

3.4ii Appendix A

Assurance Quality Plan (AQP)

If the initial review identifies the service development needs to undertake the assurance process, or assurance will be required an Assurance Quality Plan will be completed by the project manager/ release manager and assurance leads. The plan will follow the template provided. The following process will apply: -

- Proposer to complete Intended use statement within the plan (as agreed by the WIAG review)

detailing the: -

- Proposed scope
- Previous assurance etc.
- Draft plan to be submitted to Quality Manager (Regulatory Compliance) for review (as per published time scales),
- Proposer to present draft plan to WIAG, members will review the document on Microsoft Teams prior to the meeting and provide advice where possible in advance, or complete the check list at WIAG meetings,
- Once complete the Wales Informatics Assurance Facilitator will review the document and send to the Quality Manager (Regulatory Compliance) for approval of the Assurance Quality Plan (unless WIAG advise the plan should be escalated to Directors for approval).

Safety Case & Readiness Report (SCRR)

The Safety Case and Readiness report is the primary vehicle for presenting a statement concerning the safety of the informatics service at a defined point in the service's life cycle e.g., prior to use in the live environment for the approved scope. It includes the outcomes of the assurance work streams; identifies residual risks, mitigations that have been deployed to address significant and high risks, related operational constraints and limitations, and includes recommendations regarding informatics service deployment. This report is developed by the project manager / release manager.

A Safety Case and Readiness Report could be presented to the directors at three stages; either prior to the release to an early adopter site, prior to a change of scope where Directors have previously only approved a limited scope, or after the first site implementation and prior to roll out to the NHS in Wales. It must firstly be submitted to the WIAG for review and the addition of the independent assurance leads statements prior to submission to the Directors for approval. The report will follow the template document provided.

Request for Change (RFC)

Minor changes to a Service/Application may be assured using a request for Change submission. All Assurance Leads retain oversight of the change and can highlight workstreams required to assure the proposed change. WIAG

WIAG REPORT

decides as a group as to whether an RFC is sufficient to assure a proposed change.

Appendix B

Assurance Areas within the Wales Informatics Assurance Process

Application Development Support

Architecture Design & Delivery Assurance

Financial And Business Assurance

Clinical/ User Requirements

Equality Impact Assessment

Evaluation

Implementation Plan

Information Governance

Information Service

Information Standards

Infrastructure Requirements

Medical Device Applicability

Patient Safety

Primary Care Service Support

Security

Service Management & Support

Service Desk

Testing

Validation & Verification

Welsh Language

APPENDIX C

Details of Assurance Quality Plans within the reporting period.

MailMarshal Bypass:

The M365 CoE have undertaken a comprehensive security and feasibility review for the replacement of our current email security gateway solution (MailMarshal) with the existing Microsoft Exchange Online Protection (EOP) and Microsoft 365's security & compliance suites. This included some functionality testing within the CoE dev/test environment, this testing is limited due to the lack of data and use of the environment. However, to support this review, phase two requires a proof of concept to ensure a high level of confidence and readiness for actual migration across NHS Wales. To achieve this, the M365 CoE wishes to utilise DHCW as the initial PoC organisation to bypass MailMarshal security controls and content filtering completely, allowing us to generate data as part of the proof of concept, and develop the best security baseline possible ahead of said migration.

Canisc Palliative Care replacement

The objective of this programme workstream is to deliver digital Specialist Palliative Care (SPC) processing within the Welsh Clinical Portal (WCP) application and all instances of the Welsh Patient Administration System (WPAS), as part of the Cancer Informatics programme. This new functionality will replace the Palliative Care processing currently provided in CaNISC. Digital forms (e-form) and supporting functionality in WCP will provide the ability to move away from the CaNISC legacy system and populate the single digital patient record with SPC records. This will enable the records to be viewed by authorised clinicians across Wales, including primary and secondary care.

The current CaNISC system is end of life and requires replacement. The SPC functionality is pivotal to recording care events and managing patients referred to SPC teams across Wales. Delivering replacement functionality through WCP and WPAS will mitigate risks associated with CaNISC impending unavailability.

Digital Growth Chart for Wales- Single Record

The aim of this programme is to deliver a growth chart e-form within Welsh Clinical Portal (WCP) that will allow clinicians to record, store and review patient's height, weight, head circumference and other growth marker data. This capability will utilise the Royal College of Paediatrics and Child Health's Digital Growth chart API, and the data will be stored in a national repository.

The initial development is targeted at secondary care paediatric clinical staff users, with further developments intended to widen the scope of use across multiple use

cases and care settings. Our long-term vision is to deliver a digital equivalent of the red book available across care settings, and for the information to be integrated with population data to enable advanced child population research that will inform health policy and practice.

Swansea Bay MEDIALOGIK Cloud WRRS Feed

The Welsh Results Reports Service (WRRS) is a single diagnostic information repository that provides Welsh Clinical Portal (WCP) users with the ability to view diagnostic reports and requests for their patient, regardless of where they were produced. During April 2018 all instances of WCP (and GPTR) were connected to WRRS for diagnostic pathology, radiology and cardiology result viewing.

The objective of the project is to develop, test and implement secure DHCW architecture to receive Swansea Bay University Health Board (SB UHB) Endoscopy PDF diagnostic results reports from the MEDIALOGIK (Microsoft UK Azure cloud hosted) Endoscopy Management System (EMS) version 2 provider system, into the WRRS, making the results visible in WCP to All Wales health care practitioners (HCPs).

WISDM Diabetes View

Diabetes View pilot commenced in December 2022 for select users in Cwm Taf Morgannwg University Health Board. The functionality delivers a composite single summary screen of valuable patient's diabetes information that is pulled from existing systems and infrastructure. Diabetes View sits within the Welsh Clinical Portal.

Diabetes View is part of the wider Welsh Information Solution for Diabetes Management (WISDM) project, which digitises and standardises diabetes patient data to support patient care and enhance information sharing.

Patient Access Push Notification

The Patient Access Project forms part of the Digital Medicines Transformation Portfolio (DMTP) and is governed by the Primary Care Electronic Prescription Service (EPS) Programme Board, with oversight from the DMTP Board.

The Patient Access Project is commissioning two medicine-related features for the NHS Wales App, in collaboration with the Digital Services for Patients and Public (DSPP) programme and Kainos who are the third-party supplier. These features are core deliverables for the Primary Care EPS programme in DMTP.

Demographics in CDR

The project objective is to provide an open architecture demographics solution for Health and Care in Wales, where patient identification can be queried and maintained within FHIR in the Care Data Repository.

The proposed approach is to maintain Gold and Silver records in the CDR, Gold records will be those with a traced NHS number and silver records will be created where there is no traced NHS number using a hospital number. The strategic approach for demographics in CDR will enable merging of records to allow silver records to be merged into a single Silver record or 'upgraded' to a Gold record. The CDR will be updated with demographic registration and update messages from WDS and PAS systems and will become the source for demographic queries.

Endoscopy ETR

A clinician with requesting rights can create an Endoscopy test request from the Menu option within patient context in Welsh Clinical Portal (WCP). Both secondary care adult inpatients and outpatients will be catered for as well as ones that come in through A&E.

The UI of the Endoscopy ETR form will have consistent header (demographic information) and footer (sign off information) with the other WCP test request forms, as defined in the agreed ETR template. This will ensure consistency across the suite of ETR forms in WCP.

ACS Pathway

The ACS pathway form is a structured and standardised data collection form capturing timely data to allow clinical decision, analysis, and future research opportunities in line with NDR IMTP objectives. The form will be used within pilot hospital sites by clinical staff in line with delivering the ACS care pathway. Primary deployment location will be Morriston Hospital with an option to extend to Royal Glamorgan Hospital. Clinical users will record ACS pathway data, launched via WCP, able to review historical records.

All structured clinical data will be assured according to emerging clinical data standards. The objective is to create, develop and test a data collection application across the Health Boards who are actively involved in the early stages of development. Initial testing of the concept and subsequent benefits has demonstrated a consistency and fitness for purpose of data, allowing increased agility in the data being made available to support reporting, research, and onward service improvements. The clinical data will be stored as part of the Acute Coronary Syndrome (ACS) pathway digital tool into the Clinical Data Engine (CDE), with the API providing the ability to create, retrieve, update, and delete data stored in the openEHR repository.

Onboarding Qualifying Community Optometrists to NADEX and M365

The aim is to onboard qualifying Community Optometrists to NADEX & M365 (inc. EM&S) – maximum of 1,800 F3 & F5 licenses - with specific focus on:

- Delivering a safe platform to meet business needs which could be exploited by future projects eg WGOS Implementation, Open Eyes: Electronic Referral System (ERS) and Electronic Patient Record (EPR)
- Safely onboarding this cohort of users
- Learning lessons from a proof of concept/early adopter to inform a full implementation/roll out:
 - Creating new and reviewing existing relevant processes
 - Reviewing support mechanisms and documentation
- Making a recommendation regarding full implementation/roll out.

NHS Exec into NDAP

The NHS Executive is seeking to migrate its data infrastructure to the NDR's National Data Analytical Platform, which uses Google Cloud Platform (GCP), to enhance data management, analysis capabilities, and collaboration efforts. The primary objective of this change is to improve patient outcomes, streamline data processes, and enable more effective decision-making across NHS Wales and its affiliated care partners.

The specific changes include:

- Migration of data from legacy databases to GCP's secure and scalable storage solutions.
- Utilization of Google Big Query for real-time data analysis and querying.
- Development of data analysis pipelines to extract valuable insights from large datasets.

LIMS 2.0

The aim of the LIMS2.0 Programme is to enable the development of modern, safe, sustainable pathology services through end-to-end information systems & services. It underpins the delivery of the Welsh Government Pathology Statement of Intent.

The programme commenced in August 2023 (when contract change notice signed with InterSystems).

A key component is to further standardise pathology services across Wales and the implementation of a standardised laboratory information management system (LIMS) service.

APPENDIX D

Details OF Safety Case and Readiness Reports within the reporting period

Swansea Bay MediLogik MPI Cloud Feed

The confirmed scope of the Safety Case is to assure a secure MPI patient demographics query (PDQ) feed and user access to the MEDIALOGIK Endoscopy Management System (EMS) Microsoft UK Azure cloud hosted application, at Swansea Bay University Health Board.

The MPI feed re-utilizes existing DHCW infrastructure and MPI application components previously implemented for MEDIALOGIK EMS v2 cloud application instances at Powys and Betsi Cadwaladr health boards.

MailMarshal Bypass:

The M365 CoE have undertaken a comprehensive security and feasibility review for the replacement of our current email security gateway solution (MailMarshal) with the existing Microsoft Exchange Online Protection (EOP) and Microsoft 365's security & compliance suites. This included some functionality testing within the CoE dev/test environment, this testing is limited due to the lack of data and use of the environment. However, to support this review, phase two requires a proof of concept to ensure a high level of confidence and readiness for actual migration across NHS Wales. To achieve this, the M365 CoE wishes to utilise DHCW as the initial PoC organisation to bypass MailMarshal security controls and content filtering completely, allowing us to generate data as part of the proof of concept, and develop the best security baseline possible ahead of said migration.

DSPP NHS Wales App Public Beta WP9 R12:

The scope of this safety case and readiness report relates to the next software 'Milestone Release' during the Public Beta phase of the NHS Wales App. 'Work Package 9 Release 7' (WP 9 R7) Milestone Release includes two new features of a Health Timeline and a Health (Wellbeing) Journal which will greatly improve the functionality and usability for patients of the NHS Wales App.

The Health Timeline has been developed as a navigational tool able to display summary details of 'date-stamped' health and care events where personal health related data exists in other, independent source (or feeder) systems. The date of the event as well as the type of event are displayed and can be used to navigate to information of interest. The Health Timeline feature can display the summary information that has been provided by the source system. It can also display the necessary 'jump off' (clickable link) to an integrated service, passing the event identifier to allow the integrated system to show more details relating to the event,

should the user choose to click the jump off. This information is displayed within the NHS Wales App user interface pulling that information from the source system.

SBU Medilogik Cloud WRRS Feed

The scope of this assurance plan is to secure the Endoscopy HL7 observational result (ORU) report feed traffic, originating from the MEDIALOGIK EMS v2 cloud application, for processing SB UHB Endoscopy results from Morrison, Singleton and Neath Port Talbot Hospital locations into WRRS, making the reports visible in WCP to all Wales clinicians.

WISDM Diabetes View:

Three health boards are currently live with WISDM – Hywel Dda, Swansea Bay and Cwm Taf Morgannwg University Health Boards. National release of Diabetes View will be deployed initially into these three health boards, but work is ongoing to make the Diabetes Consultation Note and Diabetes View available in Betsi Cadwaladr, Cardiff and Vale and Aneurin Bevan, so Diabetes View will be available to these health boards once adoption is agreed.

On average, over 7,000 Diabetes Consultation Notes are created across CTM, SBU and HDD each month as of October 2023 – each consultation note reflects one patient contact. It is not anticipated that Diabetes View will be used at each of these patient contacts – although all patient contacts require use of the Diabetes Consultation Note, Diabetes View is read only supporting functionality with no write back. Minimal impact on infrastructure is anticipated, and to date there have been no support calls relating to Diabetes View, so operational support required will be minimal.

Welsh Clinical Worklist Manager:

The scope of this assurance plan is for a minimal viable product Welsh Clinical Worklist Manager (WCWM) to be developed, built, tested, and deployed by the Single Record Team (in conjunction with Cancer Informatics Programme) for 2 uses; in Palliative care for Caseload management and for printing Cardiology test requests. Any further use of the application for different worklists will need further assurance from WIAG. There will be 2 separate elements of the WCWM for its first iteration, Caseload Manager (for Palliative care worklists) and Cardiology worklist (for Cardiology test request worklists).

WRAPPER Phase 2b:

The intention of WRAPPER is to enable users to view the patient journey on a Wales-wide basis, irrespective of where the patient activity took place.

The type of information being shared includes:

- Demographics
- Referrals
- Outpatients
- Admission, Discharge and Transfer (ADT)
- Pathway Management
- Cancer tracking data
- Patient MDT Scheduling

Cardiff and Vale UHB (C&V) have their own PAS (known as PMS). Connecting with WRAPPER will not only provide an all-Wales view of PAS data but will also enable C&V to book their patients into other health boards/trusts MDTs, and for health boards/trusts to book their patients onto MDTs hosted by C&V (functionality that is currently provided by CaNISC which is to be replaced).

Anticoagulation eForm:

The objective of this project is to:

- Produce a set of e-forms which will allow clinical users of Welsh Clinical Portal (WCP) to create, edit and view anticoagulation care plans for inpatients – bespoke to Direct Oral Anticoagulation (DOAC) or Warfarin.
- Deliver a digital copy of the anticoagulation care plan to GPs upon sign-off.

Since submission of the Assurance Quality Plan and following consultation with the Clinical Anticoagulation Implementation Group, the ability to create an Anticoagulation eForm in an outpatient setting has been removed from scope for delivery for this phase. This has been added to the requirements catalogue for consideration in the future.

ACS Pathway:

The objective is to create and test a pilot application for the ACS Pathway data for a limited number of Health Boards involved in the Cardiac Network Wales using standardised clinical models in openEHR.

Acute Coronary Syndrome Pathway is intended to be used by a health professional in a non-emergency situation. It is completed on or after admission of a patient to a cardiac ward and throughout the patient's pathway. It is not necessarily completed contemporaneously. It is used to collate information ready for a referral for an angiography and record the outcomes. Information it collects includes physiological data, treatment/procedural information, medication, test results, patient history, background and a screening questionnaire.