

Appendix 4

COMMON NATIONAL DATASET

The use of a common national database will facilitate the pooling of data from screening programmes across the country to allow epidemiological analysis. This not a minimum national dataset (i.e. not all fields are essential); please refer to the coding guide for essential fields.

Corresponding to these forms there is an electronic database, available from the NHSCSP, which initially will be used by the QARC. This appendix provides paper forms for the collection of data coordinated by the HBPC (Hospital Based Programme Coordinator). Different forms are to be completed by different laboratories/clinics either by a specialist from the relevant area or by the person responsible for the collection of data. We would encourage you to return the forms even if there is one or two fields missing. It is not necessary to complete all sections in the audit in order to submit data, however Sections A & B are essential.

The Electronic Database (Access) is available upon request and is provided in conjunction with an explanatory manual. Please e-mail nhscsp.audit@cancer.org.uk for a copy and/or more details.

Contents

PAPER FORMS

SECTION A.	Personal and Cancer Details
SECTION B.	Cytology History
SECTION C.	Colposcopy History
SECTION D.	Histology History
SECTION E.	Cytology Review
SECTION F.	Histology Review
SECTION G.	GP Notes
SECTION H.	HPV DNA Testing

SECTION A. Personal and Cancer Details**PART A1. FOR LOCAL USE ONLY**

Study ID

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Surname _____ First Forename _____

Other Forename(s) _____ Surname at Birth/Maiden Name _____

NHS Number

--	--	--	--	--	--	--	--	--	--

GP Number

--	--	--	--	--	--	--	--	--	--

Address _____

Postcode

--	--	--	--

--	--	--

------(CUT HERE)-----

PART A1. FOR LOCAL, REGIONAL AND NATIONAL USE

Study ID

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Date of Birth

D	D	M	M	Y	Y	Y	Y

Date First Registered with GP

--	--	--	--	--	--	--	--

(date provided by Open Exeter and AJ-CRUK)

Index of Multiple Deprivation

--

(derived from postcode by electronic database)

CASES ONLYDate of Diagnosis
(use Cancer Registries Algorithm)

--	--	--	--	--	--	--	--

Stage of Tumour (FIGO)

--	--	--

Histology (Codes required for AJ-CRUK)

--

(S=Squamous A=Adeno B=Adeno-squamous, U=Undifferentiated, O=Other, X Unknown)

Screen Detected* (1=Yes 2=No)

--

Laboratory Code (where case was identified)

--

*Screen detected means that the discovery of cancer resulted originally from a woman having a routine screening test. She could be a regular attender, a lapsed attender or a woman who has never been screened before.

Treatment received -please tick one only

- ☐ None
☐ LLETZ/Cone Biopsy
☐ Trachelectomy
☐ Simple hysterectomy
☐ Radical hysterectomy
☐ Hysterectomy plus radiotherapy

- ☐ Hysterectomy plus chemotherapy
☐ Hysterectomy plus radiotherapy plus chemotherapy
☐ Radiotherapy only
☐ Chemotherapy only
☐ Radiotherapy plus chemotherapy

(End)

April 2007

SECTION B CYTOLOGY

STUDY ID

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Tick if **no cytology** was found
☐
If **ceased** prior to diagnosis please give **reason**
☐
Please state **reason** for no cytology
☐

(see codes)

(see codes)

CYTOLOGY HISTORY (most recent first)

	<u>Date test was taken</u>	<u>Result of test</u> (see codes)	<u>Action Code</u> (see codes)	<u>Source</u> (see codes)
	D D M M Y Y Y Y			
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Result Codes

1. Inadequate
2. Negative
3. Mild Dyskaryosis
4. Severe Dyskaryosis
5. ?Invasive cancer
6. ?Glandular neoplasia
7. Moderate dyskaryosis
8. Borderline dyskaryosis

Action Code

- A. Routine Screening/Call/Recall
- H. Result Recorded but no change in current action code
- R. Early recall at interval specified by lab
- S. Suspend recall pending referral

No Cytology Reason

1. Not on Exeter System
2. Invited but did not attend
3. Not yet called
4. Ceased
5. Unclear

If Ceased Reason

1. Age
2. Absence of cervix
3. Informed Choice
4. Other/ unknown

Source

(not provided by AJ-CRUK)

1. GP
2. NHS Community Clinic
3. GUM clinic
4. NHS Hospital
5. Private
6. Other

(End)

April 2007

[illegible]

11

SECTION D CERVICAL HISTOLOGY

STUDY ID

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

HISTOLOGY HISTORY

PART D1. CANCER DIAGNOSIS

Date of Specimen								Type of Specimen (see codes)	FIGO Stage (as recorded in histology notes)	Pathological Diagnosis (see codes)	Details
D	D	M	M	Y	Y	Y	Y				

Number of histology specimens found for this woman. Cross out if NONE.

PART D2. SPECIMENS TAKEN PRIOR TO DIAGNOSIS (generally colposcopic) - (most recent first)

Date of Specimen								Type of Specimen (see codes)	Pathological Diagnosis (see codes)	Clear Margins (Yes/No)
D	D	M	M	Y	Y	Y	Y			

Type of Specimen

1. Punch Biopsy
2. Polyp
3. LLETZ (loop)
4. Laser excision/cone
5. Knife Cone
6. Trachelectomy
7. Hysterectomy
8. Other complete cervical excisions

Pathological Diagnosis

(For details/decimals see colposcopy history on the coding guide)

0. Normal
- X. Inadequate Biopsy
1. HPV Changes
2. CIN
3. CGIN
- 3.5 SMILE
4. Squamous Carcinoma
5. Adenocarcinoma
6. Adenosquamous
7. All other Cervical Malignancy
- 7.1 Small Cell Carcinoma
8. Benign lesions
9. Non-cervical Malignancy

Details

Site for non-cervical cancer
Type of other cervical malignancy
Mixed diagnosis, e.g. CIN3 & HGCGIN
Foci of invasion

FIGO Stage

1A	1B	2	3	4
1A1	1B1	2A	3A	4A
1A2	1B2	2B	3B	4B

(End)

April 2007

SECTION E CYTOLOGY REVIEW

STUDY ID

[illegible]

If the slide was not available for review state reason
(1.Not Found,2. Not Released, 3.Not Suitable)

7

Details

Beams _____

PART E1. ORIGINAL SLIDE DETAILS

<u>Lab Code</u>	<u>Slide ID</u>	<u>Date of Original Test</u>	<u>Test Type</u> (see code)	<u>Cytology Type</u> (see codes)	<u>Original Test Result</u>	<u>First Referral</u> (Y/N)
		D D M M Y Y Y Y				

PART E2. **REVIEW** RESULTS (please enter one line per reviewer. **START** with Local reviewers)

Reviewed at (1.Local/ 2.Regional level)	Type of Reviewer (see codes)	Date	Review Result (see code)	Factors likely to lead* to false positive results	Factors likely to lead* to false negative results
☐	☐	☐ ☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☐ ☐	☐		
☐	☐	☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☐ ☐ ☐	☐		
☐	☐	☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☐ ☐ ☐	☐		
☐	☐	☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☐ ☐ ☐	☐		
☐	☐	☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☐ ☐ ☐	☐		
☐	☐	☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☐ ☐ ☐	☐		
☐	☐	☐ ☐ ☒ ☐ ☐ ☒ ☐ ☐ ☐ ☐ ☐	☐		

*Please enter as many factors as necessary. Leave blank if it does not apply

Result Codes

1. Inadequate
2. Negative
3. Mild Dyskaryosis
4. Severe dyskaryosis
5. ?Invasive cancer
6. ?Glandular neoplasia
7. Moderate dyskaryosis
8. Borderline dyskaryosis

Type of Reviewer

1. Screener
2. Checker
3. Advanced Practitioner
4. Consultant

Potential False Negatives

1. Small Cell Dysk
2. Pale Cell Dysk
3. Microbiopsies
4. Small Keratinized cells
5. Sparse Dysk(<200 cells)
6. Other (Specify)

Test Type

1. Routine Screening
2. Repeat (following abnormal)
3. Surveillance (following Colp)
4. Symptomatic
5. Colposcopy
6. Other

Potential False Positive

- A. Normal Endometrial Cells
- B. Endometriosis/tubo-endo metaplasia
- C. LUS Endometrial Sampling
- D. Histiocytes
- E. Follicular Lymphocytic cervicitis
- F. IUCD Effect
- G. Other (Specify)

Cytology Type

1. Conventional
2. LBC (SurePath)
3. LBC (ThinPrep)
4. LBC (other)

SECTION F HISTOLOGY REVIEW PRE DIAGNOSTIC SPECIMEN

STUDY ID

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

If the sample was not available for review state reason (1. Not Found, 2. Not Released, 3. Not Suitable)

Details

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

PART F1. ORIGINAL SPECIMEN DETAILS

There is a separate form for cancer specimens (see F3 and F4)

In how many pieces was the specimen received?

Lab Code	Specimen ID	Date of Original Specimen	Type of Specimen	Original Pathological Diagnosis (see codes)
		D D M M Y Y Y Y 		

Biopsy Size (Length x Width x Depth) in mm

 x x
PART F2. HISTOLOGY REVIEW RESULTS (use one line per reviewer. **START** with Local reviewers)

Reviewed at (1. Local/ 2. Regional level)	Date D D M M Y Y Y Y	Review Pathological Diagnosis (see code)	Difficulties in interpretation

Type of Specimen

1. Punch Biopsy
2. Polyp
3. LLETZ (loop)
4. Laser excision/cone
5. Knife Cone
6. Trachelectomy
7. Hysterectomy
8. Other complete cervical excisions

Pathological Diagnosis

(For details/decimals see colposcopy history on the coding guide)

0. Normal
- X. Inadequate Biopsy
1. HPV Changes
2. CIN
3. CGIN
- 3.5 SMILE
4. Squamous Carcinoma
5. Adenocarcinoma
6. Adenosquamous
7. All other Cervical Malignancy
- 7.1 Small Cell Carcinoma
8. Benign lesions
9. Non-cervical Malignancy

Difficulties in Interpretation

Open field. Some examples are:
Diathermy Artefact
Epithelial Stripping
Fragmented

Details

Site for non-cervical cancer
Type of other cervical malignancy
Mixed diagnosis, e.g. CIN3 & HGCGIN
Foci of invasion

(continued)

April 2007

SECTION G GP NOTES

STUDY ID

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Please tick if no correspondence was found. Cross out if the GP records were not searched.

--

PART G1. CORRESPONDENCE

D	D	M	M	Y	Y	Y	Y	SENT FROM	SENT TO	Action/Contents

PART G2. SPECIAL PERIOD/EVENT

FROM								TO								Reasons for Special Period
D	D	M	M	Y	Y	Y	Y	D	D	M	M	Y	Y	Y	Y	

Other relevant information

--

Sent From/To

- GP
- Patient
- Cytology Lab
- Histology Lab
- Gynaecologist
- PCT
- Private Doctor

(End)

Action/Contents

- Referral
- Discharge
- Invitation
- Complaint
- Opted for private care
- Postpone
- Opted out of recall
- Other (please specify)

Reasons for Special Period

- Pregnant
- Abroad
- Hospitalized
- Hysterectomy
- Other (please specify)

April 2007

SECTION H HPV DNA TESTING

STUDY ID

This section applies only to women who have had an HPV test the result of which might have impacted on the clinical management. If HPV testing becomes routine this information will be recorded in section B.

Date of Sample	Result (+/-)	Type of Test (e.g. HC-II, GP5+/6+)	Name of Study (e.g. HART, Triage pilot, ARTISTIC, TOMBOLA)	Other Details (Threshold (if non- standard), HPV types, Context (dual testing, triage))
D D M M Y Y Y Y				

Appendix 5

CODING GUIDE FOR NATIONAL DATASET

The use of a common national coding guide will facilitate the pooling of data from screening programmes across the country to allow epidemiological analysis.

The Coding Guide for the National Dataset is divided into sections and is intended to be used either on its own or in conjunction with the database. It will allow a quick overview of the fields and sections the audit aims to record. The last section provides a list of fields that are essential for Audit purposes. The fields that are not mentioned are desirable and an effort should be made to collect the data. Please ensure that desirable fields are complete before submitting data.

The Electronic Database (Access) is available upon request and is provided in conjunction with an explanatory manual. Please e-mail nhscsp.audit@cancer.org.uk for a copy and/or more details.

Contents

Coding

- ◆ Personal Details
- ◆ Cytology History
- ◆ Colposcopy History
- ◆ Histology History/Review
- ◆ Cytology Review
- ◆ GP Notes

Essential Fields

Personal and Cancer Details

Postcode It is essential that postcode is recorded in full. Postcodes are available from www.royalmail.com.
The postcode will be used to obtain an Index of Multiple Deprivation for each woman.

Index of Multiple Deprivation

The index can be obtained by typing the Postcode into the appropriate space in the Access database, the database will automatically return the corresponding Index. This index is calculated by the Office of the Deputy Prime Minister, it is based on geographical areas (Super Output Areas) each of which includes approximately 1,500 residents. The index is ranked and the percentile is recorded.

Study ID Study ID is 14 characters long and is assigned automatically by AJ-CRUK (Exeter) at the same time that the controls are assigned to the case.

It has the following format TES/QT2/CCYY/NNNX, where

- TES = HA cipher
- QT2 = Q code of Case/Control as at the date of diagnosis
- CCYY = the year of the case's diagnosis
- NNN = a sequence number for the Qcode and year of diagnosis
- X = the Case/Control type identifier. If:
 - o X = 1 – indicates a Case
 - o X = 2 – indicates a GP Control
 - o X = 3 – indicates a District Control
 - o X = 4 – an Adjusted Screened Control
 - o X = 5 – an Abnormal Control
 - o X = 6 – an Unadjusted Screened Control.

Dates All dates are of the form DD MM YYYY (eg. May 7, 1992 becomes 07 05 1992)
If only the year is available then leave the day and month blank.
(Most of the dates can be obtained from Open Exeter or AJ-CRUK)

Stage Pretreatment FIGO staging should be used. 1A, 1A1, 1A2, 1B, 1B1, 1B2, 2, 2A, 2B, 3A, 3B, 4A, 4B. Convert Roman numerals to Arabic numerals. E.g. IIIb becomes 3B. Micro-invasive (1A) should be recorded by the laboratory.
NOTE: valid stage codes for AJ-CRUK are: 1A, 1B, 2, 2A, 2B, 3, 3A, 3B, 4, 4A, 4B, X. "X" should be used for unknown stage and "IN" if the tumour is known to be worse than micro-invasive, but the stage is not available (this can also be labeled as "1B+")

Histology (this coding must be used in order to run Exeter AJ-CRUK and should only be used in reference to this output)

S. Squamous
A. Adeno
B. Adeno-squamous
U. Undifferentiated
O. Other
X Unknown

CYTOLOGY HISTORY

No Cytology

1. Not on Exeter System
2. Invited but did not attend
3. Not yet called
4. Ceased
5. Unclear

Ceased

1. Age
2. Absence of cervix
3. Informed Choice
4. Other/ unknown

Result

If there is a conflict between the result recorded on Exeter and the one in the laboratory records, this should be brought to the attention of the QARC as a matter of urgency. Leave blank if the sample was only used for HPV DNA testing.

Use standard codes:

1. Inadequate
2. Negative
3. Mild dyskaryosis
4. Severe dyskaryosis
5. ?Invasive cancer
6. ?Glandular neoplasia
7. Moderate dyskaryosis
8. Borderline dyskaryosis

Action Code

- A. Routine screening/ Call/ Recall
- H. Result recorded but no change in current action code
- R. Early recall at interval specified by lab
- S. Suspend recall pending referral

Cytology Source (this field is not provided by AJ-CRUK)

1. GP
2. NHS Community Clinic
3. GUM Clinic
4. NHS Hospital
5. Private
6. Other

COLPOSCOPY HISTORY

Please give details of all known relevant colposcopy appointments prior to diagnosis date.

Satisfactory Examination

Defined as able to see the squamocolumnar junction

Exam (Satisfactory Examination)

1. Satisfactory
2. Unsatisfactory
3. Not Recorded
4. DNA(Did not attend)

TZ Type (Transformation Zone)

0. Not Recorded
1. Fully Visible(completely ectocervical)
2. Fully Visible(endocervical component)
3. Not Fully Visible
4. Unsatisfactory Exam

Colposcopist

1. Consultant
2. Medical Non-Consultant
(Associate specialist/Registrar/SHO/Clinical assistant)
3. Nurse
4. Trainee

Colposcopic Impression

1. Normal
2. HPV only
3. Low Grade
4. High Grade
5. Invasive Cancer
6. Not Recorded
7. CGIN
8. Micro-invasive

Colposcopic/Surgical Procedure

0. None
1. Punch Biopsy
2. LLETZ (loop)
3. Laser excision/cone
4. Knife Cone
5. Laser Ablation
6. Cold Coagulation
7. Cryotherapy
8. Not Recorded
9. Radical Diathermy

Pregnant

Leave blank if the woman is NOT pregnant.
Write "NK" if NOT KNOWN.

Follow-up

Leave blank if unknown. Write 99 if patient was discharged

Pathological Diagnosis Codes

- 0.** Normal (include cervicitis, infection)
- X** Inadequate Biopsy
- 1.** HPV Changes only
- 2.** CIN - not otherwise specified
 - 2.1 CIN 1
 - 2.2 CIN 2
 - 2.3 CIN 3
- 3.** CGIN- not otherwise specified
 - 3.1 Low grade CGIN
 - 3.2 High grade CGIN
 - 3.5 SMILE (Stratified Mucin-producing Intraepithelial Lesions)
- 4.** Invasive Squamous Carcinoma- not otherwise specified
 - 4.1 Keratinizing
 - 4.2 Non-Keratinizing
 - 4.3 Basaloid
 - 4.4 Verrucous
 - 4.5 Warty
 - 4.6 Papillary
 - 4.7 Lymphoepithelioma-like
 - 4.8 Squamotransitional
 - 4.9 Small Cell Squamous Carcinoma
- 5.** Adenocarcinoma of Cervix – not otherwise specified
 - 5.1 Mucinous (5.11 Endocervical, 5.12 Intestinal, 5.13 Signet-ring cell, 5.14 Minimal deviation, 5.15 Villoglandular)
 - 5.2 Endometrioid
 - 5.3 Clear cell
 - 5.4 Serous
 - 5.5 Mesonephric
- 6.** Adenosquamous Carcinoma - not otherwise specified
 - 6.1 Glassy cell carcinoma variant
- 7.** All other Cervical Malignancy (please specify)
 - 7.1 Small Cell Carcinoma
 - 7.2 Other Neuroendocrine
- 8.** Benign squamous cell lesions (include condyloma, papilloma, polyp)
 - 8.1 Benign glandular lesions (include mullerian, polyp)
 - 8.2 Non-cervical Atypia
 - 8.3 BAUS (Borderline abnormalities of uncertain significance)
- 9.** Non-cervical Malignancy (include secondary tumours)

HISTOLOGY HISTORY AND REVIEW

Type of Specimen

1. Punch Biopsy
2. Polyp
3. LLETZ (loop)
4. Laser excision/cone
5. Knife Cone
6. Trachelectomy
7. Hysterectomy
8. Other complete cervical excisions

Pathological Diagnosis Codes

(see under Colposcopy History)

Details (this is an optional field)

Site for non-cervical cancer or type of other cervical cancer.

Type of other cervical malignancy.

Mixed diagnosis, e.g. CIN3 & HGCGIN.

Foci of invasion.

Any extra information not covered by the Pathological Diagnosis codes.

FIGO Stage (if you are carrying out HISTOLOGY REVIEW please use 1B+ for non micro-invasive cancers where clinical staging is necessary)

1A	1B	2	3	4
1A1	1B1	2A	3A	4A
1A2	1B2	2B	3B	4B

Difficulties in Interpretation

This is an open field. Some examples of possible difficulties encountered are:

Diathermy Artefact, Epithelial Stripping, Fragmented, Small Focus of Tumour, Tumour Necrosis / Haemorrhage, Poor Preservation or Few, Small, Pale, Obscured, Unusual or Poorly Preserved Abnormal Cells.

CYTOLOGY REVIEW

Test Type

1. Routine Screening
2. Repeat (following abnormal)
3. Surveillance (following colp)
4. Symptomatic
5. Colposcopy
6. Other

Cytology Type

(This field should be filled in by the first reviewer)

1. Conventional
2. LBC (SurePath)
3. LBC (ThinPrep)
4. LBC (other)

Type of Reviewer

1. Screener
2. Checker
3. Advanced Practitioner
4. Consultant

Factors that contribute to Potential False Negatives

1. Small Cell Dyskaryosis
2. Pale Cell Dyskaryosis
3. Microbiopsies
4. Small Keratinized Cell
5. Sparse Dyskaryosis (<200 abnormal cells)
6. Other (specify)

Factors that contribute to Potential False Positives

- A. Normal Endometrial Cells
- B. Endometriosis/tubo-endo metaplasia
- C. Lower uterine segment (LUS) Endometrial Sampling
- D. Histiocytes
- E. Follicular Lymphocytic cervicitis
- F. IUCD Effect
- G. Other (Specify)

GP NOTES

Sent From/To

1. GP
2. Patient
3. Cytology laboratory
4. Histology laboratory
5. Gynaecologist
6. PCT
7. Private Doctor
8. Other (specify)

Action/Contents

1. Referral
2. Discharge
3. Invitation
4. Complaint
5. Opted for private care
6. Postpone
7. Opted out of recall
8. Other (please specify)

Reasons for Special Period

1. Pregnant
2. Abroad
3. Hospitalized
4. Hysterectomy
5. Other (please specify)

HPV DNA

This section applies only to women who have had an HPV test the result of which might have impacted on the clinical management. If HPV testing becomes routine this information will be recorded in section B.

Essential Fields

Study ID required for all sections

SECTION A & A1

Personal and Cancer Details

NHS Number
Date of Birth
Date of Diagnosis
Stage of Tumour (FIGO)
Histology

SECTION B

Cytology

No cytology found
Date test was taken
Result of Test

SECTION C

Colposcopy

Number of colposcopic appointments
Date of colposcopy
Satisfactory Examination or DNA
Surgical Procedure

SECTION D1

Histology Cancer Diagnosis

Date of Specimen
FIGO Stage
Pathological Diagnosis

SECTION D2

Specimen History

Date of Specimen
Type of Specimen
Pathological Diagnosis
Clear Margins

SECTION E Cytology Review

E1. Original slide

Slide ID
Date of Original Test
Cytology Type
Original Test Result

E2. Review Results

Reviewed at
Review result

SECTION F Histology Review

F1. Original Specimen

Specimen ID
Date of Original Specimen

F2. Review Results

Review Pathological Diagnosis

F3. Cancer Original Specimen

Specimen ID
Date of Original Specimen

F4. Cancer Review Results

Review Pathological Diagnosis

SECTION G

GP Notes

Although Section G is not essential, if you attempt to collect data, all fields are required

SECTION H

HPV DNA Testing

Date of Sample
Result