Revised Minimum Dataset for Colposcopy Services

1 Introduction

This document intends to provide an upgrade of the existing minimum dataset supplied by the BSCCP Minimum Dataset Working Group (1999) to facilitate quality assurance of colposcopy services via the KC65 return to the Department of Health and the Colposcopy Pre-visit Dataset. Patient episode data for benchmarking and colposcopy training are also included. Since 1999 the NHSCSP has revised its guidelines for colposcopy (2004) with a considerable increase in the number of practice standards. Some of these standards can be collected at QA visits but others must be collected at each patient episode. It is these latter standards which are relevant to the Revised Minimum Dataset for Colposcopy Services. Changes to the minimum dataset are listed and will have implications to the design and upgrade of local colposcopy IT systems. Modified or additional fields and menus are listed on pages 11-16. For reference a list of standards relevant to the minimum dataset is presented on pages 17-20.

This dataset described is a minimum dataset and many clinical units will wish to collect more data or more detail. However local datasets collecting additional data should code down to the 'minimum dataset' to ensure uniformity of data collection. The BSCCP Executive in consultation with the NHSCSP should decide future changes to the minimum dataset.

2. Data Definitions

There are 38 fields in the minimum dataset (if all three histology fields are completed i.e. two recorded cervical and one recorded vaginal histologies). Of these 38 fields, 19 relate to 16 menus which are detailed below. Seven fields relate to the first attendance only.

2.1. Referral

To ensure adequate maintenance of skills:

- a) Number of new cases managed **by** individual colposcopist per year referred due to abnormal cytology.
- b) For training units, the number of cases where trainees are directly supervised by individual colposcopists per **year**.
- c) The status of the colposcopist [Menu 1]

2.2. Demographic data

To determine range of patients seen and reason for referral to colposcopy clinic

a) Basic PAS data for patients

(Provider Unit Number) This is the hospital or colposcopy case record number and is unique to the patient
(NHS number)
(Patient Last Name)*
(Patient Initial)*
(Patient D.O.B) Recorded as ddmmyyyy
(Provider Unit ID) Each Trust has a unique provider code obtainable from 'Organisation Code Files'

*Whilst not considered a part of the minimum dataset, these are considered optional for those units who may also wish to use the dataset for clinic management purposes (i.e. sending letters).

b) (Referral indication) [Menu 2]

- A 'clinically suspicious cervix' is selected as the referral indication when the referring agency considers that the cervix has an abnormal appearance and raises the possibility of malignancy. This includes marked contact bleeding when taking a smear.
- 'Suspicious symptoms' is selected as the referral indication when the referring agency states that this is the reason for referral (post-coital bleeding, discharge etc). if the patient offers such symptoms following direct questioning in the clinic this is NOT a referral indication.
- 'Other' is **only** used when none of the alternatives are applicable.

2.3 Attendance data

To ensure adequate timeliness of diagnosis:

Waiting time for colposcopic assessment for all referrals: number of days from the date on the referral letter to date of first appointment (whether seen or not) by referral smear:

a) (Referral Cytology) [Menu 3]

This is the most recent cytology sample that initiated the referral and may not be the most severe smear. For example, a woman may be referred following two consecutive abnormal samples, a mild dyskaryosis followed by a borderline. The referral cytology would be recorded as borderline.

b) (Referral Cytology Date)

This is the date cytology was taken that initiated the referral.

c) (Referral Date Sent)

As referral may come via more than one route, the date of referral should be taken as the date on the referral letter, or in the case of direct referral from a cytology laboratory, the date that the cytology sample was reported.

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This corresponds to the 'screening result sent date' (to conform with KC65 part A).

d) (Date Referral Letter Received)

This is the date that the referral is received by the colposcopy clinic. Letters should be date stamped on receipt/ opening by the clinic.

2.4 Event data (data collected at each colposcopy clinic visit)

To determine attendance rate and colposcopist:

a) Visit Date)

This is the appointment date given, and not the date that the patient attended (this would be recorded as a subsequent 'event' in the case of a cancellation or default.

b) (Visit Number)

This is the logical sequence of appointments given and not just attendance visits

c) (Colposcopists Name)

This is for internal and CME use only and can be coded as one wishes.

d) (Trainers Name)

This is for the electronic trainees record and can be used for re-certification. This is only applicable for those cases where a trainee is performing a colposcopy under direct or indirect supervision.

e) (Colposcopist Status) [Menu 1]

The 'other' option is for those not certificated or in a training programme such as an experienced visiting colposcopist or those who currently practice without certification.

f) (Visit Description) [Menu 4]

The 'treatment' option does not include those patients where treatment is performed at the first visit. Such visits are classed as 'new patient'. The 'discussion only' option is for follow up appointments where neither cytology nor colposcopy is performed. 'Other' is only used when none of the alternatives are applicable.

g) Visit Attended: [Menu 5]

(Attended/ defaulted)

Default is defined as non-attendance of a scheduled appointment that was initiated by the patient. This includes both patient cancellation (colposcopy clinic informed of intention to non-attend) and default (colposcopy clinic unit not informed)

Data from the colposcopic examination to ensure quality and accuracy of the diagnosis:

(Visibility of squamo-columnar junction)

Is recorded as seen if the entire squamocolumnar junction was seen regardless of whether it was sited within the canal. This is recorded as not seen when the SCJ is not visualised in its entirety.

(Colposcopic opinion of lesion) [Menu 7]

This is irrespective of whether the SCJ is seen or not seen.

Definitions

Normal:	This is when no abnormality is detected
HPV/ inflammatory/ other:	This is when changes are present which are thought to be viral,
	inflammatory or other changes not amounting to CIN.
CIN/ low grade:	Appearances thought to be compatible with CIN 1.
CIV/ high grade:	Appearances thought to be compatible with CIN2 or CIN 3.
Invasion:	Appearances thought to be compatible with squamous or
	adenocarcinoma.
Other:	This may include situations as when colposcopy of the cervix is
	attempted but the whole of the cervix is not seen or when the
	colposcopist genuinely is undecided.
Not performed:	When colposcopy is not performed such as when the intention is
	only to perform cytology.
No cervix:	When the woman has had a previous hysterectomy.

(Cervical Cytology) [Menu 3]

This menu also includes the result of any cytology taken at the colposcopy visit 'cytology result'.

c) Percentage of women at first visit having: 1) Cervical biopsy or 2) LLETZ by referral smear/ proportion treated under local analgesia.

(Biopsy Type) [Menu 9]

No biopsy means that no specimen was taken for histological purposes. 'Directed (punch) biopsy' means a single biopsy taken with punch biopsy forceps from one part of a lesion. 'Multiple directed (punch) biopsies' means more than one punch from several areas of the lesion. 'Excisional biopsy' means a biopsy taken with the intention of primarily providing a histological sample but where the whole lesion was removed. 'Wedge biopsy (diagnostic loop)' refers to the rare situation in pregnancy or from a cervical cancer where a larger, non-excisional biopsy is taken for a satisfactory histological diagnosis.

(Treatment Method) [Menu 10]

'Loop with top hat (extended loop)' means a loop excision with an additional superficial loop or laser ablation to the adjacent ectocervix. 'Other' is **only** used when none of the alternatives are applicable.

(Analgesia) [Menu 11]

d)	(Histology Result 1: Cervix)	[Menu 13]
	(Histology Result 2: Cervix)	[Menu 13]
	(Histology Result 1: Vagina)	[Menu 13]

Only one value should be recorded for the same pathology. Record the highest grade of histological abnormality e.g. if CIN 1 and CIN 2 both on the pathology report only record CIN 2. If there are two distinct pathologies (not just different grades) in one specimen e.g. CIN 3 and CGIN in a LLETZ specimen record two values.

2.5 <u>Communications data</u>

To ensure women are adequately informed about treatment.

Re 'date letter to patient' and 'date letter to GP/ referring practitioner'. The time to informing the patient and GP/ referring practitioner is the interval between the date on which the biopsy was taken and on which the patient was informed in writing of the biopsy result. The 'date patient informed' is the date that is printed on the letter that is sent to the patient (to conform with KC65)

3. Implementation

3.1 Data collection:

The mechanism of collection and subsequent analysis must be robust if the data are to be part of a reliable record. There are many different methods of data collection and analysis. Individual clinics will be able to choose one that will suit their own circumstances. Users will need to ensure that the data fields that comprise the revised minimum dataset are included in their databases and be able to generate outputs compatible with the KC65 as a minimum based on the revised Minimum Dataset for Colposcopy Services. Those planning to purchase systems should ensure that the system will collect the data required.

3.2 Standards:

Standards define the desired quality of care. The minimum dataset can be used to monitor the achievement of these standards and to monitor and confirm health gains.

Code:	A code to identify as unique the provider unit where colposcopy is taking place
Provider Unit Number:	A unique number in a provider unit
String:	An alphanumeric entry made via keyboard
Number:	Numeric data entered on a keyboard that can be used in
	calculations
Flag:	A Yes/No or True/False Response
Date:	Date field to allow calculations in days between various recorded events (record
	as ddmmyyyy)
Menu:	An item selected from a predefined data list. Items on the list can have "hidden"
	embedded codes.

4 Alterations to Fields and Menus

4.1 Data items added (on pages 12-17)

Field

1. for trainees trainer name

Field

2. pregnant

Field and Menu 5

- 3. Visited attended
- 4. Visit Defaulted

Cancelled by patient in advance Cancelled by patient on the day Cancelled by clinic DNA (no advance warning) DNA (arrived late) DNA (left without being seen)

Field and Menu 6

- 5. extent of lesion
 - a. ectocervix
 - b. extends into endocervical canal (upper limit seen)
 - c. extends into endocervical canal (upper limit not seen)
 - d. extends onto vagina

Field

6. histology result date

Field and Menu 8

- 7. consent
 - a. written
 - b. verbal
 - c. not recorde

Field and Menu 12

- 8. complications
 - a. was additional haemostatic technique in addition to the treatment method needed
 - b. admission to hospital

Field and Menu 14

- 9. Incompletely excised at endocervical margin
- 10. Completely excised at endocervical margin
- 11. Excision status not specified
- 12. Not applicable

Field and Menu 15

13. excision quality

- c. number of pieces of excision biopsy
 - piece 1
 - piece 2+
- depth of excision biopsy
 7mm or less
 8mm or more
 - unable to assess

Field

14. date letter to GP/ referring practitioner

15. date letter to patient

4.2 Modification to existing menus (on pages 14-17)

Menu l

Change to 'certificated' Change trainee to 'direct supervision' and 'indirect supervision'

Menu 3

Correct to include current BSCC cytological classification

Menu 4

Change to New patient Review post treatment Review no treatment Treatment Discussion only Cytology only Other BSCCP IT Group Add 'cervix/vagina' Add 'punch' to directed biopsy and multiple directed biopsies. Add 'diagnostic loop' to wedge biopsy.

Menu 10

Add cold coagulation, cryotherapy, diathermy and laser. Add loop with top hat (extended loop)

Menu 13

Add 'inadequate' to unsatisfactory Separate 'normal' from 'HPV/ cervicitis' Change invasive squamous (>1a) to '(1b+)'. Merge cGIN (low grade) and cGIN (high grade) Add 'result not known by clinic'. Parentheses added to CGIN (can be added in addition to CIN) and Invasive adenocarcinoma (can be added in addition to invasive squamous).

Menu 15

Add 'MDT review'.

5. Fields and Menus

Field Name	Data Type	Menu	Visit
Provider Unit	Code	N/A	First Visit
Provider Unit No	Number	N/A	All Visits
NHS No	Number	N/A	All Visits
Patient Last Name	String	N/A	First Visit
Patient Initial	String	N/A	First Visit
Patient D.O.B	Date	N/A	First Visit
Referral Indication	Menu	Menu 2	First Visit
Referral Cytology	Menu	Menu 3	First Visit
Referral Cytology	Date	N/A	First Visit
Date			
Referral Date Sent	Date	N/A	First Visit
Date Referral Letter	Date	N/A	First Visit
Received			
Pregnant	Flag	N/A	All Visits
Visit Date	Date	N/A	All Visits
Visit Number	Number	N/A	All Visits
Visit Description	Menu	Menu 4	All Visits
Visit Attended	Menu	Menu 5	All Visits
Colposcopist Name	String	N/A	All Visits
Colposcopist Status	Menu	Menu 1	All Visits
Trainer Name	String	N/A	All Visits
SCJ Seen	Flag	N/A	All Visits
Extent of lesion	Menu	Menu 6	All Visits
Colposcopic	Menu	Menu 7	All Visits
Opinion			
Cytology Result	Menu	Menu 3	All Visits
Cytology Result	Date	N/A	All Visits
Date			
Consent	Menu	Menu 8	All Visits
Treatment Method	Menu	Menu 10	All Visits
Analgesia	Menu	Menu 11	All Visits
Віорѕу Туре	Menu	Menu 9	All Visits

Field Name	Data Type	Menu	Visit
Complications	Menu	Menu 12	All Visits
Cervix Histology I	Menu	Menu 13	All Visits
Cervix Histology 2	Menu	Menu 13	All Visits
Vagina Histology	Menu	Menu 13	All Visits
Histology result	Date	N/A	All Visits
date			
Margin Status	Menu	Menu 14	All Visits
Excision quality	Menu	Menu 15	All Visits
Future Plan	Menu	Menu 16	All Visits
Date letter to GP/	Date	N/A	All Visits
referring			
practitioner			
Date letter to patient	Date	N/A	All Visits

Menu 1: Colposcopist's Status

Certificated Trainee, direct supervision Trainee, indirect supervision Other

Menu 2: Referral Indication

Abnormal screening cytology Abnormal smear after colposcopy Clinically suspicious cervix Suspicious symptoms Other

Menu 3: Cervical Cytology

No cytology	
Negative (normal cytology)	
Inadequate specimen	
Borderline change	
Borderline ?high grade	
Borderline endocervical	
Mild dyskaryosis	
Moderate dyskaryosis	
Severe dyskaryosis	
Severe ?invasive cancer	
? Glandular neoplasia	

Menu 4: Visit Description

New patient Review post treatment Review no treatment Treatment Discussion only Cytology only Other

Menu 5: Visit Attended

Visited attended	
Visit defaulted	
Cancelled by patient in advance	
Cancelled by patient on the day	
Cancelled by clinic	
DNA (no advance warning)	
DNA (arrived late)	
DNA (left without being seen)	

Menu 6: Extent of lesion

Ectocervix
Extends into endocervical canal (upper limit seen)
Extends into endocervical canal (upper limit not seen)
Extends onto vagina

Menu 7: Colposcopic Opinion

Cervical	Vaginal
No cervix	
Normal	Normal
HPV/ inflammatory/ benign	HPV/ inflammatory/ benign
CIN low grade	ValN low grade
CIN high grade	VaIN high grade
Invasion	Invasion
Other	Other
Not performed	Not performed

Menu 8: Consent

Written Verbal

Not recorded

Menu 9: Biopsy Type*

No biopsy Directed (punch) biopsy Cervix Vagina Multiple directed (punch) biopsies Cervix Vagina Excisional biopsy Wedge biopsy (diagnostic loop)

*can enter more than one biopsy type.

Menu 10: Treatment Method

No treatment Ablation Cold coagulation Cryotherapy Diathermy Laser Loop/ laser excision Loop with top hat (extended loop) Knife cone Hysterectomy Other

Menull: Analgesia

No analgesia	
Local analgesia	
General anaesthesia	

Menu 12: Complications

Additional haemostatic technique in addition to the treatment method needed

Admission to hospital

Menu 13: Histology

Unsatisfactory/ inadequate Normal (no HPV or cervicitis) HPV or cervicitis CIN 1 CIN 2 CIN 3 Invasive squamous (la1) Invasive squamous (la2) Invasive squamous (lb+) CGIN (can be added in addition to CIN) Invasive adenocarcinoma (can be added in addition to invasive squamous) Other ValN 1 ValN 2 ValN 3 Invasive vaginal carcinoma Result not known by clinic

Menu 14: Margin Status*

Incompletely excised at endocervical margin Completely excised at endocervical margin Excision status not specified Not applicable

*excision status not applicable to directed (punch) biopsies

Menu 15: Excision Quality

Number of pieces of excision biopsy	Depth of excision biopsy
piece 1	7mm or less
piece 1 piece 2+	8mm or more
	unable to assess

Menu 16: Future Plan

Colposcopy clinic follow up Treatment MDT review* Cancer treatment Discharge Other 16

*unable to collect attendance at MDT for benchmarking. Numbers of MDT/year can be collected as required for NHSCSP No. 20.

6 List of Standards by Section from Colposcopy and Programme Management (NHSCSP No. 20) relevant to the Minimum Dataset.

Section 4

- At least **90%** of women with an abnormal test result should be seen in a colposcopy clinic within eight weeks of referral.
- At least **90%** of women with a test result of moderate or severe dyskaryosis should be seen in a colposcopy clinic within four weeks of referral.

Section 5

- Information with regard to visit and results of investigations should be communicated to the patient within four weeks of her attendance (best practice 90%) or eight weeks (minimum standard 100%).
- Results and management plans should be communicated to the referring practitioner within four weeks of the patient's attendance at the clinic (best practice 90%) or eight weeks (minimum standard 100%).
- The default rate should be less than **15%**.
- Colposcopists practising within the NHS CSP must see at least 50 new abnormal smear referrals per year.

Section 6

- 6. The following data should be recorded at the colposcopic examination
 - reason for referral (100%)
 - grade of cytological abnormality (90%)
 - whether the examination is satisfactory; this is defined as the entire squamocolumnar junction having been seen, and the upper limit of any cervical lesion also being seen (100%).
- 7. An excisional form of biopsy is recommended (95%):
 - when colposcopic appearances indicate high grade abnormality
 - when low grade colposcopic change is associated with severe dyskaryosis or worse

- when a lesion extends into the canal (sufficient canal must be removed in these situations).
- 8. Reasons for not performing a biopsy must be recorded (100%).
- 10. Biopsy should be carried out unless an excisional treatment is planned, when the cytology indicates persisting moderate dyskaryosis or worse, and always when a recognisably atypical transformation zone is present (100%). Pregnancy is an exception.
- 11. All patients must have a biopsy or biopsies taken prior to local destructive treatment (100%). Unless there are special circumstances, the result of the biopsy or biopsies should be available (best practice).
- 12. Of all biopsies taken (directed and excisional) >90% should be suitable for histological interpretation.
- 13. If colposcopically directed biopsy is reported as inadequate for histological interpretation, it should be repeated if there is a residual colposcopic lesion **(95%)**.
- 14. For those with satisfactory colposcopic examination, the predictive value of a colposcopic diagnosis of a high grade lesion (CIN 2 or worse) should be at least **65%**.

Section 8

- 15. Ablative techniques are only suitable when:
 - the entire transformation zone is visualised (100%)
 - there is no evidence of glandular abnormality (100%)
 - there is no evidence of invasive disease (100%).
- 16. Cryocautery should only be used for low grade CIN and a double freeze thaw-freeze technique must be used (100%).
- 17. When excision is used, at least **80%** of cases should have the specimen removed as a single sample.
- 18. For ectocervical lesions, excisional techniques should remove tissue to a depth of greater than 7mm (95%).
- 19. Treatment at first visit for a referral of borderline or mild dyskaryosis should only be used in exceptional cases, and only when audit has identified that CIN is present in **≥90%** of the excised specimens.
- 20. All women over the age of 50 years who have CIN 3 at the endocervical margin and in whom satisfactory cytology and colposcopy cannot be guaranteed must have a repeat excision performed to try and obtain clear margins (100%).
- 21. Among women with adenocarcinoma in situ/ cGIN, those wishing to retain fertility can be managed by local excision. Incomplete excision at the endocervical margin requires a further excisional procedure to obtain clear margins and exclude occult invasive disease (95%).

- 22. All women needing treatment must be informed that treatment will be required and their consent, either written or verbal, recorded (100%).
- 23. All women needing treatment must have had a colposcopic assessment (100%).
- 24. All treatments must be recorded (100%).
- 25. All women must have had their histological diagnosis established prior to destructive therapy (100%).
- 26. The proportion of women managed as outpatients with local analgesia should exceed **80%**.
- 27. The proportion of women treated at the first visit who have evidence of CIN on histology must be **>90%**.
- 28. The proportion of treatment associated with primary haemorrhage that requires a haemostatic technique in addition to the treatment method applied must be **<5%**.
- **29**. The proportion of cases admitted as inpatients owing to treatment complications must be <2%.

Section 9

- 30. All women remain at risk following treatment and must be followed up (100%).
- 31. Follow-up should start at six months following treatment and not later than eight months following treatment (>90%).
- 32. All women who do not have negative test results after treatment must be re-colposcoped at least once within 12 months (100%).
- 33. The proportion of treated women with no dyskaryosis six months following treatment should exceed **90%**.
- 34. The proportion of confirmed histological treatment failures should not exceed **5%** within 12 months of treatment.
- 35. Biopsy should be undertaken in **>95%** of women with high grade abnormalities.
- 36. If at follow up a high grade cytological abnormality persists, excisional treatment is recommended (90%).
- 37. Women referred with moderate dyskaryosis or worse cytological abnormalities who have a colposcopically low grade lesion and who are not treated should have multiple biopsies (90%).
- **38.** If a low grade lesion has not resolved within two years of referral to colposcopy, at least a biopsy is warranted (>90%).

Section 10

39. If colposcopy has been performed during pregnancy, post-partum assessment of women with an abnormal cervical sample or biopsy proven CIN is essential **(100%)**.

40. Colposcopic evaluation of the pregnant woman requires a high degree of skill. If invasive disease is suspected clinically or colposcopically, a biopsy adequate to make the diagnosis is essential (100%).

Section 12

41. Colposcopic assessment is essential in the presence of cytological glandular abnormality (100%).

Acknowledgement

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