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Electronic Prescription Service Release 2 Clinical Assurance

ETP Programme

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Reviewers:

Name	Signature	Title	Date of Issue	Version
Dr Maureen Baker		National Clinical Lead for Safety	21/05/2008	0.4
Dr Manpreet Pujara		National Clinical Lead - GP	21/05/2008	0.4
Ian Lowry		ETP Programme Manager	21/05/2008	0.4
Ian Powell		ETP Project Manager	21/05/2008	0.4
John Whiteside		Technical Architect	21/05/2008	0.4
Nicola Young		ETP Assurance Manager	21/05/2008	0.4
Ian Harrison		Clinical Safety Architect	21/05/2008	0.4
Stuart Harrison		Safety Engineer	21/05/2008	0.4
Matthew Barrow		ESP Compliance Manager	21/05/2008	0.4

Approvals:

This document requires the following approvals.

Name	Signature	Title	Date of Issue	Version
Dr Maureen Baker		National Clinical Lead for Safety	18/06/08	1.0
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Dr Manpreet Pujara		National Clinical Lead - GP	18/06/08	1.0

Document Status:

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Related Documents.

These documents will provide additional information.

Ref no	Doc Reference Number	Title	Version
1	NPFIT-NPO-GEN-IP-0067	Glossary of Terms Consolidated.doc	Latest
2	NPFIT-ETP-EDB-0286	EPS GP CAP Procedure	Latest
3	NPFIT-ETP-EDB-0287	EPS Dispenser CAP Procedure	Latest
4	NPFIT-ETP-ECAP-0004	EPS R2 dm+d requirement	Latest
5	NPFIT-ETP-ETO-0025	EPS R2 interoperability	Latest

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1 Introduction

The purpose of this document is to provide a clear account of the clinical assurance processes for the Electronic Prescription Service Release 2 (EPS R2) that will take place to assure that the implementation of a prescribing or dispensing system is delivered, deployed and operates in an acceptably safe manner for patients and that suppliers have reduced all identified risks and hazards to a level as low as reasonably practical.

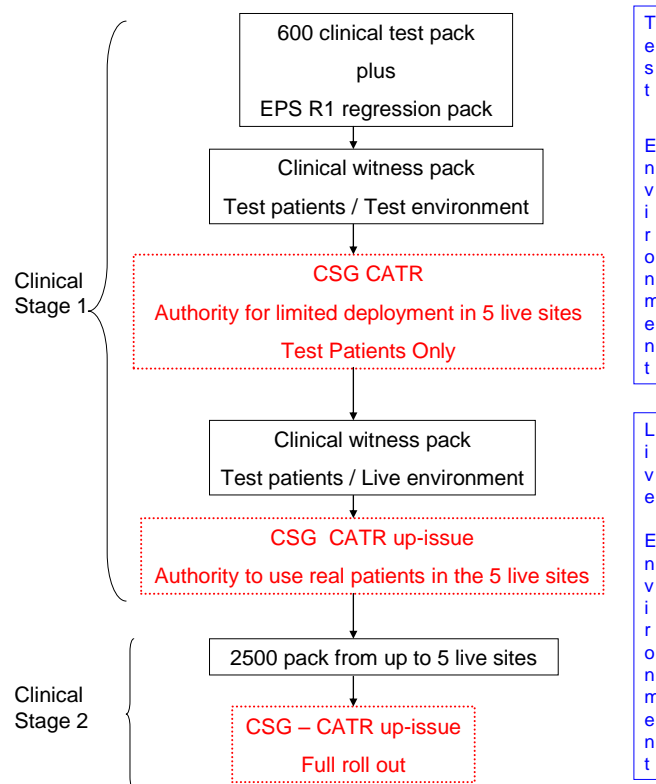
2 Audience

This document has been written for NHS CFH staff and prescribing and dispensing system suppliers.

3 Clinical Assurance EPS R2

The clinical assurance of a prescribing or dispensing system is an integral part of the Common Assurance Process. The role of NHS Connecting for Health is that of assurance and system suppliers must perform robust testing of their system prior to clinical assurance to ensure that all identified hazards and risks have been reduced to as low as reasonably practical.

3.1 Summary Diagram – EPS R2 Clinical Assurance



Clinical stage 1 (Development)

In this stage the system will be tested within the NHS CFH National Integration Centre environment. A minimum of 600 items will be tested using a NHS CFH 600 pack. From previous experience this process will be an iterative one with 'issues' identified, fixed and re-tested. In addition to the completion of the 600 pack, clinical witness testing will also take place as well as a review of Suppliers training material, guidance etc and the completion of an EPS R1 regression test pack.

Test NIS environment	- 600 Test Pack + EPS R1 Regression Test Pack - Clinical Witness Pack – Test patients/Test environment
Controlled Live environment	- Clinical Witness Pack – Test patients/Live environment
NHS CFH Review	- Suppliers training material, guidance

Following successful completion of the 600 test pack, regression pack, document review, suppliers own clinical safety work and clinical witness pack-test patients/test environment, Clinical Safety Group (CSG) approval will be required to achieve a Clinical Authority to Release (CATR) limited to up to 5 live sites and test patients, prior to undertaking the second stage of clinical witness testing i.e. the clinical witness pack – test patients within the controlled live environment.

Following successful completion of clinical stage 1 (600 test pack, regression pack, both clinical witness test packs, document review and suppliers own clinical safety work) the EPS Clinical Safety Assurance Manager will present the information to the CSG for approval and up- issue of the CATR to allow use of live patients in the 5 sites.

Clinical Stage 2 (Deployment)

In this stage the system will be deployed in up to 5 live sites where a minimum of 2500 items will be examined. This set of data is required to contain the various scenarios and prescription types. From previous experience this process will be an iterative one with 'issues' identified, fixed and re-tested. Re-testing may require a further 2500 items or a sufficient quantity as determined by the EPS Clinical Safety Assurance Manager to assure themselves that the issue has been fully resolved.

Following successful completion of clinical stage 2 the EPS Clinical Safety Assurance Manager will present the information to the CSG for approval and up-issue of CATR for full roll out.

The following are common to both clinical stages:

- Testing will be of EPS R2 but will include regression testing of EPS R1 and that the system can support non-EPS prescribing
- Testing will ensure all identified risks or hazards have been mitigated or reduced to as low a level as possible
- Testing will take the form of Clinical witness testing in situ, specific testing packs, review of training materials

In stage 1 a range of scenarios will be tested covering the full functionality of the system. In stage 2 the use of 'live' data for testing may require further items or the use of 'dummy' data within the live environment to assure the system. These tests are in addition to the suppliers own testing and the functional tests provided by the Technical Assurance Group.

Clinical stage 3 (post deployment)

This is a new stage and will act in much the same way as an 'MOT'. At regular intervals (determined by the Clinical Safety Assurance Manager) throughout the 'life span' of a system suppliers will be required to supply a set of 'live' messages for review or undertake a test pack to determine that the behaviour of the system is still as expected. Please note this is in addition to the Standing Order pack that must be completed for changes to the system to ensure that functionality has not been altered following the change.

3.4 Test Packs

600 Packs

This pack will be used primarily in clinical stage 1 – integration testing in Sandpit. This pack will include approximately 600 EPS R2 prescriptions. The products used will be a majority of the most popularly prescribed items and additional products to cover 'product type' gaps, more complicated rarely prescribed items etc. Both positive and negative tests will be included. A range of different prescribing and dispensing scenarios covering the new and existing functionality of EPS will be covered, in addition to the mitigation, where possible, of the specific hazards identified in the Patient Safety Assessment (NPFIT-FNT-TO-TOCLNSA-0352).

In addition to their use in clinical stage 1 a system undergoing a significant change may be required to undertake this test pack.

EPS R1 Regression Pack

This pack will contain approximately 50 prescriptions taken from the 600 pack. These prescriptions will be either prescribed by a prescribing system as EPS R1 or dispensed by a dispensing system as EPS R1.

Clinical witness test pack

A clinical witness test pack will be developed to assist with interoperability assurance (section 3.5 below). This test pack will contain test patients and will test the end to end transmission of a prescription in addition to the testing of prescribing and dispensing scenarios covering the new functionality.

Standing Order packs

Suppliers are required to prescribe or dispense a standing order pack whenever they make a change to their system under the Supplier Change Note (SCN) process, regardless of whether the change affects EPS functionality. This provides an assurance that the existing functionality has not been affected by the change. There will be a clinical review of the packs to ensure a variety of packs are available and a record will be kept of previous packs issued to suppliers to ensure they are not consistently using the same pack. There will be between 30-50 items in a standing order pack

Specific Test Packs

Experience of EPS R1 testing has highlighted some areas that have identified issues. Specific packs addressing these issues plus similar potential issues will be produced as and when required.

3.5 Interoperability

The aim is to ensure that all prescribing and dispensing systems can operate EPS R2 safely and can interoperate with each other i.e. send and/or receive EPS R2 messages between any legitimate combination of systems. Testing will be performed within integration testing to ensure interoperability between systems can be achieved.

The assurance stages, described in 3.3 above, will be supplemented by additional interoperability tests, These are described in EPS Interoperability Assurance during Integration Testing, go-live preparation and Deployment Verification (NPFIT-ETP-ETI-0025).

In summary, the purpose of interoperability assurance, is to positively confirm the end-to-end transmission of a prescription from a prescribing system, to EPS, and on to a dispensing system, and finally to transmit the completed prescription to the PPD system for reimbursement.

Clinical interoperability assurance occurs prior to Initial Implementation in two stages, using the clinical witness test pack.

A fully assured system (which must have successfully completed assurance of 600 clinical test prescriptions) will be deployed to the test environment within the NIC test Lab with access to the sandpit and a clinical witness test pack used to ensure that a prescription can pass through the full life cycle using test patient data – clinical witness test pack / test environment.

This testing takes place in the NIC 'sandpit' environment provided by the Technical Assurance Group. The ETP clinical safety assurance manager will 'witness test' the system using the clinical witness test pack and present the results to the Clinical Safety Group (CSG). Once fully approved the system can be deployed to a limited number of sites

A second clinical interoperability test will be carried out during the 'go-live preparation' stage using the same test data pack and test patient data in the initial implementer live sites – clinical witness test pack / live environment - before the system will be allowed to manage live patient data.

Both assurance steps require the approval by the Clinical Safety Group before the system may move to the next stage.

4 NHS dm+d

4.1 Native use of dm+d

The current position of NHS Connecting for Health (NHS CFH) is that native use of dm+d should be achieved through the creation of all relevant detail within a system's medicines and devices database directly from the distributed dm+d data. However, in recognising the issues faced by certain system vendors the concept of allowing a mapped solution has been accepted as an interim measure.

However, the NHS CFH position with regards the responsibility for any adverse incident arising because of an inaccurately produced map or direct embedding on the part of a system vendor or their subcontractor remains as has been previously stated: NHS CFH will not validate or underwrite the accuracy of any dm+d solution.

NHS CFH can and will only perform an assurance role to satisfy itself that the implementation of NPFIT conformant messages meets its own patient safety requirements. This will entail reviewing and signing off implementation plans for patient safety and end to end message testing across a series of scenarios and occasional spot checks. This will not however imply any interrogation or audit of the underlying mapping or direct embedding of dm+d in the system, which remains the suppliers responsibility.

In summary therefore, the maintenance, validation and medico-legal responsibility for the embedding and / or mapping of dm+d into an implemented system rests with the supplier of that system.

4.2 NHS dm+d Requirement for EPS R2

Suppliers will be required to sign up to the licensing requirement for dm+d before entering EPS R2 integration testing.

As part of the Clinical Assurance of the Electronic Prescription Service (EPS) Release 2, suppliers are required to provide a statement of compliance with the EPS R2 dm+d requirement (NPFIT-ETP-ECAP-0004) within their hazard log as part of the Common Assurance Process (The hazard log forms part of the Patient Safety Assessment). The requirement sets out the requirements of NHS CFH for system suppliers when using a mapped solution to define one-to-one mappings within individual systems, to ensure ongoing maintenance, update and progressive mapping (where required) to dm+d, to assure all mapping with the supplier's own systems and to document adherence to the published requirement on an ongoing basis according to common assurance requirements.

5 Document Filing Structure

Documentation will be stored within FileCM