with REQUIREMENT submission (version 1.2) are also included

with this submission (see **Appendix 1**) as follows:

- Letter of sponsorship from Department of Health (Cathy Hamlyn, Head of Sexual Health)
- Support from Jeremy Thorp, Connecting for Health
- Letter of Endorsement from MEDFASH
- Supporting letters from PIAG
- British Association of Sexual Health and HIV (BASSH) – representing all Genitourinary (GUM) clinicians
- Faculty of Family Planning and Reproductive Health (FFPRH) – representing clinicians within the Community Contraceptive Services (CCS)

We have engaged with the Royal College of General Practitioners to seek their comments during the stakeholder consultation (see Appendix 3) and to seek RCGP representation on the CDSSH board. This has not yet been forthcoming. In the absence of such representation, the plan has been to build the necessary evidence of acceptability and feasibility within the GP setting. To this end, a representative of the RCGP Sexual Health Working Group is a participant in our ongoing pilot plans. Subject to her experience of the CDSSH pilot process and those of other GPs we hope to secure the necessary support

Dialogue has been opened with other stakeholder groups to seek additional comment. CDSSH details have been sent to Royal College of Nursing, the Nursing and Midwifery Council, and the National association of Nurses for contraception and sexual health (NANCSH). Informal feedback from these sources as at August 2006, is supportive in line with that of other consultation. More formal comment will be sought as and when appropriate. RCN has sent out CDSSH consultation documentation to selected members within working groups for sexual health, practice nurses, and midwives and will distil these into a response within September/October. Dialogue with the Nursing and Midwifery Council revealed that they had no representational role for nurses or midwives, so was not progressed as the Developers felt this was already adequately covered by RCN. The Developers will continue to liaise with the RCN.

The Developers have not consulted with patients as the CDSSH project seeks only to extract and analyse anonymised patient data. Therefore it would seem that if there is a need for consultation with the public we consider that this should simply be part of the broader consultation on NPfIT.

The Developers will extend consultation to include considered patient groups such as the Terence Higgins Trust

It is also our intention to provide CDSSH detail and Phase 2 pilot plans to the Joint GP-IT Committee for their comment. The Developers will first await the known outcome of this submission as a Draft Operational Information Standard and aim to provide the aforementioned detail within 2 weeks of that outcome

IT suppliers

To facilitate our Phase 2 pilot testing, we are working with key suppliers of existing IT systems to the three main clinical settings providing sexual health services throughout England (i.e. Genitourinary Medicine/GUM clinics, Community Contraceptive clinics, and General Practitioners). These suppliers are:

Clinical setting	List of IT suppliers
GU clinics / CCS	Blithe Computer Systems Limited
	Mill Systems Ltd
	Clinisys Solutions Ltd
GP	EMIS

IMPACT OF NOT PROGRESSING

- Without a formal dataset the accuracy of any data in the sexual health environment cannot be validated.
- A lack of a formal standard would lead to the continuation of inadequate information within the sexual health arena, significantly reducing the ability to improve current sexual health performance
- The current inability in GU units to provide timely and consistently reliable quality data, with potentially similar issues arising within CCS and GP settings.

Appendices

Appendix 1	Endorsements
Appendix 2	CDSSH: Summary of Data items and expected collection by each clinical setting
Appendix 3	Report: Stakeholder consultation pre-pilot Phase 1
Appendix 4	CDSSH: Description, Rationale and Outputs (Guidance pack)
Appendix 5	Report of Phase 1 pilot tests (i.e. conformance tests)
Appendix 5a	Supplementary report on additional GP pilot tests: Phase 1 (incl. Technical guidance, Human/Organisational guidance).
Appendix 6	Funding: estimated costs of implementation