NHS Digital

DCB2112 Amd 28/2019 FGM-IS Local System Integration Implementation Guidance

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Data Coordination Board

This information standard (DCB2112) has been approved for publication by the Department of Health and Social Care under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Coordination Board (DCB), a sub-group of the Digital Delivery Board.

This information standard comprises the following documents:

- Change Specification
- Requirements Specification
- Implementation Guidance.

An Information Standards Notice (DCB2112 Amd 28/2019) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the NHS Digital website. Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

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Glossary of Terms

See Requirements Specification.

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1 Overview

This document describes the steps which should be undertaken to implement this information standard. Details on the purpose, background and context of the standard are shown in the supporting Requirements Specification.

2 Summary

Standard	
Standard Number	DCB2112
Standard Title	Female Genital Mutilation - Information Sharing (FGM-IS) – Local System Integration
Description	This information standard requires in-scope NHS funded healthcare providers to update their local applicable IT system(s) to automatically display an alert message when a patient with female genitalia under 18 years old has a family history of FGM, as recorded in the FGM-IS core service (a national Spine application). The search undertaken to display the alert is made of all genders, to cater for any patient adopting a new gender identity, and all patient records that have this flag will be displayed. This ensures all are treated fairly and no additional risk is created, as is required by the Equality Act 2010[1]. The decision to update the FGM-IS core system with a family history of FGM is a local clinical decision, informed by the individual personal circumstances and supported by the NHSE/I guidance for clinicians on FGM prevention alongside local FGM prevention protocols. An ‘applicable IT system’ is the term used to describe those local NHS IT systems to which this standard applies and includes any electronic information system that supports the provision of NHS funded healthcare for in-scope clinical settings in England that are accessed by children. At this time it is only mandatory for those systems working in primary care settings. In addition, an ‘applicable IT system’ will use a verified NHS number to link the patient to their electronic health record. The system must also have access to the national Spine either directly or via a Spine Mini Services Provider (SMSP). This information standard describes the integration of the FGM-IS information held on the NHS Spine within in-scope clinical settings to support the clinician with improved access to information of those under the age of 18 with a family history of FGM, which informs local safeguarding procedures.

[1] http://www.legislation.gov.uk/ukpga/2010/15/contents

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	It supports the overall objectives of the DHSC and NHSE/I FGM prevention work in that it is expected to: • support clinicians to meet their local safeguarding responsibilities • support the prevention of FGM, through the provision of accurate information to all relevant care professionals • improve the awareness of FGM • eventually help to eradicate the practice. This information standard forms part of the national solution across England so that whenever and wherever the child is provided with health care, a family history of FGM will be known which will lead to better outcomes for children at risk of FGM in society.
Applies to	• Mandatory requirement for primary care NHS funded healthcare providers • Optional (may implement) requirement for other NHS funded healthcare providers (local decision)
Release	
Release Number	Amd 28/2019
Release Title	Version 2
Description	Provision of an automatic alert in local NHS IT systems (applicable IT systems) when a family history of FGM has been previously recorded on the FGM-IS core service. Note that previously this alert indicated a patient's risk of FGM but following a change in the FGM-IS service this now indicates a patient's family history of FGM. This release makes the following changes: 1. name change to Female Genital Mutilation Information Sharing (FGM-IS), rather than FGM RIS (Risk Indication System) 2. mandatory implementation requirement for primary care only and an optional requirement for other care settings, rather than all NHS funded services being in-scope 3. allows the local storage of the family history indicator if it is associated with a clear date and time stamp indicating when FGM-IS indicator was retrieved from the core FGM-IS system. Local storage, which is not a mandatory requirement (or the default approach), may be used for example to record the status of the flag in historical records (the 'as at' position). **Notes**: (i) as per the initial release of this standard the indicator must only be presented up to age 18, and (ii) local storage has information governance consequences (see implementation guidance, section 7) regarding data controller. Previously local storage was not allowed. 4. requirement to display FGM-IS for any patient regardless of NHS system classification of gender identity.
Implementation Date	This information standard gives notice to NHS funded primary care healthcare providers in England and those that manage NHS IT system supplier contracts to achieve compliance by 31 March 2021.

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	Implementation should commence immediately following publication of this standard.
Full Conformance Date	31 March 2021

2.1 Scope

2.1.1 In-Scope

This information standard is **mandatory** (MUST implement the requirements described in section 3) for primary care NHS funded healthcare providers in England:

- GPs and other users of primary care systems, such as practice nurses and community midwives.

It is **optional** (MAY be implemented, depending on local decision) for other health care providers in England.

Note:

- An evaluation is underway regarding FGM-IS use in hospital settings, which may lead to future mandate if there is a clear business case.
- Until this evaluation is completed NHS services will be able to use the SCRa to create, view and amend records (without local view integration).

2.1.2 Out of Scope

The purpose of this information standard is to integrate healthcare more closely into statutory safeguarding processes. As such, this information standard does not apply to local authorities / social care settings which already have well established processes in place.

Services accessed exclusively by adults are also excluded from this information standard as are any services that rely on anonymity for their success (such as sexual health clinics and addiction services).

The following are out of scope of the requirements of this information standard:

- Functionality of the FGM-IS core service contained within the national spine architecture. This includes the functionality available in SCRa such as the addition and removal of the FGM-IS Indicator.
- Professional safeguarding responsibilities which are guided by national and local policy; NHS funded healthcare providers are responsible for determining how the FGM-IS information will be used.

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2.1.3 Related Standards

Ref #	Reference	Title
1	ISB 0149	NHS Number
2	SCCI2026	Female Genital Mutilation Enhanced Dataset

3 Implementation plan and timetable

The success of this information standard is dependent on clinicians updating the FGM-IS core service, via the SCRa, based on the presence of a family history of FGM. This 'core service' capability has been available nationally since August 2015 and uptake is being led by Department of Health and Social Care and NHS England and NHS Improvement (NHSE/I)[2]. The requirements of FGM-IS have already been communicated and have been in use since March 2018. In September 2019[3]:

- FGM-IS was live in all London, Midland and Eastern Regions NHS Trusts
- FGM-IS was live in 198 of 208 settings across England,
- The SCRa Indicator was added 904 times in the six months ending April 2019, and viewed 1287 times

4 Supporting Documentation

Supporting documents are available on the NHS Digital FGM-IS web pages at:

https://digital.nhs.uk/services/female-genital-mutilation-information-sharing/nhs-it-system-suppliers

4.1 FGM-IS

An overarching FGM-IS User Guide has been produced to help clinicians understand what the FGM-IS is and how to use it to help prevent FGM.

https://digital.nhs.uk/services/female-genital-mutilation-information-sharing/

4.2 FGM-IS core service (SCRa)

An implementation toolkit is available to help organisations implement and use the FGM-IS core service and add, view and remove a FGM family history using the SCRa. This includes the following guides:

- FGM-IS SCRa User Guide
- FGM-IS SCRa Implementation Guide
- FGM-IS SCRa Quick Reference Guide

[2] Focused on maternity settings via the commissioning NHS Digital Implementation and Business Change team.
[3] NHS Digital Implementation and Business Change reporting, and FGM-IS Transaction Summary Reporting

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A communications toolkit is also available for local printing by organisations using the FGM-IS. This includes the following leaflets which will be presented on the FGM-IS website:

- FGM-IS Patient Leaflet
- FGM-IS Staff Leaflet

4.3 FGM-IS Local Integration – Implementation Plan

This document is provided to help in-scope NHS funded healthcare providers adopt this information standard.

Although the primary purpose of this standard is for safeguarding purposes it is considered as in-scope of DCB0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems[4] and DCB0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems[5]. Consequently, a Clinical Safety Case Report has been completed.

It is expected that Manufacturers and Organisations will take ownership of this risk and make the necessary additions to their respective Clinical Safety Case Reports.

Below are the steps which the implementing organisation will need to follow in order to successfully implement this standard. These are established as a result of the programme team working with the early implementers and learning from their experience.

Note: both new and existing users of the standard should review the items, considering the move from risk assessment to recording FGM family history.

- the local provider decides to implement the standard. The recipient of the Information Standards Notice (ISN) must ensure that all relevant contacts are notified in the following areas: Information Governance (including Caldicott Guardian), ICT, the PAS, other Clinical Systems Administrators, Training, Safeguarding, and Risk Management and the relevant system suppliers.
- the nominated person within the implementing organisation works with their internal IT and local system suppliers and the safeguarding lead to commence the work to implement the standard. This nominated person can be a business manager, project lead or whoever the provider deems is responsible for carrying out this role.
- it is also important that this person works closely with the business manager or a change lead to assess the impact of this change on their local processes. They will also need to review their existing safeguarding processes to see how the indicator alert will fit within existing processes.
- once they have established the key roles and responsibilities including a potential project lead, the nominated person will work together with their local system suppliers to make them aware of the change and the need to implement the standard.
- they will then work together to develop a plan to make the necessary changes to the local system to comply with the standard.
- the business manager/ change lead will also need to communicate and inform local staff of the changes including providing awareness and training as necessary.
- they need to identify any training and development for local staff.

[4] https://digital.nhs.uk/isce/publication/dcb0129
[5] https://digital.nhs.uk/isce/publication/dcb0160

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The following documentation is provided as part of this information standard to help NHS funded healthcare providers and their IT systems suppliers to implement the 'view only' capability within their local NHS applicable IT systems:

- FGM-IS Requirements Specification, available on the NHS Digital website: http://digital.nhs.uk/isce/publication/dcb2112
- FGM RIS Domain Message Specification, available on the Data Developer Network (following publication of this standard this will be updated to reflect the move to FGM-IS): https://data.developer.nhs.uk/fhir/fgm-v2-draft-d/Chapter.1.About/index.html

4.4 General FGM and safeguarding information

- DH Female Genital Mutilation Risk and Safeguarding: Guidance for Professionals (March 2015): https://www.gov.uk/government/publications/safeguarding-women-and-girls-at-risk-of-fgm
- Health Education England is producing eLearning materials for the wider DH FGM Prevention Programme. An introductory module on FGM for all health professionals can be found at: http://www.e-lfh.org.uk/programmes/female-genital-mutilation/
- Female Genital Mutilation Act 2003: http://www.legislation.gov.uk/ukpga/2003/31
- HM Government Multi-agency statutory guidance on female genital mutilation (April 2016): https://www.gov.uk/government/publications/multi-agency-statutory-guidance-on-female-genital-mutilation
- DH Commissioning services to support women and girls with female genital mutilation (March 2015): https://www.gov.uk/government/publications/services-for-women-and-girls-with-fgm
- Information Sharing: Advice for practitioners providing safeguarding services to children, young people, parents and carers (March 2015): https://www.gov.uk/government/publications/safeguarding-practitioners-information-sharing-advicehttps://www.gov.uk/government/publications/safeguarding-practitioners-information-sharing-advice
- Children Act 2004: http://www.legislation.gov.uk/ukpga/2004/31/section/11
- Department for Education: Working together to safeguard children 2018 https://www.gov.uk/government/publications/working-together-to-safeguard-children--2
- NHS England FGM Clinics

  https://www.nhs.uk/conditions/female-genital-mutilation-fgm/national-fgm-support-clinics/

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5 Monitoring Conformance Criteria

NHSE/I will be responsible for conformance monitoring. The following information will be available to them:

- a monthly report showing the uptake of the FGM-IS core service, allowing analysis of areas of high and low uptake, so aiding planning of where resources are needed to help implementation.
- NHS IT systems suppliers may only gain access to the FGM-IS by going through the Common Assurance Process (CAP) or via an accredited Spine Mini Service Provider (SMSP).

6 Information Governance

6.1 Access

Access to FGM-IS information will be determined by each NHS funded healthcare provider locally, although it is expected that all healthcare professionals that care for children will have access to the system.

6.2 Local Audit

The FGM-IS information as described is stored on the NHS Digital provided National Spine SCR application (SCRa). The data on the SCRa is access controlled and audited at a national level. There is no requirement for local systems to keep an audit of the records on the SCRa; however, this is for local organisations to determine.

6.3 Data Controller

NHS Digital is Data Controller[6] when the family history flag is stored on the FGM-IS core service.

Storing the flag in local systems, is **not a mandatory requirement**, but depending on local system configurations may be required to ensure that the FGM-IS is displayed when the record is accessed (e.g. when it is viewed outside a set event). In these circumstances the local provider becomes data controller of the family history flag. A requirement exists for the local provider to ensure appropriate measures are in place as defined by General Data Protection Regulation (GDPR).

6.4 Data Quality

The NHS England FGM Prevention Board will monitor the use of both the SCRa and the integrated FGM-IS systems on a quarterly basis. This review will examine how the flag is being created, changed and viewed by health setting; this will allow them to identify any trends that may require national intervention.

At a local level it is expected that the audit of the FGM-IS information will be undertaken in line with the general audit of local systems. This should include, as a minimum, regular verification that the staff who are accessing the record in any form have the appropriate

[6] https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/key-definitions/controllers-and-processors/

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authorisation to do so; and to identify any trends that may cause alarm (e.g. too many creations, or deletions).

It is also expected that local FGM Prevention partnerships have a role to play in monitoring the use of the system and maintaining appropriate use.

6.5 Patient / Parent consent

Patient/parent consent is not required to view the FGM information held on the FGM-IS core service. It is accepted that information sharing is vital to safeguarding and promoting the welfare of the person. A key factor identified in many serious case reviews has been a failure by practitioners to record information, to share it, to understand its significance and then take appropriate action.

6.6 Safeguarding Procedures and Processes

NHS funded healthcare providers will already have local safeguarding protocols and procedures for helping those at risk of FGM. These should include sharing of information with multi-agency policies and procedures, consistent with those developed by their Local Safeguarding Children Board. This information standard does not replace existing safeguarding processes.

As part of this information standard, NHS funded healthcare providers are expected to review their current processes to include handling cases where FGM is alleged or known about or where there is a potential risk of FGM identified. NHS funded healthcare providers will need to determine how FGM-IS integration will be used within their safeguarding processes and ensure processes and procedures are updated accordingly. Local processes should include an assessment as to whether the person is currently at risk of FGM and this is aided by FGM-IS. Conversely it should not be assumed that if no message is displayed the person is not at risk of FGM.

7 Local Storage

As described, the FGM-IS indicator, updated via the SCRa, is stored on the NHS Digital National Spine.

It is therefore important that if local systems identifies a need to store FGM-IS indicator data locally, for example in the event that the record is viewed outside of an event (such as storing the flag which was in place at the time of a historical patient attendance), that the indicator is displayed with a date and time stamp of when the data was retrieved from the core FGM-IS system. It is required that when a new event (such a patient attendance) occurs it triggers the flag held on the FGM-IS Core system to be presented.

Presenting stored data with date and time it was retrieved mitigates the risk that healthcare professionals may be inadequately informed or misinformed. The healthcare professional should refer to the FGM-IS Core system in all instances where the recorded indicator on the local system may be seen as out of date/not timely. Section 6 describes associated information governance considerations.

This should not be confused with healthcare professionals maintaining a record of actions and decisions they may take as a result of seeing the FGM-IS indicator; nor any records that

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have been created as part of the process of establishing the need to update the indicator. This is however not within the scope of this standard.

8 Risks and Issues with suggested mitigations

As part of implementing this information standard organisation should consider identification of risk and issues and ensure that appropriate mitigations are in place.

NHS funded healthcare providers should consider the list below to determine whether the risks / issues apply to them and, if so, how they will be owned, managed and mitigated within the organisation. Please note this list is not exhaustive and the mitigations provided are only examples and the implementing organisation should undertake a review based on their circumstances:

- poor uptake of recording FGM family history on the FGM-IS core service. FGM-IS is not yet used across the full health community – NHS England is driving the implementation activities and is working with primary care sites initially to implement the FGM-IS. Secondary care services may become the focus of this standard in the future following a planned review to determine the use of FGM-IS in secondary care settings.

- presumption that there is no family history if an alert is not displayed – this is not correct, it is just that it is not known to the NHS at this time. In addition, should a system error arise it would be logged and appropriate action taken to resolve it.

- Role Based Access Codes not given to all relevant clinicians – all relevant clinicians will need to use NHS issued smart cards with the correct RBAC code. This will be part of the local implementation plan and clinical safety assessment.

- presumption of high level of risk when the FGM-IS indicator is displayed – awareness and training is available for all clinicians and local staff to help them understand more about FGM and the risks associated.

- staff unaware of safeguarding procedures and responsibilities – all local establishments have a dedicated safeguarding lead who is responsible for ensuring staff are kept up to date on any safeguarding issues.

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Pre 'Go Live' Checklist

Please complete this checklist before the FGM-IS Local System Integration 'Go live' date and before organising any training:

- ✓ Who is leading the implementation of Local Integration?
- ✓ Do you need IG sign off for the Local Integration implementation to go live?
- ✓ Which section/people within the organisation will have access to the FGM-IS Local Integration Systems?
- ✓ Do you have smartcard readers in place?
- ✓ Do all users have a smartcard?
- ✓ Does the smartcard have the appropriate authentication code and has this been tested?
- ✓ Have all users been trained on what to do when they see the alert? (It is recommended that this is the final step).

9 Issues and Maintenance

To support the implementation of this information standard any persistent issues should be fed back to the standard's developers. Feedback will be used by the developers for future development and to improve implementation of the standard. Send feedback to enquiries@nhsdigital.nhs.uk (please include 'FGM-IS information standard' in subject line).

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