

Investigation of mortality from Paediatric Cardiac Surgery in England 2009-12

8 April 2013



Dr David Cunningham
Senior Strategist, NICOR

Dr Rodney Franklin
Clinical lead for Congenital Heart Disease, NICOR

Mr Ben Bridgewater
Chairman, SCTS adult cardiac surgery database committee

Professor John Deanfield
Director, NICOR

with statistical advice and support from

Professor David Spiegelhalter,
Winton Professor of the Public Understanding of Risk
Statistical Laboratory, University of Cambridge

NICOR is the National Institute for Cardiovascular Outcomes Research. It is part of University College London and is based at 170 Tottenham Court Road, London W1T 7HA

All comments should be sent to Professor Deanfield by email: j.deanfield@ucl.ac.uk.

1. Introduction

NICOR's mission is to provide accurate data on cardiovascular outcomes for the public, healthcare providers and the medical profession. It hosts the National Congenital Heart Disease (CHD) registry which has been reporting adjusted outcomes for procedures for over a decade. The current analysis for outcomes for congenital heart surgery in England and Wales has been requested by NHS England to assist in their deliberations on CHD service provision.

2. Methods

- a) This report covers 2009-10, 2010-11 and 2011-12 as well as a composite 3 year performance for 2009-12. Comparison has been made between the 10 centres in England who undertake paediatric CHD surgery.

<u>Description</u>	<u>Reference name</u>
Alder Hey	ACH
Birmingham	BCH
Bristol	BRC
Freeman	FRE
Leicester	GRL
Great Ormond Street	GOS
Evelina	GUY
Leeds	LGI
Brompton	NHB
Southampton	SGH

Table A

- b) Outcomes are partially risk adjusted using a new model (Partial Risk Adjustment in Surgery; PRAiS) that estimates the risk of death within 30 days of a primary surgical procedure, based on specific procedure, age, weight and the patient recorded diagnoses and comorbidities (Crowe et al, JTVCS 2012 doi: 10.1016/J.JTCVS.2012.06.23). Outcomes over time are displayed using a bespoke version of the Variable Life Adjusted Display (VLAD) technique previously described. (Lovegrove et al 1997, The Lancet 350:1128-1130).
- c) Data include the total number of cases and the number of deaths within 30 days. Units vary widely in the complexity and risk of operations conducted, and so it is inappropriate to make comparisons based on crude mortality rates. The PRAiS system uses historical data to provide a PRAiS Expected number of deaths that allows for variation in case-mix – this is an important innovation from NICOR that, for the first time, allows proper risk-adjustment in this complex area.

- d) The ratio of Observed to PRAiS-Expected deaths is the Standardised Mortality Ratio (SMR), but this is based on historical levels of overall risk. In order to make comparisons within each year, the PRAiS-Expected numbers of deaths are re-calibrated by dividing by the overall SMR for all cases in England for that time period to create an Expected Mortality – this is still the PRAiS system, but adjusted for the period.
- e) The Relative Risk (RR) is the Observed number of deaths divided by the Expected deaths, and provides a comparison with national average risks during each period. The Average Risk is the Expected deaths divided by the number of cases, and is intended to give a reflection of caseload complexity. Only cases with a life status at 30 days validated by ONS tracking have been included.
- f) Results are shown using 'funnel plots', which relate the relative risk to the total expected number of deaths. Units inside the funnel have a relative risk that is not 'significantly' different from average - a raised relative risk could be due to chance alone. Units outside the 'funnel' merit attention. The funnel shape arises because Units to the left of the plot are smaller and so we would expect more variability due to chance.

3. Data Extraction

- a) There was a clear process for data submission to NICOR by individual Trusts with a CQC mandated deadline of 1 June 2012 for 2011/12 data. Following this deadline, a period of two months was allowed for units to ensure their data quality was optimised.
- b) A patient-anonymised data extract was taken in August 2012 and used to generate the analyses for 2011-12. Previous years followed a similar pattern.
- c) It was clear to the NICOR Steering Group that there were major deficiencies in the data submitted by Leeds (as exemplified by Table B). This has been addressed as actively as possible in the intervening period, as part of NICOR's process to optimize data quality.
- d) The new data included in the current analysis of 07/04/13 is the reason for the difference in the outcomes for individual Trusts from the preliminary data. The effectiveness of the data submission process could be considered as a measure of organizational culture and commitment to quality service delivery.

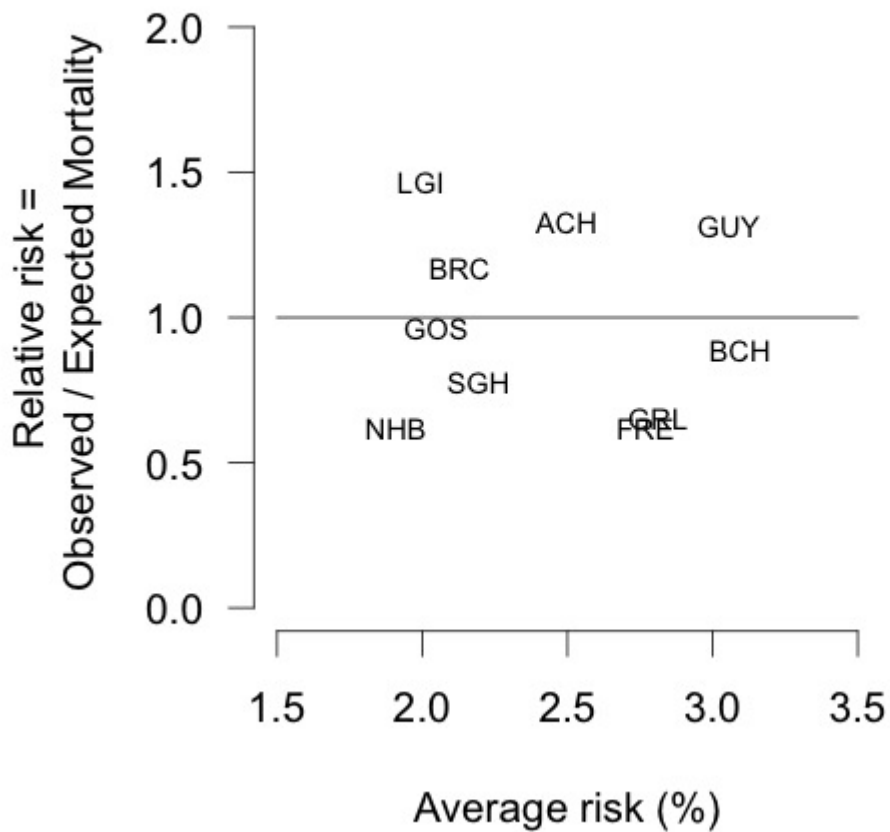
Unit	Missing weight in 2011-12 data
BRC	0%
GOS	0%
GUY	0%
NHB	0%
RAD	0%
SGH	0%
ACH	0.3%
GRL	0.5%
BCH	1.2%
FRE	1.4%
LGI	34.7%

Table B: data as submitted August 2012

4. Results

- a) The figure below shows the Relative Risk plotted against the Average Risk (measuring the complexity of cases seen by each Unit). There is no evidence that the complexity of cases is related to the Relative Risk, suggesting the PRAiS risk-adjustment system is compensating for Units taking on more difficult cases.

Congenital Heart Surgery 2009-2012



b) Outcomes For 2009-10

England 2009-10

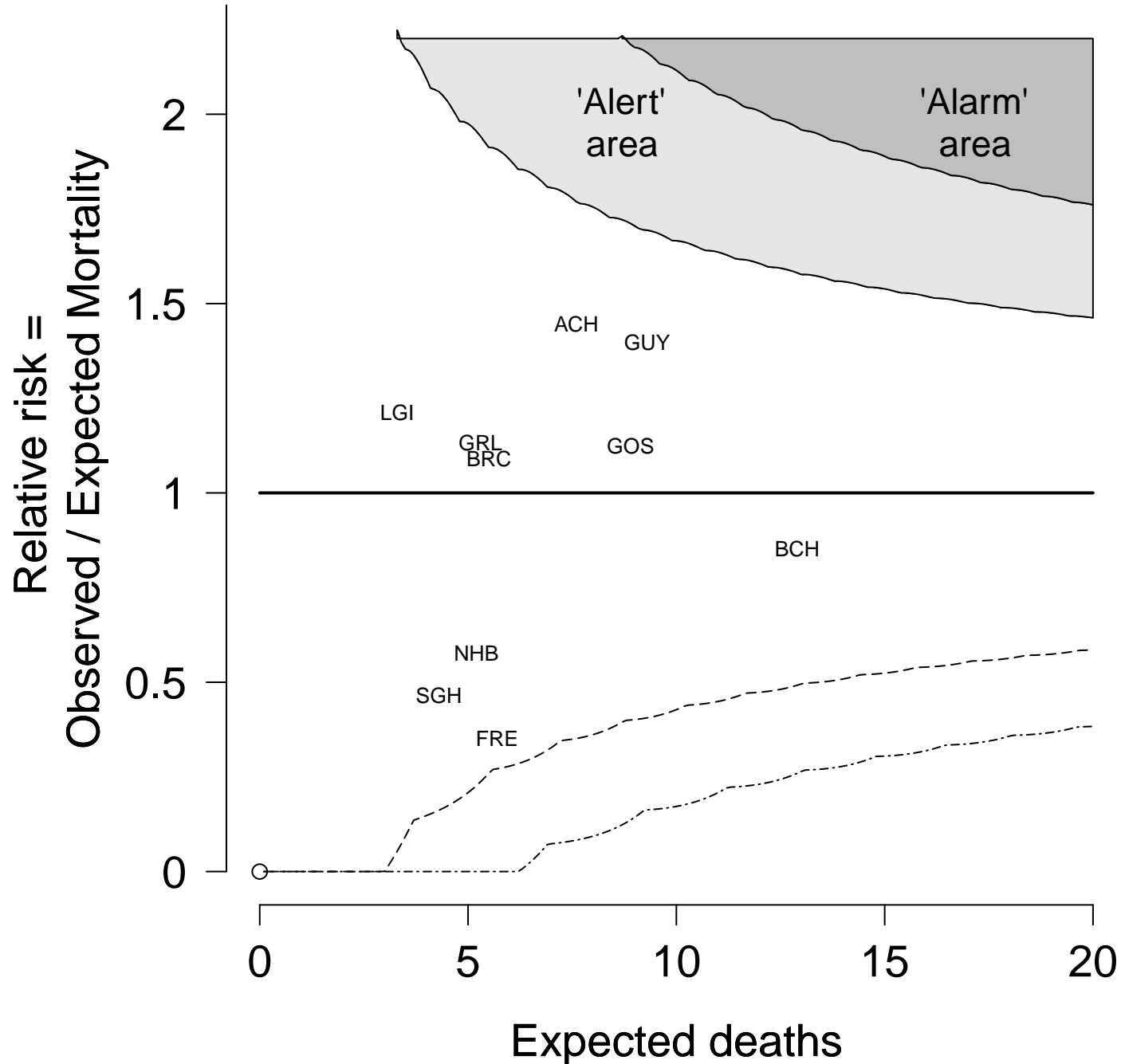
Cases	3178
Expected deaths	93.65
Observed deaths	68
SMR	72.6%

Unit	Cases	Observed Deaths	Crude Mortality Rate	PRAiS Expected Deaths	PRAiS-generated SMR	Expected (recalibrated) Deaths	Average Risk	Relative Risk	Poisson mid p-value
ACH	384	11	2.9%	10.4	105.8%	7.6	2.7%	1.46	0.112
BCH	504	11	2.2%	17.8	61.9%	12.9	3.5%	0.85	0.690
BRC	268	6	2.2%	7.6	78.7%	5.5	2.8%	1.08	0.396
FRE	224	2	0.9%	7.8	25.5%	5.7	3.5%	0.35	0.949
GRL	218	6	2.8%	7.3	82.5%	5.3	3.3%	1.14	0.360
GOS	483	10	2.1%	12.3	81.3%	8.9	2.5%	1.12	0.345
GUY	329	13	4.0%	12.8	101.3%	9.3	3.9%	1.40	0.118
LGI	215	4	1.9%	4.5	87.9%	3.3	2.1%	1.21	0.322
NHB	332	3	0.9%	7.1	42.0%	5.2	2.1%	0.58	0.822
SGH	213	2	0.9%	5.9	34.0%	4.3	2.8%	0.47	0.864

The **Poisson mid-p** value indicates the probability of observing such an extreme relative risk if the Unit was actually 'average' – values less than 0.025 have traditionally indicated an 'alert' and values less than 0.001 an 'alarm'.

All data is risk adjusted using the PRAiS model.

Congenital Heart Surgery 2009–2010



An average Unit has a 1 in 40 chance of being in the 'Alert' area, and 1 in 1000 chance of 'Alarm' area

c) Outcomes for 2010-11

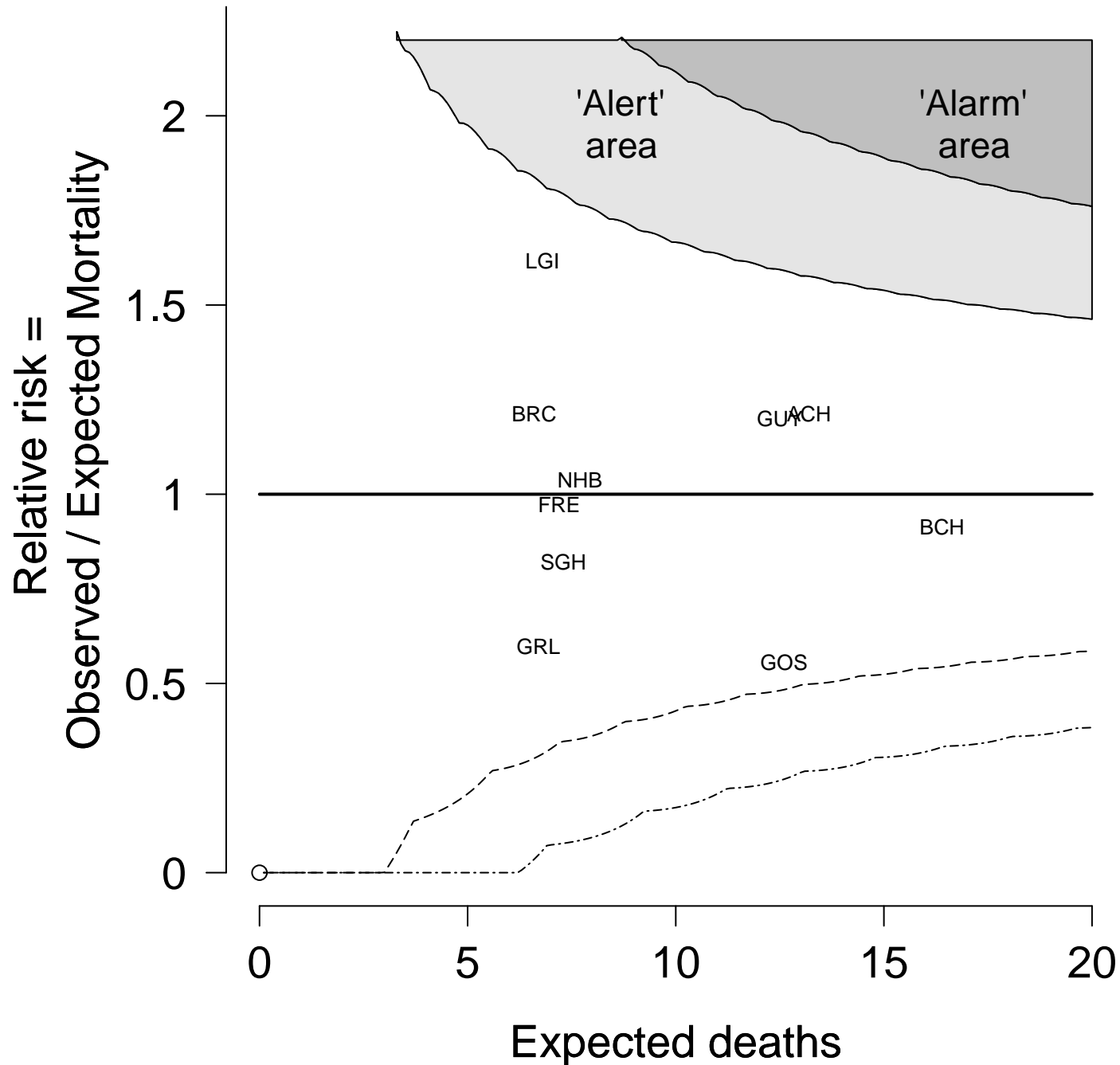
England 2010-11

Cases	3416
Expected deaths	100.62
Observed deaths	98
SMR	97.4%

Unit	Cases	Observed Deaths	Crude Mortality Rate	PRAiS Expected Deaths	PRAiS-generated SMR	Expected (recalibrated) Deaths	Average Risk	Relative Risk	Poisson mid p-value
ACH	418	16	3.8%	13.5	118.4%	13.1	3.2%	1.22	0.213
BCH	408	15	3.7%	16.7	90.0%	16.3	4.1%	0.92	0.608
BRC	300	8	2.7%	6.7	119.1%	6.5	2.2%	1.22	0.271
FRE	242	7	2.9%	7.3	96.2%	7.1	3.0%	0.99	0.492
GRL	204	4	2.0%	6.8	58.6%	6.6	3.3%	0.60	0.843
GOS	516	7	1.4%	12.8	54.6%	12.5	2.5%	0.56	0.947
GUY	356	15	4.2%	12.7	117.8%	12.4	3.6%	1.21	0.223
LGI	308	11	3.6%	6.9	158.8%	6.7	2.2%	1.63	0.061
NHB	357	8	2.2%	7.9	101.0%	7.7	2.2%	1.04	0.434
SGH	292	6	2.1%	7.4	80.5%	7.2	2.5%	0.83	0.653

The **Poisson mid-p** value indicates the probability of observing such an extreme relative risk if the Unit was actually 'average' – values less than 0.025 have traditionally indicated an 'alert' and values less than 0.001 an 'alarm'. All data is risk adjusted using the PRAiS model.

Congenital Heart Surgery 2010–2011



An average Unit has a 1 in 40 chance of being in the 'Alert' area, and 1 in 1000 chance of 'Alarm' area

d) Outcomes for 2011-12

England 2011-12

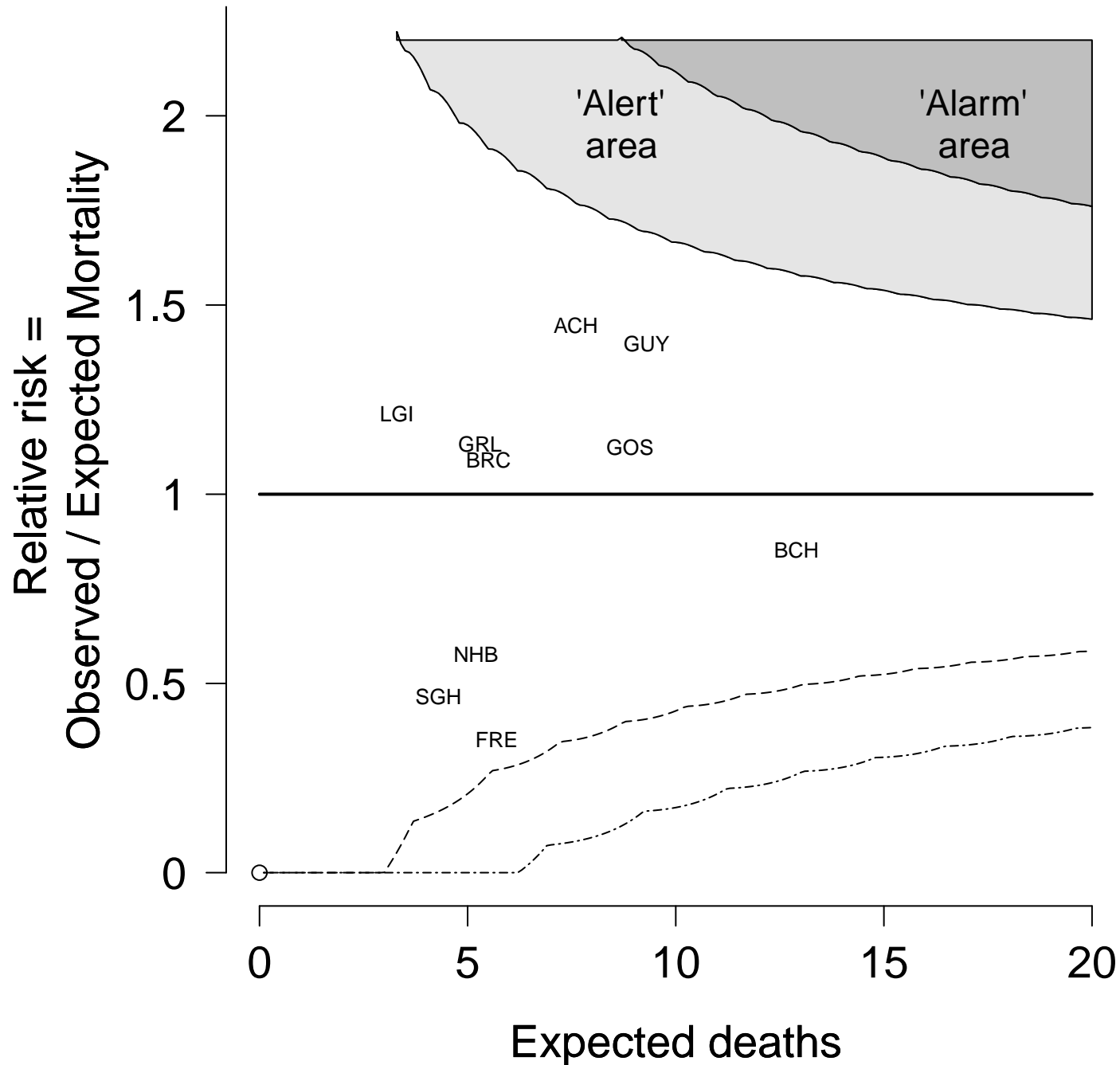
Cases	3359
Expected deaths	98.9
Observed deaths	78
SMR	78.9%

Unit	Cases	Observed Deaths	Crude Mortality Rate	PRAiS Expected Deaths	PRAiS-generated SMR	Expected (recalibrated) Deaths	Average Risk	Relative Risk	Poisson mid-p-value
ACH	375	12	3.2%	11.3	106.2%	8.9	3.0%	1.35	0.153
BCH	432	11	2.5%	15.4	71.4%	12.1	3.6%	0.91	0.611
BRC	273	7	2.6%	7.2	97.7%	5.7	2.6%	1.24	0.278
FRE	231	3	1.3%	8	37.7%	6.3	3.5%	0.48	0.912
GRL	179	1	0.6%	6.1	16.3%	4.8	3.4%	0.21	0.972
GOS	574	14	2.4%	13.5	103.4%	10.6	2.4%	1.31	0.154
GUY	359	14	3.9%	12.7	110.2%	10.0	3.5%	1.40	0.111
LGI	299	9	3.0%	8.2	109.8%	6.5	2.7%	1.39	0.162
NHB	322	1	0.3%	8.1	12.4%	6.4	2.5%	0.16	0.993
SGH	315	6	1.9%	8.3	72.7%	6.5	2.6%	0.92	0.559

The **Poisson mid-p** value indicates the probability of observing such an extreme relative risk if the Unit was actually 'average' – values less than 0.025 have traditionally indicated an 'alert' and values less than 0.001 an 'alarm'.

All data is risk adjusted using the PRAiS model.

Congenital Heart Surgery 2011–2012



An average Unit has a 1 in 40 chance of being in the 'Alert' area, and 1 in 1000 chance of 'Alarm' area

e) Outcomes 2009-12

England 2009-12

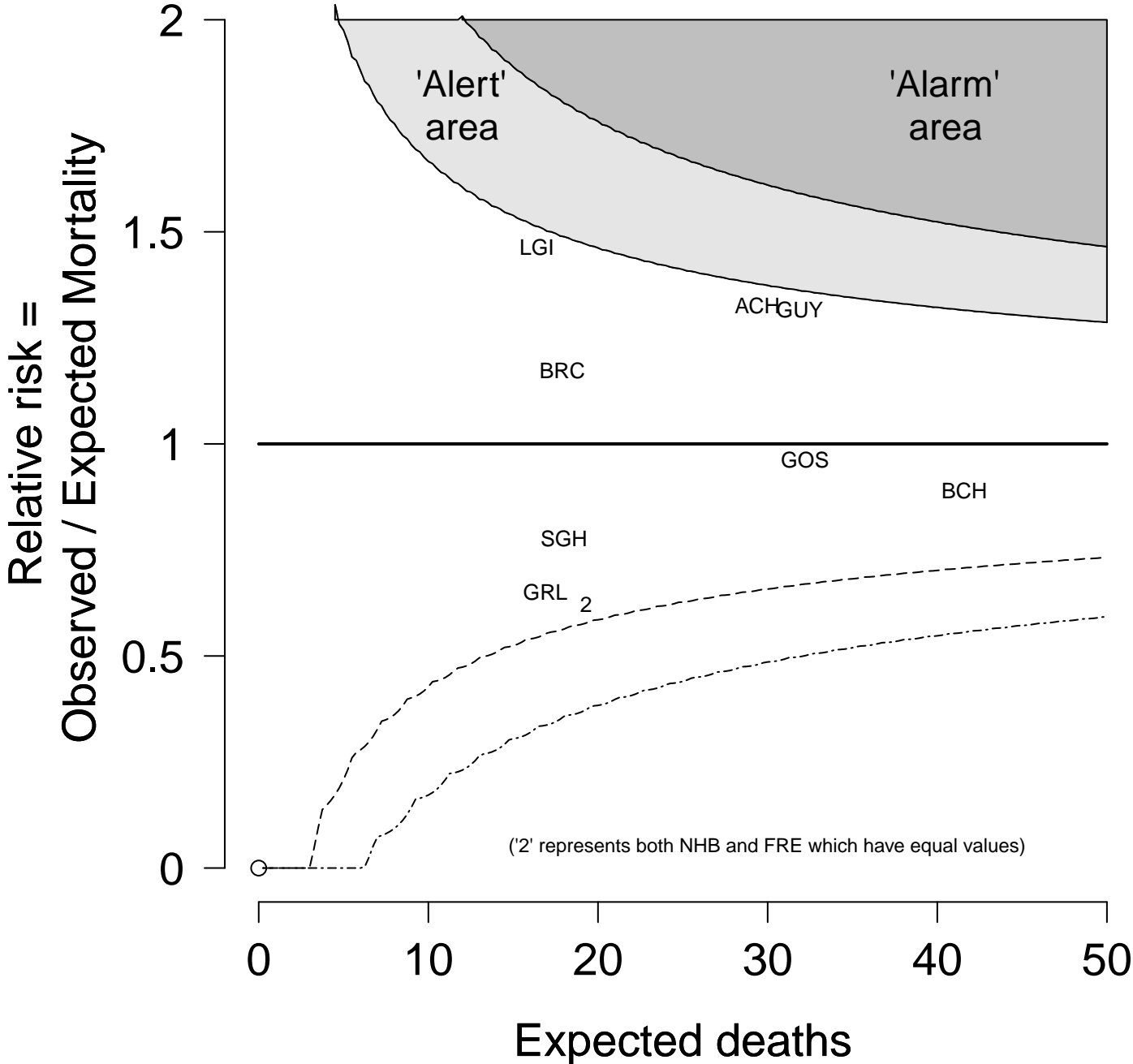
Cases	9930
Expected deaths	291
Observed deaths	243
SMR	83.5%

Unit	Cases	Observed Deaths	Crude Mortality Rate	PRAiS Expected Deaths	PRAiS-generated SMR	Expected (recalibrated) Deaths	Average Risk	Relative Risk	Poisson mid p-value
ACH	1177	39	3.3%	35.2	110.8%	29.4	3.0%	1.33	0.044
BCH	1344	37	2.8%	49.9	74.1%	41.7	3.7%	0.89	0.761
BRC	841	21	2.5%	21.5	97.7%	18.0	2.6%	1.17	0.232
FRE	697	12	1.7%	23.1	51.9%	19.3	3.3%	0.62	0.958
GRL	601	11	1.8%	20.2	54.5%	16.9	3.4%	0.65	0.929
GOS	1573	31	2.0%	38.6	80.3%	32.2	2.5%	0.96	0.575
GUY	1044	42	4.0%	38.2	109.9%	31.9	3.7%	1.32	0.042
LGI	822	24	2.9%	19.6	122.4%	16.4	2.4%	1.47	0.037
NHB	1011	12	1.2%	23.1	51.9%	19.3	2.3%	0.62	0.958
SGH	820	14	1.7%	21.6	64.8%	18.0	2.6%	0.78	0.827

The **Poisson mid-p** value indicates the probability of observing such an extreme relative risk if the Unit was actually 'average' – values less than 0.025 have traditionally indicated an 'alert' and values less than 0.001 an 'alarm'.

All data is risk adjusted using the PRAiS model.

Congenital Heart Surgery 2009–2012



An average Unit has a 1 in 40 chance of being in the 'Alert' area, and 1 in 1000 chance of 'Alarm' area

5. Conclusions

- Using data available on 05/04/13, no centre crosses the standard criterion for an 'alert', neither in individual years nor for the pooled 3 year period.
- By definition, around half of all Units will have more deaths than 'expected'. It is therefore inappropriate to label centres as 'blameworthy' for these deaths, as the analysis does not show a significantly increased mortality rate.
- In 2011-12, LGI experienced nine 30-day deaths compared to 6.5 expected (recalibrated). This is compatible with chance variation.
- Over the pooled 3-year period 2009-2012, LGI experienced 24 deaths compared to 16.5 expected (recalibrated), a relative risk of 1.46. With this pooled data, they were very close to the 'alert' threshold, as were 2 other centres.
- These findings do not indicate a 'safety' problem in any centre.
- However, centres with 3-year outcomes approaching the alert threshold may deserve additional scrutiny and monitoring of current performance.

6. Comments

- Data submission by individual Trusts to NICOR has been very variable. Leeds have underperformed consistently in this regard. The data submission could be considered as a measure of the organisation and commitment to Quality Service delivery and excellence by Trusts. Additional data from all centres is being submitted, with a 'window' until 19 April 2013 to allow full PRAiS methodology to be used. We do not, however, expect this to change materially the output of the current analysis of 7 April 2013.
- PRAiS software represents an incremental advance in risk adjustment for CHD surgery. It has undergone prospective validation, but will be further refined and tested with use. It has been made available to all 10 Trusts and will be installed within the next month to facilitate local QC/QA.
- The data in this analysis provides a good guide to centre performance with respect to operative mortality. The data should, however, not be considered in isolation when judging unit overall performance.