perinatal institute for maternal and child health	Project	GROW-Service API
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	Version	1.0
	Date	24.11.2015

GROW-Service API Clinical Safety Case and Hazard log Report

- *Pre-Deployment*

Amendment History:

Version	Date	Amendment History
0.1	27/08/2015	First draft to comment
0.2	04/11/2015	Revised to address comments from internal appraisers.
1.0	24/11/2015	First version

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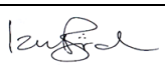
Ian Bird		IG and IT Manager - Author	04/11/2015
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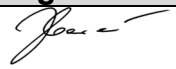
Jason Gardosi		Director /Caldicott Guardian	24/11/2015

Distribution:
The intended audience for this report is the:

- Perinatal Institute clinical and IT departments
- GROW-Service API developers
- Maternity Information System providers
- Hospital/Trust GAP leads, IG leads and clinical safety officers

Document Status:

This is a controlled document. Whilst this document may be printed, the electronic version maintained internally by the owning department is the controlled copy. Any printed copies of the document are not controlled.

Related Documents:

Title	Date	Version
Agreement GROW-Service	21/10/2015	1.3
GAP Outline Specification – New users 15/16	21/10/2015	1.1
API Manager Guidance	19/10/2015	1.2
GROW-Service - User Interface Guidance	21/10/2015	1.2
GROW-Service - REST API for V1.1.7	21/10/2015	1.1.7
GROW-Service - Developer Guidance	20/10/2015	1.2
Helpdesk Support Spec	05/02/2015	3

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Glossary of Terms

Acronym / Term	Definition
ALARP	As low as reasonably practicable
Access Credentials	The confidential security information provided by the Perinatal Institute to the MIS for use of the API
Clinical Safety lead	Person in the organisation responsible for ensuring the safety of a Health IT System in that organisation through the application of clinical risk management
Clinical risk	Combination of the severity of harm to a patient and the likelihood of occurrence of that harm
Clinical risk analysis	Systematic use of available information to identify and estimate a risk
Clinical risk evaluation	Process of comparing a clinical risk against given risk criteria to determine the acceptability of the clinical risk
Clinical risk management	Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling clinical risk
Clinical Risk Management File	Repository of all records and other documents that are produced by the clinical risk management process
Clinical Risk Management Plan	A plan which documents how the Manufacturer will conduct clinical risk management of a Health IT System
Clinical Risk Management Process	A set of interrelated or interacting activities, defined by the Manufacturer, to meet the requirements of this standard with the objective of ensuring clinical safety in respect to the development and modification of a Health IT System
Clinical safety	Freedom from unacceptable clinical risk to patients
Clinical Safety Case	Accumulation and organisation of product and business process documentation and supporting evidence, through the lifecycle of a Health IT System
Clinical Safety Case Report	Report that presents the arguments and supporting evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment at a defined point in a Health IT
DHID	Department of Health Informatics Directorate
GAP	The Growth Assessment Protocol; a program developed and provided by the Perinatal Institute, comprising various components including training and policy best practice

GROW-Service	Suite of applications that support the GAP programme and GROW (Gestational Related Optimal Weight) software
GROW-Service API	The application programming interface provided by the Perinatal Institute as part of the GROW-Service
Harm	Death, physical injury, psychological trauma and/or damage to the health or well-being of a mother or baby
Hazard	Potential source of harm to a mother or baby
Hazard Log	A mechanism for recording and communicating the on-going identification and resolution of hazards associated with a Health IT System
IG	Information Governance
Likelihood	Measure of the occurrence of harm
Lifecycle	All phases in the life of a Health IT System, from the initial conception to final decommissioning and disposal
MIS	Maternity Information System
Patient	A mother or baby who is the recipient of healthcare
Patient safety	Freedom from harm to the mother or baby
PDF printout (GROW)	A paper copy of the customised growth chart
PI	Perinatal Institute, UK-based provider of GROW software and services
Post-deployment	That part of the lifecycle of a Health IT System after it has been manufactured, released, deployed and is ready for use by the Health Organisation
Release	A specific configuration of a Health IT System delivered to a Health Organisation by the Manufacturer as a result of the introduction of new or modified functionality
Residual clinical risk	Clinical risk remaining after the application of risk analysis
Safety incident	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare
Safety Incident Management Log	Tool to record the reporting, management and resolution of safety incidents associated with a Health IT System
Severity	Measure of the possible consequences of a hazard
SWIFT	Structured What If Technique
Top Management	Person or group of people who direct(s) and control(s) an organisation and has overall accountability for a Health IT System

Introduction

This report reviews the pre-operational clinical safety for the use of the GROW-Service API and is part of a set of clinical safety documentation, which has been produced in order to meet requirements of the ISB0129 standard of clinical risk management and review. It contains the software definition, clinical hazards and mitigation and supporting evidence to provide an assurance statement on the clinical safety of the GROW-Service API software.

Background

Fetal growth restriction (FGR) is associated with stillbirth, neonatal death and perinatal morbidity. Confidential enquiries[1] have demonstrated that most stillbirths due to fetal growth restriction are associated with suboptimal care and are potentially avoidable.

A recent epidemiological analysis[2] based on the comprehensive West Midlands database has underlined the impact that fetal growth restriction has on stillbirth rates, and the significant reduction which can be achieved through antenatal detection of pregnancies at risk.

Customised assessment of birth weight and fetal growth using GROW (Gestation Related Optimal Weight) has been shown to improve antenatal detection of growth restriction and has been recommended by RCOG Green Top Guidelines since 2002, and re-emphasised in the recently published 2013 revision[3], as well as the 2015 NHS Care Bundle for Saving Babies Lives[4]

The Perinatal Institute provides tools for assessment of fetal growth and birth weight for the UK and International partners by defining each pregnancy's optimal growth

[1] http://www.pi.nhs.uk/pnm/clinicaloutcomereviews/index.htm

[2] http://www.bmj.com/content/346/bmj.f108

[3] https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg31/

[4] http://www.perinatal.org.uk/pdfs/NHSE_Care_Bundle_Element_2_Draft_2015.pdf

potential through the Gestation Related Optimal Weight software (GROW-Service), including:

- GROW-Chart – A web-based application that produces customised antenatal charts for manual plotting of fundal height and estimated fetal weight.
- GROW-Centile – A web-based application for the calculation of customised birth weight centiles for each pregnancy, or a database of pregnancies (bulk centile calculator).
- GROW-App - A web-based application that produces a customised growth chart for fetal growth during pregnancy, manual and auto-plotting of fetal size (fundal height or estimated fetal weight), for calculation of the customised birth weight centiles for each baby at birth and reporting of FGR rates and antenatal detection rates.
- GROW-Service API – A web service that links to local maternity information systems in order to produce the customised growth chart at the beginning of pregnancy, auto-plotting of assessments of fetal size during pregnancy and for the calculation of the customised birth weight centiles for each baby at birth.

In order to assure safe and accurate use of the GROW-Service, the software is only provided to Trusts/hospitals that are accredited in the Growth Assessment Protocol (GAP)[5] programme. The programme includes:

1. Implementation of evidence based protocols and guidelines
2. Training and accreditation of all staff involved in clinical care
3. Rolling audit and benchmarking of performance

This clinical safety case documents the rigorous testing/safety checks, risk assessments and evaluation of the GROW-Service API product during its development and testing.

[5] http://www.perinatal.org.uk/FetalGrowth/GAP/GAP.aspx

Software Definition

Definition of project and role of the software

GROW-API is part of the GROW software options produced by the Perinatal Institute for assessment of customised fetal growth and birth weight by defining each fetus/baby's growth potential through the Gestation Related Optimal Weight (GROW) software. The API functions include:

- **GROW-Chart** - customised antenatal charts for plotting fundal height and estimated fetal weight
- **GROW-Centile** - for calculation of customised birthweight centiles for each pregnancy
- **GROW-Reporting** - data collection and reporting of rates of small for gestational age/fetal growth restricted babies (birthweight below the tenth customised centile) and their antenatal referral and detection rates.

The GROW-API produces the customised growth chart in two ways:

1. **PDF** – PDF print out of the GROW chart for manual plotting of fetal size (fundal height and estimated fetal weight measurements) during pregnancy. Only one PDF should be printed per pregnancy and used as the master document for all measurements.
2. **Embedded Image** – The embedded GROW chart (along with referral criteria) is displayed within the MIS and auto-plotting of fundal height and estimated fetal weight measurements is possible. This allows clinicians to access a GROW chart with plots at any time.

A protocol on the use and workflows will be agreed with each Trust prior to going live.

The benefits of using the GROW-Service API via a hospital and community's MIS over the other software options are:

- reduced need for double entry of data, saving valuable clinician time
- allowing the customised centiles to be part of the electronic patient record for future reference, audit and informing the management plan

- reducing the chances of human error by auto-plotting of fundal height and estimated fetal weight measurements.

Audience of the software

The intended audience/users of the software are clinicians in primary and secondary care involved in providing care to women during pregnancy, birth and the postnatal period (obstetricians, midwives, ultrasonographers, GPs).

Technical Specification

The GROW-API is a REST web API built using C#, the ASP.NET Web API framework and .NET 4.5. Data is stored on a Microsoft SQL 2012 database. The environments hosting the API and database/s are Windows Server 2008 R2 Standard edition with ESET Enterprise antivirus protection. There is a full audit trail on which hospital/Trust did 'what and when' in relation to each record and the MIS will also store details on which clinician did 'what and when' and viewed 'what and when'.

Testing Strategy

The API and the MIS will be rigorously tested prior to going live. The testing consists of:

- Data testing – automated testing of all co-efficients and calculations (TOW-term optimal weight, centile, BMI, gestation) within the API and manual testing of the MIS.
- End User testing – Manual testing of the MIS to ensure it follows the guidance within this clinical safety case and the user interface guidance.

Testing documentation will be provided for each deployment and on request.

Clinical Risk and Management Plan

Timetable of Review Process

The proposed timeframe for pre-implementation Assessment and Review is detailed in the table below:

Timeframe/Date	Activity
Jan - March 2015	Define the GROW-Service API clinical safety team
Jan - March 2015	Define the requirements of the solution (software definition) including the requirements of the MIS for integration.
Feb - April 2015	Scope of clinical risk activities and the assignment of responsibilities (including PI, MIS and Trust/hospital)
Feb - April 2015	Define the risk acceptability criteria
April – May 2015	Clinical risk procedures and processes (clinical risk management plan)
April – May 2015	Criteria for clinical risk analysis and acceptability
May – June 2015	Clinical risk analysis and hazard log
July – Aug 2015	Clinical risk evaluation and benefit analysis
Nov 2015	Pre-deployment clinical safety case report finalised
Dec 2015 - ongoing	Clinical risk analysis, evaluation and benefit analysis - MIS
Dec 2015 - ongoing	Clinical risk analysis, evaluation and benefit analysis – Hospital/Trust
Deployment - ongoing	Undertake and verify clinical safety actions, controls and measures
Deployment - ongoing	Safety incident identification, management and reporting

The GROW-Service API Clinical Safety Team

The list below identifies the key people responsible for clinical safety within the GROW-Service API project at the PI. All members of the safety team integrate clinical safety into every aspect of their clinical and development work. In addition, all involved have had appropriate awareness raising and education locally by the clinical safety and IG lead that are working with the ISB0129 and are due to complete the HSCIC Clinical Safety training course.

- Mandy Williams – Clinical Safety lead, project lead for the GROW-Service API and registered midwife (soon to be accredited clinician)
- Ian Bird – IT manager and IG lead (soon to be accredited clinician)
- Angela Mushing – Project lead for the MiApp software at the PI and registered midwife
- Suneel Loi – GROW-API technical lead
- Mitchell Griffiths – IT Testing lead
- Sally Giddings – Head of Midwifery of the PI and UK GAP programme co-ordinator
- Professor Gardosi – Director of the PI and Caldicott Guardian

The clinical safety team meet with the design team on a regular basis (at least once per month) to review the clinical safety approach, the hazard logs, mitigations and residual risks for the current software and potential future releases.

Alongside the GROW-Service API clinical safety team, a joint clinical safety review group with the MIS and Trust will also be established. These members include a Hospital/Trust GAP lead and clinical safety officer and the MIS IG lead and clinical safety officer. This is to ensure clinical safety has been assessed and mitigated in respect of these areas (in line with ISB0160) as well as the GROW-Service API. Further details on the responsibilities of the MIS and Trust will be documented in the hazard log section and expanded upon in collaboration with this external clinical safety group prior to deployment.

Each clinical safety team will maintain a Safety Incident Management Log. This will be reviewed as part of the ongoing risk assessment and hazard log - https://www.perinatal.org.uk/incidents

All documents created as part of the GROW-Service API Clinical Safety Management System are maintained, version controlled and managed by the Clinical Safety lead. Documents are stored on the shared local network, which has appropriate access control measures in place.

Hazard and Risk Assessment

In order to quality assure the GROW-Service API prior to deployment, a pre-operational end-to-end safety hazard and risk assessment has been completed by the PI clinical safety team. This hazard log will be continually maintained and updated as required and is based on the risk matrix by the Department of Health Informatics Directorate (DHID):

- **Hazard:** At each step of the process; a list of possible 'things that could go wrong' are documented. This hazard assessment considers IT security, information governance and human behavioural / usability hazards and threats that could potentially have an impact on patient safety. This method is known as the Structured What If Technique (SWIFT).
- **Cause:** For each identified hazard, all the reasons as to why the hazard or threat might occur have been considered?
- **Risk matrix grade (Appendix 1) based on:**
    - **Consequence:** For each combination of cause and hazard, were the hazard to be realised, what potential outcomes for patient safety are there
    - **Severity:** The seriousness of each consequence is considered, in terms of individual patient harm
    - **Likelihood:** How likely each identified consequence is to actually occur
    - **Grade:** Each risk is graded by consensus opinion (combination of consequence severity and likelihood), using the DHID Risk Matrix (see Appendix 1).
- **Actions:** Actions taken or proposed to prevent or reduce the safety risk where possible
- **Acceptability:** What top management consider to be acceptable risks and why (see 'Acceptable Safety and Tolerance Levels' section for further details)
- **Review:** How often each residual risk/hazard is reassessed and actions evaluated

The subsequent approach for review and re-evaluation of these hazards will be the responsibility of the clinical safety group which will include:

- Consider the existing safeguards which would prevent or reduce the safety risk.

- Given those safeguards, grade each risk using the combination of consequence severity and likelihood.
- Identify recommendations for mitigation or controlling hazards to reduce risk.
- Given those mitigations, re-grade each risk using the DHID risk matrix.

Acceptable Safety and Tolerance Levels

Providing evidence that residual risk has been mitigated to an acceptable level is the ALARP (As Low As Reasonably Practicable) concept. Determining that a risk has been reduced to ALARP involves an assessment of the risk and the cost, time and effort involved establishing controls to mitigate the risk, and a comparison of the two. However, as the GROW-Service API is seen to have overall clinical benefits in relation to previous practices, clinical benefits of the solution against the residual clinical risk will also be assessed by the clinical safety group and later with the Trust (see 'Evaluation' section).

The GROW-Service API project has set acceptable residual risk levels and management of clinical risk as follows (refer to the DHID Risk Matrix at Appendix 1):

- Residual risks graded as "Low" (green [1] category) are deemed 'acceptable', with no further action required.
- Residual risks graded as "Moderate" (yellow [2] category) are deemed 'tolerable' where cost of further reduction outweighs benefits gained for GROW. In this category appropriate recommendations for further mitigation will be identified and all efforts made to reduce residual risk further.
- Residual risks graded as "Significant" (pink [3] category) are deemed to have an 'undesirable' level of risk. Attempts will be made to eliminate or control to reduce risk to an acceptable level. The risk shall only be acceptable when further risk reduction is impractical or unacceptable and is considered less than the clinical benefits of the solution to the organisational top management and hospital/Trust clinical safety officer.
- Residual risks graded as "High" (purple [4] category) or "Very High" (red [5] category) are deemed to carry an 'unacceptable' level of risk. These risks would require mandatory elimination or control to reduce risk to an acceptable level.

Results

ID	Hazard	Consequence	Cause	Risk Grade	Actions	Review
Information Governance / Security						
1	Inappropriate or unauthorised access to the application and/or data (could include malicious manipulation of the data)	Damage to reputation of hospital, MIS provider, Perinatal Institute. Damage to patient confidence resulting in withholding of patient information, potentially compromising accuracy of future care. Distress to patients (if data accessed). If malicious manipulation of data also present - Inaccurate growth assessment could lead to fetal growth restriction not being detected antenatally and in rare cases stillbirth.	Lack of appropriate level of security at physical environments	**2 (Rare / Considerable)** **3 (Rare/Catastrophic - if data manipulation involved)**	Physical access to servers and environments are restricted to authorised IT technicians. ISO27001 standards of security are in place, with appropriate audit and review frameworks, to enable minimisation of risk. In the rare event of serious security breach and unauthorised data access/manipulation of data, appropriate escalation to HSCIC via serious incident reporting tools would be undertaken.	Quarterly
			Acceptability – Like any electronic patient record, unauthorised access/data manipulation could happen. However, this would be extremely rare due to the security in place. Organisational top management agree that with the above actions, we can minimise the risks as much as possible and conclude that using the GROW-Service API with these risks is more beneficial than not using the software for the assessment of fetal growth.			
			Lack of appropriate user account security	**2 (Rare / Considerable)** **3 (Rare/Catastrophic - if data manipulation involved)**	User account access is limited to personnel who have successfully passed the GAP programme mandatory training; user accounts password policy in place; user accounts password changes required once every six months. Every record edited or deleted has an audit trail and can be recalled. In the rare event of serious security breach and unauthorised data access/manipulation, appropriate escalation to HSCIC via serious incident reporting tools would be undertaken.	Quarterly

			Acceptability – Like any electronic patient record, unauthorised access/data manipulation could happen. The deployment clinical safety case will be a joint agreement between the PI, MIS and Trust, that will guarantee the high level of security required. Organisational top management agree that with the above actions, we can minimise the risks as much as possible and conclude that using the GROW-Service API with these risks is more beneficial than not using the software for the assessment of fetal growth.			
			Lack of appropriate security during transmission of data	**2 (Rare / Major)**	Transport layer security is in place to ensure securely encrypted transmission of data; SHA256 encryption ensures compliance with industry standards. The pseudo-anonymised nature of the data as it is stored eliminates direct identification of patients.	Quarterly
			PI employee failure to comply with standards of Information Governance, such as inappropriate use of portable media/clear desk policy/user account management	**2-3 (Rare / Considerable or Catastrophic [if data manipulation involved])**	PI staff undergo standard Information Governance and DPA training, with spot-checking throughout year designed to audit knowledge of and adherence to minimum standards toward Information Governance. Every record edited or deleted has an audit trail and can be recalled. In the rare event of serious security breach and unauthorised data access/manipulation, appropriate escalation to HSCIC via serious incident reporting tools would be undertaken.	Annually
			Acceptability - Human error inevitably will occur in rare circumstances. However, organisational top management agree that with the above actions, errors can be mitigated against as much as possible and conclude that using the GROW-Service API with these risks is more beneficial than not using the software for the assessment of fetal growth.			

Accuracy						
2	Inaccurate customised growth chart being used in clinical practice	Inaccurate growth assessment could lead to fetal growth restriction not being detected antenatally and in rare cases stillbirth. Damage to reputation of hospital, MIS provider and Perinatal Institute.	Clinician completing data fields incorrectly in the MIS (e.g. height, weight, ethnicity, parity, EDD, previous baby details)	**3 (Unlikely / Major)**	Hospital/Unit - Yearly training for all clinicians (E-learning or face-to-face) with competency assessment and training log to ensure compliance. Clinicians are asked to verify these data items at each view of the chart (embedded chart image and PDF printout displays the data items on the chart). MIS and API - In-built validation rules to reduce chances of error. Hospital/Unit - Retrospective focused audit on FGR cases not detected during pregnancy to look for clinician error and training needs completed. Any training issues identified – Trust clinical risk manager (and supervisor of midwives if appropriate) informed and renewal of training recommended.	Yearly assessment Deployment, six monthly and/or upgrades 6 monthly (>10 SGA cases)
			Acceptability – Human error inevitably will occur with data inputting. However, organisational top management agree that with the above actions, errors can be mitigated against as much as possible and conclude that using the GROW-Service API with these risks is more beneficial than not using the software for the assessment of fetal growth.			
			Maternity Information system (MIS) error	**2 (Rare / Major)**	MIS - Data quality and user acceptance testing - MIS to inform the PI prior to each upgrade that would affect GROW. All - The deployment clinical safety case and accompanying clinical protocol will be reviewed with the MIS and Trust, to ensure the robust development, testing and implementation.	Deployment, six monthly and/or upgrades Agreement with Trust and MIS

			GROW-API error	**2 (Rare / Major)**	PI - Inbuilt automated data testing and user acceptance testing.	Deployment, six monthly and/or and upgrades
			Inaccurate/Out-of-date chart due to two hospitals/units using different chart types (embedded and PDF printout)	**2 (Rare / Major)**	Hospital/Unit - A master copy PDF printout should be held by the woman to ensure an up-to-date chart is always accessible. API - The MIS will produce a ChartGET call to confirm the most up-to-date information held within GROW. The MIS will then highlight any data discrepancies to be resolved. The PDF printout states that there could be another electronic chart with plots to review so the end user is always aware to check for another electronic chart if the woman has received care from another hospital.	Agreement with Trust Ongoing (via Safety Incident Management Log) and yearly review
3	Inaccurate manual plotting of fundal height or estimated fetal weight measurements	Inaccurate growth assessment could lead to fetal growth restriction not being detected antenatally and in rare cases stillbirth. Damage to reputation of hospital, MIS provider, Perinatal Institute.	Clinician error	**3 (Unlikely / Major)**	Hospital/Unit - Yearly training for all clinicians (E-learning or face-to-face) with competency assessment (including plotting) and training log. API - Charts have gridlines to assist in manual plotting. Hospital/Unit - Retrospective focused audit on FGR cases not detected during pregnancy to look for clinician error and training needs completed. Any training issues identified – Trust clinical risk manager (and supervisor of midwives if appropriate) informed, training needs analysis performed, and renewal of training recommended.	Yearly assessment Yearly 6 monthly (>10 SGA cases)

			Acceptability – Human error inevitably will occur with manual plotting. However, organisational top management agree that with the above actions, errors can be mitigated against as much as possible and conclude that using the GROW-Service API with these risks is more beneficial than not using the software.			
4	Inaccurate automated plotting of fundal height or estimated fetal weight measurements	Inaccurate growth assessment could lead to fetal growth restriction not being detected antenatally and in rare cases stillbirth. Damage to reputation of hospital, MIS provider, Perinatal Institute.	Clinician error – data input incorrectly	**3 (Unlikely / Major)**	Hospital/Unit - Yearly training for all clinicians (E-learning or face-to-face) with competency assessment (including plotting) and training log. MIS and API - Inbuilt validation rules to reduce chances of error. Hospital/Unit - Retrospective focused audit on FGR cases not detected during pregnancy to look for clinician error and training needs completed. Any training issues identified – Trust clinical risk manager (and supervisor of midwives if appropriate) informed, training needs analysis performed, and renewal of training recommended.	Yearly assessment Yearly 6 monthly (>10 SGA cases)
			Acceptability – Human error inevitably will occur with data inputting. However, organisational top management agree that with the above actions, errors can be mitigated against as much as possible and conclude that using the GROW-Service API with these risks is more beneficial than not using the software.			
			Maternity Information System error	**2 (Rare / Major)**	MIS - Data quality and user acceptance testing - MIS to inform the PI prior to each upgrade that would affect GROW. MIS and API - Inbuilt validation rules to reduce chances of error. All - The deployment clinical safety case and accompanying clinical protocol will be reviewed with the MIS and Trust, to ensure the robust development, testing and implementation. Hospital/Unit - Retrospective focused audit on FGR cases not detected during pregnancy	Deployment, six monthly and/or and upgrades Yearly Agreement with Trust and MIS 6 monthly (>10 SGA cases)

					to look for clinician error and training needs completed. Any training issues identified – Trust clinical risk manager (and supervisor of midwives if appropriate) informed, training needs analysis performed, and renewal of training recommended.	
			GROW-API error	**2 (Rare / Major)**	PI - Inbuilt automated data testing and data quality and user acceptance testing.	Deployment, six monthly and/or and upgrades
			Discrepancy in plots between the embedded chart (auto plots) and PDF printout (manual plots)	**2 (Rare / Major)**	Hospital/Unit - Yearly training for all clinicians (E-learning or face-to-face) with competency assessment (including plotting) and training log. All - The MIS will produce a ChartGET call to confirm the most up-to-date information held within GROW. The MIS will then highlight any data discrepancies to be resolved. The PDF printout states that there could be another electronic chart with plots to review, so the end user is always aware to check for another electronic chart if the woman has received care from another hospital. Hospital/Unit - Retrospective focused audit on FGR cases not detected during pregnancy to look for clinician error and training needs completed. Any training issues identified – Trust clinical risk manager (and supervisor of midwives if appropriate) informed, training needs analysis performed, and renewal of training recommended.	Yearly assessment Ongoing (via Safety Incident Management Log) and yearly review 6 monthly (>10 SGA cases)
5	Inaccurate customised birth weight centile	Inaccurate birthweight centile could mean incorrect diagnosis of fetal growth restriction	Clinician completing data fields incorrectly (e.g. birth date, sex, birth weight etc)	**2 (Unlikely / Considerable)**	Hospital/Unit - Yearly training for all clinicians (E-learning or face-to-face) with competency assessment and training log.	Yearly

		and subsequent postnatal management could be inappropriate (too much or too little intervention). Also, management of the next pregnancy could be affected. Damage to reputation of hospital, MIS provider, Perinatal Institute.			MIS and API - Inbuilt validation rules to reduce chances of error. Hospital/Unit - Retrospective focused audit on FGR cases not detected during pregnancy to look for clinician error and training needs completed. Any training issues identified – Trust clinical risk manager (and supervisor of midwives if appropriate) informed, training needs analysis performed, and renewal of training recommended.	Yearly 6 monthly (>10 SGA cases)
			Maternity Information System error	**2 (Rare / Considerable)**	MIS - Data quality and user acceptance testing - MIS to inform the PI prior to each upgrade that would affect GROW. All - The deployment clinical safety case and accompanying clinical protocol will be reviewed with the MIS and Trust, to ensure the robust development, testing and implementation.	Deployment, 6 monthly and/or upgrades Agreement with Trust and MIS
			GROW-API error	**2 (Rare / Considerable)**	PI - Inbuilt automated data testing and data quality and user acceptance testing.	Deployment, 6 monthly and/or upgrades
6	Inaccuracy due to differing co-efficients used for pregnancy and birth	Inaccurate growth assessment could lead to fetal growth restriction not being detected antenatally and in rare cases stillbirth. Damage to reputation of hospital, MIS provider, Perinatal Institute.	Update in co-efficients not properly implemented	**2 (Rare / major)**	When there is an upgrade to the co-efficients, current records in the system will stay as the previous co-efficient version and new records will have the new updated version. PI - Inbuilt automated data testing and data quality and user acceptance testing.	Deployment, 6 monthly and/or upgrades
			Co-efficients coded incorrectly	**2 (Rare / major)**	PI - Inbuilt automated data testing and data quality and user acceptance testing.	Deployment, 6 monthly and/or upgrades

7	Accidental deletion of record	Delay (within 24 hours) in obtaining growth assessment. Damage to reputation of hospital, MIS provider, Perinatal Institute.	MIS Administrator error	**2 (Rare / Major)**	MIS - The ability to delete a record in the API is an MIS administrator task only. Guidance on deleting records will be given to the administrator/s prior to deployment. Every record edited or deleted has an audit trail with the ability to recall if required.	Training prior to deployment and yearly update Yearly
Access						
8	Unable to access GROW chart for a given antenatal appointment / labour	Inconvenience to clinician and mother if another appointment needed. No assessment of fetal growth for a given timeframe which could lead to fetal growth restriction not being detected antenatally and in rare cases stillbirth.	GROW PDF printout not available (e.g. woman forgot her notes) [temporary]	**2 (Rare / Major)**	Hospital/Unit - If MIS available, to reprint PDF printout and get previous plot information from the embedded chart. Hospital/Unit - If no MIS available, clinician to produce a new chart using the GROW-App and measure as per the hospital protocol. Also arrange a further appointment at 2 weeks to ensure velocity of growth is acceptable OR arrange for another appointment asap (within 72 hours) ensuring the woman brings her PDF printout.	Yearly
			GROW PDF printout lost [permanent]	**2 (Rare / Major)**	Hospital/Unit - If MIS available, to reprint PDF printout and get previous plot information from the embedded chart. Hospital/Unit - If no MIS available, clinician to produce a new chart using the GROW-App and assess fetal growth as per the local protocol. Also arrange a further appointment at 2 weeks to ensure velocity of growth is acceptable.	Yearly
			Maternity Information System downtime	**2 (Rare / Major)**	Hospital/Unit - Clinician to produce a new chart using the GROW-App / GROW-Chart as per the hospital protocol OR arrange for another appointment asap (within 72 hours)	Yearly

					to ensure fetal growth is assessed within the recommended timeframe. Hospital/Unit - Log helpdesk call with MIS provider and monitor uptime percentage against MIS standard.	 Ongoing and yearly review
			GROW-API downtime	**2 (Rare / Major)**	Hospital/Unit - Clinician to produce a new chart using the GROW-App / GROW-Chart as per the hospital protocol OR arrange for another appointment to ensure fetal growth is assessed within the recommended timeframe (2-3 weeks). Hospital/Unit - Log helpdesk call with GROW-Service and monitor resolution within SLA timeframe standard. (see helpdesk SLA).	Yearly Ongoing and yearly review
			Mother moved to another Trust for pregnancy care	**2 (Rare / Major)**	All – Clinician to enter chart ID number (from PDF printout master) into MIS. The MIS will produce a ChartGET call to confirm the most up-to-date information held within GROW. The MIS will then highlight any data discrepancies to be resolved. The PDF printout states that there could be another electronic chart with plots to review, so the end user is always aware to check for another electronic chart if the woman has received care from another hospital.	Ongoing (via Safety Incident Management Log) and yearly review
9	Unable to access the customised birth weight centile	The birth weight centile is essential to inform postnatal management. However, there are numerous ways to obtain a birthweight centile (GROW-App or contacting the hospital	Clinician unable to access internet (no connectivity)	**2 (Likely / Minor)**	Hospital/Unit - Clinician to ring the hospital to get another midwife to obtain the birth weight centile or get to a place where connectivity is possible within 4 hours of birth.	Yearly
			Maternity Information System downtime	**1**	Hospital/Unit - Clinician to obtain birth weight centile from GROW-Centile or GROW-App. Hospital/Unit - Log helpdesk call with MIS	Yearly Ongoing and

		for another clinician to obtain it) so would be of minimal consequence.		**(Rare / Minor)**	provider and monitor uptime percentage against MIS standard.	yearly review
			GROW-API downtime	**1 (Rare / Minor)**	Trust - Clinician to obtain birth weight centile from GROW-Centile or GROW-App Trust - Log helpdesk call with GROW-Service and monitor resolution within SLA timeframe standard. (see helpdesk SLA)	Yearly Ongoing and yearly review
10	Access an incorrect record (wrong chart ID for woman)	If an incorrect record is accessed and updated two records could be incomplete/inaccurate for fetal growth. Inaccurate growth assessment could lead to fetal growth restriction not being detected antenatally and in rare cases stillbirth Damage to reputation of hospital, MIS provider, Perinatal Institute	Maternity Information System Error	**2 (Rare / Major)**	PI - Data quality and user acceptance testing. MIS to inform the PI prior to each upgrade that would affect GROW MIS - The Chart ID should not be an editable field for any user of the system (developer, admin, end user). All - All API calls request a prefix (initials of woman) and chart ID and are checked prior to returning any data/chart images. The MIS will produce a ChartGET call to confirm the most up-to-date information held within GROW. The MIS will then highlight any data discrepancies for the end user to resolve. All - The deployment clinical safety case and accompanying clinical protocol will be reviewed with the MIS and Trust, to ensure the robust development, testing and implementation.	Deployment, 6 monthly and/or upgrades Ongoing (via Safety Incident Management Log) and yearly review Agreement with Trust and MIS
			GROW-API error	**2 (Rare / Major)**	Inbuilt automated data testing and user acceptance testing prior to deployment and upgrade	Yearly and upgrades

Evaluation and Recommendations

The clinical risk team and organisational top management can confirm that all pre-operational risks have been mitigated to as low as reasonably practical (ALARP) in line with the tolerance levels agreed. This clinical safety case report needs to be reviewed by all collaborating hospitals and MIS providers' clinical safety teams to ensure all risk actions are addressed. Once these reviews have taken place a further clinical safety case report will be completed at deployment.

Appendix 1

RISK MATRIX:

Likelihood	Minor	Significant	Considerable	Major	Catastrophic
Certain	3	4	4	5	5
Likely	2	3	3	4	5
Possible	2	2	3	3	4
Unlikely	1	2	2	3	4
Rare	1	1	2	2	3

Consequence

HAZARD RISK INDICATORS:		
5	**Very High**	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.
4	**High**	Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.
3	**Medium**	Undesirable level of risk. Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	**Moderate**	Tolerable where cost of further reduction outweighs benefits gained.
1	**Low**	Acceptable, no further action required.

LIKELIHOOD AND CONSEQUENCE DEFINITIONS:

Likelihood Category	Interpretation	
Certain	Will undoubtedly happen / recur, expected to occur in most circumstances.	
Likely	Will probably happen / recur, but is not a persisting issue.	
Possible	Might happen or recur occasionally.	
Unlikely	Do not expect it to happen / recur, but is possible it may do so.	
Rare	Probably never happen / recur only in very exceptional circumstances.	
Consequence Category	**Interpretation**	**Patients Affected**
Catastrophic	Death	Multiple
	Permanent life changing incapacity and any condition for which the prognosis is death or permanent life changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term.	Multiple
Major	Death.	Single
	Permanent life changing incapacity and any condition for which the prognosis is death or permanent life changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term.	Single
	Severe injury or severe incapacity from which recovery is expected in the short term.	Multiple
	Severe psychological trauma.	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term.	Single
	Severe psychological trauma.	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma.	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term.	Single
	Significant psychological trauma.	Single
	Minor injury from which recovery is expected in the short term.	Multiple
	Minor psychological upset; inconvenience.	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence.	Single