Public Health
England

Protecting and improving the nation's health

HIV and AIDS Reporting System: Requirement Specification

Version 1.0/ October 2016

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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Published October 2016
PHE publications gateway number: 2016403

SCCI Standardisation Committee for Care Information

This information standard (SCCI1570) has been approved for publication by the Department of Health under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Standardisation Committee for Care Information (SCCI), a sub-group of the National Information Board.

This information standard comprises the following documents:

- Requirement Specification
- Change Specification
- Implementation Guidance.

An Information Standards Notice (SCCI1570 Amd 20/2015) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the NHS Digital website. Any copies held outside of that area, in whatever format (eg paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 31 October 2016

Contents

Glossary

Term	Acronym	Definition
Acquired Immune Deficiency Syndrome	AIDS	Acquired immune deficiency syndrome is a disease of the human immune system caused by HIV.
Antiretroviral therapy	ART/ARV	The combination of several antiretroviral medicines used to slow the rate at which HIV makes copies of itself (multiplies) in the body.
British Association for Sexual Health and HIV	BASHH	UK professional association representing professionals involved in sexual health care. It acts as a national advisory body to professions and other organisations on all aspects of sexual health.
British HIV Association	BHIVA	UK professional association representing professionals involved in HIV care. It acts as a national advisory body to professions and other organisations on all aspects of HIV care.
Genito-urinary Medicine	GUM	This is a specialised service, whose primary function is the provision of screening, diagnosis and management of sexually transmissible infections and related genital medical conditions.
Genito-urinary Medicine Clinical Activity Dataset	GUMCAD	Dataset for case-based disaggregate surveillance system used to monitor the number of sexually transmitted infections in England, Wales and Northern Ireland.
Health Protection Agency	HPA	The HPA was a non-departmental public body whose remit is to provide an integrated approach to protecting UK public health through the provision of support and advice to the NHS, local authorities, emergency services, other Arms Length Bodies, the Department of Health and the Devolved Administrations. The HPA transferred to Public Health England in 2013.
HIV and AIDS reporting system	HARS	The name of the new HIV dataset.
Human Immunodeficiency Virus	HIV	The virus that causes AIDS.
National Reference Group	NRG	The group overseeing the development of the HARS standard and its implementation.
National Tariff Payment System	NTPS	Supersedes Payment by Results.
Patient identifiable information	PII	Information collected for surveillance that is sensitive.
Payment by Results	PbR	A rules-based system for paying health care trusts. Payment is linked to activity and adjusted for casemix.

		Superseded by NTPS.
Public Health England	PHE	The successor public organisation into which the HPA was integrated in 2013.
Public Health Laboratory Service	PHLS	The predecessor to the HPA and PHE.
Recent Infection Testing Algorithm	RITA	An algorithm reliant on results of a test of recent infection on newly diagnosed persons with epidemiological and clinical information to allocate patients as being either recent or non-recent HIV infections with HIV.
Sexually Transmitted Infection	STI	An infection that is transmitted sexually.
Survey of Prevalent HIV Infections Diagnosed	SOPHID	An annual census of people living with a diagnosed HIV infection. This survey has been conducted since the mid-1990s. SOPHID is in the process of being amalgamated with the new HARS dataset.
Viral load	VL	Viral load is the term used to describe the amount of HIV in the patient’s blood. The higher the viral load, the faster the CD4 cell count will fall, and the greater the risk of becoming ill due to HIV. The result of a viral load test is described as the number of 'copies' of HIV's genetic material (RNA) per millilitre (copies/ml).

Overview

Background and context

Background

In 2014, there were an estimated 103,700 people living with HIV in the UK with 6,000 newly diagnosed. Anti-retroviral treatment (ARV) for HIV was introduced nationally in the mid-1990s. It has transformed HIV infection from a fatal condition into a lifelong infection. Deaths remain low at approximately 600 a year and people living with a diagnosed HIV infection can now expect a near normal life expectancy. As a consequence, increasing numbers are accessing care. It is estimated that the annual cost of HIV is £2 billion.

Public Health England (PHE) has an established role in the surveillance of HIV which is one of the core functions of its work. Data has been collected electronically from HIV service providers for more than a decade via four surveillance systems; RITA, SOPHID and the HIV and AIDS New Diagnoses and Deaths database (HANDD). These data flows are already established between providers and PHE.

In 2012 a new system, the HIV and AIDS Reporting System (HARS), was developed and approved by the Information Standards Board (ISB):
www.isb.nhs.uk/documents/isb-1570

This information standard revolves around collating data on all people accessing HIV services including information on patient demographic, diagnostic, treatment and clinical information.

HIV is an area subject to constant, rapid change. Consequently there are items in HARS which are now out of date and require updating. This submission seeks approval to make changes to the HARS dataset in the light of developments in HIV treatment and management.

HARS rollout

HARS has been rolled out since 2013. Initially it was adopted by the main pilot sites who had already established systems to record and report HARS data. Gradually, more sites started reporting HARS data as their IT systems were upgraded and currently 173/180 (96%) of outpatient HIV service providers are successfully reporting HARS data.

Once a site has successfully transitioned to HARS, they are no longer required to report SOPHID data, thus easing their reporting burden.

HARS data reported have been validated for quality and completeness and the results were included in the publication ‘HIV diagnoses, late diagnoses and numbers accessing treatment and care – 2016 report’ published in October 2016. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/561098/HIV_diagnoses_late_diagnoses_and_numbers_accessing_treatment_and_care_NB181016v4.pdf

Overview and purpose

The HARS dataset is designed to directly support the public health surveillance of HIV infection in the UK. All fields collected within HARS directly inform surveillance outputs. This is described in the section. The HARS dataset also enables the production of two secondary analyses detailed in the two following sections.

Primary function: HIV surveillance

The primary aim of HARS is to streamline the reporting of HIV data from four separate systems into one return, thus lightening the burden and simplifying reporting for providers. The HARS dataset will facilitate the continuing requirement for public health surveillance of HIV in England. HIV data are also now an Official Statistic.

The current large range of data outputs enabled by existing surveillance will continue. They will be produced more efficiently through the HARS dataset. These outputs are critical in informing the public health response to the HIV epidemic and for the targeting and evaluation of prevention initiatives. A small selection can be found at the following links:

- HIV in the United Kingdom: https://www.gov.uk/government/statistics/hiv-in-the-united-kingdom
- HIV annual data tables: https://www.gov.uk/government/statistics/hiv-annual-data-tables

Secondary function: quality of care indicators

The role of PHE in response to the HIV epidemic in the UK has expanded from the traditional surveillance of the numbers living with HIV infection to measuring the quality of care and outcomes of people accessing HIV services. Using fields derived from the HARS dataset, PHE will monitor the following centrally and report back at the national, local and service provider level in conjunction with the data sharing policy. Examples of outputs include:

- proportion and total diagnosed late
- time from HIV diagnosis to integration into care
- proportion and total newly diagnosed seen for care within six months

- proportion and total retained in care year on year
- proportion and total treated according to national guidelines;
- proportion and total starting ARV who have a undetectable viral load within six months
- proportion and total in care for at least 12 months who have a CD4 count above 350 cells
- mortality rates stratified by CD4 count at diagnosis.

The benefits of monitoring these markers of quality care through surveillance systems include reducing the burden of work for service providers who would otherwise have to make an additional submission summarising these indicators to NHS England who monitor these to provide assurance on the quality of care. (https://www.england.nhs.uk/commissioning/spec-services/npc-crg/spec-dashboards/).

Independent processing of the data flowing to PHE is a better guarantee of objectivity.

Secondary function: commissioning of HIV services

Analyses of the data from HARS inform the commissioning of services through directly reporting to a national HIV outpatient tariff in line with the National Tariff Payment System (previously known as Payment by Results).

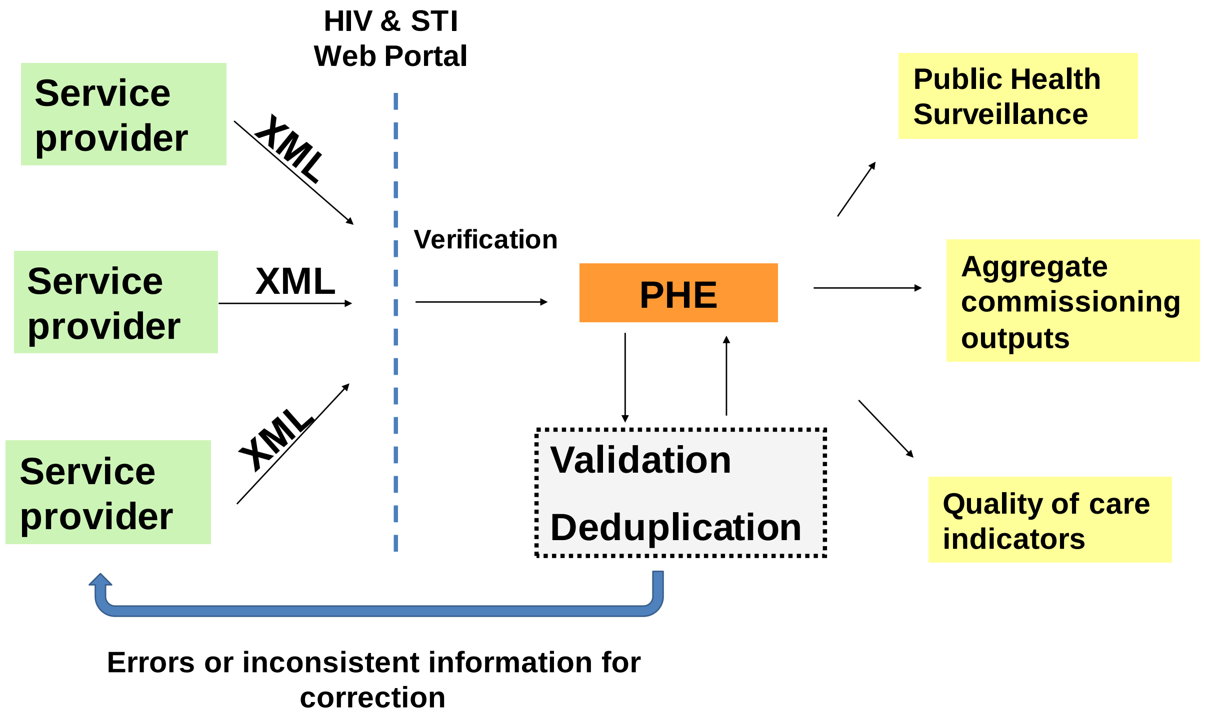
The HIV outpatient currency is a clinically designed clinical pathway for each of three groupings of patients that supports an annual year of care tariff approach. The groupings are:

- Category 1 (newly diagnosed or newly on ARV drugs)
- Category 2 (stable patients)
- Category 3 (medically complex patients).

Operational Context

A schematic diagram of the data flow of the HARS dataset is shown in Diagram 1. There are no proposed changes to this mechanism.

Diagram 1: Schematic diagram of the HARS dataset data flow



To summarise:

1. The provider collects data on each HIV attendance and records on an IT system.
2. At the end of each reporting quarter, the provider extracts a HARS XML file covering all attendances in that period and uploads to the secure HIV and STI web portal.
3. On upload, the file undergoes an automatic two stage validation process (see below). Any errors are flagged to the provider for correction and resubmission
4. XML verification – ensures the file precisely matches the HARS XML schema.
5. PHE validations – checks against a pre-defined list of validations to ensure high quality data.
6. Once data are accepted (no major errors), the data are further processed to create a final dataset.
7. Three sets of outputs are produced from the final dataset:

a. public health information (quarterly; national and local).
b. quality of care outcomes (annually; nationally, locally and at the provider level.
c. commissioning outputs processed for National Tariff purposes (quarterly; national, local and at the service provider level).

The HARS dataset is categorised into seven sections .There are no changes to this structure:

- Demographics

This contains information such as patient ethnicity, country of birth, age group, gender, residence and year of arrival into the UK (if born outside the UK). This information is used for public health surveillance through identifying which populations are at risk of HIV infection.

- Service Information

This contains information about the service provider, previous HIV care received elsewhere, shared care and current status of the patient (e.g. alive, transferred). This information will be used to monitor the outcomes of patients.

- HIV clinic attendance

This contains information on the HIV attendance date and the purpose of the attendance.

- Diagnosis information

This contains information about where and when the patient was diagnosed with HIV; recency of infection; and how the infection was acquired. This information will be used for public health surveillance by identifying where, when and how a patient acquired their HIV infection.

- Treatment information

This contains information about when patients started ARV and their current specific regimens.

- Clinical information

This contains information about the clinical stage of the HIV infection. For instance CD4 counts indicate what stage of HIV infection a patient has reached and viral loads indicate how infectious a patient may be. Co-morbidities are collected to help aid service planning.

- Death

This is used to monitor mortality rates among the HIV-infected population.

The reporting schedule of HARS is quarterly and attendance based. The dataset has been designed to enable surveillance to continue as sites gradually adopt the HARS dataset.

Collection of patient identifiable information (PII)

The HARS dataset collects limited PII: Soundex, gender and first initial, date of birth and Lower Super Output Area (LSOA).

This important information allows patients who attend more than one site for a diagnosis or for care to be deduplicated. Protocols to deduplicate patients attending more than one service have been developed and are regularly audited by PHE. Through the collection of PII, we know approximately 6% of people living with a diagnosed HIV infection attend more than one site per year; this is approximately 4,000 people. Over a five year period this rises to 23%. Without the collection of PII, the number of people living with HIV would be overestimated in surveillance outputs and for commissioning purposes. Audits include verifying linkages ascertained through PII against other information such as ethnicity and treatment history.

The list of the data fields that are limited patient identifiers are listed below. It is important to note that these are not new fields. This information is already collected by HARS and there are no plans to expand the collection of PII in this submission.

Sdex (patient’s surname soundex - encoded surname)
This is needed (with date of birth, gender and initial) to identify patients diagnosed at more than one site, patients accessing care at more than one site. This is also needed to track important aspects of patient care over time, for instance to determine the impact of late HIV diagnoses on subsequent patient morbidity. The suitability and accuracy of using these fields in combination to identify duplicate patients is regularly audited. This involves cross checking “matched” patients against other information to sense check (eg ethnicity, patterns of attendance etc).

Initial (patient’s initial of first name)
As soundex.

Date of birth (patient’s date of birth)
As soundex. It is also used to derive the age of the patient. This enables us to examine the demographic characteristics of those living with HIV and monitor inequalities.

LSOA (LOWER SUPER OUTPUT AREA of residence)
This is used to derive the residence area of the patient. This has several purposes. Firstly it serves to monitor patterns to access to HIV care nationally. Secondly, it links with indices of deprivation from the Office for National Statistics to examine the demographic characteristics of those living with HIV and to monitor inequalities. Thirdly, it enables the reporting of public health outputs by geographic region.

Patient ID (Clinic ID – local identifier at service provider):
This is needed to identify the same patient within one service provider.

Together, soundex, date of birth and sex provide an accurate tool to link patients occurring in the database more than once. This is necessary to avoid overestimating the number of people living with HIV and to produce public health measures.

While there is much less risk of identifying somebody living with HIV from soundex, date of birth and sex, compared to full name, it is clear that these still comprise patient identifying information although there is no possibility of accurately decoding the soundex to the original surname.

Further information can be found at Mortimer JY, Salathiel JA. 'Soundex' codes of surnames provide confidentiality and accuracy in a national HIV database. Commun Dis Rep CDR Rev. 1995 Nov 10;5(12):R183-6.

PHE takes the protection of patient data very seriously. Below is a list of a few of the ways patient data is protected:

1. Soundexing is undertaken by the site prior to data submission. There is no possibility of decoding once data is submitted to PHE.

2. Data are submitted through a secure web portal where only authenticated users can upload data: https://hivstiwebportal.phe.org.uk/login.aspx

3. The HIV and STI department has a data sharing policy designed to explain what levels of data are available and to whom. This ensures the risk of identification of patients in the dataset is minimised: https://www.gov.uk/government/publications/hiv-and-sti-data-sharing-policy

4. All systems collecting patient data in PHE are risk assessed and a system level security policy is developed. This outlines the risks involved: a method to report a breach, a process to identify why it happened and how to prevent its recurrence. These are reviewed annually.

5. PHE has a personal information charter which explains how personal information is protected and how you can find out more about data protection processes: https://www.gov.uk/government/organisations/public-health-england/about/personal-information-charter

Legality of flow for surveillance

When HARS was approved by ISB in 2012, the HPA was the organisation responsible. The HPA was registered under the Data Protection Act 1998 (registration number Z7749250) to handle data for diagnostic, public health and other purposes.

The HPA was also registered under section 251 of the Health and Social Care Act 2001 and had approval from the Patient Information Advisory Group (PIAG) to handle data for purposes that include surveillance and the control of disease, even where specific patient consent has not been given.

Statutory Instrument 2002 No. 1438 in The Health Service (Control of Patient Information) Regulations 2002 provided the legal basis for this data handling. Details of this can be found at: http://www.legislation.hmso.gov.uk/si/si2002/20021438.htm

A PHE Caldicott group ensured the agency fulfilled its legal and regulatory obligations when processing patient identifiable information at any time.

The HPA was transferred to PHE in 2013. PHE has legal authority to collect HIV surveillance data under section 251 of the NHS Act 2006 as enacted through Regulation 3 (articles 3.1: a, b and c) of Statutory Instrument 1438 to process identifiable data for public health purposes. Support for section 251 is provided by PHE under devolved powers from CAG under Regulation 3.

Legality of flow for commissioning and quality of care

The secondary purpose of HARS is to support the commissioning of HIV services through the collation of data to inform the national HIV tariff. In addition, HARS data are used within PHE to conduct performance management at local and national level.

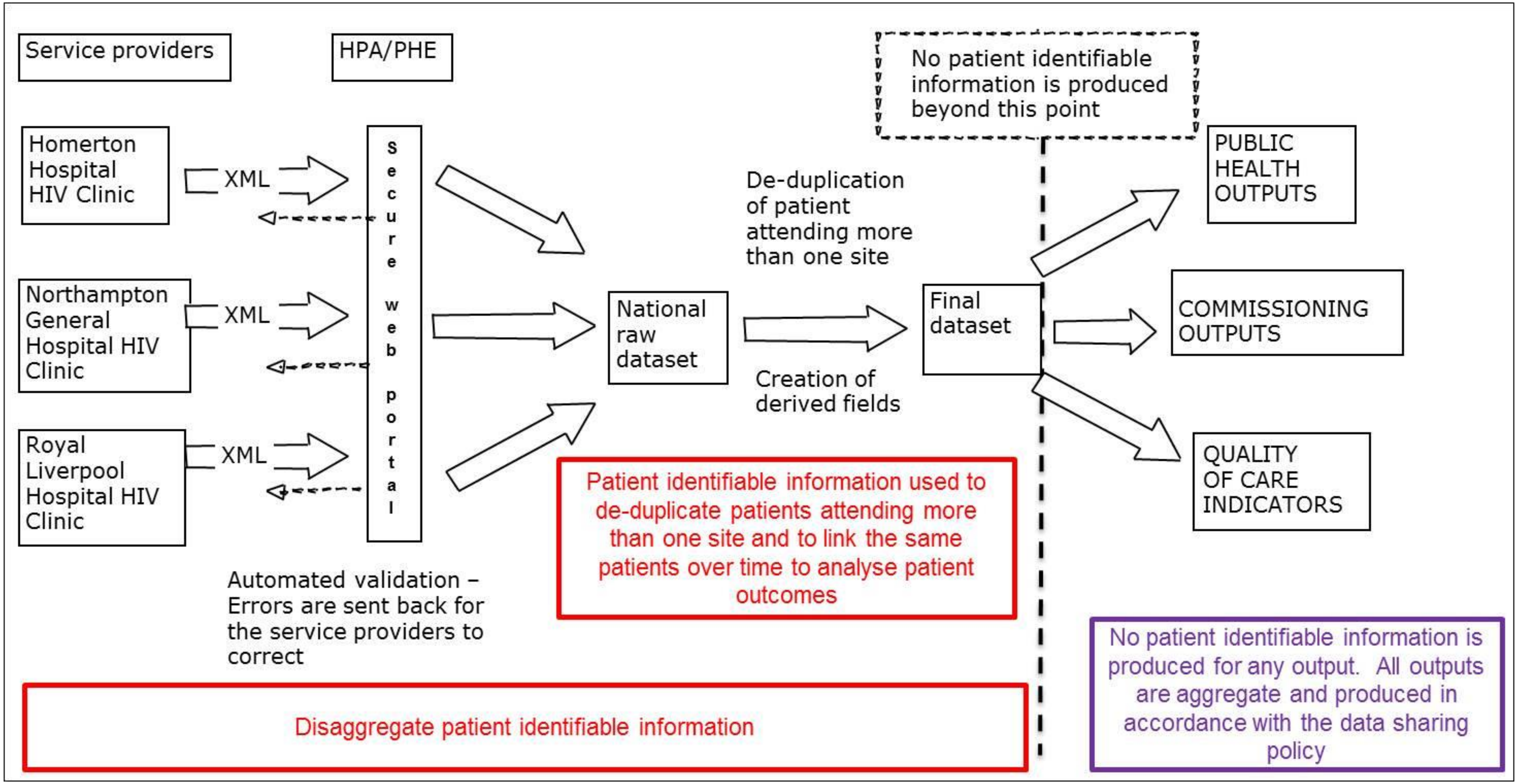
This arrangement is cost efficient since it reduces the burden of work from trusts (ie data providers who otherwise would have to provide these data on a trust by trust basis) and ensures that data used for commissioning, and the monitoring of quality of care are collected, analysed and interpreted using robust, consistent methods.

In relation to the legal basis for the collection of PII for these secondary purposes of HARS, the commissioning and quality of care outputs produced through secondary analysis are stripped of any identifying information (see diagram 2). It is important to note that there are no changes to the flow of information, nature or scope of data since the original ISB/SCCI approval. This means that the legal basis for commissioning/quality of care is irrelevant since it is no longer patient data.

NHS England holds contractual agreements with all trusts providing HIV care that specify the requirement to submit timely data to PHE for surveillance and commissioning purposes; the secondary use of these data are made clear to trusts and commissioners. It is precisely this arrangement that protects information governance. Specifically, this arrangement negates the need for a separate collection of data for commissioning which would otherwise require the collection of either patient information or anonymised data by commissioners directly from trusts. In the first scenario, commissioners would have to demonstrate the legal authority to collect this identifiable information. In the second instance, the absence of patient identifiers and a central database would mean that the data outputs would substantially overestimate the number of people accessing HIV care at each site.

This position has been checked and confirmed with Dr Robert Kyffin, Data and Information Policy and Partnerships Lead, Public Health England, t. 0207 654 8052, m. 07789 617 513, e. robert.kyffin@phe.gov.uk.

Diagram 2: Schematic diagram of flow of PII to HARS



Managing objections

If patients do spontaneously express concern regarding supplying their data and it being reported to the PHE (consent should not be requested), health care workers at the site should explain the uses to be made of the data ie the limited information recorded and reported aims to improve the service and to protect public health. Patients should be reassured that their personal data are held in strict confidence and that no personally identifiable information will be reported to PHE. Patients can also be provided with the PHE leaflet on the topic for further information:
https://www.gov.uk/government/organisations/public-health-england/about/personal-information-charter

If there are still ongoing concerns, the systems allow for the use of aliases, provided that these are consistently collected for an individual patient. However, reporting sites are advised that this is not a desirable outcome, but preferable to not reporting an individual patient at all.

If a patient raises a concern about the collection of their data, after these data have been submitted, the same process should be followed. This means, the health care worker should provide reassurance that the data are held securely and outline the service and public health benefits of the data. If the patient still wishes for their information to be removed, the health care worker should contact the HIV and AIDS reporting team. The team will remove the PII for this patient and substitute it with aliases. The reporting site will be requested to submit future data with consistent aliases for this patient from that point onwards.

There is also a mechanism within PHE for patients to register a complaint about the way their personal data have been handled. Those registering a complaint will get a response within 20 working days. This is listed in the link above.

The above position and procedure are made explicit in the system specification and is consistent with other systems related to sexual health (eg GUMCAD, CTAD).

Changes to HARS

HIV is a fast moving field and consequently there are items in HARS which are now out of date and require updating. We have also reviewed the initial data flowing in and analysed feedback from providers to simplify or amend data items.

The amendments in this change are summarised as follows:

Addition of new data fields to capture information on:

- last contact with GP
- trans status
- persistent viraemia
- latent TB screening
- human papilloma virus (HPV) vaccination uptake.

The deletion of the following variables:

- gender birth - work with the LGBT Foundation and the transgender community has informed that it is not good practice or possibly even legal to ask for gender at birth therefore we propose to remove this field from the dataset
- Clinical Trial Indicator - this field is no longer required as it will be captured through the ARV data item.

The amendment of the categories or formatting to data fields:

- gender identity - revised categories based on feedback from the trans community and the LGBT Foundation
- HIV care type - expanded categories to capture the purpose of the HIV consultation in greater detail
- diagnosis setting - expanded categories to capture new setting where HIV testing takes place which was not available when HARS was originally approved
- test for recent infection result - amended format to allow a decimal point based on new tests which were introduced after the initial HARS release
- post exposure prophylaxis (PEP) / pre-exposure prophylaxis (PrEP)
- Hepatitis B and C - expanded categories to identify if infection is acute or chronic
- ARV code - mapped to dm+d coding
- AIDS illness - mapped to SNOMED CT coding.

Summary

The changes introduced by this update of HARS will ensure HARS is up to date with developments in HIV treatment and testing and, where possible, future proof each item such that future developments do not affect the dataset structurally. As well as continuing with the main function of HARS to provide high quality and timely HIV surveillance outputs, this will support the delivery of benefits across a number of areas.

ARVs will be mapped to the NHS dictionary of medicines and devices (dm+d) coding which was a risk identified in the initial HARS standard and ensures that all new ARVs released will have an official code to report with as dm+d is updated weekly. Capturing accurate and up to date ARVs will allow for assessing the effectiveness of ARVs, ensuring the best possible patient care and value for money.

AIDS illnesses will be mapped to SNOMED CT coding, a risk identified in the initial HARS standard.

The formatting of the field to collect data on recent infection will allow for decimal points which will hopefully mean results from potential changes in tests can still be captured without having to change the standard. This will also reduce confusion from providers as to why their files are failing validation despite providing clinically correct data.

Persistent viraemia is a ‘complex’ defining condition and will be captured directly so calculating ‘complex’ patients can be done in ‘real time’ and is less likely to suffer from data validation issues. This means providers will be more accurately credited with their allocation of new, stable and complex patients which in turn has a direct effect on the funding they receive for HIV care. It also provides a mechanism for data quality on ARV and VL to be validated independently.

Issues found in the XML schema previously provided will be rectified and will allow providers to submit accurate and correct data.

Scope

Options

This information standard is designed to directly support the public health surveillance of HIV infection in the UK. This is a continuation of the function of the current surveillance system.

The scope of the standard is a result of consultation with stakeholders. Initially, all that was required was an update to the ARV field to include new ARVs and to change to one field capturing recent HIV infection to allow a decimal point in the result; simple but essential changes to the dataset. As it was advised this process would require a lengthy change request through SCCI, the opportunity was taken to review the dataset and address concerns raised by providers. Stakeholders have agreed on and support all amendments that have been included in the development of this standard.

Scope

The scope of the HARS dataset includes:

1. Review current methods of HIV surveillance to establish if they are fit for purpose.
Undertake an evaluation of current methods to undertake HIV surveillance in terms of their efficiency, duplication and output quality.

2. Provide an up to date standardised dataset.
A dataset that is unambiguous, fit for purpose and consistent with other data items contained within the NHS data model and dictionary

3. To continue an established, consistent, secure and sensible data flow.
Build upon current established surveillance reporting flows to improve the efficiency (in terms of automation) of data flow and alignment with other data flows (eg GUMCAD)

4. To further refine an established validation process.
The dataset will be developed into an XML Schema which will enable the dataset to be cleaned and validated for formatting and structure at the point of leaving the sites. An improved set of validation rules will be developed and implemented as part of the rollout of this new standard.

5. Maintain confidentiality of HIV patients.
The security of sensitive information is essential. The dataset will adhere to established published standards for the handling of sensitive data.

Out of scope

This standard does not apply to the following:

- paediatric HIV patients (aged under 15 years)
- Northern Ireland, Wales and Scotland
- patients accessing non-NHS funded providers.

Future standards

There are clear potential benefits to be derived from expanding this standard to include all new HIV diagnoses and not only to those accessing HIV care. It would provide a comprehensive means of collating data on new HIV diagnoses through one system without the need for additional matching and processing.

Applies to:

This information standard applies to all specialist HIV outpatient service providers.

Proposed dates

This submission was approved in June 2016. The following dates are for implementation and conformance:

- implementation: 1 November 2016
- conformance: 31 March 2017.

The data are important for commissioning so it is important that they are submitted as soon as possible. PHE will be working with software and service providers ahead of these dates to ensure they can be met.

Requirements

IT system suppliers

#	Requirement [i]
1	Suppliers of IT and software systems to HIV service providers MUST ensure that the systems supplied to HIV care providers are consistent with the updated HARS XML schema (subject to contract).
2	Suppliers of IT and software systems to HIV service providers MUST ensure systems can capture all the data fields in the updated HARS (subject to contract).
3	Suppliers of IT and software systems to HIV service providers MUST ensure dm+d codes are referenced on a regular basis to ensure future releases of ARVs can be captured and reported in the system (subject to contract).

Conformance criteria

This section describes the tests that can be measured to indicate that the information standard is being used correctly by an IT system supplier.

#	Criteria
1	Every XML output produced MUST produce zero formatting errors when validated against the updated XML schema.
2	Every XML output produced MUST contain the updated HARS data fields where the field is applicable.
3	Every ARV code captured in the XML output file MUST contain a valid ARV code in dm+d.

Public Health England (PHE)

#	Requirement
1	PHE MUST ensure a system is developed to receive and validate HARS XML files and relay errors to the IT system supplier for testing their XML output function.
2	PHE MUST ensure a system is developed to receive and validate HARS XML files and relay errors to the service provider when they submit HARS data once fully operational.
3	PHE MUST ensure that all valid dm+d ARV codes and SNOMED CT AIDS codes are available to system suppliers and providers where required.

4	PHE MUST produce detailed user guidance documents and data validation list for use by systems suppliers and providers

Conformance criteria

This section describes the tests that can be measured to indicate that the information standard is being used correctly by PHE.

#	Criteria
1	System suppliers MUST receive clear and detailed feedback on any errors in the HARS test file once submitted.
2	It must be possible for HIV service providers to identify and correct any errors in the HARS XML file based on feedback.
3	Only valid dm+d ARV codes and SNOMED CT AIDS codes are received in the HARS XML files received.
4	Data from system suppliers and providers MUST pass the mandatory validations.

Healthcare organisations

Note: It is recognised that individual healthcare professionals' conformance with these requirements will only be possible when the IT system suppliers and PHE have delivered on their respective requirements, which is subject to the contract between the two parties.

#	Requirement
1	Staff completing information for HARS MUST use the HARS software provided to collate information based on the updated HARS dataset
2	Providers MUST submit HARS data on a quarterly basis
3	Providers MUST address any 'A' errors identified after the HARS data is uploaded
4	Providers MUST provide training to all staff in completing HARS data

Conformance criteria

#	Criteria
1	The HARS XML file received MUST reflect changes as required in the updated HARS
2	A HARS XML file from each provider MUST be received for the relevant reporting period by the specified deadline
3	A HARS XML file is accepted into the database if it passes the

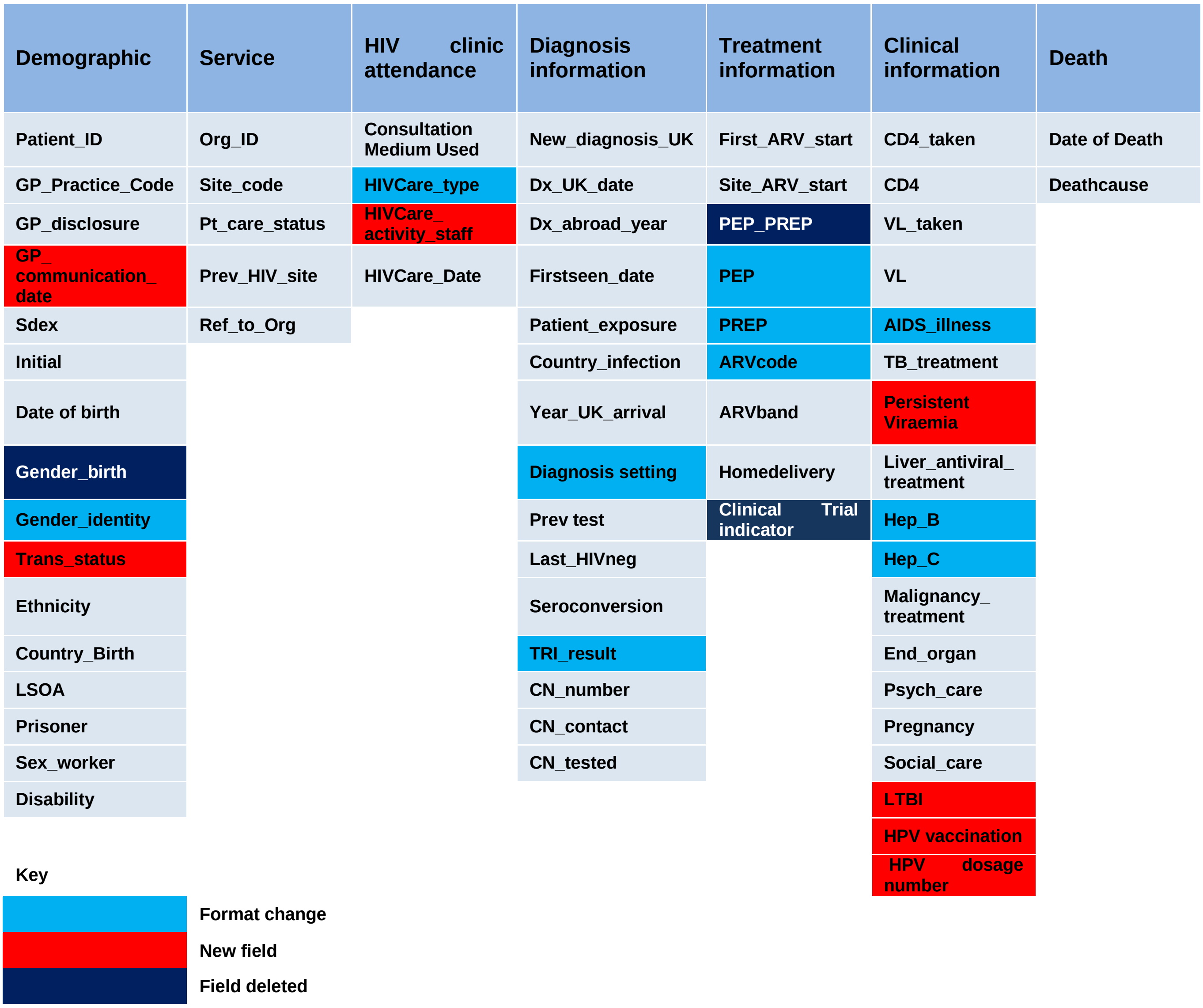
	minimum level for data completeness and quality
4	The XML file received passes validations or in the event of errors these can be easily rectified by the user

[i] The key words MUST, SHOULD and MAY are defined here: https://www.ietf.org/rfc/rfc2119.txt

High level process

The diagram represents at a high level, the HARS data fields in this information standard.

HARS data fields



Demographic	Service	HIV clinic attendance	Diagnosis information	Treatment information	Clinical information	Death
Patient_ID	Org_ID	Consultation Medium Used	New_diagnosis_UK	First_ARV_start	CD4_taken	Date of Death
GP_Practice_Code	Site_code	HIVCare_type	Dx_UK_date	Site_ARV_start	CD4	Deathcause
GP_disclosure	Pt_care_status	HIVCare_activity_staff	Dx_abroad_year	PEP_PREP	VL_taken	
GP_communication_date	Prev_HIV_site	HIVCare_Date	Firstseen_date	PEP	VL	
Sdex	Ref_to_Org		Patient_exposure	PREP	AIDS_illness	
Initial			Country_infection	ARVcode	TB_treatment	
Date of birth			Year_UK_arrival	ARVband	Persistent Viraemia	
Gender_birth			Diagnosis setting	Homedelivery	Liver_antiviral_treatment	
Gender_identity			Prev test	Clinical Trial indicator	Hep_B	
Trans_status			Last_HIVneg		Hep_C	
Ethnicity			Seroconversion		Malignancy_treatment	
Country_Birth			TRI_result		End_organ	
LSOA			CN_number		Psych_care	
Prisoner			CN_contact		Pregnancy	
Sex_worker			CN_tested		Social_care	
Disability					LTBI	
					HPV vaccination	
					HPV dosage number	

Key

🟦	Format change
🟥	New field
⬛	Field deleted

Data quality

PHE is responsible for the collation, processing and analysis of data to support the implementation of this change. PHE has an in-depth data validation process which is run on every record received.

Data can only be accepted into the database if it passes a two stage validation process:

- stage 1: XML validation: checks for correct formatting and presence of mandatory fields
- stage 2: Once a file passes the XML validations, further validations are run on the contents of the data fields against PHE business rules. These are categorised into:
  - A errors: these errors result in the file being rejected and MUST be corrected
  - B errors: these errors limit the level of analysis that can be run on the data but the file will be accepted if they cannot be corrected
  - C errors: these are minor issues or data inconsistencies which do not require correction

This two stage validation ensures high quality data is received.

Funding

The implementation of this change will require collaboration across all HIV service providers and their system suppliers.

PHE costs

Some of the costs of implementation will fall to PHE. As the author of the standard, PHE will undertake the role of programme management for the implementation work. A small central programme team is required to co-ordinate the activity across all HIV service providers. This currently exists and is operational hence the additional costs for PHE to implement this change request will be minimal.

The team currently consists of a programme manager, a project manager, an information analyst and an information officer who all work on HARS as well as the other HIV surveillance systems which HARS is replacing.

There is also one software developer responsible for developing and maintaining the software to receive, validate and store the data for the national HIV dataset.

PHE will fund the training sessions with system suppliers (excluding travel costs), and training for the reporting sites (excluding travel costs). This has been met by core budget costs, since this work is a departmental priority.

System supplier costs

A number of systems across the NHS will have to make changes in order to implement the Standard.

System suppliers have already developed and rolled out software to capture and report HARS data. The changes required relate to capturing new data and do not affect the overall process of collating and reporting. It is therefore expected that the cost will be minimal.

System suppliers have advised they will only start development of this standard on the publication of an ISN.

Local NHS costs

There may be costs to local NHS organisations to implement this information standard. System changes will be managed by the suppliers and, subject to contract, there may be a cost implication.

The costs involved relate to staff time on training and system down time for the software upgrade for the updated HARS. Providers have it written into their contracts to provide HARS data so the cost to implement HARS and report these data are subject to the contract between them and their supplier.

Burden assessment has been carried out for the ‘end-to-end’ process of collating and reporting HARS data. Through the burden assessment, it was estimated the cost to all providers in England to collect and report HARS data is £1,615,899. This cost is expected to be met by the provider through their contract with their commissioning team.

The overall treatment cost for people living with diagnosed HIV infection in the UK is £1.08 billion per year. The BAAS estimate (which over estimates the true costs though including the start-up costs for sites) represents 0.2% of this total cost.

Communication

Stakeholder engagement and consultation

Development of this information standard has been undertaken in consultation with a number of key stakeholders. The clinical reference group (CRG) for HIV has been consulted throughout the process and implementing this standard and approved the clinical content of the changes. Membership of this group has included Department of Health, NHS England, clinical leads for HIV and patient groups. There is now a data lead within this group who will lead on HARS development.

In addition, interviews have been conducted with clinicians, health advisors, data manager and other NHS staff working on HARS data; with the software suppliers of HIV systems and with commissioners and trust finance staff.

Ongoing engagement with the CRG data lead stakeholders and will continue throughout the process to refine and publish the standard.

Communications

The communications strategy seeks to ensure users are aware of the changes to the dataset and the reasons for the change and provide for comprehensive stakeholder involvement in its development. It will use a multi-faceted campaign comprising:

- web communications
- user involvement
- commissioner and provider engagement
- software supplier engagement
- stakeholder seminars
- reporting, briefing to national patient groups

The communications strategy ensures that it takes into account the needs of users and patient groups. A number of one to one discussions have taken place with the software suppliers and national patient groups, BHIVA and BASHH to ensure that their views can be incorporated into the standard.

Service users have had and continue to have the opportunity to engage with the surveillance and commissioning activities undertaken by PHE

Training

Training will be provided to software suppliers, who will in turn, provide training to the data providers. The HARS system has been implemented through this method to 95% of data providers nationally. The changes for which we are seeking approval are minor and training required is consequently is similarly minimal. Extracts from the BAAS report (25/05/2016) provide further evidence that minimal training will be required.

Implementation

The implementation of the HARS will be managed and directed by PHE. PHE has an excellent collaborative relationship with HIV and GUM clinics throughout the country. PHE has also had experience of rolling out standard updates to existing datasets: GUMCADv2, which replaced the original GUMCAD and the CTAD system has also successfully gone through a standard update. We will build on the success of the initial HARS rollout and the standard updates to GUMCADv2 and CTAD and use this process as a template for the roll out of the proposed HARS updates.

The dataset contains items that have been reported to PHE through HARS which has been successfully implemented in over 90% of HIV service providers in England. The commissioning data fields are directly collected through routine HIV surveillance data flows and the retention of the surveillance-commissioning link will facilitate the roll out of the HARS.

A staggered implementation is proposed. The nature of the changes in this standard is considered minor and should not cause major difficulties to developers who have already developed a system to record and report HARS data. The overall process to collate and report data will remain the same.

As part of the process to gain ISN, an updated HARS XML schema will be produced. This will be used by PHE to update the database structure in house. New validations will also be developed and implemented into the PHE database.

In parallel to PHE development, system suppliers will also be provided with the updated HARS XML schema and will be given six months to develop an updated system to collect and report to the updated HARS. System suppliers will also have to test their outputs against the PHE developed upload and validation system.

It is expected that software suppliers will develop and rollout the updated software by 31 March 2017.

Outline benefits

The benefits of the HARS dataset include:

- improved efficiency of data collection and reduction of duplication
- reduction in costs resulting from reductions in duplications
- a single point of collection to enable consistency of reporting information
- a single source of data collection for surveillance and commissioning
- reduced reporting demands by reducing the burden of reporting and collection on clinic staff
- assist evidence based public health and policy formulation
- improved standards and standardisation of care and transparency of service delivery
- information used to identify areas for service improvement
- improved visibility of the nature and accessibility of HIV services
- more effective sharing of knowledge and information to encourage and support collaborative working.

The additional expected benefits of this standard are as follows:

- the ability for providers to report up to date and accurate clinical data – essential for surveillance
- inclusion of data to better inform the accurate commissioning of HIV services
- amendment of data items based on feedback from patient groups
- inclusion of data items to collect data on HPV vaccination to be used to assess the uptake and outcomes and to inform the commissioning of these services
- amended data items designed to reduce need for further amendments in future
- data provided to PHE can ensure indicators of outcomes can be produced by PHE and not by providers directly hence ensuring higher quality data and saving each provider a significant amount of work.

Maintenance strategy

Change process

The full implementation of this change is expected to take six months from publication of the ISN and we would not expect any changes to the standard during that time. A programme of work, with accompanying programme board, will be convened to manage the implementation. Whilst the implementation is under way the programme board will be responsible for agreeing any changes to the standard.

It is recommended that the programme board undertakes a formal review of the standard as part of the programme ending process before the board disbands. Any potential changes to the standard can be considered at this point. The most likely changes to the standard would be to expand its scope to include care instances other than prescribing and/or clinicians other than prescribers. This should be considered by the programme board as part of the formal review.

Once the implementation is complete and the programme board has disbanded, any changes would need to be carefully consulted. It is recommended that representatives from the following groups would need to be consulted about any proposed changes to the standard:

- Department of Health
- NHS England
- PHE
- NHS Digital
- Clinical Reference Group
- IT System Suppliers
- the relevant clinical group, depending on what changes were proposed

As a minimum it is recommended that a consultation group with members as indicated above be convened to review the standard once every three years.

Contact

The HIV and AIDS Reporting Section in PHE will act as the change manager for this Standard; they can be contacted via HARSQueries@phe.gov.uk

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