4 HAI PREVALENCE STUDY SUBMISSION TO DATA STRATEGY GROUP

Approved at an extra-ordinary data strategy meeting on 25 May 2005.

A form D has been submitted as part of the HPS register of systems.

The following document presents evidence that the criteria are being met.

Amended for submission to Caldicott Guardians on Wednesday, 02 May 2007. This includes an explanation of the criterion that have to be met to conform to the requirements of the HPS Data Strategy Group.

Criterion:

Sections should be clear about why we need to have the data set including Patient Identifiable Information (PIIs)

Definition of public health benefit:

To provide the HAI Task Force with baseline information on the total prevalence of HAI in Scottish hospitals and its burden in terms of health service utilisation and costs. This information will be available to guide priority setting in the development of strategy and policy.

Definition of health protection function:

To develop a consistent methodology for prevalence surveys which when repeated at intervals will allow the impact of measures taken nationally to reduce the burden of HAI to be evaluated through an analysis of trends over time.

Criterion:

Sections should be clear about the use of individual PIIs in achieving objectives detailed in criterion 1

Listing of the PIIs

CHI number if implemented or Patient Hospital Record Number (whichever is being used by the hospital being surveyed)

System generated unique record identifier (Accession number)

Gender

Date of Birth

Definitions of how each will be processed

See attached Standard Operating Procedure (SOP) for the Prevalence Study.

The project will be managed using the SCIEH Information and Security Policy and SOPs for data management.

Definition of how each will be used in any output or data operations

The data collectors will use a patient identifier: CHI number (if implemented) or Patient Hospital Record Number - after initial data collection to record Date of discharge. The pilot study tested if this was sufficient information to allow all the discharge information to be recorded, because there were issues with some hospitals using a combination of CHI numbers and some using patient record numbers the addition of the date of birth enabled a validation if required. External Consultants undertaking statistical and economic analysis will not have access to this information. Once the survey is complete this data will be deleted.

System generated unique record identifier (Accession number) – this will be considered a PII for the length of the study because it will be linked on the tablet PCs to the CHI or Patient Hospital Record Number until all the discharge data has been collected. Once the survey is complete and the link between the accession number and Patient identifier is removed this will no longer be considered a PII.

Gender – this will be collected in order to provide sex adjusted prevalence rates for all hospitals and for individual hospitals. This will remain in the data set for analysis.

Date of Birth – this will be collected in order to calculate age in years and as a check to allow confirmation if there are any transcription errors in the CHI or patient hospital record number. Age in years in necessary for modelling for age adjusted HAI rates. This will allow for comments on the age distribution of the total population compared with previous studies.

Criterion:

Sections should limit the number of PIIs to those which serve the purposes

Clarification that each PII has a separate purpose

Patient Identifier: Required for quality checking and retrieval length of stay data

System generated unique record identifier (Accession number): Required for labelling distinct records

Gender: Required for modelling of rates adjusted for sex

Date of Birth: Required for modelling of rates adjusted for age

Definition of how each PII will enhance the objectives of criteria 1

Patient Identifier: Required for quality checking and retrieval length of stay data which will be used to evaluate the additional length of stay for HAI patients and the burden on NHS time and cost.

System generated unique record identifier (Accession number): Required for labelling distinct records. This is essential for data management and validation of the survey.

Gender: Required for modelling of rates. This will provide sex adjusted prevalence rates that can be compared with future studies.

Date of Birth: Required for modelling of rates. This will provide age adjusted prevalence rates that can be compared with future studies.

Criterion:

Section should limit access to PIIs to those who need to know

Listing of HPS or other staff who need to know

Project Manager

Data Manager

Data Collectors

Systems Developers

Clarification of grounds for including those on list

All staff on the list are subject to NHS confidentiality agreements and have signed and agreed to the HPS confidentiality agreement.

Project Manger will deliver the database and reports and conduct a validation study of the data collection process.

Data collectors will need to record the Patient Identifier (CHI number if implemented or Patient Hospital Record Number) in order allow the collection of discharge details.

Systems developers may need to make adjustments to the database during the study and in doing so may need to view the PII details.

Audit Trail

The tablet database is designed to record the time and date of the creation of an individual patient record. This will record information on which data collector has accessed the notes. In addition to this as a fail-safe a detailed project plan records each ward visited, what date the ward was visited and by whom.

Indication that there is a process for revising this preferably in the SOP

See attached SOP for Prevalence Study.

Listing of the procedures for access e.g. archiving and data handling

See attached SOP for Prevalence Study.

Indication of how those on the list receive training in data protection and security

Local HPS staff will provide basic training on data protection and security.

Criterion:

Sections should protect data from those who do not need to know accessing them

Listing of procedures for limiting access e.g. Password protection, archiving and data handling

Tablet PCs on which data is collected are stand-alone, password protected and password access is limited to the list shown. The database is also password protected and is limited to the list shown above. The passwords will be maintained in accordance with the SCIEH SOP 1 and The Prevalence Study SOP (see attached details archiving and data handling procedures).

5 HAI PREVALENCE STUDY INFORMATION SECURITY SOP

The SOP references refer to the HPS Information Security Standard Operating Procedure (11).

5.1.1 General

This Standard Operating Procedure (S.O.P.) is to be implemented by all members of Health Protection Scotland (HPS) Prevalence Study staff to safeguard the confidentiality, integrity and availability of data held by the HPS Prevalence Study in computer systems and manual filing systems.

5.1.2 Passwords (In accordance with S.O.P.1 Passwords)

Passwords have been allocated to each tablet PC and to the Prevalence Study Database.

The system developer will ensure that when a person leaves HPS employment permanently, their password is changed within 24 hours of the person's departure. The password change is to remain in force for a maximum period of 30 days at which time the users account is to be removed from the system. Refer also to the HPS Exit Process held by the Personnel Department. The project manager will inform the systems developer when members of staff begin work or leave post. The tablet PC will be accessible only by the data collector and the system administrator.

5.1.3 Data Collection (In accordance with S.O.P.8 Confidentiality Rules and S.O.P. 10 Release of Named or Patient Identifiable Data)

Data will be collected on tablet PCs in the wards. All information sources available will be used. The survey will only record details relating to the patients HAI and the identifiable information will be the four items mentioned above. The Protocol for data collection contains a listing of all the data items and a description of the data item and a rationale for recording the item.

Data collection

This will be undertaken on a rolling basis by trained data collectors, two being allocated at any one time to one hospital. Data will be collected in each hospital over a period of days or weeks but all data collection in one ward must be completed within one day. Data collection will be undertaken on weekdays. Data will be entered into specially designed data collection proforma held on a tablet PC. Data items will be collected on the following data entry forms: ward, patient, infection, antibiotics, invasive devices, workload, surgery, and discharge forms. A record will be made of the time taken to complete the patient forms and of the staff involved

in data collection. The data collectors will be assisted in data collection by local clinical staff and/or members of the infection control or audit departments who are familiar with the methodology and with the clinical environment.

An infection will be considered to be present if the patient meeting the case definition is symptomatic or receiving treatment on the day of the survey. The final decision on whether an infection is present will rest with the project data collectors who will seek help from the project leader where they are in doubt. Data collected from the hospitals will be exported into a database held at HPS and managed by the data manager. The data collectors have RAS (Remote Access Server) accounts that allow them to remotely log on to their HPS accounts. These accounts are considered to be a secure network and data will be transferred by e-mail to HPS offices. Data will also be collected on the characteristics of the ward (ward type, bed numbers, staff numbers and types) on the day of data collection.

5.1.4 Training

The data collectors have undergone an initial period of training in diagnosis of HAI based on the use of a series of case studies prepared by the project leader. They have also had a pilot period under observation in a hospital, their diagnoses being checked against that of the project leader. Validation of data collection will be undertaken throughout the survey period in order to ensure consistency and accuracy of data collection. Data collectors will be given training on security and confidentiality. Throughout the survey monthly meetings will be undertaken to allow discussion of any issues which arise during the course of the survey and recording any decisions for inclusion in future protocols.

5.1.5 Informing Local Staff

A leaflet and poster has been produced which informs ward staff about what is involved in the data collection process. This will be sent one month before the survey to distributed by the Infection Control Contact at the Hospital.

5.1.6 Informing Patients (In accordance with SOP7 - Patient Information Leaflets)

HPS have produced a leaflet for patients that explain the legal responsibilities of HPS and what their role is. These are available to inform patients of what happens to the data. They can also be given the staff information leaflet if they require further information about the survey.

5.1.7 Data management

This will be consistent with the Data Protection Act 1998. All databases will be password protected. Only members of the HPS Prevalence Study Project Team will have access to the data. The only PIIs recorded will be Patient identifier, gender and Database accession number and age.

5.1.8 Audit Trail

The tablet database is designed to record the time and date of the creation of an individual patient record. This will record information on which data collector has accessed the notes. In addition to this as a fail-safe a detailed project plan records each ward visited, what date the ward was visited and by whom.

5.1.9 Ethical approval and Confidentiality

Consultation with the Scottish Executive Health Department has indicated that Ethics Committee approval for the prevalence survey is not required. The confidentiality of the patient will be protected.

The only patient identifiers will be Patient identifier (CHI or Patient Hospital Record Number) that will be held on the patient record for the course of the data collection, an automatic accession number will be allocated to each patient record, which will be considered PII for the duration of the data collection. After data collection is complete the CHI or Patient Hospital Record Number will be deleted and the link between the accession number and the patient will be removed and this will no longer be considered PII. Age in years will be collected and not date of birth and is therefore not considered to be PII.

The master list linking patient identifier, necessary to collect length of stay and discharge diagnosis retrospectively, and to enable the checking of data items, will be held by and available only to the local staff. The data collection staff will sign confidentiality agreements in the hospitals before having access to any patient data. Permission to examine patients' notes has been sought from the Medical Director (Caldicott Guardian) of the hospital

Only the age in years and gender will be issued to the external consultants who will be performing the analysis. The Patient record numbers will be removed from the database as soon as length of stay data has been collected.

Length of Stay data will be requested from the Infection Control Teams by the data manager who will send a list of required patient identifiers to the hospital contact, once this data has been recorded the link between patient identifier and accession number will be permanently deleted.

5.1.10 Backups (In accordance with S.O.P.2 Backups)

HPS

Data held in HPS is to be the subject of a controlled backup procedure as detailed in SOP2 Backups.

Archived data and recovery data is to be accorded the same security as live data.

The backup procedure for the Prevalence Study Database is to be administered by the data collectors themselves and is to be taken nightly Monday to Friday. A USB stick will be used to collect the backup data and an automated method of backup from the database. Encrypted

USB sticks were procured for trial in the pilot study. The data is backed up onto encrypted USB sticks so that the data are saved and encrypted.

When the data is transferred to HPS the data will be backed up in accordance with the SCIEH/HPS backup procedure (Information and Security Policy and SOP2 Appendix 1). The role of the data manager is to coordinate and manage the collation of the data from the data collectors in the field. The collated database will be stored on the HPS/O:SSHAIP on SCIEHAP01/HAI Prevalence folder which is backed up nightly in accordance with SOP2 and Annex 1).

5.1.11 External Sites

The backup procedure for the Prevalence Study Database is to be administered by the data collectors themselves and is to be taken nightly Monday to Friday. A USB stick will be used to collect the backup data and an automated method of backup from the database. The USB sticks have been encrypted so that in the unlikely event of them being lost or stolen they will be password protected secure.

The USB Sticks will be securely stored separately from the tablet PCs.

6 REFERENCES

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