| Document filename: SCCI2026 Post Implementation Review | | | |
|---|---|---|---|
| **Directorate / Programme** | Cross Government Programme | **Project** | FGM Prevention Programme |
| **Document Reference** | | | |
| **Project Manager** | Donna Braisby | **Status** | Final Draft |
| **Owner** | Donna Braisby | **Version** | 0.7 |
| **Author** | Sam Sibeko | **Version issue date** | 17 June 2016 |

# FGM Enhanced Dataset
# Post Implementation Review

# Document Management

## Revision History

| Version | Date | Summary of Changes |
|---|---|---|
| 0.1 | 17th Nov 2015 | Initial Draft |
| 0.2 | 17th Nov 2015 | General update |
| 0.3 | 15th Jan 2016 | General update |
| 0.4 | 11th Feb 2016 | General update |
| 0.5 | 9th Mar 2016 | General update |
| 0.6 | 15th Mar 2016 | DH comments |
| 0.7 | 17th Jun 2016 | Final DH Comments |

## Reviewers

This document must be reviewed by the following people: author to indicate reviewers

| Reviewer name | Title / Responsibility | Date | Version |
|---|---|---|---|
| Donna Braisby | HSCIC FGM Programme Manager | 17/06/2016 | 0.7 |
| Astrid Fairclough | DH FGMP Programme Manager | 17/06/2016 | 0.7 |
| Julie Michalowski | HSCIC FGM Clinical Audit Support Manager | 17/06/2016 | 0.7 |

## Approved by

This document must be approved by the following people: author to indicate approvers

| Name | Signature | Title | Date | Version |
|---|---|---|---|---|
| Astrid Fairclough | | DH FGM Programme Manager | 17/06/2016 | 0.7 |
| Donna Braisby | | HSCIC FGM Programme Manager | 17/06/2016 | 0.7 |

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# Contents

# 1 Introduction

Female Genital Mutilation (FGM) is illegal in the UK, as is taking a child abroad to undergo FGM, as legislated in the 2003 Female Genital Mutilation Act. It is child abuse. FGM is medically unnecessary, extremely painful and has serious health consequences both at the time when the mutilation is carried out and in later life.

The FGM Enhanced Dataset requires NHS organisations (Acute Trusts, including Mental Health Trusts and GPs) to record and collect information about the prevalence of FGM within the female population as treated by the NHS in England.

The FGM Enhanced Dataset builds on the previously implemented 1610 FGM Prevalence Dataset, providing a greater level of FGM information captured from various different health settings.

The FGM Prevention programme, led by the Department of Health, is a change programme to improve the NHS response to FGM, including the provision of health services and safeguarding of girls at risk. This work is currently ongoing with the FGM Enhanced Dataset being one element to better understand the patient population effected by FGM, and to help inform where services and support are needed.

The FGM Enhanced Dataset includes requirements on what information needs to be shared locally for the provision of care for a woman or girl, and also includes what information needs to be submitted to HSCIC.

The FGM Enhanced Dataset was implemented on 1st April 2015 and has been collecting submissions from Acute Trusts (including Mental Health Services) and GP practices since then.

It is assumed the reader will already be familiar with the FGM Enhanced Dataset, but if further information is required about the requirements and the implementation guidance, these can be found at: http://www.hscic.gov.uk/isce/publication/scci2026.

Further to the above, there is also additional supporting guidance available from: http://www.hscic.gov.uk/fgm

## 1.1 About this Document

This document, aims to provide a review of the FGM Enhanced Dataset following the implementation of this standard in April 2015, and assess the success of this against the initial objectives.

This document will focus on the following areas:

- Collection of data
    - Organisations being compliant with the standard
    - Is FGM information being collected?
        - GPs and the collection of data
        - Mental Health Trusts and the collection of data
    - Comparisons with the FGM Prevalence data collected
    - Published Data
    - Reporting
    - Is the data collected of value?
    - Assessment against conformance criteria
    - Data Quality
    - Burden Assessment Advise Service
    - Corrigendum Items
    - Caldicott Guardians
- Addressing Issues and Concerns
    - Development Approach
    - Consultation
    - Information Governance
    - Perceived Burden
    - HSCIC Development Approach

# 2 Executive Summary

The FGM Enhanced Dataset is achieving the primary objective to collect information about patients being treated who have FGM.

It is still early to determine and evaluate the value of the FGM information submitted. However as more data has been received, the reports have been published with increasingly much more information being available at a granular level.

There have also been some areas of concern following implementation. These have in part been and will continue to be addressed.

The following section provides a summary of the review undertaken which is explored further within this document.

| | |
|---|---|
| | Collecting Data |
| 1 | **Status:**<br>The main objective of the SCCI2026 FGM Enhanced Dataset is to collect FGM information<br>**Finding:**<br>Data has been flowing from Acute Trusts where it was expected data would flow. Some data has been flowing from Mental Health Trusts. Data flow from GPs is still very low.<br>**Lessons:**<br>• Ongoing engagement and work is required specifically targeting GPs and Mental Health Trusts to support organisations submit the data<br>• Earlier communication and stakeholder engagement to help address concerns raised, specifically by GPs. It is anticipated however, that the levels of GP participation will continue to increase |
| 2 | **Status:**<br>Submission rates from Acute Trusts indicate that FGM information is continuing to be collected in line with the FGM Prevalence Dataset (Apr 2014 – Mar 2015). This can't be verified for Mental Health Trusts and GPs as they were out of scope of the Prevalence Dataset.<br>**Lesson:**<br>• Submission rates from Mental Health Trusts and GP practices may have been improved if the implementation approach for these organisations led from a similar approach that Acute Trusts have had chance to build on. |
| 3 | **Status:**<br>The FGM information collected, provided and published is of value and sufficient data is now being submitted to allow publication of information at CCG level, with the expectation this will continue to support Trust level publications in the near future.<br>**Lesson:**<br>• To continue to assess the data being collected, and review how this can be used to provide more granular information, e.g. Trust level submission data if applicable to do so |
| | Approach |
| 4 | **Status:**<br>Confirmation on which clinical settings should be collecting and submitting FGM data |

| | |
|---|---|
| | **Finding:**<br>Some clinical settings included within the original scope needed to be reassessed as being suitable to do so, following publication of the standard<br>**Lesson:**<br>• Earlier and more detailed assessment on the impact of collecting FGM data from all clinical settings, could have prevented some initial confusion for some settings, e.g. sexual health clinics |
| 5 | **Finding:**<br>Although CAP is already used in a number of Acute Trusts, this was not the case for Mental Health and certainly not for GPs, resulting in extensive guidance being required.<br>**Lesson:**<br>• Although CAP has many benefits, greater explanation of these benefits and the reasons why CAP was decided as the right platform could have been explained in more detail |
| 6 | **Status:**<br>Appropriate conformance criteria needs to be used for assessment against the FGM Enhanced Dataset requirements<br>**Finding:**<br>Some of the original conformance criteria defined wasn't tested in detail until the Post Implementation Review. It has since been identified that new or additional conformance criteria may have been more suitable<br>**Lesson:**<br>• More detailed research into the setting of conformance criteria |
| 7 | **Status:**<br>Directions have been provided to HSCIC providing the legal basis to collect FGM information, but this could have been more clearly articulated<br>**Finding:**<br>Some confusion has been outlined, with regards to Directions, fair processing, consent and objection handling processes, which have led to some concerns being raised.<br>**Lesson:**<br>• Explicitly clear guidance is required much earlier in the development of the standard in relation to;<br>- the legal basis for the flow of data,<br>- explanation of what fair processing is (including guidance on how to implement)<br>- patient consent and how this relates to the Directions<br>- how objections will be handled<br>which all need to be explicitly clear and unambiguous |
| 8 | **Status:**<br>The data standard was consulted upon at some length and this was recognised within comments from SCCI.<br>**Findings:**<br>Stakeholders have since publication of the standard, stated that they do not agree that the consultation was sufficient.<br>**Lesson:**<br>Whilst the consultation was, at the time felt to be sufficient, it is always possible to |

| | |
|---|---|
| | consult more widely, in greater detail and with more time. It should be noted however that there were significant time pressures upon the work. |
| 9 | **Status:**<br>Since publication, HSCIC have developed the Data Provision Notice (DPN) mechanism; this was not available to the project at the time.<br>**Lesson:**<br>The DPN, if available, would have been issued in conjunction with the ISN publication, which would have led to a better co-ordinated and clearer explanation of the requirements and implementation guidance to support General Practices. |
| 10 | **Status:**<br>Following publication it was identified that the DH and HSCIC teams have since interpreted the reporting requirements differently.<br>**Lesson:**<br>Clarity is required in the initial development of any standard to confirm exactly what these outputs will be and how they will be supported |
| 11 | Recommended that a further review of the FGM Enhanced Dataset is undertaken in late 2016, to reassess progress. |
| 12 | Earlier identification of the scale of the work required for the development team and more detailed resource analysis |

# 3 Implementation Review

The development of this post implementation review resulted from the recommendation from SCCI that one should be undertaken.

The findings of this review have been undertaken as a result of;

- engagement with the clinical support unit analysts within HSCIC in order to determine what information has been provided, and therefore confirming has or has not been flowing from the relevant organisations
- addressing the queries received following implementation, either received directly within HSCIC and the FGM clinical audit support unit teams or through engagement with DH

## 3.1 Collection of FGM Information

One of the primary objectives of the FGM Enhanced Dataset is to collect the prevalence of FGM and associated FGM information in order to better understand the issues around FGM for patients and to support the provision of evidence in the development of commissioned services.

Whilst the patient identifiable information will not ever be published, this level of data has been required to help identify the FGM information associated for a woman or girl, where they may have attended across a number of different health organisations within a given reporting period and therefore improve on the level of data quality associated with the information submitted. Once this analysis has been undertaken, all patient identifiable information is then removed from being published.

The following questions were considered as part of this review:

### 3.1.1 Are organisations registered to submit FGM data?

To ensure that organisations can submit data to HSCIC they must register their organisation (and users) to submit FGM information to the Clinical Audit Platform (CAP).

A system activity report determines which organisations have registered to CAP. This helps because:

1. It verifies that the FGM Enhanced Dataset standard has been effectively communicated, because organisations have engaged in the initial steps to submit data.
2. It enables those organisations to be ready to record and submit FGM information when it is identified locally.

The table below shows, as at 2 March 2016, how the rate of organisation registration on the CAP system, taken from the CAP system reports.

| | Number of Organisations Registered[1] | Total Number Organisations (Acute & Mental Health) | % |
|---|---|---|---|
| Registered Trusts | 172 | *216* | 79.6 |
| *(Acute)* | *139* | *157* | 88.5 |
| *(Mental Health)* | *33* | *59* | 56.0 |
| Registered GP Practices | 572 | 8046 | 7.1 |
| Total Registered | 916 | 8262 | 11.1% |

As can be seen from the table:

- the total number of registered Acute Trusts is encouragingly high
- Mental Health Trusts have reached a reasonable rate of registration
- Registration within GP practices is very low

Further consideration of these outcomes is explored further within this document.

### 3.1.2 Is FGM information being submitted?

Since 1 October 2015, it has been mandatory for Acute, Mental Health Trusts and GPs to comply with SCCI2026 FGM Enhanced Dataset, including submitting FGM data to HSCIC via the CAP system. Submission between April 15 and June 15 for Acute Trusts and between April 15 and September 15 for other organisations was encouraged but voluntary.

The table below outlines the total number of unique organisations that have submitted FGM information to HSCIC via CAP, between 1st April 2015 and 3rd March 2016.

| | Number of Organisations Submitting[2] | Total Number Organisations (Acute & Mental Health) | % |
|---|---|---|---|
| Submitting Trusts | 112 | 216 | 51.9 |
| *(Acute)* | *98* | *157* | 62.4 |
| *(Mental Health)* | *14* | *59* | 23.0 |
| Submitting GP practices | 51 | 8046 | 0.6 |
| Total Submitting | 163 | 8262 | 1.9 |

As can be seen from the table:

- the total number of Acute Trusts that are submitting data is encouraging
- the submission rates from Mental Health Trusts is low
- the number of GP practices submitting information is very low

[1] As at 2nd March 2016

[2] As at 19th Jan 2016

### 3.1.3 FGM Prevalence and Enhanced Dataset Comparisons?

The FGM Prevalence Dataset was implemented in April 2014 and was retired in Mar 2015. For further information about the Prevalence Dataset, this is available from: http://www.hscic.gov.uk/isce/publication/SCCI2026, at the bottom of the page.

The Prevalence Dataset collected a minimal amount of information at an aggregate level and was only applicable for Acute Trusts (excluding Mental Health Trusts).

By comparing the return rates from the FGM Prevalence Dataset and the registration to CAP rates for the FGM Enhanced Dataset, this provides a reasonable comparison of compliance with the standard.

Further to this, the number of Trusts submitting newly identified FGM returns from the FGM Prevalence Dataset (which were not nil returns), can be compared to the newly recorded cases within CAP for the FGM Enhanced Dataset information.

| | Total number of Trusts returning FGM Data (including Nil Returns) or Registered to submit data | Percentage of Trusts returning FGM Data or Registered to submit data % | Total number of Trusts submitting actual FGM information | Percentage submitting actual FGM information % |
|---|---|---|---|---|
| FGM Prevalence Dataset | 156 | **96.3** | 102 | **62.9** |
| FGM Enhanced Dataset | 139 | **88.5** | 98 | **70.5** |

Between September 2014 and March 2015, there were 156 Trusts that were submitting responses to HSCIC[3], (or 96%) of Trusts submitting FGM responses (this also included nil returns). With the FGM Enhanced Dataset, 139 Trusts have registered to CAP (or 89%) of Acute Trusts.

From the 156 Trusts with the Prevalence Dataset, 102 submitted actual FGM information, which is just under 63% returning FGM information, not just nil returns.

By comparison the submission of FGM information to CAP by those Trusts registered to do so (139 Acute Trusts), was 98 Trusts which is just over 70% of Trusts nationally, which are sending actual FGM information.

This information confirms that FGM is being treated across large areas of the country. Considering the more detailed information requested from the FGM Enhanced Dataset, these findings indicate that Trusts at least, are able to identify, record and submit a greater amount of FGM information than compared to the Prevalence Dataset.

Through direct comparison of the list of the trusts who submitted information under the FGM Prevalence Dataset and those who have so far submitted information under the FGM Enhanced Dataset, that there are only 6 Trusts which had previously provided FGM data as part of the Prevalence Dataset but have not yet submitted any information under the FGM Enhanced dataset. There are a further 18 Trusts which have not registered to CAP, which also never submitted information through the FGM Prevalence Dataset previously.

[3] FGM Prevalence Dataset Report - Sept 2015 to March 2015

### 3.1.4 What information has been published?

HSCIC have successfully analysed and published experimental statistics as initially intended.

Outlined below is a list of the data that is currently reported against at Commissioning Region level and at CCG level, but it is anticipated that the more data that is received, the greater level of analysis that can be undertaken and therefore published:

- Total number of organisations registered and submitting data
- Total number of newly recorded women or girls within CAP and Total Attendances
- FGM activity identified (FGM Type 1, 2, 3, 4 and Unknown)
- Age at attendance
- How FGM was identified (Self-reported by patients, or following clinical examination)
- Country of Birth
- Treatment Function Area (those departments impacted)
- Pregnancy status
- Daughters born at attendance
- Deinfibulation procedures undertaken

For further information with regards to the contents of the FGM reports, please visit: HSCIC FGM Reports.

#### 3.1.4.1 System Reporting

There is system reporting capability which reports on which organisations are registered to CAP to submit data, and which reports on those organisations submitting data.

NHS England can receive these reports. This has given NHS England the capability, which has been routinely and regularly used, to directly engage with those organisations which have not registered nor have submitted data and to increase compliance.

#### 3.1.4.2 Management Information Reports

At the time of writing there are ongoing discussions about the provision and use of management information. This should provide specific information to support the commissioning of services, using bespoke reporting outcomes aimed at the development of specific commissioning requirements.

#### 3.1.4.3 Annual Reports

Further to the quarterly reports, it is expected that an annual report will published in summer 2016.

### 3.1.5 Is the data being collected of value?

One of the primary intentions of collecting FGM information was to support NHS England with the commissioning of new services and to help them assess the impact on local services who treat and support women and girls who have been subjected to FGM.

#### 3.1.5.1 How has information been used so far?

Whilst FGM information is being provided to HSCIC from NHS organisations, it is (at the time of writing) too early to assess the long-term value of the data being collected. At a local level (Trust or CCG level) there is significant suppression of low numbers meaning it will take more time for the information to reach a level of maturity which allows publication to support the primary objective. The project team are receiving some reports of the information informing local decisions and local narratives, but these are not evidenced or widespread at this point. The following outlines some of the key uses of the data being collected:

- Ongoing engagement with NHS England is underway to ensure that the FGM information identified can be provided to them in a timely manner to best exploit this resource. It is anticipated that the more data that is received over time, the increase in the value it will be. The first FGM reports produced by HSCIC in September 2015 could only be published at the NHS England Commissioning Regional level (North, South, Midlands & East and London).
- The second FGM report produced in December 2015 included the associated FGM information at the CCG level. It is anticipated that for future published reports, the associated FGM information will also be published at Trust level.
- In December 2015/ January 2016, the data was used by York Health Consortium to inform a report they were commissioned to produce for DH, which considered the health economics around FGM care and provision
- Significant media coverage has been made in relation to the information identified which has been used to support the public narrative
- January 2016, the data was also used by the Cabinet Office in support of a review being undertaken into the work on FGM

Early uses of the information published are in line with the stated objectives within the FGM Enhanced Dataset. This is an early point to review, and this area is likely to significantly develop in future. However the indications are positive; the published reports are being used and are of value at this point.

## 3.2 Improving Data Collection

### 3.2.1 Submissions from General Practice

In section 3.1, it is noted that 7.1% of GP practices are currently registered to submit information and only 0.6% of the GP practices have submitted information. These rates are very low.

It should be noted that GPs were only mandated to collect and submit data from 1 October 2015. Since this, the closing date for submissions of returns for the first mandatory period (1st Oct – 31st Dec 2015), closed on 31st January 2016.

The review identified the follow potential reasons for the low rates:

- awareness of the standard and what is required of them

  this links into a broader question about how information standards are communicated by HSCIC to ensure all organisations are in receipt of the standards required of them, which is now being addressed through the expected publication of the Data Provision Notice
- minimal awareness of FGM in general practice
- minimal or no patients with FGM within the local community or patients
- initially the unavailability of the GP templates in which to collect the FGM information from within existing systems

As part of the GP engagement process, NHS England hosted several workshops in the early part of 2015. At these, the workshops identified that improvements were needed to ensure that GPs could;

a) be better supported in how they record FGM information and,

b) better supported in how they submit this information to HSCIC.

At that time, changes to the FGM Enhanced approach was not possible due to the imminent implementation date of the standard, but prior to this there had been some initial discussions held about how GPs could be supported, specifically focussing on the use of GPES (General Practice Extraction Service), but unfortunately the project timelines for providing the capability for FGM meant that GPES would not be an option.

Ideally, earlier engagement could have supported improving how GPs could record and submit data, but nonetheless additional support has been provided since that time, to help improve in how GPs can submit data to HSCIC.

The support outlined was in the form of the CCN033 FGM Enhanced Dataset, which requested GP suppliers to develop a new FGM template, tailoring existing functionality across the suppliers which allow GPs to be able to record FGM information directly into their systems using clinical terminologies (READ and SNOMEDCT). Whilst the initial implementation guidance did not restrict GPs from creating their own FGM templates, using the CCN approach has meant that suppliers could develop the capability once and share this to all their users, reducing efforts required at each practice to develop this capability in isolation.

In addition to being able to record this information, the CCN expands further with regards to the development of reports from those existing systems, which can then be used more easily locally to populate the relevant CAP Upload files, bulk uploading all patients with FGM into CAP. Some of the suppliers are planning to go further than this also, with a view to developing the relevant report so that it can translate the clinical terminologies (that have been recorded) and produce the reports in the same required format with the required values as the CAP Upload file.

Although the introduction of the CCN033 will enable GPs to support the FGM Enhanced Dataset more easily, the timing of the release of this capability and that of the latest submission period ending in 31st Jan 2016, has meant that improvements in the submission

from GPs is unlikely to be seen in the March report. Up until that time though it will be possible to monitor GPs submission rates, through the use of the CAP system reports.

The CCN033 was achieved in Jan 2016 and now at the time of writing GPs can now record and submit FGM information more easily to HSCIC.

### 3.2.2 Improving Engagement with GP Representatives

Stakeholders have raised questions about the DH and HSCIC consultation with GP representatives.

The consultation report, compiled as part of the SCCI process, outlines how stakeholder engagement was taken forward. The RCGP representative at the FGMP programme working group changed after publication of the standard.

As the DH and HSCIC teams engaged in several conversations, it was discussed at the FGMP working group to set up a special interest group, to specifically discuss the challenges faced in this area. This group has been established and continues to meet, with membership from BMA, GMC and RCGP with HSCIC and DH.

A number of actions have been identified following requests from the group:

- Improved fair processing information for patients and professionals
- A single page pathway to combine the mandatory reporting duty and the dataset, and in due course, the FGM Risk Indication System (RIS)

These will be taken forward by the HSCIC and DH teams.

### 3.2.3 Improving Communications with General Practice

At time of publication, HSCIC did not have a formal route to inform GPs about standards, though such a mechanism was in place for communicating with Acute and Mental Health Trusts.

In the absence of a formal mechanism, the FGMP programme was delivering a postal drop to all GP practices, including training and safeguarding guidance. Within this pack, circulated in May 2015, the programme included a copy of a short summary of how to implement the FGM Enhanced Dataset, as well as copies of the FGM patient leaflets. These were posted to all GP practices.

As the various teams were receiving a number of questions along similar lines, and the programme team were identifying that there were inaccurate rumours circulating, it was decided to issue a statement clarifying the issues which were being raised. This was drafted in conjunction with key stakeholders.

These measures were taken because it was acknowledged that a suitably robust communication channel was not in place.

Since publication, the HSCIC have introduced a formal notification process, called the Data Provision Notice. The plan is to issue such a notice retrospectively in the near future.

Further information about the Data Provision Notice Procedure is available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/449435/dpnprocedure.pdf.

*Recommendation:*

- Earlier engagement with GPs to identify and address their concerns
- Use of the DPN to provide formal notification of the standard

### 3.2.4 Submissions from Mental Health Trusts

In section 3.1, it is noted that 56 % of Mental Health Trusts were registered to submit FGM information and 23% of Mental Health Trusts have submitted FGM information up to March The registration rate whilst improving could be higher as could the submission rate which again has been noted as increasing but is still relatively low

It should be noted that Mental Health Trusts were only mandated to collect and submit data from 1 October 2015. Since this, the closing date for submissions of returns for the first mandatory period (1st Oct – 31st Dec 2015), closed on 31st January 2016.

The review identified the follow potential reasons for the low rates:

- awareness of the standard and what is required of them

  this links into a broader question about how information standards are communicated by HSCIC to ensure all organisations are in receipt of the standards required of them
- minimal awareness of FGM in general

  ongoing conversations are taking place between NHS England and Mental Health organisations to encourage the recording and submitting of FGM information
- minimal or no patients with FGM within the local community or patients

  whilst this may be a factor associated with “we don’t deal with FGM survivors so why do we need to participate”, this approach still doesn’t account for potential changes in local demographics at a later stage

Further engagement specifically for Mental Health Trusts was undertaken by NHS England in Feb 2016, specifically focussing on improving the support for how and when FGM information should be collected. This workshop was aimed at both safeguarding leads and information team staff to help promote and support best practice with regards to identifying and recording FGM information

### 3.2.5 Improving Engagement with mental representatives

As part of the review, it has been identified that there are no specific mental health representatives on the standard governance groups, and consultation with these bodies has been minimal in the development of the standard. However, as part of attempts to encourage wider support within Mental Health, NHS England had run specific Mental Health workshops, focussing on the key concerns in the collecting and submitting of FGM information from this specific setting.

*Recommendation:*

*Review membership of groups and include appropriate Mental Health stakeholders*

## 3.3 Conformance Criteria Assessment

The original conformance criteria, outlined within the SCCI 2026 FGM Enhanced Dataset requirements are outlined in the table below, with in addition an assessments of those criteria being met:

| Conformance Criteria | | Criteria Assessment | Met |
|---|---|---|---|
| 1 | All (M)andatory components of the FGM Enhanced dataset MUST be collected as specified. | CAP has been specifically designed to ensure that the submission of FGM information must at the very minimum, include the Mandatory data items. If this information is not included, then the user is advised of the information that is missing and further to this the information cannot be submitted.<br>All submissions undertaken to date within CAP all include the mandatory dataset items as specified and this criteria has been met. | Met |
| 2 | The FGM Enhanced Dataset MUST be submitted via the Clinical Audit Platform template from Acute and Mental Health Trusts for each NHS Funded provider for the specified reporting period. | The only way in which FGM data can be submitted to HSCIC is via CAP, and by being able to determine which organisations have registered to CAP (in order to submit data), the submission rates to CAP and by comparing the information against the previous Prevalence Dataset, it can be seen that this criteria has been met. | Met |
| 3 | Centrally issued guidance SHOULD be used to steer local decisions with regards to implementation. | Ongoing development of guidance has been produced and made available via http://www.hscic.gov.uk/fgm.<br>In addition to this, there have been a number of additional documents produced as part of the wider DH FGM Prevention Programme on Risk Assessment, Safeguarding and Commissioning of FGM services.<br>Without thorough analysis taken from each organisation on the approaches used locally, it will be difficult to assess how centrally issued guidance has helped steer local decision making. The primary evidence to suggest that it has been, is the return of data to HSCIC | Partially |
| 4 | All data MUST be validated and analysed by all Acute/ Mental Health Trusts and GP Practices, prior to the submission via the Clinical Audit Platform against the Data Quality conformance criteria outlined within the Data Quality section.<br>All relevant mandatory fields MUST be completed prior to submission through CAP and CAP MUST alert the submitter where a record has not been completed. | CAP has been designed to self-validate and provide local users with details of incomplete or missing fields, when data is submitted.<br>If Mandatory items are not included then the submission cannot take place locally and the user is advised accordingly.<br>If Required fields are not completed a warning is provided to the user, but submissions can still be undertaken. Further detailed analysis would be required to confirm locally if on receipt of a warning, further action has been undertaken when and if required. | Met |
| 5 | Quality assurance MUST be undertaken by Acute/ Mental Health | As part of the publication of the quarterly reports, the rigorous official statistics | Full |

| | | | |
|---|---|---|---|
| | Trusts and General Practitioners to ensure that a woman's FGM information is not counted twice, within a given reporting period, unless this is done so for legitimate reasons, i.e. that a patient was identified more than once within a submitting organisation within the reporting period. | processes are adopted to ensure the quality of the data that is published is accurate. This requires senior analysts and statisticians to approve final release of the data, which also includes ensuring that NHS numbers received, be it from multiple health care settings, the information associated to the unique NHS number is undertaken prior to any publication. | |
| IT Suppliers | | | |
| 6 | Suppliers of IT and software systems to NHS organisations MUST ensure that where SNOMED CT, CTV3, Read or OPCS is currently supported, the FGM clinical classifications and clinical codes related to FGM can be recorded against health records by Apr 2015.<br>These codes will be the existing FGM codes as published in April 2014 | All system suppliers have included the FGM Enhanced Dataset items as per the FGM Clinical Terminologies published in April 2015. | Full |
| 7 | Suppliers of IT and software systems to NHS organisations MUST ensure that where SNOMED CT, CTV3, Read or OPCS is currently supported, the new FGM clinical classifications and clinical codes related to FGM can be recorded against health records by Oct 2015.<br>The new FGM codes will be published in April 2015 specifically;<br>• History of Deinfibulation<br>• History of FGM Type 3<br>These codes are detailed further within this document. | As above, and in addition to this, with the development of the approach specifically to support GP suppliers via the GPSoC CCN033, the primary GP suppliers have confirmed the development of these templates which include the new FGM codes. These codes are also available for other suppliers to use | Full |
| 8 | Suppliers of IT and software systems to NHS organisations MAY ensure that the new FGM clinical codes to be published in Apr 2015, (and detailed further within this document), can be recorded against health records from April 2015 | As above | Full |
| 9 | Suppliers of IT and software systems to NHS organisations MAY ensure that the relevant FGM Enhanced dataset can be recorded within existing systems from April 1st 2015. | As above | Full |
| 10 | Suppliers of IT and software systems to NHS organisations MUST ensure that the relevant FGM information can be recorded locally within existing systems by Dec 2015. | With CAP it is possible locally to be able to support manual and direct entry to populate manually all FGM information. Locally this may be preferred to do so and therefore not require their systems to include this capability.<br>Without further detailed analysis and supplier engagement this would prove difficult to assess against the criteria.<br>GP system suppliers have included this | Partially |

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| | | capability as outlined in a previous conformance criteria and the submission of FGM data to HSCIC suggests that this development may not be required locally | |
| 11 | Suppliers of IT and software systems to NHS organisations MUST ensure that it is possible to extract the relevant FGM information from their systems by Information Teams or Practice Managers, enabling the update of the FGM Enhanced dataset submission to HSCIC. | As above | Partially |

The majority of Acute Trusts have been compliant with the FGM Enhanced Dataset, in ensuring that they are submitting FGM data to HSCIC. This is backed up by the number of organisations registered to CAP.

The main GP system suppliers have all undertaken existing system GP templates within their systems, which can be used to better support their from being able to record the relevant FGM information as required.

In review of the conformance criteria, the review has identified the following areas where improvements could be made:

- analysis on the number of organisations to have registered to use CAP, over a period of time
- analysis against the Prevalence Dataset to assess which Trusts and areas FGM data would be expected from as FGM, in line with what had previously been identified
- Identification of a method to be able to assess how the identification of the sharing of FGM information for the provision of care, e.g. being easily able to assess that FGM information was regularly and consistently being shared within maternity discharges.

## 3.4 Data Quality Assessment

As part of the development of the FGM Enhanced Dataset, a data quality report was required to help ensure the quality of the data received from organisations. The table below outlines a review of the data quality, now that data has started to be received.

| Data Quality Requirements | | Met |
|---|---|---|
| 1.1 | Restrictions on what information can be entered manually by a clinician will be included within the FGMP Collection Tool. This will validate the FGM information that can be recorded, by restricting each mandatory field to a pre-defined list of coded values both in the FGMP Collection Tool and CAP. This will restrict the capability to enter 'any' data within the mandatory fields. | Met:<br>CAP has been designed to validate mandatory data items |
| 1.2 | To ensure the validation of the NHS number populated, within the FGMP Collection Tool, a modulus 11 check against the NHS number will be undertaken, indicating to the user that the NHS number populated is in a valid format. This same modulus 11 check to validate the NHS number will restrict entry when the clinician directly populates CAP.<br>It is acknowledged and accepted that the *verification* of the NHS number, (confirming that an NHS number received is for the right person), will not be possible, only that the NHS number has been validated | Met:<br>CAP has been designed to include modulus 11 check against NHS number entry |
| 1.3 | Completeness of the FGMP Collection Tool will be supported through;<br>• The information analysts ensuring the completeness of the FGM Collection Tool on receipt from clinicians, prior to submission to CAP via the FGMP Upload Tool<br>• Alerting the user if any of the mandatory fields have not been populated<br>• Each mandatory dataset item being clearly identified<br>• A clear and brief statement reminding clinicians that all mandatory items must be completed | Met:<br>CAP has been designed to ensure, Alerting, Identification and Reminders are provided to users when mandatory dataset items have not been populated.<br>It will however, not be possible to ensure that all data has been collected locally, as CAP will only identify what has been entered |
| 1.4 | Completeness of CAP will be supported by;<br>• restricting the submission for that record if all the mandatory fields are not populated, and;<br>• highlighting to the clinician, which mandatory items have not been populated | Met |
| 1.5 | As the FGM Enhanced dataset will be applicable to all Acute (Foundation and Non-Foundation Trusts), Mental Health Trusts and General Practices, it will be possible to monitor and identify which organisations have not submitted the relevant FGM information, enabling further engagement with those organisations to identify the reasons why. | Met:<br>The development of the Registering Organisations and Submitting Organisations from within CAP supports this |
| Conformance Requirements | | |
| 2.1 | The threshold on the coverage of organisations submitting the FGM Enhanced dataset is still to be determined, but initial expectations are that;<br>• 95% of all FGM specialist clinics will submit data<br>• 70% of all remaining Trusts will submit data | Partially Met:<br>• 100% of FGM specialist clinics have submitted data from their Trust<br>• 59% of Trusts are |

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| | • It still to be determined what the percentage of GPs will be required to support the usability of the FGM information received | submitting data<br>Trusts only submit data when FGM has been identified, on reflection and based on FGM Prevalence dataset 59% is more in line with previous submission rates than the anticipated 70% |
| 2.2 | The threshold on the completeness of initial submissions from organisations is still to be determined. | N/a |
| 2.3 | It is expected that all mandatory FGM Enhanced dataset items will be 100% validated, when manually entering the data into the FGMP Collection Tool. | Met<br>CAP has been designed to validate mandatory data items when uploading via the CAP Upload File |
| 2.4 | It is expected that all mandatory FGM Enhanced dataset items will be 100% validated, when clinician's directly enter the data into CAP. | Met:<br>CAP has been designed to validate mandatory data items when clinicians directly enter data |
| 2.5 | It is expected that all NHS numbers will be 100% validated, when clinician's manually record data in the FGMP Collection Tool, or, directly record data within CAP, as a result of the modulus 11 check undertaken within the FGMP collection tool. | Met:<br>CAP has been designed to include modulus 11 check against NHS number entry |
| 2.6 | It is acknowledged that Required data items will not have the same validation restrictions to ensure completeness, but analysis will be undertaken within HSCIC to help identify, where the same submitting organisation omits any Required or Optional FGM information.<br>Whilst it will be legitimate to submit non mandatory FGM dataset items, continual omission of this information 'could' provide an indication of non-compliance of the dataset.<br>The non-completeness of Required and Optional data items will be analysed by HSCIC and used to;<br>• Engage with those organisations to determine why this information is not being regularly captured<br>• Escalate to the DH FGMP Programme in order for the DH to engage with those organisations further<br>The threshold on the omission of Required and Optional dataset items is still to be determined. | Not Met:<br>This level of analysis has not been undertaken at this time |
| 2.7 | The FGM Enhanced dataset will be provided by all Acute (Foundation and Non Foundation) Trusts, Mental Health Trusts and General Practices, on a monthly basis. Where no FGM information was identified locally, it will still be mandatory to provide a Nil return.<br>As part of the management information and future production of Official Statistics, HSCIC will keep a record locally of all those organisations that have submitted the FGM Enhanced dataset and those that hadn't.<br>This will allow HSCIC to;<br>• Engage with those organisations to determine why they are not completing the FGM Enhanced | Partially Met:<br>Change in scope means that this criteria is redundant. Nil returns are no longer required<br>With regards to submitting organisations and engaging with these organisations, the Submitting Organisations report is provided to NHS England who have been actively engaged with those Trusts to encourage |

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| | dataset, nor submitting this<br>• Escalate to the DH FGMP Programme if the organisations continue not to submit the FGM Enhanced dataset, in order for the DH to engage with those organisations further | registration to CAP and submitting the FGM information |
| 2.8 | Initial analysis of FGM Type Unknowns being received within the dataset, will provide a baseline figure, used to help identify where additional training and FGM awareness may be required. Further to this, the initial baseline will be used to confirm the improvements in training, although the threshold on the expected reduction in the number of FGM Type Unknown is still to be determined. | Met:<br>FGM Type Unknown is currently being published. Further analysis may be undertaken by NHS England |
| Data Quality Rationale | | |
| 3.1 | Validity of the mandated items will be controlled through the restrictions embedded within the FGMP Collection Tool, the Upload Tool and within CAP. | Met |
| 3.2 | The FGMP Collection Tool will be designed to ensure all mandatory fields not completed are identified by Information analysts prior to submission via the FGMP Upload Tool<br>This will allow the Information Team analysts to engage locally with the relevant clinicians to determine why the FGMP Collection Tool was not populated. | Met |
| 3.3 | As this is a local collection tool, the FGMP Collection Tool, may be used locally to support the FGMP Upload Tool submissions, the FGMP Upload Tool will also be designed to ensure all mandatory data items to be completed are identified and highlighted to the Information analysts in order to confirm where a submission is incomplete | Met |
| 3.4 | To ensure validity of the information entered by clinicians directly into CAP, if there are fields not completed;<br>If they are Mandated fields not completed, CAP will not allow the submission of the record<br>If they are Required or Optional fields not completed, then as this is a legitimate possibility, no further action will occur. However, the continual non-completion of Required and Optional fields will be identified following the management information reports produced to identify this (as per 2.7). | Met |
| Process and Methods | | |
| 4.1 | The source of the FGM information, will be identified by the clinician following consultation with the woman | N/a:<br>Whilst it is expected to be the case, there is no way to confirm where the source of the FGM information has come from |
| 4.2 | All FGM information recorded can be manually recorded separately to patient healthcare records, and used to inform the completion of the manual FGMP Collection Tool | Met: |
| 4.3 | All FGM information recorded can be directly entered within the patient healthcare record and extracted by the information team analysts. It will therefore be necessary for the development of patient healthcare systems locally to include all of the FGM Enhanced dataset items, and also for this information to be extractable by information analysts to populate the FGMP Upload Tool. | Met:<br>It is unknown exactly how each organisation has acquired the FGM information locally |

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| 4.4 | There will be different mechanisms to support the collection of the FGM information, to support differences in when, how and where FGM is identified, specifically;<br>• Clinicians who are experienced in the identification and recording of FGM<br>• Clinicians who rarely if ever encounter women who have had undergone FGM, due to the demographics within their locality<br>• Clinical settings where the identification of FGM is more likely than other settings, e.g. maternity services, gynaecology<br>The FGMP tool will be used by all organisations to apply consistency in the information submitted to HSCIC.<br>Where clinicians directly input FGM information into CAP, the collection forms within CAP will replicate the FGMP Upload Tool and prior to any final submission within a reporting period from an organisation, all records locally will be submitted together. | Met |
| 4.3 | The quality of the source data will be reliant on the clinician's experience of women with FGM, in order to ensure population of the FGM Enhanced dataset. | N/a |
| 4.4 | Upon submission to HSCIC, the FGMP Upload tool will inform the submitter where records have not been completed. If the FGM Upload tool is still submitted, then CAP will undertake a quality check to ensure all mandatory fields have been completed and if they have not been, the submission of that record will be rejected. | Met |
| 4.5 | Monthly assessment of the FGM information received will direct the HSCIC into establishing where the FGM information provided is suitable for recording. Following each monthly assessment, a further month will be given to HSCIC in order to analyse and assess the information that has been received, prior to any reporting from HSCIC. | Partially Met:<br>The scope has changed in that monthly reporting is no longer required. This is now quarterly reporting, but there still remains the capability to submit data one month after the reporting period |
| 4.5 | Although the detailed process is to be outlined further as part of the FGM Enhanced dataset development, it is expected that where the data quality requirements have not been met, HSCIC will engage with those submitting organisations in order to clarify what has been submitted, why submissions have not been received at all, and where necessary for HSCIC to engage directly with DH to support further action that may be required. | Partially Met:<br>As there is no requirement to submit nil returns, there is no easy way to identify why an organisation may not have submitted data.<br>Further analysis may be required in order to determine if a Trust has submitted one quarter, but not another. More data required to assess this |
| Accuracy | | |
| 5.1 | Accuracy of the data has not been selected as a data quality measurement. There are known issues with the ability to accurately identify the FGM Types, even by experienced clinicians following clinical examination.<br>Where the FGM Type is unable to be clearly identified, there is the capability to record FGM Type Unknown, to at least continue to support the capture, Prevalence of FGM through the inclusion of this option. | Met:<br>Further analysis may be required as more data has been received in order to determine where consistent recording of FGM Type Unknown is received |

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| 5.2 | Further to the above, the receipt of FGM Type Unknown information, will actually help to support the Department of Health's wider FGM Programme of work, identify where improvements in FGM training and awareness for clinicians may be required, as a result of FGM Type Unknown consistently being submitted by various organisations. | Met:<br>As above |

## 3.5 Burden Assessment

As part of the SCCI recommendations, it was suggested that further burden assessment should be undertaken post implementation to qualify the anticipated burden on organisations trying to submit data to HSCIC.

At the time of writing, this assessment has not been undertaken and is not expected to be completed before the end of March 2016.

## 3.6 Corrigendum Items

Following implementation in April 2015, it was identified that there were a small number of clarifications needed, resulting in a corrigendum.

The published Requirements Specification and Implementation Guidance of the FGM Enhanced Dataset standard needed to be updated accordingly. The corrigendum items included:

- Additional guidance developed and provided around Information Governance, including legal basis to collect data, patient consent, fair processing and patient objections
- Sexual Health and GUM clinics being exempt from the submission of FGM data to HSCIC. This resulted from those settings where services typically provide services on an anonymised basis and therefore do not typically identify patients. It is acknowledged that wider clinical engagement and a better understanding of the processes undertaken locally within these settings could have prevented the need for this update
- Changing the mandation of a how FGM was identified. This was to support how FGM information could be collected, specifically supporting CCN033 and GPs recording FGM information from within their systems using clinical terminologies. As it was identified that it would not be possible to easily create a specific clinical code to record one of the values associated to how FGM was identified, this would have caused considerable difficulties if this dataset item remained as a mandatory item. Therefore with agreement from DH, the mandation around this item was loosened to being an optional item. Without this change CCN033 could not be supported.

### 3.6.1 GP Caldicott Guardians

An issue identified as following publication when GPs began to submit questions to the HSCIC FGM help desk was with how GPs register on CAP. The FGM Enhanced Dataset was the first time GPs had been required to use CAP, meaning that the registration process was previously unknown to them.

The issue is that the process to register requires the GP Caldicott Guardian signs off as to who can access CAP locally. On receipt of the CAP registration form, the named Caldicott Guardian is then checked against the list of registered GPs from within the National Caldicott Guardian Register: http://systems.hscic.gov.uk/infogov/caldicott. . If the Caldicott Guardian was not outlined within the National Register, then HSCIC could not verify that they were who they said they were.

To ensure this gap could be closed an additional link was provided outlining how Caldicott Guardians could register to the National Caldicott Register. Evidence of this working has

been seen from the Organisation Data Services team responsible for the updating of the national register as they have outlined an increase in GPs being added.

## 3.7 Issues and Concerns

As part of the implementation of the FGM Enhanced Dataset, there have been a small number of queries made to the FGM@nhs.net mailbox, managed by the Clinical Audit Support Unit responsible for managing CAP. Some e of these issues and concerns have been identified post implementation, and have also been some of the same issues and concerns raised to the DH FGM Prevention Programme and NHS England.

### 3.7.1 Approach

In 2013, Tackling FGM in the UK, Intercollegiate recommendations for identifying, recording and reporting was published by the Royal College of Midwives. One of its recommendations was to document and collect information on FGM and it its associated complications in a consistent and rigorous way.

http://www.equalitynow.org/sites/default/files/Intercollegiate_FGM_report.pdf

This report, in part, led to the commissioning of HSCIC to develop the FGM Prevalence Data for an initial snapshot on the prevalence of FGM within England. The implementation of the FGM Prevalence dataset also laid down the blueprint for implementing the more detailed FGM Enhanced Dataset.

For the HSCIC FGM Prevention programme to support the collection of FGM information and associated issues there were a number of factors that had to be considered to help support the collection of this information:

- Implementation and deployment timescales
- Available funding
- System development to collect the information
- Dataset definition
- Clinical terminology capabilities locally

Given the considerations outlined above, it was proposed that the Clinical Audit Platform could be used, with details of how the information would be collected via CAP within the SCCI2026 FGM Enhanced Dataset Implementation Guidance.

The main reasons for using CAP resulted from

- CAP being owned, managed, developed and serviced by the Clinical Audit Support Unit and therefore reducing development time and avoiding procurement costs for a new system and therefore providing value for money in terms of provision of capability.
- A single collection platform being required to support submissions from various clinical settings, and thus avoiding the need to:
    - support multiple collection platforms (including service management, development, query handling, supporting documentation development)
    - remove the reliance on data linkages between patients attending different clinical settings and data collected from different platforms
    - availability of funding for several collection platforms
- Limited supplier funding available to support a national roll out of development of any local systems
- Minimal implementation time available, and as CAP collects for other clinical audits, this vastly reduces the need to support the development of a new service.
- A need to be able deploy rapidly to support all organisations impacted by the implementation of the dataset. With CAP being a web portal, this removed the need for any compliance to any messaging standards or local development

## 3.7.2 Consultation

One concern that has been raised stems from the initial consultation approach and the wider engagement, prior to the development of the FGM Enhanced Dataset standard. This has led to a small minority feeling as if their concerns have not been addressed.

Whilst it is acknowledged that further consultation would of course be valuable to undertake, there was a great deal of consultation undertaken already through the development stages, including engagement with Royal College representatives, patient groups and wider healthcare worker conferences, facilitated by both DH and NHS England that were held nationally across the country.

Consultation and engagement continues, specifically with GP representatives and Mental Health representatives with DH and NHS England, supported by the HSCIC FGM Prevention Programme. In addition to that specific engagement, further conferences have been undertaken in the NHS England North region for example, which have been attended in high numbers by patient groups and healthcare workers. These conferences have been undertaken as part of the wider FGM Prevention Programme, raising awareness about FGM, example development of local clinical pathways, the criminal implications of FGM practices and also includes presentations on the FGM Enhanced Dataset to help communicate the need for collecting FGM information.

## 3.7.3 Information Governance

One of the key areas of concern raised is around information governance, specifically the legal basis to share patient identifiable information, patient consent, fair processing and objection handling.

### 3.7.3.1 Directions and Legal Basis

HSCIC no longer needs to apply for Section 251 support when directed or requested to collect person confidential data. This is set out in Sections 254 and 255 of the Health and Social Care Act 2012.

However, all data providers must still ensure compliance with the fair processing requirement of the Data Protection Act 1998. To meet these requirements, data providers (NHS organisation collecting and submitting data) must make information and guidance available to patients and/or their legal guardians to inform them that their data will be used for secondary uses purposes.

As a result, the proposed changes for the FGM Enhanced Dataset Information Standards Notice (ISN) do not require Confidentiality Advisory Group (CAG) approval.

Although HSCIC is permitted to collect, hold and process patient-identifiable FGM information under the Health and Social Care Act 2012, it is obliged to ensure that there is a legal gateway in place before sharing this data with third parties, not only is it not intended that patient-identifiable data will be shared with other parties, under the current Directions applicable to data currently being collected, it will not be possible to share this data. Such activity would require explicit patient consent, Section 251 support under the NHS Act 2006, or another statutory gateway.

It is intended however, that the FGM information collected and disseminated using the Clinical Audit Platform will support the publication of patient-anonymised Official Statistics.

### 3.7.3.2 Fair Processing

As outlined above, fair processing is required to support the collection and flow of this data to HSCIC. The current circumstances include definition within the requirements and implementation guidance as part of the standard, in addition to this being included within the FGM leaflets produced by DH. Following concerns and queries being raised specifically about fair processing, this process is in the process of being reviewed.

### 3.7.3.3 Patient Consent

As the FGM Enhanced Dataset will be underpinned as a result of DH Directions to HSCIC, this has meant that no explicit patient consent is required in order to collect this information and subsequently share this with HSCIC. Whilst this is underpinned by the Directions to support this collection, as with the fair processing, it is acknowledged that greater clarity around the handling of patient consent is managed could have been outlined to provide a greater level of reassurance about the handling of this sensitive patient level data.

It may be worth noting that after the publication of the standard in April 2015, a wider Caldicott review is being undertaken, around how HSCIC supports objections and patient handling. At the time of writing this review is yet to publish its findings

### 3.7.3.4 Local Patient Objections

As part of existing local IG Toolkit requirements[4], there is the provision to ensure that patient objections can and must be upheld locally. With this capability locally, where a woman or girl objects to their data being sent to HSCIC, following being advised through fair processing, it is possible for no data for that patient to be sent to HSCIC. Again, this guidance should have been made more explicitly clear through the development of the standard to avoid concerns about how patients could object.

### 3.7.3.5 HSCIC Patient Objections Handling

In conjunction with patient objections being upheld locally, it is urged that HSCIC should also be contacted to uphold a patient objection, to ensure that if data for that same patient is recorded within a different clinical setting, that patient's data will not be used in any published statistics.

As part of the development of the Direction, providing the legal basis to share this information, that on receipt of a patient objection, whilst not required to do so, HSCIC will automatically uphold that objection ensuring that it is handled immediately.

There is an objections handling process in place to support patients from having their data used in any of the published data, but this process has been caught up in a much wider organisational approach across all programmes with regards to how data is handled by HSCIC, specifically around Type 1 and Type 2 objections. At the time of writing, there is the expectation that the Dame Fiona Caldicott Review into amongst other areas how patient objections are upheld by HSCIC is currently expected.

Concerns have also been raised about the complexity for patients to object with HSCIC, and also that the objections process is currently only available in English. Following a review of the wider Caldicott review, this may result in improving and simplifying how objections are handled by HSCIC, including potentially the use of other languages.

Recommendations:

In general, the primary theme with regards to Information Governance is in relation to providing greater clarity and communicating this more effectively. This is specifically in relation to;

- Directions, and how they provide a legal basis to flow data, and further to this, how this legal basis directly relates to the practical implementation
- Clearer explanation of what fair processing is, how this relates to consent and objection handling, but also the practical implementation of this, for both the clinician and the patient

[4] GP Practices: Information Governance Toolkit Requirement 13-212: https://www.igt.hscic.gov.uk/RequirementQuestionNew.aspx?tk=422477393778945&lnv=2&cb=12e8a681-d0fe-42f3-86bb-77c7a1aa2336&sViewOrgType=4&reqid=2686

Mental Health and Acute Trusts: Information Governance Toolkit Requirement 13-202: https://www.igt.hscic.gov.uk/RequirementQuestionNew.aspx?tk=422477393778945&lnv=2&cb=0d155ce9-5eed-4a36-8951-fab0649f5a6b&sViewOrgType=5&reqid=2678

- Providing greater clarity on why explicit patient consent is not required when Directions are provided and again, clearly articulating the practical implications of this on both patients and for clinicians
- Local patient objections which should be understood locally, but greater communication and clear guidance should be provided, reminding more clearly of the responsibilities locally with regards to how patient objections should be handled

### 3.7.4 Perceived Burden

With the introduction of any new collection of data, there will always be a certain level of burden to do support this. Even though the guidance provided within the Implementation Guidance in relation to what data needs or should be submitted, further clarification has been required to explicitly outline that whilst there are 30 dataset items defined, there are only 5 mandatory dataset items to collect and submit; three being patient identifiers, one the date FGM was identified and the final one, the actual FGM activity identified.

Due to the sensitive nature of FGM it is fully expected that not all the associated FGM information that could be collected and submitted, will be possible to collect, either as a result of this information not being known or not being available.

Best efforts have been undertaken to clarify what data is required for collection and submission, and on the whole this appears to be understood. Where additional clarification is or has been required this will or was provided.

### 3.7.5 HSCIC Dataset Development

The following review is the view from the HSCIC FGM Prevention programme responsible for the development of the FGM Enhanced Dataset in consultation with DH. These views are subjective with regards to a review of the initial development, which led to the implementation of the standard.

On the whole, the support provided by SCCI was very supportive, but there were a few issues raised through the development of the standard, that if observed, may support any future developments.

#### 3.7.5.1 SCCI Development Support

The support provided to the HSCIC FGM Prevention programme by the SCCI Development team was welcome and appreciated, especially given the timescales on development and delivery.

Ideally, earlier support could have been provided especially around the provision of guidance through the new process, but in fairness, the SCCI process was in it's infancy with the FGM Enhanced Dataset being one of the first standards going through this new approach.

Due to the immaturity of these processes and the establishment of the team, there was some initial confusion and delays about the approach, but it should be noted, as time progressed, the support provided did help with navigation through each stage.

#### 3.7.5.2 SCCI Review Process and Engagement

During the development of the standard it was identified that the Independent Standards Assurance Service (ISAS) review panel, whilst acknowledging the need for independence, did on occasion, delay the development of the standard, as a result of this intended barrier not allowing for the easy clarification and communication of issues that had been identified. Greater flexibility to allow engagement, not to influence decisions, but to clarify review comments, could have prevented some of those delays. Again in fairness as time has progressed, improvements in the process, and acceptance that additional communication may be required has moved this process forward.

### 3.7.5.3 SCCI Patient Safety Review

As part of the completion of the required Patient Safety Review, whilst there is a team within HSCIC that focuses on Clinical Safety, there was confusion about Patient and Clinical safety and how this could be better supported. The Clinical Safety Team provided assurances that they did not believe there was a clinical safety issue, whereas ISAS were insistent there was. Linked to the issues above with respect to engagement, spending time and effort clarifying what these perceived patient safety issues were, before being able to address them, led to delays in providing this analysis.

Ultimately however, a pragmatic approach was taken, which led to greater communication about these issues enabled the HSCIC FGM Programme to address these concerns.

### 3.7.5.4 Clinical Audit Support Unit and Data Dictionary Teams

One of the shortfalls for the collection via Clinical Audit Platform is that it currently does not support xml, clinical terminologies or is integrated with NHS Spine Services. This does limit the capability to:

- support direct upload from system extracts easily
- support clinical terminologies being recorded from within those local systems and being included within the system extract
- trace patient demographics to identify the relevant patient's NHS number

The above however does not inhibit the collection of data, but it has meant that the way in which the information is collected locally does require greater consideration for how this can be supported locally, and how this will be achieved to support local business processes. One benefit of having to do identify the needs locally however, has resulted in greater awareness of FGM and its associated issues locally across all organisations

Some of the key benefits however, of using CAP are that:

- it is a service that is currently supporting other collections and with relatively minimal development is already available
- it's a fully managed and supported service
- it's support use of the NHS number
- as it's owned by HSCIC it's less expensive to develop
- as it's a secure web portal application, requiring secure single sign on by a user, development and implementation locally is not required, saving a huge amount in terms of supporting any deployment.
- it also provides an opportunity to use real language rather than obscure clinical terminologies.

As part of the development of the standard which requires the Data Dictionary team involvement to ensure the quality, accuracy and consistency of terminology used, at the time this did not automatically align to the way in which CAP is typically developed.

As CAP is an existing platform created within the historic Information Centre, this meant that it was not obliged to adhere to the data dictionary definitions.

This misalignment at the organisational level, did lead to some very challenging issues to address. As CAP is not an interoperable solution but a standalone collection platform, specific definitions required for the Data Dictionary Team, could not be met easily by the CAP Team.

These differences were reflected as part of the Data Dictionary position statement, which was required to support the development of a standard, and yet HSCIC as an organisation did not mandate that CAP had to adhere to the data dictionary standards, as this had not had to do so previously.

The reason for outlining these differences is to hopefully avoid any future difficulties where CAP is used to support any future development, and it is also now acknowledged that greater alignment is considered as part of the development process.