Public Health England

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Confidential Data Supplement for the reports:

- **External review into the North Lancashire and South Cumbria Breast Screening Programme (November 2014).**

- **Confidential report of the investigation into the complaint of the behaviour of North West (NW) Quality Assurance Team in their assessment of performance of NLSCBSP (November 2014).**

About Public Health England

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Published: May 2015 (originally published November 2014)
PHE publications gateway number: 2015054

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Executive summary

This confidential data supplement should be read in conjunction with two reports:

- External review into the North Lancashire and South Cumbria Breast Screening Programme (November 2014).
- Confidential report of the investigation into the complaint of the behaviour of North West (NW) Quality Assurance Team in their assessment of performance of NLSCBSP (November 2014).

The data contained within this report contains small numbers which if published could lead to disclosure of identity of individuals and therefore has been removed from the main reports.

Key findings

North West Quality Assurance Reference Centre

There is no evidence that NW QARC were biased in their approach to analysis of data presented to them by one of the whistle-blowers. However, the data presented in the report 'Review of Interval Cancers from Assessment in the North Lancashire and South Cumbria Breast Screening Service 2005-2011' (2 May 2014) was neither adequate nor correctly analysed to draw conclusions about the performance of radiologists in NLSCBSP.

Radiologists performance prior to 2011

There is evidence that Radiologist C performance prior to 2011 (the current screening round) in individual assessment cases was sub-optimal and in some cases sub-standard. There were some recurring themes, even though the number of cases is small. Concerns about mammographic interpretation of spiculate lesions, the quality of ultrasound scanning and ultrasound guided core biopsy and repeated under sampling at biopsy were raised by the review.

The statistical data collected by North West QARC indicates that Radiologist C performance at assessment was at the lower end of the distribution for performance for radiologists in the North West region for missed cancers during the period 2005 to 2009.

Radiologist F performance at assessment is also at the lower end of the distribution for performance of radiologists in the North West for missed cancer rates for the period 2005 to 2009.

Radiologist D and E's performance at assessment is at the higher end of the distribution for performance of radiologists in the North West for missed cancer rates for the period 2005 to 2009.

There is insufficient evidence to draw any further conclusions regarding Radiologist C, D, E or Fs performance at assessment as this review has only considered a small sample of these clinicians work during the period 2005 to 2011.

Recommendations

Findings contained in this data supplement regarding the practice of radiologists should be used to inform the external review of current practice.

No further look back of assessment cases prior to 2011 should be undertaken as women who may have had their cancer detected during this period would have presented by now as either interval or screen detected cancers and there would be no value undertaking any further lookback.

Women who have had their interval and screen detected cancers reviewed as part of this audit and review should have their results communicated to them in line with national guidance, if not already done so.[1]

Audits of interval cancers and screen detected cancers need to be done with appropriate methodology to ensure false conclusions are not drawn from results.

Analysis of data as 'missed cancers' is an unhelpful way of presenting these data. As with other screening programmes, sensitivity would be the preferred way to present this information.

[1] Disclosure of audit results in cancer screening advice on best practice (Cancer Screening Series no.3 April 2003) http://www.cancerscreening.nhs.uk/publications

Introduction

This confidential data supplement is to be considered alongside two documents.

- External review into the North Lancashire and South Cumbria Breast Screening Programme (November 2014).

- Confidential report of the investigation into the complaint of the behaviour of North West (NW) Quality Assurance Team in their assessment of performance of NLSCBSP (November 2014).

These data include cases where the numbers of cases are small and therefore publication in a public document could lead to disclosure of identity of individuals.

Information presented in data supplement

Section one: Data that was analysed by North West QA team in their report 'Review of Interval Cancers from Assessment in the North Lancashire and South Cumbria Breast Screening Service 2005-2011' (2 May 2014) and a commentary on the analysis of this data within this report.

Section two External radiological review of assessment cases:

- R1: All films and images of the 24 cases from the false negative assessment interval cancer audit as submitted by one of the whistle blowers.
- R2: Cases screened and assessed 1st April 2005 - 30th March 2008 arising as interval cancers between May 2005 and July 2011.
- R3: Cases screened and assessed 1st April 2007 - 30th March 2011 arising as screen detected cancers between April 2012 and September 2013.
- R4: Review of assessment practice most recent screening round
- R5 :Review of assessment practice most recent screening round (Sept – Dec 2011) where routine recall without needle biopsy
- R6: Review of assessment practice most recent screening round where routine recall without needle biopsy

The external review of assessment films in R1, R2, R3, R4, R5 and R6 were carried out by the External QA radiologists as part of the external review into NLSCBSP.

Audience for data supplement

The contents of the data supplement will be shared with the following organisations and individuals:

1. UHMBT: The Trust should be able to review the contents of this supplement in order that they can ensure that women who have been found to have a missed cancer as part of an audit are managed according to principles in guidelines and Duty of Candour.
2. NHE England: As commissioners of the service, NHS England should be able to review the content of this supplement to assure themselves that the Trust are responding appropriately to the External Report and their response to the findings of the audit.
3. CQC: As regulators of the Trust, CQC should be able to view the content of the supplement to assure itself that women are being correctly managed and where relevant Duty of candour is being followed.
4. Radiologists who are sighted in the report should be able to consider the information in this report that is pertinent to their own practice and reflect on it to inform their own clinical practice as part of Good Medical Practice
5. QA team members should be able to view the data supplement to reflect on the strength and weakness of their analysis in the May 2014 report

Use of information contained in this report

As this supplement contains confidential information which could be used to identify either patients or clinicians it has not been included in the main reports and should therefore not be disclosed. Any circulation, disclosure or distribution of the data supplement or its contents would contravene the principles of the Data Protection Act.

Current guidance in the NHSBSP

The Quality Assurance Guidelines for Breast Cancer Screening Radiology (NHSBSP pub 59, March 2011) introduced the mandatory formal audit of false negative assessment cases. These constitute women who have been previously assessed for the same side and site as a cancer which subsequently presents as an interval cancer or cancer at the following screening episode. These cases are required to be reported to the QA reference centre within 3 months of ascertainment. After publication of the guidance, an audit form was developed, known as form 4 . This allowed comparison of procedures undertaken at the original assessment and following audit, what would be considered appropriate to constitute adequate assessment now (in hindsight).

This information is used to form a summary opinion as follows:

- Optimal assessment (follows NHSBSP protocols)
- Suboptimal assessment (minor deviation from NHSBSP protocols)
- Substandard assessment (significant deviation from NHSBSP protocols)
- Reassessment required (where review of assessment practice is being undertaken)

Statistical interpretation of false negative assessment rates

It is not routine practice or currently required to record rates of false negative assessments in the NHSBSP, either at unit or individual level.

There is no nationally agreed methodology of how to calculate missed cancer rates from assessment or definition of what “missed cancers” constitute.

The numbers of “missed cancers”, however defined, are likely to be extremely small at the individual level, even if many years performance are aggregated for comparison, which leads to inherent statistical instability.

Interval cancers which were previously assessed undergo radiological audit to categorise them into the following groups:

1. (normal/benign)
2. (uncertain)
3. (suspicious)

There is always a degree of subjectivity around categorisation which can compromise direct comparison of rates at the individual, screening service or regional level. Due to the very small numbers of cases which constitute false negative assessment interval cancers (category 3s), statistical analysis is difficult. The range of false negative assessment in the literature is varied and based on small scale studies (0.49% Ciatto, 0.56% Burrell, 0.76% Warren, 2.76% Duijm and 2.97% Duijm).

Screen detected cancers, which were previously assessed for the same abnormality, require completion of a “form 4”. Following audit of these cases, only those which have a categorical outcome of substandard assessment or requiring re-assessment may constitute “missed cancers”. Many cases of “false negative assessment” presented to the external review team were categorically not false negative due to presentation at a different site or side as previously assessed. A very small number of cases on review were for the same lesion although assessment at the time was optimal.

Section one: North West Quality Assurance Report (May 2014 report).

The data presented in the May 2014 report was neither adequate nor correctly analysed to draw conclusions about the performance of radiologists in UHMBT.

Table 1 in the May 2014 appeared to present the data whether or not the QA radiologists agreed with the findings of the radiologist who originally conducted the audit. This was not a helpful way to present the findings of their review of the assessment films.

A more appropriate way to present the data would have been to categorise the assessment films according to the agreed method.

- Category 1 – normal/benign
- Category 2 – Uncertain
- Category 3 – Suspicious
- Cancer at a different site.

The text of the document does refer to categorisation of the 24 cases in this way but does not present the data according to category and by radiologist and it is not possible to extract this information from the text of the document.

Table 1 and 2 below provides this information in this format. Table 1 is the findings of the External QA radiologists who re-read the 24 assessment cases as part of the PHE External Review into the North Lancashire and South Cumbria Breast Screening Programme (November 2014) . Table 2 presents the findings of the North West QA radiologists who wrote the North West QA report in May 2014 having extracted this data from their original data collection forms.

Table 1: Analysis A. Allocation of assessment films for 24 missed cancers (interval/screen detected cancers) to categories and by radiologist based on rereading of assessment films by external QA radiologists

RADIOLOGIST	Cat 1	Cat 2	Cat 3	Diff site	TOTAL
A	0	1	0	3	4
C	0	6*	5	4	15**
D	0	0	2	2	4
E	0	0	0	1	1
TOTAL	**0**	**7***	**7**	**10**	**24***

Includes 1 lymphoma case. Lymphomas are not primary breast cancers so they are not technically "interval cancers previously assessed". However, the lymphoma was present but not observed at

the previous assessment episode, hence the assessment was deemed sub-standard.

(Note: this data is the same information contained in Table 3 but presented in a different way)

Table 2: Analysis B Allocation of assessment films for 24 missed cancers (interval/screen detected cancers) to categories and radiologist based on N W QA reading of assessment films in May 2014.

RADIOLOGIST	Cat 1	Cat 2	Cat 3	Diff site	TOTAL
A	0	1	0	3	4
C	1	6	3	5	(+lymphoma)15
D	0	1	1	2	4
E	0	1	0	0	1
TOTAL	**1**	**9**	**4**	**10**	**24(including lymphoma)**

It should be noted that although the categorisation is different, that in the view of both external QA radiologists and the independent expert, this variation is an acceptable difference in categorisation of interval/screen detected cancers.

This does show a preponderance of category 2 and 3 for radiologist C. This should serve as an alert, but in itself is inadequate to judge whether or not performance is sub-standard. This is because the analysis does not use a denominator nor was the cohort of women to be included in the audit considered before the audit was conducted.

The North West QA report (May 2014) included a final line in the document which stated that the performance of radiologist C was comparable to other radiologists in the region. The rational for making this statement was not included in the report.

A subsequent analysis two days after the North West QA report (May14) was sent to the Medical Director. This was undertaken by the NW QARC data analyst, and compared the miss-cancer rate of NLSCBSP radiologists to all radiologists in the North West region for missed cancers during the period 2005 to 2009 (Appendix 1, Chart 1).

This analysis appeared to show radiologist C as an outlier as compared to other radiologists in the region for a missed cancer rate over the period 2005-2009 as confidence intervals for radiologist C appeared not to overlap with the confidence intervals

Commentary on analysis of missed cancer rates Appendix 1, Chart 1.

The calculation of confidence intervals in Chart 1 has been checked by an independent statistician and a clinical epidemiologist. Confidence Intervals have been recalculated Appendix 1, Chart 2.

They concluded that:

- The confidence intervals used by the North West QA were incorrect; the sample size assumed in the calculation of the standard error was the number of assessments rather than the number of cancers.
- There will inevitably be variation in performance across radiologists over and above sampling error. When compared to the distribution of miss rates of radiologists in the North West, the results for radiologist C, suggest performance at the lower end (higher miss rate) of the distribution. Interpretation is further complicated by the possibility that differences might be explained to some degree by factors such as age of women who were assessed.
- The other radiologists in UHMBT during the period 2005-9 exhibited performance at the upper end of the normal distribution and therefore comparing radiologist C just with radiologists at UHMBT could inadvertently make radiologist C appear to be a poor performer.

Commentary on presentation of data in North West QA report (May 2014)

Radiologist C's performance between 2005- 2011 at assessment judged on review of cases and benchmarking of data against other radiologists in the UHMBT is considered to be at the lower end of the distribution of performance and would not be considered an outlier.

The North West QA team's recommendation should have been that based on findings from the audit, further questioning of staff and their analysis of benchmarking data (recognising that this has subsequently shown to be flawed) that the current performance of radiologist C should be reviewed.

Section Two: External radiological review R1, R2, R3, R4, R5

R1: 24 interval cancers submitted for audit by the whistle- blower

Background

The precise methodology used by the whistleblower for identifying this audit group is uncertain. It appears that approximately 60 interval cancers with "form 4s" were reviewed (the time period is not known). The clients were initially assessed between 2005 and 2011. These 24 cases were all felt to represent false negative assessments and therefore brought for review.

Methodology

All 24 diagnostic symptomatic images were compared with images at previous assessment and the previous assessment process was reviewed using "form 4s" where appropriate. An interval cancer classification was assigned to all 24 cases as appropriate and compared to the classification which had been assigned by the UHMBT service.

Results:

Radiologist	Adequate Assessment at same side/site	False negative Assessment	Cancer presenting at different site previous adequate assessment	TOTAL
A	0	1	3	4
C	1	10*	4	15*
D	0	2	2	4
E	0	0	1	1
Total	1	13*	10	24*

Table 3: Outcome of audit of 24 interval cancer cases submitted for review

*Includes 1 lymphoma case. Lymphomas are not primary breast cancers so they are not technically "interval cancers previously assessed". However, the lymphoma was present but not observed at the previous assessment episode, hence the assessment was deemed sub-standard.

External Radiological Opinion

- 10 of 24 cases were categorised previously assessed interval cancers but they did not constitute false negative assessment as the cancer arose at a different site to the area of interest in the previous assessment episode. Hence “form 4” was not required for completion and there was a fundamental flaw in the audit methodology applied by the service.
- One difficult case was assessed previously for the same side and site but assessment was deemed adequate at the time.
- One case was a lymphoma which technically does not constitute a screen detected interval cancer. However, the management of this case at assessment was considered sub-standard.
- Of 13 false negative assessments, 10 were attributable to Radiologist C (which included the lymphoma case). Some of the cases raised concerns about mammographic interpretation of spiculate lesions, the quality of ultrasound scan images and ultrasound guided biopsy, and repeated under sampling at biopsy.
- All interval cancers were categorised by the external reviewers and their outcomes compared with the local UHMBT team. Category of interval cancer was upgraded in one quarter of cases reviewed; cat 1 to cat 2 (n. 3), cat 1 to cat 3 (n. 1), cat 2 to cat 3 (n. 2).

R2: Previously assessed cases (2005 – 2011) arising as interval cancers at the subsequent screen (2005 – 11)

Methodology

Audit period:	Women screened and assessed 1st April 2005 - 30th March 2008 arising as interval cancers between May 2005 and July 2011.
Cases reviewed:	65 / 67 cases available for review (Radiologists A, C, D, E, F). 20 of the cases reviewed here are also included in the review of “24 audit cases” which were initially presented for review by the whistleblower.
Appraisal of assessment:	Adequate assessment was defined as an appropriate process was followed such that another clinician working at the same time period would have felt it reasonable to arrive at the same outcome with the information available.

In parallel with the review of current assessment clinics management, all radiologists diagnostic practice was compared to standards and recommendations in the NHSBSP Guidance "Clinical guidelines for breast cancer screening assessment (second edition), publication 49, 2005. "Form 4s" are required for completion in the NHSBSP to audit cases which subsequently arise as interval cancers or screen detected cancers that were assessed at the previous screen for the ***same site and side*** (appendix 7). These forms were completed to establish whether assessment practice at the time was "optimal", "suboptimal" or "sub-standard".

Results

Outcomes of the external radiology review by individual clinician who performed the previous assessment are shown in table 4. As shown, of 65 cases deemed to be false negative assessment, only 24 were previously assessed at the same side and site as the subsequent presentation of cancer thus constituting cases mandatorily requiring audit from the service (completion of "form 4").

Assessor	Total Cases Reviewed	Diff. Side/ Site to Interval Cancer	Total	Same side/site as interval cancer but Optimal Assessment		Suboptimal Assessment		Substandard Assessment	
				Y	%	Y	%	Y	%
A	16	12	4	3	75.0	1	25.0	0	0.0
C	22	7	15	3	20.0	2	13.3	10*	66.7
D	20	16	4	0	0.0	2	50.0	2	50.0
E	6	5	1	1	100.0	0	0.0	0	0.0
F	1	1	0	0	0.0	0	0.0	0	0.0
Total	**65**	**41**	**24**	**7**	**29.2**	**5**	**20.8**	**12***	**50.0**

Table 4: Outcome of audit of 65 previously assessed interval cancers (arising as cancers May 2005-July 2011)

*Includes 1 lymphoma case. Lymphomas are not primary breast cancers so they are not technically "interval cancers previously assessed". However, the lymphoma was present but not observed at the previous assessment episode, hence the assessment was deemed sub-standard.

External Radiological Opinion

- 41/65 (63.0%) cases available for review did not constitute false negative assessment as they were previously assessed for a different site or feature
- 24/65 (37%) cases were previously assessed for the same site and same lesion. Of these, 7(29%) were felt to be optimally assessed previously, 5 (21%) were sub-optimal and 12 (50%) were deemed sub-standard assessment (one of which was a lymphoma)

R3: Previously assessed cases (2007-11) arising as screen detected cancers at the subsequent screen (2012-13)

Methodology

Audit period:	Women screened and assessed 1st April 2007 - 30th March 2011 arising as screen detected cancers between April 2012 and September 2013.
Cases reviewed:	25 / 27 cases were available for review (Radiologists A, B, C, D, E, F, G).
Appraisal of assessment:	Adequate assessment was defined as an appropriate process was followed such that another clinician working at the same time period would have felt it reasonable to arrive at the same outcome with the information available. In parallel with the review of current assessment clinics management, all radiologists diagnostic practice was compared to standards and recommendations in the NHSBSP Guidance "Clinical

guidelines for breast cancer screening assessment (second edition), publication 49, 2005. "Form 4s" are required for completion in the NHSBSP to audit cases which subsequently arise as interval cancers or screen detected cancers that were assessed at the previous screen for the ***same site and side*** (appendix 7). These forms were completed to establish whether assessment practice at the time was "optimal", "suboptimal" or "sub-standard".

Results

Assessed by	Total screen detected previously assessed	Total reviewed	Total screen detected same side/site	Optimal Assessment		Suboptimal Assessment		Sub-standard Assessment	
				Y	%	Y	%	Y	%
A	8	8	3	1	33.3	2	66.7	0	0.0
B	1	1	1	1	100.0	0	0.0	0	0.0
C	6	6	3	0	0.0	1	33.3	2	66.7
D	5	5	1	0	0.0	1	100.0	0	0.0
E	2	2	0	0	0.0	0	0.0	0	0.0
F	1	1	0	0	0.0	0	0.0	0	0.0
G	1	1	0	0	0.0	0	0.0	0	0.0
Unknown	3	1	0	0	0.0	0	0.0	0	0.0
Total	**27**	**25**	**8**	**2**	**225.0**	**4**	**50.0**	**2**	**25.0**

Table5: *Outcome of audit of 25 previously assessed screen detected cancers (arising as cancers April 2012-September 2013)*

External Radiological Opinion

- 17 of 25 (68%) cases available for review did not constitute false negative assessment as they were previously assessed for a different site or feature.
- 8 of 25 (32%) cases were previously assessed for the same site and same lesion. 2 were felt to have been optimally assessed previously, 4 sub-optimally and 2 were deemed to be sub-standard at the previous assessment episode.
- In the 2 substandard assessment cases, the initial screening mammogram features indicated biopsy was needed, but this was not performed at that time.

R4: Review of assessment practice most recent screening round

- No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)
- 6 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)
- Recall for repeat assessment was recommended for 2 cases.

R5: Review of assessment practice most recent screening round where routine recall without needle biopsy

- No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)
- 11 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)
- Recall for repeat assessment was recommended for one case

R6: Review of assessment practice most recent screening round where routine recall without needle biopsy

- No cases were classified as substandard assessment (significant deviation from NHSBSP protocols)
- 17 cases were classified as suboptimal assessment (minor deviation from NHSBSP protocols)
- Recall for repeat assessment was recommended for 3 cases.

Conclusions regarding assessment performance of radiologists prior to 2011

There is evidence that Radiologist C performance prior to 2011 (the current screening round) in individual assessment cases was sub-optimal and in some cases sub-standard. There were some recurring themes, even though the number of cases is small. Concerns about mammographic interpretation of spiculate lesions, the quality of ultrasound scanning and ultrasound guided core biopsy and repeated under sampling at biopsy were raised by the review.

The statistical data collected by North West QARC indicates that Radiologist C performance at assessment was at the lower end of the distribution for performance for radiologists in North West region for missed cancers during the period 2005 to 2008.

Radiologist F performance at assessment is also at the lower end of the distribution for performance of radiologists in the North West for missed cancer rates for the period 2005 to 2008.

Radiologist D and E's performance at assessment is at the higher end of the distribution for performance of radiologists in the North West for missed cancer rates for the period 2005 to 2008.

There is insufficient evidence to draw any further conclusions regarding Radiologist C, D, E or Fs performance at assessment as this review has only considered a small sample of these clinicians work during the period 2005 to 2011.

Recommendations

Findings contained in this data supplement should be used to inform the external review of current practice.

No further look back of assessment cases prior to 2011 should be undertaken as women who may have had their cancer missed during this period would have by now presented as either interval or screen detected cancers and there would be no value undertaking any further lookback.

Women who have had their interval and screen detected cancers reviewed as part of this audit and review should have their results communicated to them in line with national guidance, if not already done so.

Audits of interval cancers and screen detected cancers need to be done with appropriate methodology to ensure false conclusions are not drawn from results.

Analysis of data as ‘missed cancers’ is an unhelpful and potentially misleading way of presenting data. As with other screening programmes, sensitivity would be the preferred way to present this information.

APPENDIX 1

Chart 1: compiled by North West QARC – using incorrect confidence intervals.

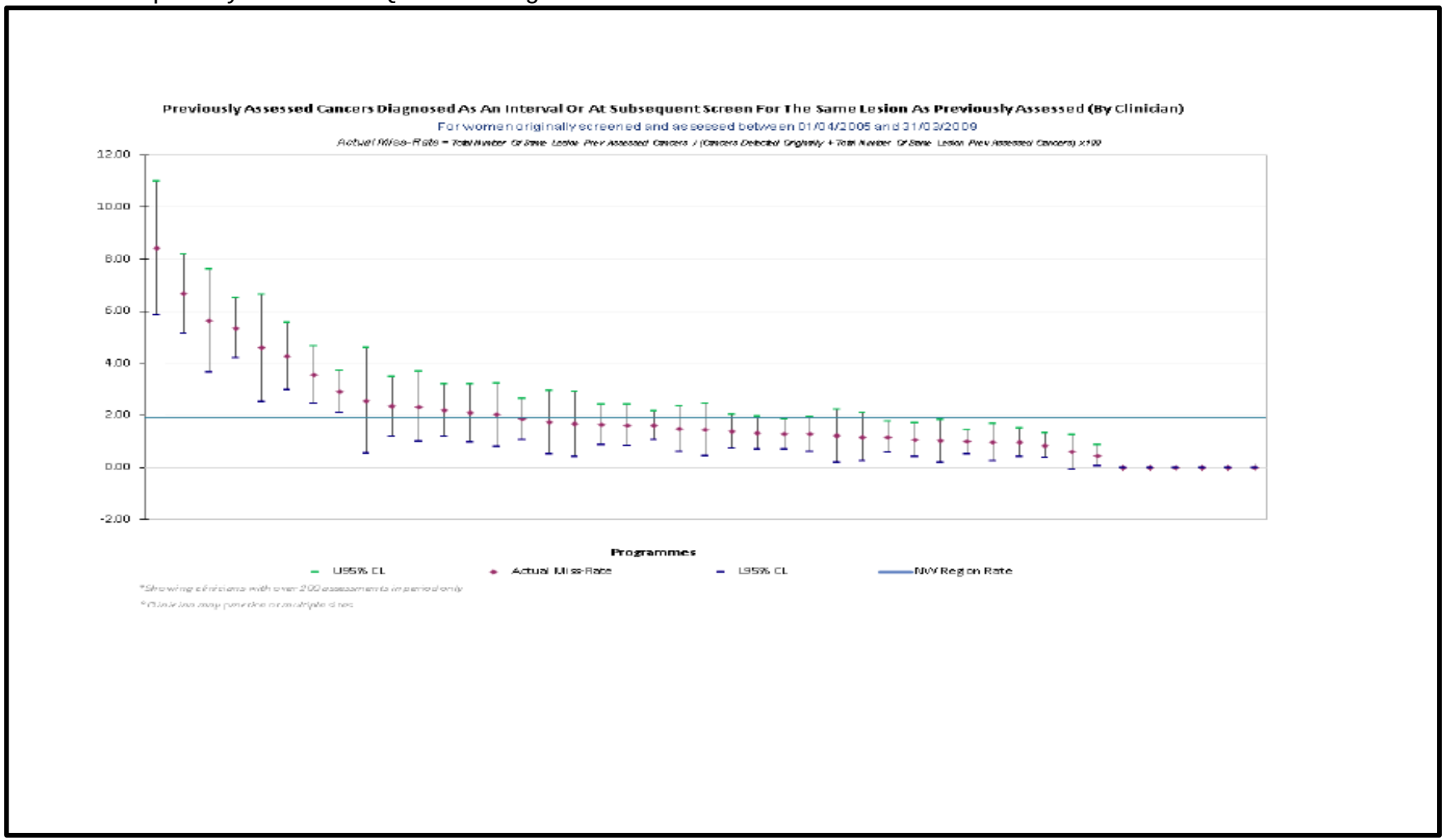

Chart 2: Same data recalculated using correct confidence intervals.
Estimated miss rates with 95% confidence intervals. The numbers above the intervals are the clinician IDs