Area Drug and Therapeutics Committee

Policy Statement

Safe Use of the Prescribing Information System (PIS)

1.0   INTRODUCTION

The Prescribing Information System (PIS) is a software package that enables authorised NHS staff to access the full NHS Lothian prescription database, including patient level information, remuneration data and e-pharmacy data. The PIS is created by the payment processing of prescriptions by the Practitioner Services Division of NHS National Services Scotland (NHS NSS). PSD are responsible for the processing and pricing of all prescriptions dispensed in the community in Scotland.[1] PIS is accessed through a web based portal known as SAP Business Objects. NHS NSS is responsible for the output data.

The PIS offers a unique opportunity as work on epidemiology of multimorbidity highlights the importance of medicines as indicators of co-morbidity. There will be opportunities for the prescribing dataset to be used, as other patient level datasets are, to link with TRAK and assess patient outcomes.

The NHS Scotland Information Assurance Strategy[2] emphasises that Boards need to focus on using the information they hold wisely and well, as well as responsibly and with care. In this context Boards recognise the importance of the availability, integrity and confidentiality of information as well as their duty of care.

1.1   AIM OF POLICY STATEMENT

To ensure PIS data is utilised safely in line with Caldicott principles, information governance policies, processes and good practice, for the purposes of improving care of current and future patients through service delivery, teaching, training, audit research and evaluation.

1.2   OBJECTIVES

1.2.1   To describe and define roles and responsibilities of NHS NSS, NHS Lothian and individual users in relation to the use of PIS data.

1.2.2   To describe appropriate governance and analytic framework.

1.3   SCOPE

This policy statement applies to all users of PIS data. Users are defined as those with access to the full NHS Lothian prescription database as described in 1.0 above.

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2.0   ROLES AND RESPONSIBILITIES

2.1   NHS NATIONAL SERVICES SCOTLAND (NSS)

2.1.1   NHS NSS produces guidance on the safe and secure use of personal health information.[3]

2.1.2   NHS NSS defines four types of PIS user:

- Confidential access to all classes - Full access
- Confidential access with no remuneration - Access to patient identifiers but not to financial data
- Non-confidential access to all classes - Access to patient and financial data but excluding patient identifiers
- Non-confidential access with no remuneration - Access to patient (excluding patient identifiers) but not to financial data

This approach requires that training, security and volume of data accessed is tailored, first to specific types of activity and then to categories of user. When applied correctly, this approach reflects international best practice. Financial data is identified as a section called Remuneration. Confidential (patient identifiable) items are marked with a 'C'.

Non-confidential access to PIS restricts the ability of users to run certain types of patient-based analysis. Without confidential access, it is not possible to restrict your analysis to only return items with patient information. As a result, the number of items would be inflated, and in turn the calculation of items dispensed per patient also. This is something that has to be kept in mind when building patient-based PIS Standard Reports, both at a local and at national level.

Therefore it is not recommended to have this level of access. If data is needed from PIS but user cannot get confidential access then the data must be compiled by a user who does have confidential access, providing the output is aggregated to prevent disclosure. This is to avoid errors in the data.

2.1.3   An electronic User Access System (UAS) https://useraccess.nhsnss.scot.nhs.uk is used to process access requests to ISD Datamarts. The approval process is determined locally. NHS NSS review individuals' access to PIS on a six-monthly basis via the UAS. Renewal reminder emails are sent automatically to individuals about six weeks before expiry and renewal must be requested via the UAS otherwise access will be removed on the expiry date. A number of audit reports list all the approved requests with the details entered in the authorising box. Emails received are also stored as records.

2.2   NHS LOTHIAN

2.2.1   NHS Lothian Information Governance[4] provides a framework for handling information in a confidential and secure manner to appropriate ethical and quality standards and provides professional support to NHS Lothian staff. NHS Lothian must comply with guidance and legislation from a number of sources and make sure that all employees know their responsibilities.

2.2.2   Freedom of Information (FOI) Requests. PIS should only be used to respond to requests that cannot be answered using PRISMS. If patient data is needed to compile a response then PIS must be used. For example if an FOI asks for the data to be split by patient age band then PIS must be used as PRISMS has no patient information.

The FOI response must comply with data protection legislation, therefore users must suppress confidential or disclosive data appropriately or restructure the data in such a way that patient information is protected.

2.2.3   **Authorisation of applications for access to PIS**. NHS NSS electronic UAS auto-generated emails are sent to Lothian authorisers. All applications must be carefully considered and scrutinised by the authorisers, and advice sought from the Caldicott Guardian if required. Authorisation for access is provided by a member of Lothian Analytical Services (LAS), nominated by the Caldicott Guardian.

Following an application by an individual, an automated email is sent to the first person on the UAS approvers list noting that there is an access request awaiting approval. The LAS member of staff (indicated in 2.2.3) will check the request and then send an email to the individual and their line manager as follows:

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I have received your request to access to PIS through the User Access System. The local
Lothian process for approval requires the following actions:

1.  Confirm by email that you have read and understood the Statistical Disclosure Guidance
    published at http://intranet.lothian.scot.nhs.uk/NHSLOTHIAN/HEALTHCARE/A-
    Z/PUBLICHEALTH/ANALYTICALSERVICES/Pages/InformationGovernance.aspx
    This is to ensure appropriate use of the data when extracted and analysed.
2.  Confirm by email that you have read and understood the ADTC Policy on Safe use of PIS
    published at
    http://intranet.lothian.scot.nhs.uk/NHSLothian/NHSLothian/BoardCommittees/AreaDrugTher
    apeutics/MedicinesGovernancePoliciesADTCPolicyStatements/Pages/default.aspx
    This is to ensure appropriate use of the data when extracted and analysed.
3.  Confirm that the reason for access by answering the following:
    a) Please specify the intended use of the data

    Once I receive your response, I will review it and approve your request through the
    User Access System, if appropriate.
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Once a reply has been received from the applicant, the approver opens the request in UAS, records authorisation for the individual, which includes that the individual has confirmed they have read disclosure guidelines and provided reason for access. This is then approved and access granted.

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2.3 DATA ANALYSIS/EXTRACT PROCESS

Please refer to *Appendix 2*, NHS Lothian PIS Information Governance Flowchart, for the process to be followed where a requester has requested a user to extract PIS data.

Definitions of requesters:

External requesters – non-confidential aggregated data;

If an external requester has requested non-confidential data then the user must adhere to the NHS Lothian Information Governance Policy when releasing the data.

External requesters – confidential

If the external requester has requested confidential data such as CHI, Name, Address, Postcode or patient level de-identified data, the external requester must complete a Caldicott Application and send it to the Caldicott Guardian for approval.

Internal requesters – non confidential aggregated data

If an internal requester has requested non-confidential data then the user must adhere to the NHS Lothian Information Governance Policy when releasing the data.

Internal requesters – confidential

If an internal requester has requested confidential data such as CHI, Name, Address, Postcode or patient level de-identified data, their line manager or equivalent must return a completed PIS request form via email and confirm that the data is needed for the requester to perform their role at NHS Lothian. This email must be stored for future reference. The PIS request form is included in this policy statement as *Appendix 1*, and is available from the Lothian Analytical Services Team.

Internal requesters who have the same level of PIS access as the user

If these requesters have asked for PIS data because they do not have the expertise to extract it themselves then no approval is needed. The requester will have read and agreed with the NHS Lothian Information Governance policy when they gained access to PIS.

The user should guide the requester through the analysis/extract to allow sharing of knowledge and experience.

2.4 INDIVIDUAL USERS

2.4.1 It is the individual's responsibility to ensure they apply for and maintain access to PIS via the UAS https://useraccess.nhsnss.scot.nhs.uk

2.4.2 In some instances of data sharing it is necessary to ask the Caldicott Guardian for formal approval to share patient identifiable data by submitting an application form, available at http://intranet.lothian.scot.nhs.uk/NHSLothian/Corporate/A-Z/Caldicott/Pages/default.aspx

The main reasons for seeking formal approval are:

1. Storage of patient identifiable data on any removable or portable media (e.g. USB stick, recording device)
2. The sending of patient identifiable data out with Lothian, either
    a. Electronically out with Lothian's computer system
    b. Physically, e.g. by post
3. Use of patient identifiable data for which patient consent has not been obtained for that specific use
4. Use of email to patients relating to their treatment in exceptional circumstances

2.4.3 It is the user's responsibility to comply with the NHS Lothian information governance policy when using PIS. The user must also confirm with the local Information Governance Manger if there is any doubt about releasing data.

2.4.4 It is the user's responsibility to ensure that PIS data has been used correctly in order to provide reliable output. Users should request access to the ISD Prescribing Wiki for access to more information about the data by emailing the prescribing team: NSS.isdprescribing@nhs.net

Users should seek Quality Assurance from the Primary Care Pharmacy Data Analyst in Lothian Analytical Services: analysts.PCCO.PCP@nhslothian.scot.nhs.uk or the prescribing team at ISD.

2.4.5 The user must make the ISD prescribing team aware of any issues with the data or the national standard reports. Issues with runtimes and problems accessing Business Objects should be addressed to product support: NSS.isdSHIS@nhs.net

2.4.6 The user must ensure that confidentiality of commercially sensitive information is understood, maintained and not breached[4] and add the following disclaimer to all PIS Reports which are confidential:

Disclaimer: This file contains PIS data. The data presented have not been adjusted to protect against potential disclosure risks and are released for clinical and management information purposes. The data presented may contain information which enables (perhaps with the aid of further knowledge of the topic) an individual patient to be identified. Please ensure access is restricted and that patient confidentiality is not compromised.

2.4.7 Store and transmit PIS reports securely within the policies and procedures of NHS Lothian.

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2.4.8 Exceptionally, Information Analysts may be granted specific permission, directly from the Caldicott Guardian, to utilise PIS to obtain data related to potential criminal and fraudulent activity and to assist with controlled drug related adverse incident investigations.

2.4.9 The user has a duty to share reports created in the PIS universe that may be of interest to other board employees. The user should ask the Primary Care Pharmacy Data Analyst to save their report in the Lothian Public Folder in Business Objects. Users must ensure that the report has undergone the quality assurance process and is set to 'refresh upon opening', meaning any data populated is deleted upon opening the report. This means that users will only be able to access the data they are permitted to see.

This provides an opportunity to create standard reports for other users of PIS in the Health Board. Users can also learn tried and tested techniques from these reports such as conditional formatting, layouts, formulae, etc. Using the Lothian Public Folder in Business Objects will also promote good use of version control as users will access the report from the same place.

3.0   LIST OF APPENDICES

Appendix 1   PIS: Information Request Form [available from the Lothian Analytical Services Team]

Appendix 2   NHS Lothian PIS Information Governance Flowchart

4.0   REFERENCES

1. PIS Data Manual. Version 2.4. NHS National Services Scotland. 2014: www.prismsweb.scot.nhs.uk/np_PIS-Roll-Out.htm
2. NHSScotland Information Assurance Strategy. CEL 2011 (26). The Scottish Government. 15 November 2011. www.sehd.scot.nhs.uk/mels/CEL2011_26.pdf
3. Safe and secure use of personal health information. ISD. NHS National Services Scotland. December 2012. www.isdscotland.org/About-ISD/Confidentiality/Safe_and_secure_use_of_personal_health_info_Dec2012.pdf
4. NHS Lothian Information Governance: http://intranet.lothian.scot.nhs.uk/NHSLothian/Corporate/A-Z/ehealth/operationsandinfrastructure/InformationGovernance/Pages/default.aspx

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PIS: Information Request Form [available from the Lothian Analytical Services Team]

Requester Details:

Name:	
Title:	
Department:	
E-mail:	
Phone Number:	

Timescale:

Date Request Submitted:	
Date Information Required By:	

Request Details:

Brief Description of Requirements:	Please provide a brief outline of the information required, including the following relevant details where possible: • Drug(s) (Brand/Generic name, strength, unit of measure, formulation) • Health board\HSCP\Practice Cluster\Practice • Age Restrictions (e.g. Under 16)/Age banding • Dose • Ward Codes used in TRAK • Year(s) of interest • Break down of timescale e.g. financial year, monthly • Cost, number of patients, number of prescriptions, quantity • BNF chapter/paragraph/section/subsection • How often the data will be required e.g. quarterly, monthly • Format of report e.g. Excel, PDF

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Intended Use of Information:	Please include a brief summary of the purpose that the information will be used for and who shall be involved with the data. Examples include: • Patient care • Monitoring • Optimisation of therapy • Quality Improvement • Prescribing • Will the dataset be linked to another?

Do you require any confidential data terms? **	**Yes:** ☐ ☐ **No:** ☐
	** Please refer to the links for further guidance: Safe use of the Prescribing Information System (PIS) Policy http://intranet.lothian.scot.nhs.uk/NHSLothian/Corporate/A-Z/Caldicott/Pages/FAQs.aspx ** If you require confidential data items, please include what data and rationale for this in the Additional Comments section below.

Additional Comments:

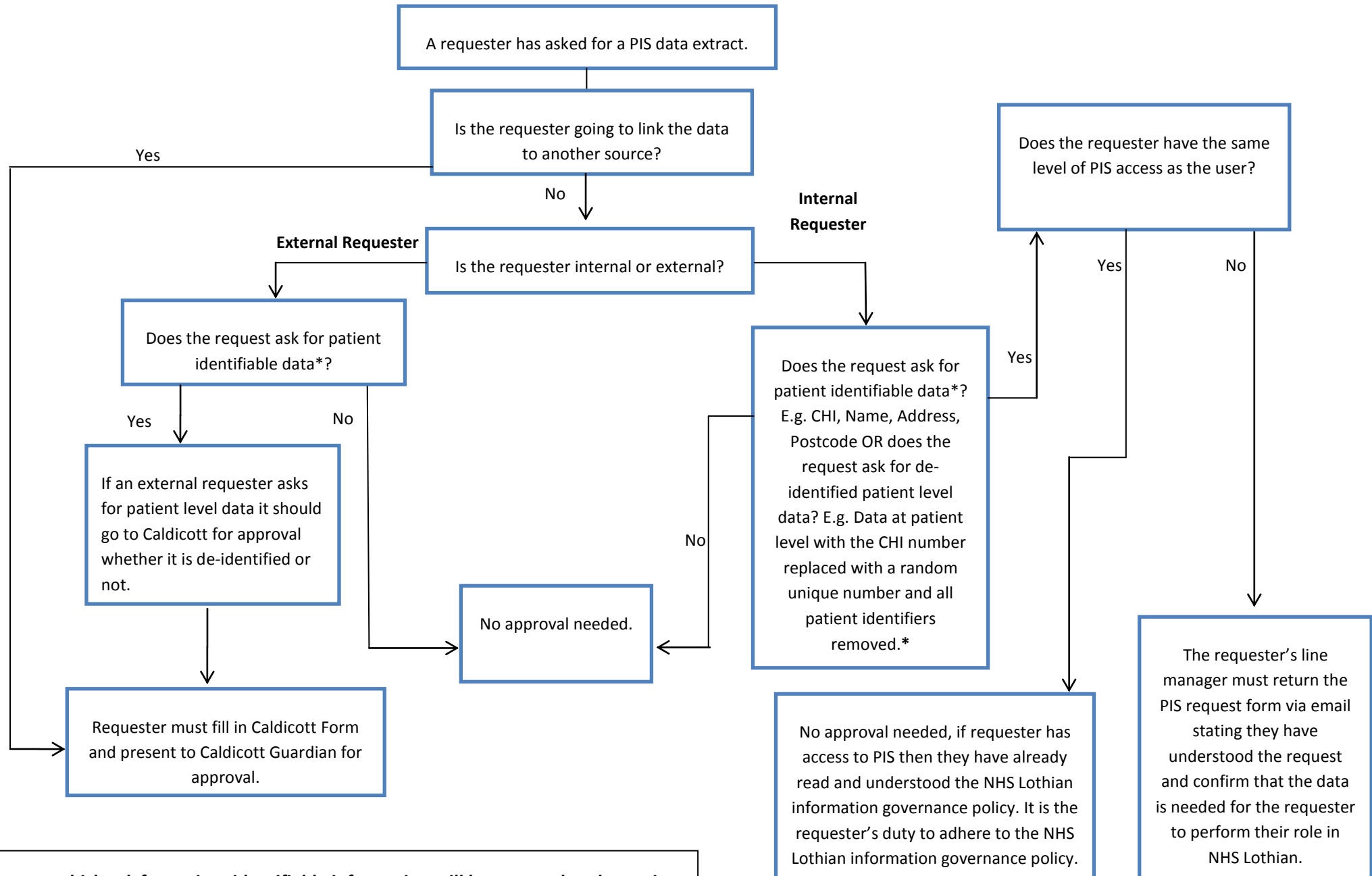| Please provide any further details that are relevant to your request here.	

To be completed by PIS User undertaking request:

Further Information:	

Appendix 2 NHS Lothian PIS Information Governance Flowchart

In all cases the extract/analysis must adhere to the NHS Lothian Information Governance Policy.

A requester has asked for a PIS data extract.

Is the requester going to link the data to another source?

Yes

No

External Requester

Internal Requester

Is the requester internal or external?

Does the request ask for patient identifiable data*?

Yes

No

If an external requester asks for patient level data it should go to Caldicott for approval whether it is de-identified or not.

No approval needed.

Does the request ask for patient identifiable data*? E.g. CHI, Name, Address, Postcode OR does the request ask for de-identified patient level data? E.g. Data at patient level with the CHI number replaced with a random unique number and all patient identifiers removed.*

No

Yes

Does the requester have the same level of PIS access as the user?

Yes

No

Requester must fill in Caldicott Form and present to Caldicott Guardian for approval.

No approval needed, if requester has access to PIS then they have already read and understood the NHS Lothian information governance policy. It is the requester's duty to adhere to the NHS Lothian information governance policy.

The requester's line manager must return the PIS request form via email stating they have understood the request and confirm that the data is needed for the requester to perform their role in NHS Lothian.

*Requests which ask for patient identifiable information will be assessed to determine whether de-identifying the data is a more appropriate alternative before progressing.