Kent and Medway Cervical Screening Programme

Policy for ensuring the quality of cervical samples submitted to laboratories and the process for early identification of issues within the cervical screening programme in Kent and Medway

April 2015
Cervical Screening Roles and Responsibilities

GP Practices and Genitourinary Medicine Clinics (GUM) and Community and Sexual Health Clinics (CASH) must as a minimum:

- Ensure that all their sample takers are authorised by the Kent and Medway Screening and Immunisation Team (KMSIT) before they submit any cervical screening samples to the local cytology laboratories. They must be in possession of their own Sample Taker Number (ST Number), allocated by the Quality Assurance Reference Centre (QARC) and sent to them via the Screening and Immunisation Team for Kent and Medway. The ST number submitted with cervical samples must be the one allocated to the person who took the sample. ST numbers must not be shared or transferred.
- Take responsibility for ensuring all their sample takers have attended appropriate basic sample taker training and hold evidence of qualification in personal files.
- Employers must also ensure sample takers update their skills in accordance with NHS Cervical Screening Programme National Guidance, currently it is recommended that sample takers update their training every three years. Only approved/accredited training courses can be used.
- Use Open Exeter forms and printing them in the default format.
- Appoint a nominated clinical lead for the screening programme
- Ensure there is a female sample taker available if requested.

In addition the GP Practice as a minimum must:

- Maintain electronic links with call/recall services.
- Be aware that if a result has not been received after a further 12 weeks, KPCA produces a First non-responder notification, available to the GP via the Open Exeter application ‘Practice Electronic Cards’. It is the responsibility of the GP to invite the woman to attend for a test at this stage.
- Ensure there is a system in place for identifying and contacting non-responders.
- Ensure that systems are in place so all test results are noted and appropriate follow-up/referral takes place as recommended.

Public Health England Screening and Immunisation Team responsibilities:

- Ensure every cervical screening sample submitted to our labs has been taken by an authorised sample taker.
- Providing local coordination, quality and performance monitoring of the NHS national cervical screening programme.
- Maintain the Kent and Medway cervical screening sample taker database.
- Authorise and issuing cervical screening sample taker numbers.
- Monitor cervical screening training outcomes.
- Manage incidents and issues.
- Supporting providers and sharing good practice.
- Coordinating and supporting local and national awareness campaigns.
- Working collaboratively with the practice nurse advisory team and CS programme regional quality assurance team.
Checking Eligibility - Is the woman due to be screened?

To ensure women are screened appropriately sample takers must check the woman's screening report on Open Exeter. Open Exeter records when the next screening test is due and also is useful for checking the history of women new to the practice.

Using Open Exeter can prevent the sample being taken too early; samples taken too early will be rejected by the lab and will be reported as inadequate. The woman will have to re-attend for screening and this cannot be repeated for a further 12 weeks. This could be avoided by confirming the woman’s next test date via Open Exeter prior to taking the sample.

To help reception staff and sample takers the Screening and Immunisation Team (SIT) have added a note on the invitation letter encouraging women to bring their invitation letter when booking and attending for cervical screening. This may be something sample takers could encourage in their practice.

For a copy of the user guide for Open Exeter, please contact phst@nhs.net

What is HPV triage and test of cure?

Following a national review of the Cervical Screening programme in 2012, the arrangements following colposcopy for follow up screening tests were changed. Originally women were asked to attend annually for several years; however the national programme has now added an extra screening test. In Kent and Medway we have been using the additional test for over two years and if a sample is reported as having negative cytology and with a negative HPV test, i.e. no evidence of HPV, the NHS Cancer Screening Programmes guidelines now recommend that women are returned to normal recall.

If a woman has had treatment for cervical abnormalities called CIN (cervical intraepithelial neoplasia), they will be screened again six months afterwards for a test of cure screen. If that screening result shows they have HPV, or have moderate or worse dyskaryosis, they will be invited back for colposcopy again to see if more treatment is needed. If no HPV is found, they will be called for screening again in 3 years' time.

The links below provide more information on the HPV triage and also the flow chart for you to print off and refer to:


It is imperative that all cervical screening sample takers are aware of the changes and can explain them to the woman.

3 yearly update and HPV online training

The link to the training module can be obtained by contacting the SIT on phst@nhs.net. You will need to register. Once you have registered, you will be sent an email which contains a link for you to click on to confirm your registration. Once you have accessed the course ‘ThinPrep Cervical Screening 3 Yearly Update V3’ you will be asked for an enrolment key which is ‘neoplasia’. If you are already registered, log in and then go to the top right corner. You can add your ST number by editing your profile – this will then be on your certificate.

HPV on line training is available by clicking on ‘ThinPrep Cervical Screening 3 Yearly Update V3’.
Cervical Cytology Samples Acceptance/Rejection Policy

Unfortunately cytology labs continue to receive cervical screening samples which do not meet national standards. This can result in the sample being rejected or reported as inadequate.

Sample takers are asked, as a minimum to ensure:

- The Cytology request form is completed fully and correctly, corresponds to the details on the vial and the details are checked with the woman to ensure they are correct.
- The sample is not taken too early – the woman’s next due test date can be viewed on Open Exeter prior to taking the sample. When a woman has received treatment in colposcopy, please refer to her most recent discharge letter.
- Their sample taker number is written correctly and clearly on all documentation and their name is printed after the signature.

Please note these key points:

- **The NHS Cervical Screening Programme age range is 25-64 but first invitation is sent at age 24½.**
- Young women will be invited 6 months before their 25th birthday and **may be screened** if they attend from that point. Uninvited women aged under 24½ must not be screened.
- **Cervical cytology samples should not be taken on women with symptoms.** Clinical Practice Guidance issued for management of women aged 20-24 is applicable to all women with symptoms. It is available at http://www.cancerscreening.nhs.uk/cervical/publications/doh-guidelines-young-women.html. Women with postcoital bleeding or persistent intermenstrual bleeding should have an immediate speculum examination. If the cervix looks abnormal and suspicious, which will be the case in a very small proportion, the correct action is urgent referral to colposcopy under the ‘two week wait’ rule. If there is a benign lesion, such as cervical polyp, a routine gynaecological referral will suffice. If the cervix looks normal, the recommended action will be a pregnancy test (if appropriate) and testing for cervical infection (e.g. Chlamydia, Herpes, and Gonorrhoea). Any positive tests for sexually transmitted infections would need to be appropriately treated. If the woman is not due for cervical screening, any cytology sample taken will be rejected by the laboratory.
- If the cytology laboratory contacts you about a sample please **respond as soon as possible** (preferably the same day).
- The cytology lab monitors inadequate samples and follow the Kent and Medway Service operation plan for cervical screeners who submit poor quality samples. See Appendix 2.
- The cytology labs and SIT work closely together to ensure the quality of samples submitted to the lab is maintained and follow the Kent and Medway policy for managing sample takers who submit poor quality cytology samples. See Appendix 3.
Common reasons a Cervical Screening Programme Sample may be rejected / reported as inadequate – this list is not exhaustive:

Sample out of scope – these will be rejected by the laboratory
- Age under 24½ & no screening history
- Age 24½ - 50, interval set on last test routine recall and under 3 years since last test
- Age over 64 and no recent history of abnormalities Interval set on last test 6 months and under 6 months since last test
- Test taken less than 3 months since inadequate
- Under 6 months since referral to colposcopy
- Interval set on last test 12 months and under 12 months since last test
- Interval set on last test 3 years and under 3 years since last test
- Interval set on last test 5 years and under 5 years since last test
- Previously treated for CIN, last test HPV negative and under 3 years since last test

Sample Condition issues
- Sample in a container other than a ThinPrep© vial
- ThinPrep© vial out of date or containing brush head

Sample Documentation issues
- Vial arrives without request form
- Completed request form arrives with no vial
- Insufficient identifiers on request form
- Major or more than one minor labelling error
- Vial & request form labels do not match
- More than one sample in a bag with only one request form
- Patient details differ from ‘Open Exeter’ – major discrepancy or multiple minor discrepancies (two or more)

Sample Taker issues
- Sample Taker number absent
- Sample Taker number not recognised
- Sample Taker number does not correspond with sample taker name

Clinical details issues
- Request form states “cervix not seen” or other indicator of inadequate sample taking
- Woman recorded as having no cervix

Clinical Adequacy issues
- Heavily blood stained – insufficient cells seen
- Insufficient cells present
- Mostly endocervical cells, insufficient squamous cells (not follow up of endocervical abnormality)
- Insufficient endocervical cells (follow up of endocervical abnormality)
- Squamous cells obscured by polymorphs/debris
Appendix 1

Cervical Screening Programme in Kent and Medway: Quality

Version 8 – April 2015

N.B. Women who are HIV positive or immunocompromised due to a medical condition with associated protocol recommending annual screening should have annual cytology.
Appendix 2

Public Health Service Operation Plan for Cervical Screening Sample Takers in Kent and Medway who submit poor quality cytology samples to local Cytology Laboratories

Cytology Laboratory
- Laboratory uses the South East Coast Quality Assurance Reference Centre (SEC QARC) “Guidance on Reporting LBC Samples as Inadequate”.
- If a laboratory identifies a sample taker with inadequate rates above National guidance and rates reported within local Cytology laboratory, (Sub Laboratory Pathway).

Other Source
- (e.g. Manager/Cervical Screening Lead/SIT/Practice Nurse Advisor/Trainer/Mentor)
- Has identified same sample taker with inadequate rates above National guidance and rates reported by the local cytology laboratory.

Sample Taker
- To help ensure continued competence in accordance with professional codes of conduct, sample takers should conduct continuous self-evaluation.
- Sample takers should audit and reflect on their individual rates of inadequate tests and abnormal test results compared with the rates reported by the local cytology laboratory.
- Sample Taker (ST) has identified high rates following self-audit.

Contact Screening and Immunisation Team for Kent and Medway (KMSIT)

Tel: 01227 768406
Fax: 0300 123 9054
Email: ptmt@nhs.net

KMSIT will contact the cytology laboratory and ascertain the following:
- Check the Kent and Medway database for sample takers and confirm sample taker details including dates for training/update training.
- Timeframe during which samples were taken (e.g. year, six months).
- Total number of samples taken within this timeframe.
- Total number of inadequate samples within this timeframe.
- Reasons why samples have been reported inadequate.
- Inadequate rates for the previous year.
- Previous issues with sample taker regarding inadequate rates.

Actions for KMSIT
- Contact the sample taker and their manager by phone and email.
- Inform them of the inadequate rates and reasons.
- Advise ST to contact laboratory to discuss reasons in greater detail.
- Discuss the implications of inadequate samples (recall of women to repeat sample, cost and time for lab).
- Send ST the NHS SP’s ‘Good Practice Guidance for Sample Takers’ (with reference to inadequate samples section).
- ST may be asked to undertake samples under clinical supervision of appropriate sample taker (who meets mentor criteria) to review current practices/technique and assist ST’s confidence.
- May be asked to undertake e-Learning cervical screening update/training.
- ST to continue to self-audit and monitor own inadequate rates.
- KMSIT to review inadequate rates with the laboratory in 3 month’s time.

KMSIT
- Have inadequate rates improved after 3 month period?
  - Yes
  - Cytology lab: Contact KMSIT if any further concerns.
  - Sample Taker: Continue to conduct continuous self-evaluation. Contact lab/KMSIT if any further concerns/issues.

  - No
    - Contact SEC QARC for further management. Consider:
      - Visit of Practice Nurse Advisor to assess ST.
      - Suspension of ST if assessment indicates poor technique until further management/learning considered.
      - Consider if there is a significant risk for:
        - New samples to be taken/previous samples taken.
Pathway for managing sample takers who submit poor quality cytology samples to the Kent and Medway Cytology laboratories

Actions for Cytology Laboratories within Kent and Medway

Cytology laboratory uses the South East Coast Cervical Screening Quality Assurance Reference Centre (SEC QARC) “Guidance on reporting Liquid Base Cytology samples as inadequate”.

Cytology lab will record all incidents and follow the pathway below

1st Notification

- Cytology lab logs the incident and notifies ST by sending 1st event letter for either unlabelled/mislabeled cervical sample. See page 10-11 for Letter templates.

2nd Notification

- Cytology lab sends out letter for 2nd unlabelled/mislabeled sample and refer incidents to KMSIT, see appendix for letter template. KMSIT email ST and Practice Manager with good practice advice and request double checking samples with a colleague for a period of 3 months. See page 12 for email template.

3rd Notification

- If contacted within 6 months of 2nd notification KMSIT may suspend the ST until their practice is assessed. ST will be referred to NHS England area team and PN Advisors.

Action of Screening and Immunisation Team for Kent and Medway (KMSIT)

KMSIT will:
- Check the K&M database for sample takers and confirm sample taker details including dates for training/update training then
- Contact the lab to ascertain:
  - Total number of samples taken within this timeframe and numbers of inadequate/labeling incidents
  - Reasons why the samples have been reported inadequate/mislabelled
  - Inadequate/mislabelled rates for the sample taker from the previous year
  - Any previous issues with sample taker inadequate/mislabelled rate
- Contact the sample taker and their manager using email template on page 14

If further issues arise within 6 months, KMSIT will consider:
- Suspension of sample taker if assessment indicates poor technique until further management / retraining considered
- Contact NHS England QA team and Practice Nurse Advisors for advice and further management
- Request peer review or assessment of Sample Taker’s processes and technique
- Consider a “look back” for women who have had samples taken

Version 1 – February 2015
Template sent from Lab 1st Unlabelled notification

Re: UNLABELLED CERVICAL SAMPLE
Dear Practice Nurse .............

Patients name: Forename SURNAME DOB: 00.00.1900
Patients address: .................................................., Postcode

I am writing as we were unable to process a cervical sample taken by you on ........2014 from the woman detailed above. As my colleague explained by telephone, the sample was rejected because the vial was received unlabelled.

Please inform the patient that she will not be receiving a result letter on this occasion and arrange for a repeat test to be taken after 3 months.

In the past, there have been serious incidents which have resulted in the recall of over 1000 women in this region. As a result, the Cervical Screening Quality Assurance Team and the South East Coast Screening and Immunisation teams have developed a quality assurance policy. The aim of this is to ensure that bad practice is stopped quickly and to reduce the risk of serious incidents with the associated look back / recall exercises.

This is the first time we have contacted you regarding a labelling issue, but I thought it would be beneficial to let you know, if there is a second incident we will be obliged to contact the Kent and Medway Screening and Immunisation Team who may suspend you from screening until you have undergone supervised practice.

You may be interested to note some potential remedies discussed in similar cases:
- Print the HMR101 form from Open Exeter when the woman is in room
- Ask the woman to check her details on the label and demographics on the form are correct
- Discard old labels at the time of generation into confidential waste collection bin on desk
- Keep EMIS label trace taskbar closed- open label trace up when the woman is in the room
- Ask a colleague to double check vials and paperwork

Please ensure this letter is shared with the sample taker before filing.
If you have any questions please do not hesitate to contact me.

Template sent from lab 2nd Unlabelled Notification

Re: UNLABELLED CERVICAL SAMPLE
Dear Practice Nurse .............

Patients name: Forename SURNAME DOB: 00.00.1900
Patients address: .................................................., Postcode

I am writing as we were unable to process a cervical sample taken by you on ........2014 from the woman detailed above. As my colleague explained by telephone, the sample was rejected because the vial was received unlabelled.

Please inform the patient that she will not be receiving a result letter on this occasion and arrange for a repeat test to be taken after 3 months.

As there was a previous problem with labelling in .........., we are obliged to inform the Kent and Medway Screening and Immunisation Team who will contact your Practice Manager.
Template sent from lab Mislabelled 1st Notification

Re: MISLABELLED CERVICAL SAMPLE
Dear Practice Nurse .............
I am writing as we were unable to process a cervical sample taken by you on ........2014.
As my colleague explained by telephone, the sample was rejected because............
............the vial was labelled with a different woman’s details to that written on the request form.
............the request form and the vial were labelled with a man’s name.
............the request form and the vial were labelled with a child’s name.

Details on request form; DOB
Details on sample vial; DOB

Please inform the patient that she will not be receiving a result letter on this occasion and arrange for a repeat test to be taken after 3 months.

In the past, there have been serious incidents which have resulted in the recall of over 1000 women in this region.
As a result, the Cervical Screening Quality Assurance Team and the South East Coast Screening and Immunisation teams have developed a quality assurance policy. The aim of this is to ensure that bad practice is stopped quickly and to reduce the risk of serious incidents with the associated look back / recall exercises.

This is the first time we have contacted you regarding a labelling issue, but I thought it would be beneficial to let you know, if there is a second incident we will be obliged to contact the Kent and Medway Screening and Immunisation Team who may suspend you from screening until you have undergone supervised practice.
You may be interested to note some potential remedies discussed in similar cases:
- Print the HMR101 form from Open Exeter when the woman is in room
- Ask the woman to check her details on the label and demographics on the form are correct
- Discard old labels at the time of generation into confidential waste collection bin on desk
- Keep EMIS label trace taskbar closed- open label trace up when the woman is in the room
- Ask a colleague to double check vials and paperwork

Please ensure this letter is shared with the sample taker before filing.
If you have any questions please do not hesitate to contact me.

Template sent from lab Mislabelled 2nd Notification

Re: MISLABELLED CERVICAL SAMPLE
Dear Practice Nurse .............
I am writing as we were unable to process a cervical sample taken by you on ........2014.
As my colleague explained by telephone, the sample was rejected because............
............the vial was labelled with a different woman’s details to that written on the request form.
............the request form and the vial were labelled with a man’s name.
............the request form and the vial were labelled with a child’s name.

Please inform the patient that she will not be receiving a result letter on this occasion and arrange for a repeat test to be taken after 3 months.

As there was a previous problem with labelling in ........,. we are obliged to inform the Kent and Medway Screening and Immunisation Team who will contact your Practice Manager.

Please ensure this letter is shared with the sample taker before filing.
If you have any questions please do not hesitate to contact me.
Email template from KMSIT

(ATTACH LETTERS FROM THE LAB)

Dear xxxxx

I have recently been contacted by the <WHH/Maidstone> cytology lab regarding a couple of mislabelled/unlabelled samples you submitted; please find letters attached.

<Date> <Reason>
<Date> <Reason>

I know that these appear to be simple errors but it did mean that the samples were rejected and the women had to be rescreened; this then raises concerns if the women do not return for screening.

To prevent any further samples being rejected I would be grateful if for the next three months, you could arrange for a colleague to double check your samples before they are sent to the lab. This will help ensure errors can be identified before submission and hopefully prevent the sample from being rejected.

To comply with the South East Coast Policy for Quality, if the lab contact us again within the next 6 months we may have to suspend you from cervical screening until your practice is assessed.

You may be interested to note some potential remedies discussed in similar cases:

• Print the HMR101 form from Open Exeter when the woman is in room
• Ask the woman to check her details on the label and demographics on the form are correct
• Discard old labels at the time of generation into confidential waste collection bin on desk
• Keep EMIS label trace taskbar closed - open label trace up when the woman is in the room
• Ask a colleague to double check vials and paperwork.

If you have any queries, please do let me know.

Kind regards