UK Shunt Registry

Draft Report 2017

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1. Executive Summary

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1.2 UKSR Database
This Draft Report summarizes the findings from 78,415 returns (44 units; 80.3% reporting rate; 53,767 procedures in 29,341 patients performed between 1st January 1995 and 31st December 2014.

1.3 Proportion of primary and revision procedures
There were some 3000 shunt operations in the UK each year: 1660 paediatric (33.5% primary and 66.5% revisions) and 1400 adult (53% primary and 47% revisions).

1.4 Diagnoses
The reasons for a shunt procedure included malformations, cysts, tumours, trauma, infection, intracranial haemorrhage and idiopathic intracranial hypertension in children and, in addition in adults, normal pressure hydrocephalus and miscellaneous.

1.5 Procedures
By far the commonest procedure was a ventriculo-peritoneal shunt.

1.6 Cumulative revision rates for children and adults
The cumulative revision rates for primary shunt procedures at all time points were significantly greater in children than in adults and for subsequent revisions.

1.7 Adjustable valves
There has been a progressive increase in the use of adjustable valves since their introduction into the UK market in the late 1980's and now accounts for some 40% in adults and some 15% in children. The cumulative revision rates for paediatric patients indicate no advantage for adjustable valves whereas in adults of all ages but especially aged 70 and over, there is a significant advantage in using an adjustable valve. Further analysis is in progress to adjust for case-mix, patient selection and the transition through the teenage years for which the use of different types of valve may be important.

1.8 Endoscopic third ventriculostomy
ETV appears to have a significant revision rate comparable to valved shunts. Further statistical modeling is in progress to tease out the revision rates in matched patient groups.

1.9 Reasons for revision
Underdrainage is by far the commonest reason for revision. Revisions for shunt infection take place early whereas revisions for underdrainage, overdrainage, disconnection, migration and particularly shunt fracture have a longer time course. The low incidence and long time course of overdrainage and mechanical problems (disconnection, migration and fracture) will render randomized controlled trials difficult to complete on a UK basis alone.

1.10 Infection risk
The reported overall infection risk for shunt procedures is 5.1% for children (primary 3.7%; revision 5.9%) and 2.6% for adults (primary 1.3%; revision 4.0%). There has been a reduction in infection risk since 2009.

1.11 Antibiotic coated catheters

There has been a progressive increase in the use of antibiotic-coated catheters since their introduction in 2001 that has plateaued at about 65% for adults and 55% for children. Antibiotic-impregnated catheters have been associated with a significantly reduced shunt infection risk but other factors have probably also played an important role (eg seniority of the operating surgeon, theatre protocols, skin preparation, prophylactic antibiotics).

1.12 Seniority of operating surgeon

There has been a profound increase in Consultant involvement during shunt surgery since 1995 from under 2% to over 70% (adult) and over 80% (paediatric).

1.13 Variation in risk of revision during the year

There is very little variation in infection risk or cumulative revision rate throughout the year.

1.14 Out of hours working.

There is a suggestion of a slightly higher infection risk and one-year cumulative revision rate at the weekend and out of hours. However, there is a greater proportion of shunt revisions performed out of hours (64.0%) than during the working week (48.3%). The one year cumulative revision rate for adults is 14% for primary procedures and 34% for revisions. The infection rate for adult primary procedures is 1.3% whereas it is 4% for adult revisions. The proportion of patients aged over 70 years is 13.0% during working hours and 8.1% out of hours. Both infection rate and cumulative revision rate is lower in the over 70's than in children and adults under 70 years of age. Further statistical modeling is in progress.

1.15 Performance of individual Centres.

There were no centres that were a cause for serious concern. However, there was considerable variance between centres that suggests that there is scope for learning between centres as promoted by the *Get It Right First Time* initiative (GIRFT).

1.16 The way forwards

The UKSR under the auspices of the SBNS and the British CSF Group has moved from a paper-based reporting system to the ORION-based electronic reporting system that will

- inform patients, carers, clinicians, providers and commissioners of healthcare, regulators, and implant suppliers of the outcomes achieved in surgical interventions for 'hydrocephalus',
- provide participating centres with a local reference and audit resource, including live data access and independent data for the shunt infection CQUIN measure,
- enhance patient awareness of outcomes after surgical interventions for 'hydrocephalus' to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations,
- facilitate registry-based trials, and
- support suppliers with the routine post market surveillance of implants and provide information to clinicians, patients, hospital management/procurement and the regulatory authorities.

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2. Introduction

We are delighted to share this Draft UK Shunt Registry Report 2017 with all members of the SBNS and the British CSF Group - draft because it is very much a work in progress that hopefully will encourage your active involvement. This Draft Report summarizes many of the findings from the first 20 years of the UKSR prior to its transition from paper-based to electronic reporting during 2015-2017. Considerable effort has been dedicated over the past year to cleaning up the database and updating compliance with the ever-evolving national governance mechanisms. A previous draft has been shared with the SBNS Council and with the lead for '*Get in Right First Time*'.

The UK Shunt Registry (UKSR) for hydrocephalus and other disorders of the circulation of cerebrospinal fluid was created in the early 1990's driven by concerns over unexpected deaths, particularly in teenagers (Tomlinson P, Sugerman ID . BMJ 1995;311:286-7), and high rates of infection and revision. Following extensive consultation (1989-1992) with relevant parties including ASBAH (now SHINE), the Society of British Neurological Surgeons (SBNS) and the British Association of Paediatric Surgeons (BAPS), the UKSR was established in 1993 as a pilot audit project under the auspices of the Medical Audit Committee of the East Anglian Regional Health Authority (O'Kane MC, Richards H, Winfield P, Pickard JD. Eur J Pediatr Surg. 1997 Dec;7 Suppl 1:56). Acceptance by the neurosurgical community was facilitated by the goodwill generated by the clinical audit of the Hakim programmable valve by the United Kingdom and Ireland Medos shunt audit group (Kay AD, Fisher AJ, O'Kane C, Richards HK, Pickard JD; Br J Neurosurg. 2000;14(6):535-42). Importantly, the UK shunt registry has not had to resort to 'naming and shaming' when feeding back results to individual centres.

The UK Shunt Registry was developed in parallel with the UK Shunt Evaluation Laboratory, also based in Cambridge (Chari A, Czosnyka M, Richards HK, Pickard JD, Czosnyka ZH. Hydrocephalus shunt technology: 20 years of experience from the Cambridge Shunt Evaluation Laboratory. J Neurosurg. 2014 Mar;120(3):697-707).

The Medical Devices Agency (now MHRA) recognized that its Incident Reporting Mechanism did not capture the great majority of complications of shunt implants. Hence, after the UKSR's successful pilot phase, the MDA started to contribute to its funding in 1994 in partnership with a subscription-based system shared between the contributing neurosurgery units in the UK and data access agreements with industry. This subscription-based system has proven sustainable over the long term albeit with some reinforcement.

The aims of the UKSR have been to

- define current practice in order to inform state of the art long term management of shunts and endoscopic third ventriculostomy,
- provide an accurate picture of different types of shunt,
- identify, in collaboration with the UK Shunt Evaluation Laboratory, substandard shunt systems,
- provide anonymised audit of individual centres, and
- develop criteria for risk stratification to inform future clinical trials.

At various times, the UKSR has been called upon to inform official bodies such as NHS Commissioners and the Competition and Markets Authority.

The UKSR has been followed by the creation of other Registries in Sweden (Swedish Hydrocephalus Quality Registry for adults over 18 years of age established in 2004; Sundstrom N et al. Brit J Neurosurgery 2017;31:21-27) and Australasia (nsa.org.au; 2016). In North America, there are the paediatric and adult hydrocephalus clinical research networks (founded in 2008 and 2012; hcrn.org and ahcrn.org respectively). On ClinicalTrials.Gov, there is reference to two completed Registries sponsored by Codman and Shurtleff: a Normal Pressure Hydrocephalus Registry (2004 – 2008 with recruitment of 343 patients to

define current practice patterns) and a Registry for comparing catheter-related infection rates among various shunt systems in the treatment of hydrocephalus 2006-2008 with recruitment of 433 patients).

Going forwards, the UKSR under the auspices of the SBNS and the British CSF Group has moved from a paper-based reporting system to the ORION-based electronic reporting system (see section 7).

Sir John Bell has emphasised the importance of Registries in his newly published *Life Sciences Industrial Strategy (2017):*
'National Registries of therapy-area-specific data across the whole of the NHS in England should be created and aligned with the relevant charity'.

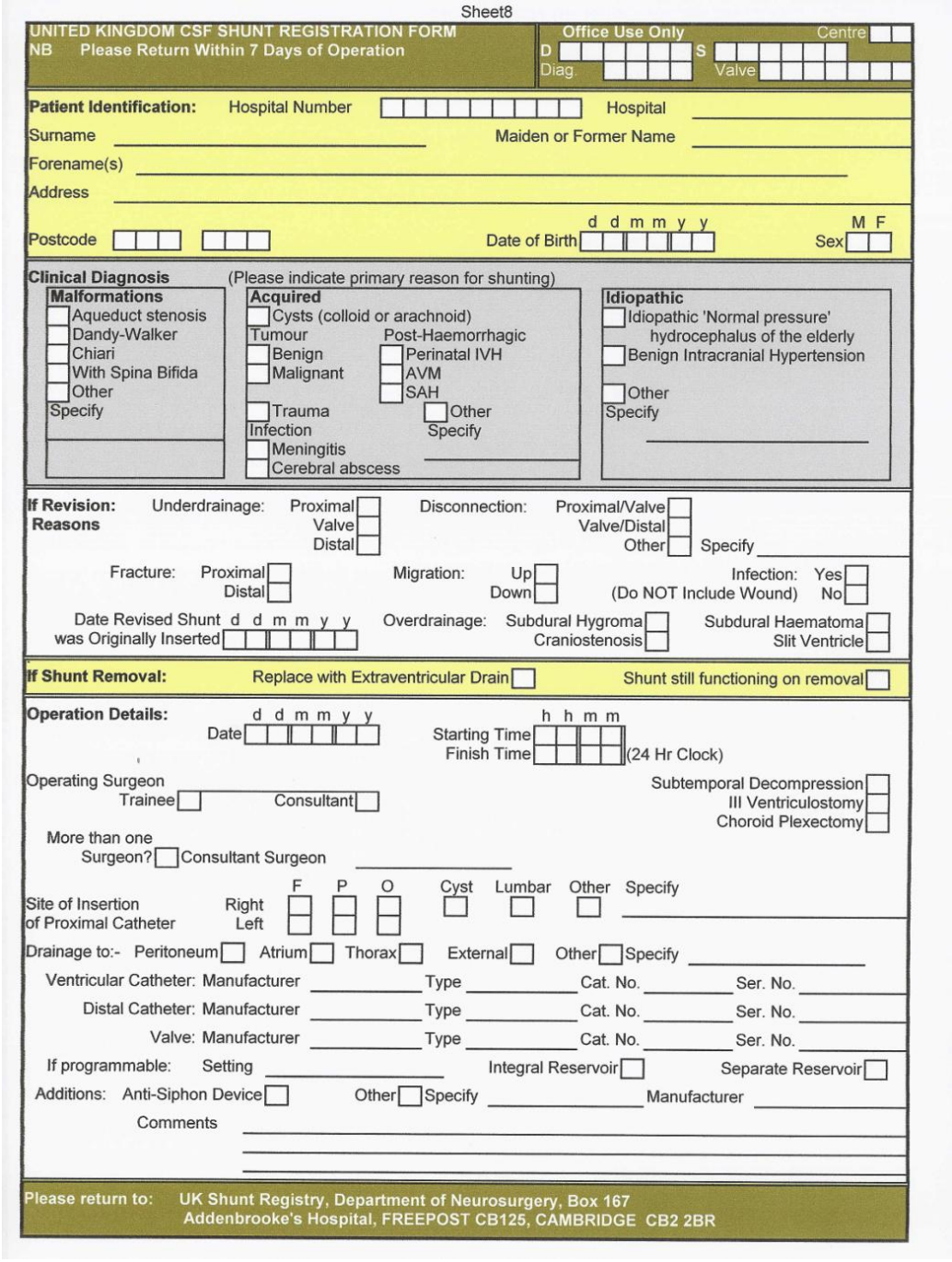
The SBNS in general and the UKSR in particular are well placed to fulfil this mission.

3. Source of data and database

During its pilot phase, the UKSR created a one-page form that seeks to capture all the essential data about operations for CSF related disturbances including:

- diagnosis,
- shunt insertions (including EVD prior to or following shunt removal)
- product details
- all shunt revisions including
    - shunt removal
    - reconnection
    - ligation
    - externalisation
    - insertion of reservoir and/or antisiphon device
- endoscopic third ventriculostomy (ETV), choroid plexectomy and subtemporal decompression.

The form has been updated in the light of experience and feedback (figure 1):



Sheet8

UNITED KINGDOM CSF SHUNT REGISTRATION FORM
NB Please Return Within 7 Days of Operation

Office Use Only — Centre ☐☐ — D ☐☐☐☐☐☐ S ☐☐☐☐☐☐ — Diag. ☐☐☐☐ — Valve ☐☐☐☐☐☐

Patient Identification: Hospital Number ☐☐☐☐☐☐☐☐☐☐ Hospital _____

Surname _____ Maiden or Former Name _____

Forename(s) _____

Address _____

Postcode ☐☐☐ ☐☐☐ Date of Birth d d m m y y ☐☐☐☐☐☐ Sex M F ☐☐

Clinical Diagnosis (Please indicate primary reason for shunting)

Malformations
- ☐ Aqueduct stenosis
- ☐ Dandy-Walker
- ☐ Chiari
- ☐ With Spina Bifida
- ☐ Other

Specify

Acquired
- ☐ Cysts (colloid or arachnoid)

Tumour
- ☐ Benign
- ☐ Malignant
- ☐ Trauma

Infection
- ☐ Meningitis
- ☐ Cerebral abscess

Post-Haemorrhagic
- ☐ Perinatal IVH
- ☐ AVM
- ☐ SAH
- ☐ Other

Specify _____

Idiopathic
- ☐ Idiopathic 'Normal pressure' hydrocephalus of the elderly
- ☐ Benign Intracranial Hypertension
- ☐ Other

Specify _____

If Revision: Reasons

Underdrainage: Proximal ☐ Valve ☐ Distal ☐

Disconnection: Proximal/Valve ☐ Valve/Distal ☐ Other ☐ Specify _____

Fracture: Proximal ☐ Distal ☐

Migration: Up ☐ Down ☐

Infection: Yes ☐ No ☐ (Do NOT Include Wound)

Date Revised Shunt was Originally Inserted d d m m y y ☐☐☐☐☐☐

Overdrainage: Subdural Hygroma ☐ Craniostenosis ☐

Subdural Haematoma ☐ Slit Ventricle ☐

If Shunt Removal: Replace with Extraventricular Drain ☐ Shunt still functioning on removal ☐

Operation Details:

Date d d m m y y ☐☐☐☐☐☐

Starting Time h h m m ☐☐☐☐

Finish Time ☐☐☐☐ (24 Hr Clock)

Operating Surgeon

Trainee ☐ Consultant ☐

Subtemporal Decompression ☐
III Ventriculostomy ☐
Choroid Plexectomy ☐

More than one Surgeon? ☐ Consultant Surgeon _____

Site of Insertion of Proximal Catheter: Right / Left — F ☐ P ☐ O ☐ — Cyst ☐ Lumbar ☐ Other ☐ Specify _____

Drainage to:- Peritoneum ☐ Atrium ☐ Thorax ☐ External ☐ Other ☐ Specify _____

Ventricular Catheter: Manufacturer _____ Type _____ Cat. No. _____ Ser. No. _____

Distal Catheter: Manufacturer _____ Type _____ Cat. No. _____ Ser. No. _____

Valve: Manufacturer _____ Type _____ Cat. No. _____ Ser. No. _____

If programmable: Setting _____ Integral Reservoir ☐ Separate Reservoir ☐

Additions: Anti-Siphon Device ☐ Other ☐ Specify _____ Manufacturer _____

Comments _____

Please return to: UK Shunt Registry, Department of Neurosurgery, Box 167
Addenbrooke's Hospital, FREEPOST CB125, CAMBRIDGE CB2 2BR

In addition, access to ONS data has been key to

- correcting the 'denominator' in Kaplan-Meier statistical analyses,
- informing the development of protocols for long term management of patients with disorders of the CSF circulation and
- informing the post-marketing surveillance process and providing independent information for the MHRA.

Consent

Historically, individual patient consent has not been required because the UKSR has had audit status as confirmed by the Cambridge LREC to the ONS in 1996. Section 60 approval (MR523) was given in 2005. Relevant section 251 approval has been granted by the Confidentiality Advisory Group (15/CAG/0166; June 9th 2017).

It is important to recognise that the UKSR provides a mechanism that may prove helpful in the direct care of an individual patient in compliance with Dame Fiona Caldicott's recommendations for data protection. The UKSR receives enquiries from neurosurgery units looking after specific patients about details of their shunts. The UKSR has been used by the MDA/MHRA to identify patients whose shunt system has been identified as substandard.

The UKSR is in the final stages of transition from its original paper-based system to an electronic system hosted on the ORION platform that includes a consent-based approach (see section 7 for further details).

Database

All data has been entered in to a dedicated database (PATS, Dendrite Clinical Systems UK) hosted on a secure server (Cambridge University Hospitals Foundation Trust). All those involved in the UKSR comply with the requirements of the Data protection Act 1998 and the NHS Act 2006.

This Report is based on anonymised data downloaded from the master database on 23rd January 2015. On that date, the database contained data from 78,415 procedures in 46,690 patients. This includes procedures from the pilot phase of the Registry and also some patients who were implanted with extra-ventricular drains (EVD) only. A working dataset for shunt procedures was prepared by identifying patients who had an insertion of a valved shunt. All procedures subsequent to this primary insertion were selected. For the purpose of this report a shunt-related procedure is defined as all procedures subsequent to the initial insertion of a CSF Shunt. Therefore patients identified as having an EVD only were not included in analyses. An EVD inserted prior to a full shunt system was also excluded. Therefore a shunt system inserted following an initial EVD does not count as a shunt revision, whereas an EVD used to replace a shunt does count as a revision, except where the form stated that the shunt was still functioning on removal.

Although the UKSR has been active since May 1994, only data from January 1995 have been included for analysis because the reporting rates were low at the initiation of the registry. This gives a shunt procedure dataset from 1st January 1995 to 31st December 2014 of 53,767 procedures in 29,341 patients. 44,663 valves were used.

4. Statistical Notes

Specific mortality data from ONS has been used to censor the life table data. The survivor function was then estimated from the censored data using Kaplan-Meier and Cox models. This was then transformed to a Cumulative Revision Rate (1-survivor function) as a percentage. The standard error of the Kaplan-Meier estimate was calculated using Greenwood's formula and transformed to a standard error of the CRR. 95% confidence limits were calculated by multiplying the standard error by the appropriated percentage point from the standard normal distribution (1.96). Because the CRR is not close to 0 or 100%, no further adjustment was made. Some analyses were done on slightly reduced datasets because of deletion of patients with no recorded data in the parameter under analysis. This was done without bias and only before any analysis has begun.

Anonymized patient demographic data has been used to identify and classify risk factors for shunt failure. The infection risk was calculated as the proportion of procedures subsequently revised for infection where the follow-up was greater than nine months. Because the numbers of patients are sufficiently large, the confidence limits quoted were calculated from a quadratic approximation of the binomial distribution.

5 Results

5.1 Overall returns by Centre

All centres which have sent over 100 forms to the registry are shown in Table 1. When the registry was originally set up, each centre was randomly allocated a unique number and these have remained unchanged, despite withdrawals due to merging with other centres. These are the numbers used in Figures 20 to 22.

Centre	Total Returns	Centre	Total Returns
Aberdeen Royal Childrens, ABERDEEN	105	Royal Manchester Childrens Hospital, MANCHESTER	1207
Clarendon Wing, Leeds General Infirmary, LEEDS	132	Queen Elizabeth Hospital, BIRMINGHAM	1228
Manchester Royal, MANCHESTER	177	Hurstwood Park Neurological Centre, HAYWARD'S HEATH	1296
Ninewells Hospital, DUNDEE	247	Alder Hey Childrens Hospital, LIVERPOOL	1433
Aberdeen Royal Infirmary, ABERDEEN	252	Royal Victoria Hospital, BELFAST	1444
Royal Hospital for Sick Children (Yorkhill), GLASGOW	337	Great Ormond Street Hospital for Sick Children, LONDON	1926
Sheffield Children's Hospital, SHEFFIELD	380	National Hospital for Neurology and Neurosurgery, Queen Square, LONDON	2023
Morriston Hospital, SWANSEA	387	Newcastle General Hospital, NEWCASTLE-UPON-TYNE	2068
Charing Cross Hospital, LONDON	465	Walton Centre for Neurology and Neurosurgery, LIVERPOOL	2292
Royal London Hospital, LONDON	508	University Hospital of Wales, CARDIFF	2607
Queen's Hospital, ROMFORD	525	Institute of Neurological Sciences, Southern General Hospital, GLASGOW	2712
The Royal Hospital for Sick Children, EDINBURGH	527	Hope Hospital, SALFORD	2773
Walsgrave Hospital, COVENTRY	581	Atkinson Morley Wing, St. Georges Hospital,Tooting, LONDON	2915
Royal Free Hospital, LONDON	626	Derriford Hospital, PLYMOUTH	2977
Royal Preston Hospital, PRESTON	678	King's College Hospital, LONDON	4060
Royal Belfast Hospital for Sick Children, BELFAST	711	Wessex Neurological Centre, SOUTHAMPTON	4142
Western General Hospital, EDINBURGH	783	Jubilee Wing, Leeds General Infirmary, LEEDS	4744
Hull Royal Infirmary, HULL	854	Addenbrooke's Hospital, CAMBRIDGE	4907
James Cook University Hospital, MIDDLESBROUGH	875	Queens Medical Centre, NOTTINGHAM	4919
University Hospital of North Staffordshire, STOKE-ON-TRENT	941	West Wing, John Radcliffe Hospital, OXFORD	4951
Royal Hallamshire Hospital, SHEFFIELD	964	Frenchay Hospital, BRISTOL	5127
Birmingham Children's Hospital, BIRMINGHAM	1131	Others	4478
		ALL	**78415**

Table 1: Total Returns By Centre (up to 23/01/2015)

5.2 Monitoring of submission rates, by centre and by year (Table 2)

Submissions rates of shunt procedures, by year and centre

	Primay shunt insertions														Shunt revisions											
Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Centre-1	-	-	-	-	-	-	-	-	-	90%	90%	-	94%	100%	-	-	-	-	-	-	-	-	-	91%	92%	-	95%	98%
Centre-2	96%	-	100%	-	99%	100%	100%	-	100%	100%	100%	-	100%	100%	93%	-	100%	-	99%	99%	99%	-	100%	100%	100%	-	100%	99%
Centre-3	96%	-	100%	100%	100%	100%	-	100%	100%	100%	100%	-	100%	100%	80%	-	100%	98%	100%	100%	-	100%	100%	100%	99%	-	100%	99%
Centre-4	99%	-	96%	-	100%	99%	99%	-	-	-	-	-	-	-	91%	-	94%	-	97%	99%	99%	-	-	-	-	-	-	-
Centre-5	-	-	-	-	100%	-	-	-	-	100%	100%	100%	100%	-	-	-	-	-	100%	-	-	-	-	98%	99%	100%	100%	-
Centre-6	-	-	-	-	87%	88%	-	82%	82%	89%	91%	88%	87%	84%	-	-	-	-	79%	83%	-	93%	93%	91%	88%	86%	84%	88%
Centre-7	-	-	-	-	-	-	85%	-	95%	93%	95%	-	96%	97%	-	-	-	-	-	-	67%	-	96%	96%	98%	-	98%	96%
Centre-8	96%	-	-	-	-	91%	90%	91%	92%	94%	100%	97%	-	94%	89%	-	-	-	-	86%	95%	88%	89%	86%	99%	94%	-	93%
Centre-9	-	-	-	-	-	-	-	-	-	-	96%	-	-	96%	-	-	-	-	-	-	-	-	-	-	96%	-	-	95%
Centre-10	75%	-	-	-	-	91%	-	-	-	-	-	-	-	-	63%	-	-	-	-	91%	-	-	-	-	-	-	-	-
Centre-11	73%	80%	-	-	-	-	-	-	-	96%	-	97%	95%	95%	42%	50%	-	-	-	-	-	-	-	100%	-	95%	95%	95%
Centre-12	-	-	-	-	-	-	-	74%	-	-	-	-	-	-	-	-	-	-	-	-	-	88%	-	-	-	-	-	-
Centre-13	-	-	-	-	100%	-	-	-	-	-	100%	-	-	100%	-	-	-	-	97%	-	-	-	-	-	96%	-	-	96%
Centre-14	-	28%	-	-	-	-	-	-	-	-	-	-	35%	32%	-	30%	-	-	-	-	-	-	-	-	-	-	41%	48%
Centre-15	-	-	75%	79%	-	86%	86%	-	80%	80%	82%	86%	85%	-	-	-	83%	80%	-	82%	96%	-	79%	78%	75%	79%	79%	-
Centre-16	-	-	81%	90%	-	78%	97%	-	74%	82%	86%	88%	90%	-	-	-	68%	79%	-	70%	89%	-	74%	81%	78%	91%	94%	-
Centre-17	-	-	-	-	44%	-	-	59%	-	59%	-	-	64%	65%	-	-	-	-	48%	-	-	56%	-	58%	-	-	60%	77%
Centre-18	-	64%	79%	-	-	68%	76%	-	64%	69%	-	63%	-	-	-	58%	70%	-	-	65%	71%	-	47%	45%	-	47%	-	-
Centre-19	-	85%	-	-	-	-	-	-	-	94%	-	-	91%	80%	-	86%	-	-	-	-	-	-	-	76%	-	-	74%	81%
Centre-20	94%	-	90%	-	-	92%	88%	-	92%	91%	76%	-	89%	100%	78%	-	92%	-	-	92%	100%	-	94%	100%	95%	-	83%	83%
Centre-21	-	-	-	-	-	-	-	-	53%	53%	-	59%	-	57%	-	-	-	-	-	-	-	-	94%	48%	-	49%	-	38%
Centre-22	-	-	-	-	-	-	-	-	-	-	58%	-	48%	54%	-	-	-	-	-	-	-	-	-	-	38%	-	50%	50%
Centre-23	-	-	-	-	-	-	-	-	79%	77%	-	-	73%	-	-	-	-	-	-	-	-	-	67%	71%	-	-	71%	-
Centre-24	14%	-	-	-	66%	-	-	-	-	-	100%	61%	-	72%	13%	-	-	-	71%	-	-	-	-	-	100%	75%	-	73%
Centre-25	-	-	-	-	-	-	-	-	-	86%	-	-	84%	-	-	-	-	-	-	-	-	-	-	83%	-	-	83%	-
Centre-26	-	-	-	-	-	-	-	-	93%	-	-	89%	-	87%	-	-	-	-	-	-	-	-	90%	-	-	92%	-	90%
Centre-27	-	-	-	-	-	-	69%	73%	77%	79%	83%	-	83%	84%	-	-	-	-	-	-	67%	70%	73%	68%	73%	-	84%	67%
Centre-28	-	-	-	-	-	-	29%	-	-	-	-	-	-	-	-	-	-	-	-	-	33%	-	-	-	-	-	-	-
Centre-29	-	-	47%	-	-	44%	69%	-	-	55%	-	61%	-	-	-	-	57%	-	-	49%	58%	-	-	68%	-	59%	-	-
Centre-30	-	-	-	-	-	-	-	-	-	45%	-	-	39%	48%	-	-	-	-	-	-	-	-	-	26%	-	-	38%	39%
Centre-31	-	-	35%	-	51%	74%	71%	-	53%	66%	61%	61%	-	88%	-	-	24%	-	48%	50%	29%	-	55%	63%	57%	56%	-	94%
Centre-32	-	-	-	-	79%	-	80%	-	-	80%	81%	79%	81%	86%	-	-	-	-	71%	-	70%	-	-	80%	76%	78%	79%	82%
Centre-33	-	-	-	-	-	-	77%	-	-	-	-	-	-	-	-	-	-	-	-	-	70%	-	-	-	-	-	-	-
Centre-34	-	-	-	-	-	95%	-	85%	75%	75%	72%	-	68%	67%	-	-	-	-	-	62%	-	73%	60%	73%	67%	-	70%	70%
Centre-35	-	-	83%	-	81%	75%	80%	-	56%	53%	23%	45%	36%	-	-	-	67%	-	83%	81%	86%	-	36%	58%	40%	50%	46%	-
Centre-36	-	-	-	-	-	-	-	-	30%	-	32%	-	-	-	-	-	-	-	-	-	-	-	31%	-	35%	-	-	-
Centre-37	-	-	-	-	-	-	-	-	-	67%	-	-	69%	71%	-	-	-	-	-	-	-	-	-	57%	-	-	67%	70%
Centre-38	-	-	-	-	77%	-	-	-	-	-	-	-	-	-	-	-	-	-	67%	-	-	-	-	-	-	-	-	-
Centre-39	-	-	-	-	-	-	-	60%	-	-	-	-	-	-	-	-	-	-	-	-	-	70%	-	-	-	-	-	-
Centre-40	100%	-	18%	-	-	-	-	-	-	-	-	-	-	-	85%	-	31%	-	-	-	-	-	-	-	-	-	-	-

>75%
50-75%
<50%
- No data available

Source: data from annual audits carried out every year, using six-month data. For 19 of the 59 Centres there is no audit data available.

Reporting rates have been monitored by the Registry Auditors (Colette O'Kane and Helen Seeley) who visited each Unit to examine the neurosurgery theatre records for all reportable shunt procedures performed for the preceding 6 months. These data were then compared with the information submitted to the UKSR to determine the overall reporting rates for primary insertions and revisions. Information on submission rates was available from 40 out of 59 centres, for an average of five years per centre. While in many of these centres, yearly submission rates were often higher than 75%, there were some centres and years where submissions fell below this standard. In 16 (40%) of the centres, submission rates were below 75% in more than half of the years for which there was information on their submission rates.

5.3 Overall reported shunt procedures (adult and paediatric)

There were some 3000 shunt operations in the UK each year: 1660 paediatric (33.5% primary and 66.5% revisions) and 1400 adult (53% primary and 47% revisions).

	ALL	1995-1999	2000-2004	2005-2009	2010-2014
First Shunt	18593	3784	4767	5309	4733
Shunt Revisions	16511	2706	3844	4956	5005

Table 3a: Reported Shunt Procedures - Adult Patients (Age 17 and above)

	ALL	1995-1999	2000-2004	2005-2009	2010-2014
First Shunt	6061	1428	1542	1635	1456
Shunt Revisions	12018	2446	3098	3352	3122

Table 3b: Reported Shunt Procedures - Paediatric Patients (Age 16 and below)

	ALL	1995-1999	2000-2004	2005-2009	2010-2014
First Shunt	53.0	58.3	55.4	51.7	48.6
Shunt Revisions	47.0	41.7	44.6	48.3	51.4

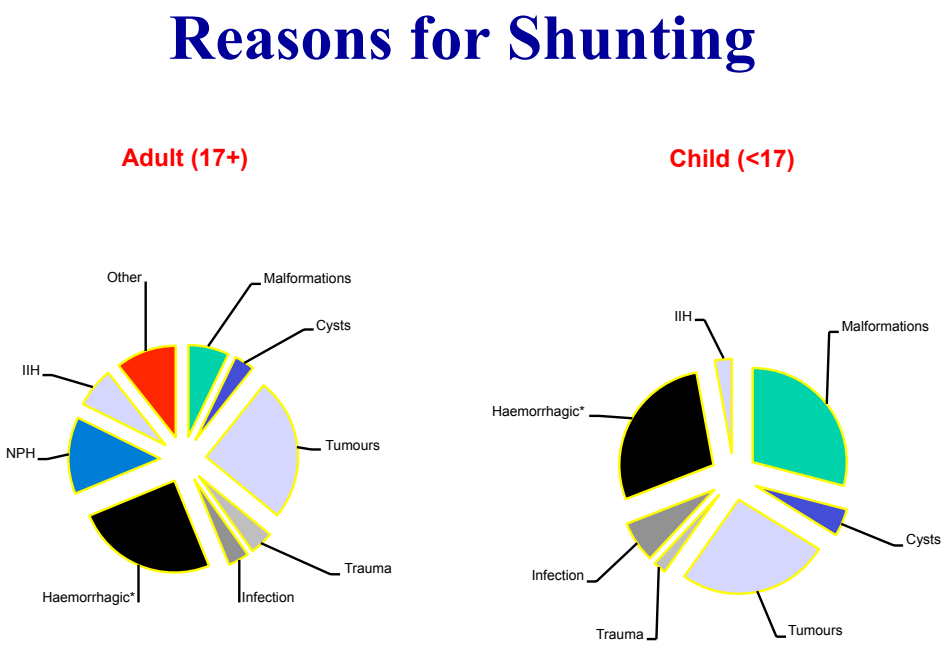
Table 3c: Returns as Percentage - Adult Patients (Age 17 and above)

	ALL	1995-1999	2000-2004	2005-2009	2010-2014
First Shunt	33.5	36.9	33.2	32.8	31.8
Shunt Revisions	66.5	63.1	66.8	67.2	68.2

Table 3d: Returns as Percentage - Paediatric Patients (Age 16 and below)

5.4 Diagnoses

Figure 2 illustrates the reasons for shunt procedures:



5.5 Operation type

Table 4a shows the type of shunt operation recorded in adults and Table 4b in paediatric patients as a percentage of total procedures. Even though there is a substantial amount of missing data, it can be seen that by far the most numerous procedure was a ventriculo-peritoneal shunt.

	1995-1999	2000-2004	2005-2009	2010-2015	TOTAL
All Cysto-	0.92	0.79	0.63	0.65	0.73
All Lumbo-	4.63	7.32	8.96	8.07	7.47
All Ventriculo-	85.86	80.22	77.36	65.01	76.51
All Other-	0.50	0.51	0.63	0.96	0.66

	1995-1999	2000-2004	2005-2009	2010-2015	TOTAL
All -Peritoneal	87.00	85.01	80.52	65.31	78.93
All -Atrial	2.19	0.80	1.02	1.11	1.22
All -Thorax	0.37	0.53	0.92	1.01	0.74
All -External	0.08	0.17	0.21	0.33	0.20
All -Other	0.18	0.27	0.37	0.90	0.44

Table 4a: Operation Type – Adult

	1995-1999	2000-2004	2005-2009	2010-2015	TOTAL
All Cysto-	1.81	1.08	0.69	0.99	1.12
All Lumbo-	1.22	2.27	2.77	1.86	2.07
All Ventriculo-	85.31	84.21	79.86	69.78	79.87
All Other-	0.80	0.40	0.94	0.67	0.70

	1995-1999	2000-2004	2005-2009	2010-2015	TOTAL
All -Peritoneal	82.81	82.94	77.76	65.55	77.39
All -Atrial	1.01	0.98	1.34	1.16	1.13
All -Thorax	0.18	0.55	0.62	0.52	0.48
All -External	0.15	0.32	0.27	0.12	0.22
All -Other	0.15	0.21	0.20	0.20	0.19

Table 4b: Operation Type – Paediatric

5.6 Revision rates

5.6.1 All valves

The overall cumulative revision rates (CRR) were calculated. As well as the overall rate, the data has been stratified into adult and paediatric and also into primary shunt insertions and shunt revisions. Figures 3a & 3b illustrate that the primary risk factors for shunt revision are the age of the patient and the presence of previous revisions.

The UK Shunt Registry collects data on the reasons for shunt revision. It must be emphasized that this data is what was available at the time of surgery and is therefore "intention to treat" data. Multiple reasons for revision were often given, and these were sometimes contradictory (see section 5.7).

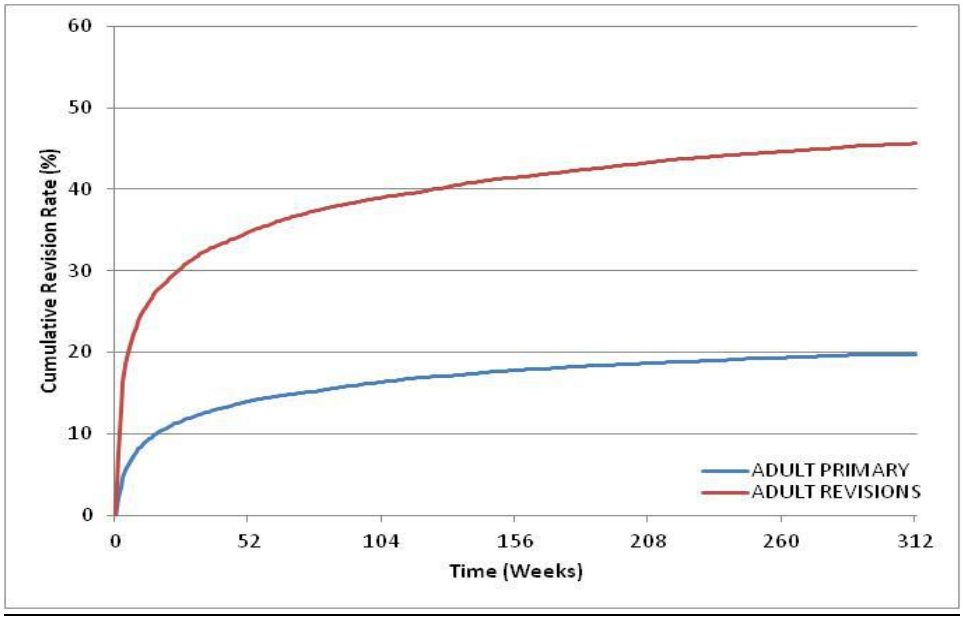


Figure 3a: Cumulative Revision Rates – Adult

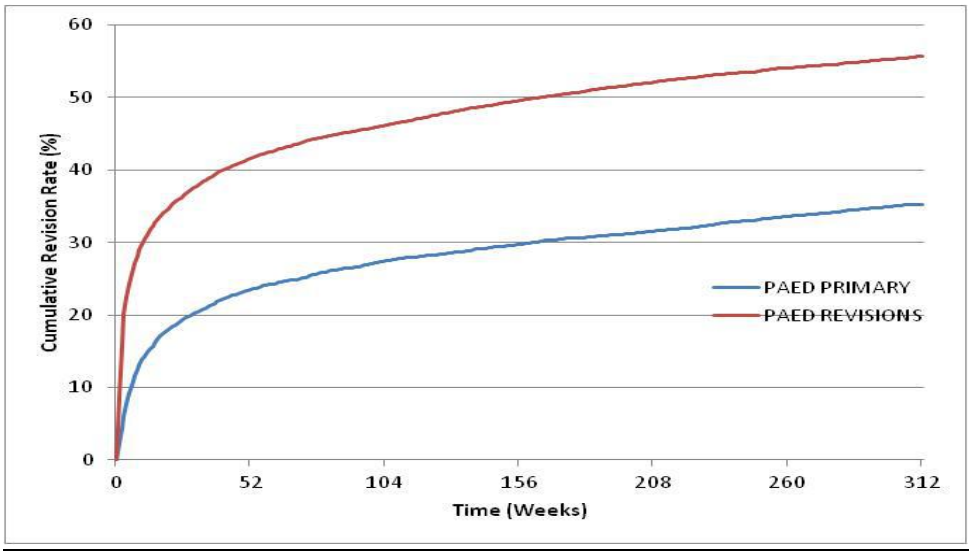
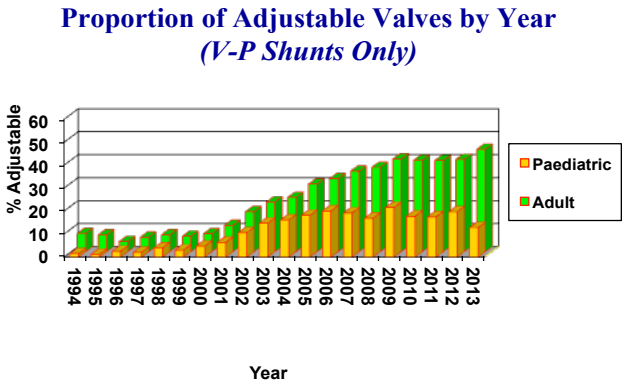


Figure 3b: Cumulative Revision Rates – Paediatric

5.6.2 Valves: fixed pressure versus adjustable

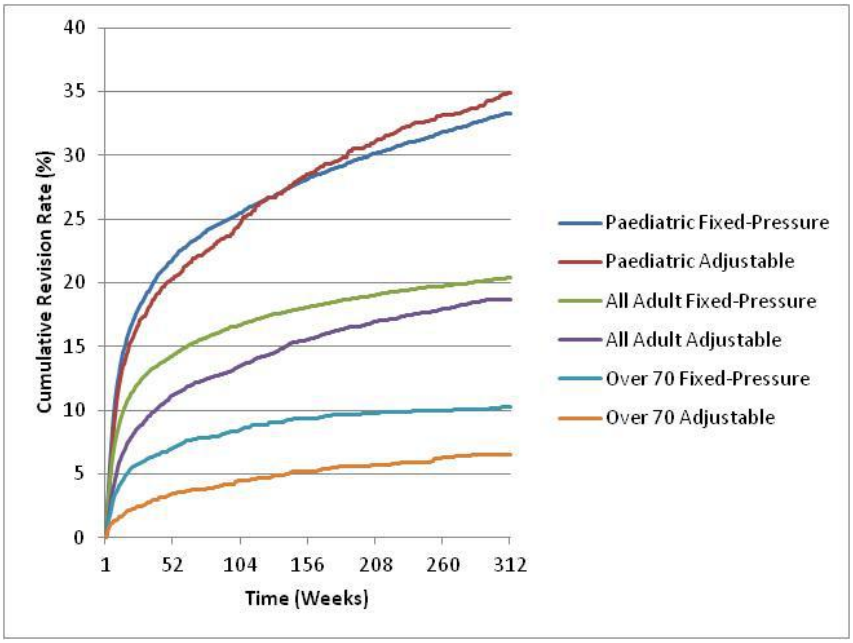
Figure 4. There has been a progressive increase in the use of adjustable valves since their introduction into the UK market in the late 1980's (Kay AD[1], Fisher AJ, O'Kane C, Richards HK, Pickard JD; United Kingdom and Ireland Medos Shunt Audit Group. A clinical audit of the Hakim programmable valve in patients with complex hydrocephalus. Br J Neurosurg. 2000 Dec;14(6):535-42).



The comparative performance of fixed-pressure and adjustable valves is shown by plotting the revision curves in Figure 5. The curves for paediatric patients indicate no advantage for adjustable valves whereas in adults of all ages but especially aged 70 and over, there is a significant advantage in using an adjustable valve (P<0.001) in terms of valve revision rate. However, there is no adjustment for case-mix, patient selection or the transition during the teenage years for which the use of different types of valve may be important.

Figure 5: Cumulative Valve Revision Rates: Fixed Pressure versus Adjustable valves.

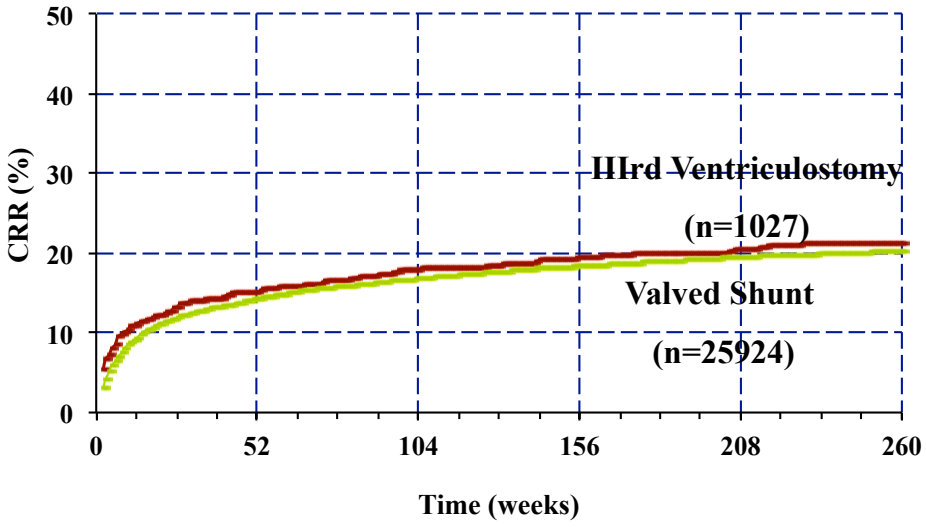
[Another type of adjustable valve is the Orbis-Sigma precision flow control valve; the CRR's for this valve are 17.8% and 22.1% (adult at one and two years respectively) and 24.1% and 28.8% (paediatric at one and two years respectively).



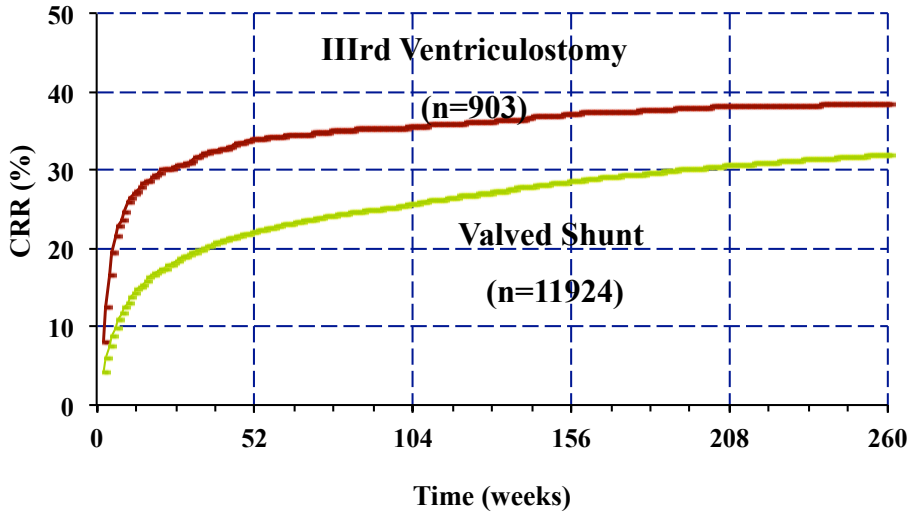
5.6.3 Endoscopic Third Ventriculostomy

Figure 6 illustrates the overall rates of revision for ETV and valved shunts. Overall, ETV appears to have a significant revision rate comparable to valved shunts. Detailed statistical modeling is in progress to tease out the revision rates in matched patient groups.

ETV versus Shunt – Adult



ETV versus Shunt – Paediatric

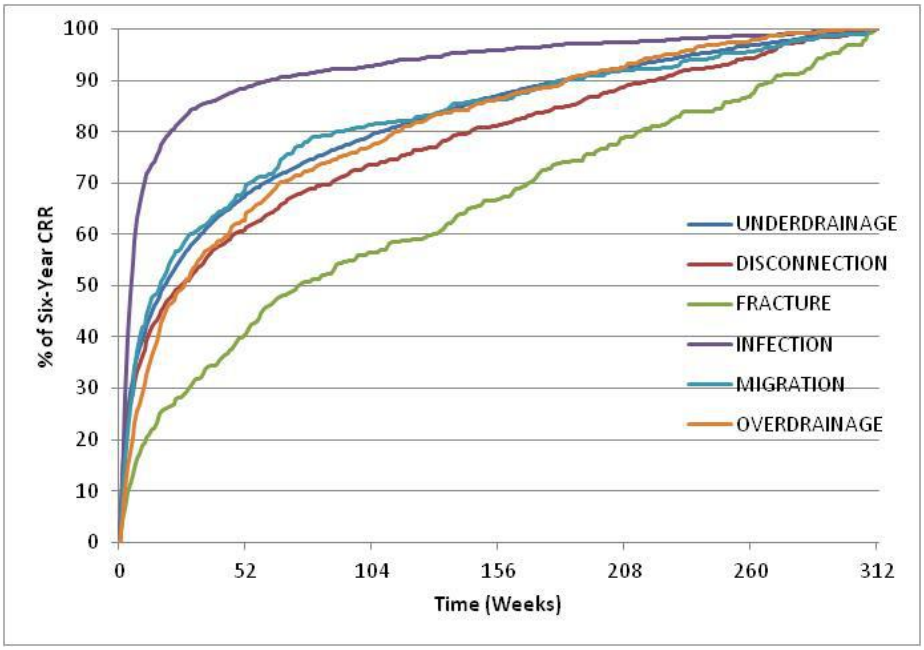


5.7 Reasons for shunt revision

5.7.1 Time course of the reasons for shunt revision

The time courses and median ages of the various reasons for shunt revisions are shown in Figure 7. The reasons for revision were reported in 14845 (52.0 %) operations of which more than one factor was identified in 1496 (10.1 %) cases. The graph shows that revisions for underdrainage, overdrainage, disconnection and migration have similar time courses. Revisions for shunt fracture have a longer time course whereas revisions for shunt infection take place early. Interestingly, there remains a significant issue with mechanical problems such as disconnection, fracture and migration.

Importantly, the low incidence and long time course of overdrainage and mechanical problems (disconnection, migration n and fracture) will render randomized controlled trials difficult to complete on a UK basis alone.



	Median Age
All	31.5
All Revisions	20.7
Underdrainage	20.0
Disconnection	22.4
Fracture	17.1
Migration	24.1
Infection	17.5
Overdrainage	25.0

Median age at operation

Figure 7: Time course and median ages of various reasons for Shunt Revisions

5.7.2 Underdrainage

By far the most common reason for shunt revision is underdrainage, given in 35% of all revisions. A breakdown of the number of revisions for underdrainage is shown in Tables 5a to 5c. 60% of shunt underdrainage (and 49.3% of all revisions) involves the proximal catheter.

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Distal	1833	163	528	329	813
Proximal	4211	561	1600	703	1347
Proximal,Distal	251	36	82	29	104
Proximal,Valve	519	78	177	89	175
Proximal,Valve,Distal	195	24	75	31	65
Valve	1348	148	397	292	511
Valve,Distal	181	20	61	28	72
Combined with other reasons for revision	525	75	173	91	186

Table 5a: Site of Underdrainage

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Distal	21.5	15.8	18.1	21.9	26.3
Proximal	49.3	54.5	54.8	46.8	43.6
Proximal,Distal	2.9	3.5	2.8	1.9	3.4
Proximal,Valve	6.1	7.6	6.1	5.9	5.7
Proximal,Valve,Distal	2.3	2.3	2.6	2.1	2.1
Valve	15.8	14.4	13.6	19.5	16.6
Valve,Distal	2.1	1.9	2.1	1.9	2.3
Combined with other reasons for revision	6.1	7.3	5.9	6.1	6.0

Table 5b: Site of Underdrainage as a percentage of Total Underdrainage

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Distal	7.5	5.1	7.4	6.3	9.2
Proximal	17.3	17.6	22.4	13.6	15.2
Proximal,Distal	1.0	1.1	1.1	0.6	1.2
Proximal,Valve	2.1	2.4	2.5	1.7	2.0
Proximal,Valve,Distal	0.8	0.8	1.1	0.6	0.7
Valve	5.5	4.6	5.6	5.6	5.8
Valve,Distal	0.7	0.6	0.9	0.5	0.8
Combined with other reasons for revision	2.2	2.4	2.4	1.8	2.1
Total	35.1	32.3	40.9	29.0	34.9

Table 5c: Site of Underdrainage as a percentage of Total Revisions

5.7.3 Overdrainage

Overdrainage is far less common than underdrainage. A breakdown of all revisions for overdrainage is shown in Tables 6a to 6c. The most common form of overdrainage reported in both paediatric and adult practice is slit ventricle. Subdural hygroma and haematoma are both reported to be more common in adults.

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Craniostenosis	24	8	13	2	1
Craniostenosis,Slit Ventricle	3	2	1	0	0
Slit Ventricle	335	33	104	44	154
Subdural Haematoma	107	15	13	51	28
Subdural Haematoma,Slit Ventricle	3	0	1	2	0
Subdural Hygroma	192	22	42	75	53
Subdural Hygroma,Craniostenosis	2	0	0	1	1
Subdural Hygroma,Slit Ventricle	5	1	0	2	2
Subdural Hygroma,Subdural Haematoma	8	1	4	2	1
Subdural Hygroma,Subdural Haematoma,Craniostenosis,Slit Ventricle	5	2	1	0	2
Combined with other reasons for revision	85	13	28	10	34

Table 6a: Evidence for Overdrainage

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Craniostenosis	3.5	9.5	7.3	1.1	0.4
Craniostenosis,Slit Ventricle	0.4	2.4	0.6	0.0	0.0
Slit Ventricle	49.0	39.3	58.1	24.6	63.6
Subdural Haematoma	15.6	17.9	7.3	28.5	11.6
Subdural Haematoma,Slit Ventricle	0.4	0.0	0.6	1.1	0.0
Subdural Hygroma	28.1	26.2	23.5	41.9	21.9
Subdural Hygroma,Craniostenosis	0.3	0.0	0.0	0.6	0.4
Subdural Hygroma,Slit Ventricle	0.7	1.2	0.0	1.1	0.8
Subdural Hygroma,Subdural Haematoma	1.2	1.2	2.2	1.1	0.4
Subdural Hygroma,Subdural Haematoma,Craniostenosis,Slit Ventricle	0.7	2.4	0.6	0.0	0.8
Combined with other reasons for revision	12.4	15.5	15.6	5.6	14.0

Table 6b: Evidence for Overdrainage as a percentage of Total Overdrainage

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Craniostenosis	0.1	0.3	0.2	0.0	0.0
Craniostenosis,Slit Ventricle	0.0	0.1	0.0	0.0	0.0
Slit Ventricle	1.4	1.0	1.5	0.8	1.7
Subdural Haematoma	0.4	0.5	0.2	1.0	0.3
Subdural Haematoma,Slit Ventricle	0.0	0.0	0.0	0.0	0.0
Subdural Hygroma	0.8	0.7	0.6	1.4	0.6
Subdural Hygroma,Craniostenosis	0.0	0.0	0.0	0.0	0.0
Subdural Hygroma,Slit Ventricle	0.0	0.0	0.0	0.0	0.0
Subdural Hygroma,Subdural Haematoma	0.0	0.0	0.1	0.0	0.0
Subdural Hygroma,Subdural Haematoma,Craniostenosis,Slit Ventricle	0.0	0.1	0.0	0.0	0.0
Combined with other reasons for revision	0.3	0.4	0.4	0.2	0.4
Total	2.8	2.6	2.5	3.5	2.7

Table 6c: Evidence for Overdrainage as a percentage of Total Revisions

5.7.4 Disconnection

Disconnection accounts for approximately 5% of shunt revisions, and is more common in children. The most common site of disconnection is not the main connections of the shunt system, but rather connections with other devices (mainly reservoirs). A breakdown of all revisions for disconnection is shown in Tables 7a to 7c .

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Other	567	62	148	120	237
Valve/Distal	316	33	119	53	111
Proximal/Valve	272	32	94	50	96
Combined with other reasons for revision	393	60	131	65	137

Table 7a: Site of Disconnection

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Other	49.1	48.8	41.0	53.8	53.4
Valve/Distal	27.4	26.0	33.0	23.8	25.0
Proximal/Valve	23.5	25.2	26.0	22.4	21.6
Combined with other reasons for revision	34.0	47.2	36.3	29.1	30.9

Table 7b: Site of Disconnection as a percentage of Total Disconnection

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Other	2.3	1.9	2.1	2.3	2.7
Valve/Distal	1.3	1.0	1.7	1.0	1.3
Proximal/Valve	1.1	1.0	1.3	1.0	1.1
Combined with other reasons for revision	1.6	1.9	1.8	1.3	1.5
Total	4.7	4.0	5.1	4.3	5.0

Table 7c: Site of Disconnection as a percentage of Total Revisions

5.7.5 Fracture

Fracture is the least common reason for revision, accounting for only 2.2% of revisions. The work of the UK Shunt Evaluation Laboratory has shown that shunt systems are physically robust. A breakdown of all revisions for Fracture is shown in Tables 8a to 8c. As expected, because of its length, the most common site of fracture is the distal catheter.

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Distal	344	63	138	40	103
Proximal	223	24	69	35	95
Combined with other reasons for revision	260	44	106	29	81

Table 8a: Site of Fracture

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Distal	60.7	72.4	66.7	53.3	52.0
Proximal	39.3	27.6	33.3	46.7	48.0
Combined with other reasons for revision	45.9	50.6	51.2	38.7	40.9

Table 8b: Site of Fracture as a percentage of Total Fracture

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Distal	1.4	2.0	1.9	0.8	1.2
Proximal	0.9	0.8	1.0	0.7	1.1
Combined with other reasons for revision	1.1	1.4	1.5	0.6	0.9
Total	2.3	2.7	2.9	1.4	2.2

Table 8c: Site of Fracture as a percentage of Total Revisions

5.7.6 Migration

Reported migrations up or down are similar. However migration down is relatively more common in children and migration up more common in adults. A breakdown of all revisions for migration is shown in Tables 9a to 9c.

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Down	302	51	95	54	102
Up	261	16	41	101	103
Combined with other reasons for revision	233	33	79	49	72

Table 9a: Site of Migration

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Down	53.6	76.1	69.9	34.8	49.8
Up	46.4	23.9	30.1	65.2	50.2
Combined with other reasons for revision	41.4	49.3	58.1	31.6	35.1

Table 9b: Site of Migration as a percentage of Total Migration

	ALL	Paediatric Primary	Paediatric Revisions	Adult Primary	Adult Revisions
Down	1.2	1.6	1.3	1.0	1.2
Up	1.1	0.5	0.6	1.9	1.2
Combined with other reasons for revision	1.0	1.0	1.1	0.9	0.8
Total	2.3	2.1	1.9	3.0	2.3

Table 9c: Site of Migration as a percentage of Total Revisions

5.7.7 Infection

5.7.7.1 Infection risks: primary and revisions, paediatric and adult

Because revision for shunt infection occurs early, it is simpler to calculate the infection risk rather than the CRR. A shunt infection rate of <10% for new shunts is now a Department of Health CQUIN and Key Paediatric Neurosurgery Measure. Calculated infection risks for adults and children are given in Table 10 and shown graphically in Figure 8.

	Procedures	Subsequently Infected	Infection Risk (%)	95% Confidence Limits
ALL	53638	1841	3.4	3.3 – 3.6
ALL PAED	18058	929	5.1	4.8 – 5.5
PAED PRIMARY	6053	224	3.7	3.2 – 4.2
PAED REVISIONS	12005	705	5.9	5.5 – 6.3
ALL ADULT	35580	912	2.6	2.4 – 2.7
ADULT PRIMARY	18523	248	1.3	1.2 – 1.5
ADULT REVISIONS	16725	664	4.0	3.7 – 4.3

Table 10: Infection Risks

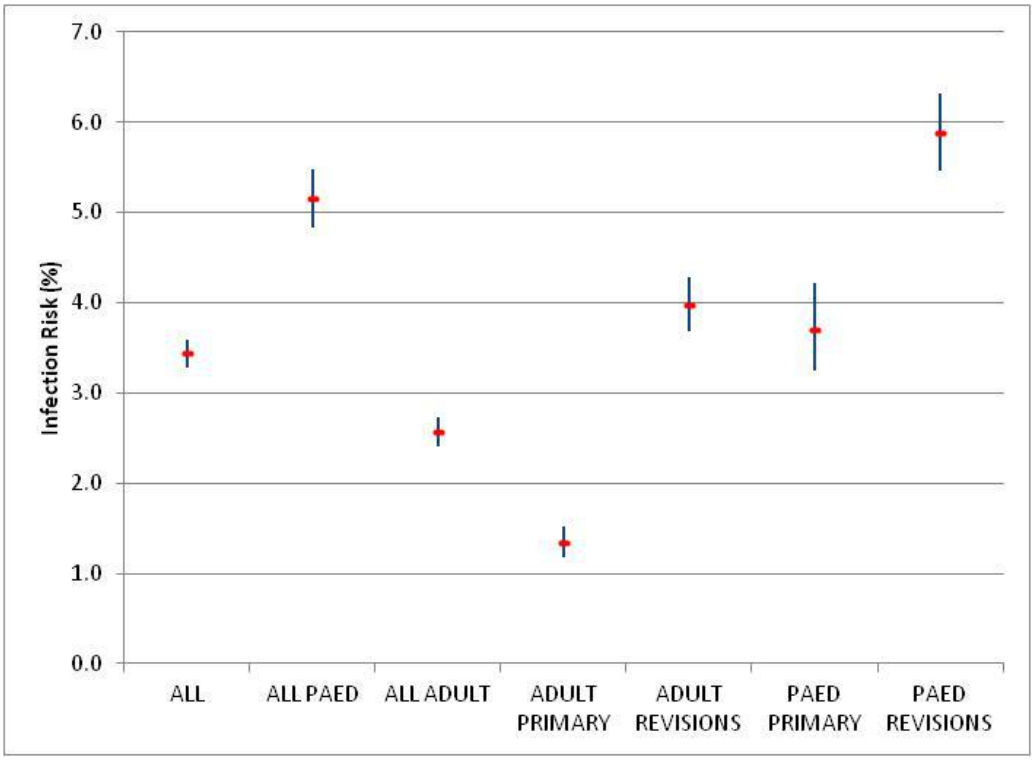


Figure 8: Infection Risks

5.7.7.2 Time trends in Overall Infection Rates

The calculation of infection risk makes it possible to examine infection trend over time. The infection risk for the years 1995 – 2013 are shown in Figures 9a and 9b. It can be seen that the trend is for a fall in shunt infection risk in both adults and children. However, a slight increase is seen in 2013. Data from 2014 is not shown because there has not been sufficient follow-up accurately to calculate risk but preliminary analysis suggests that there has been a further increase in infection risk despite expecting that the truncated follow-up would lead to an underestimate of infection risk. It should be remembered that no reason for a shunt revision was provided in 48% of cases so that there may have been some under-reporting of shunt infections.

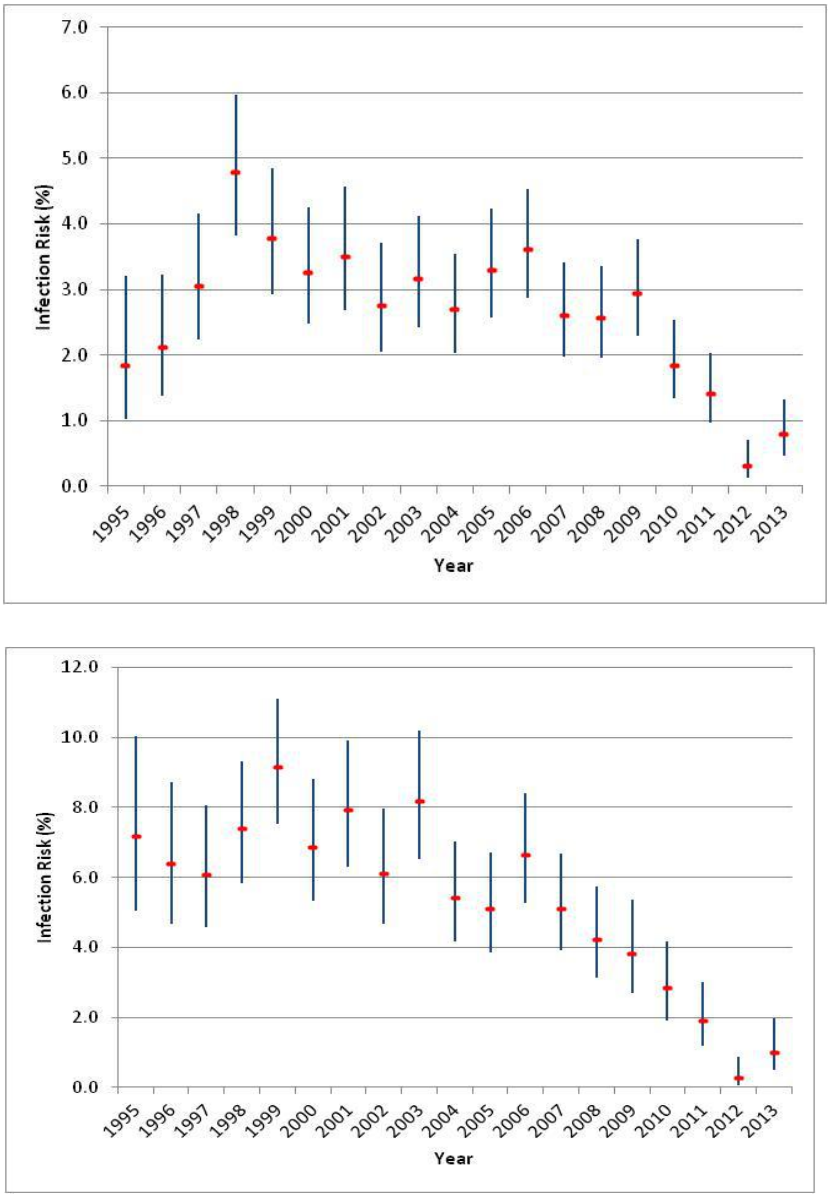


Figure 9: Infection Risk by Year for Adult and Paediatric age groups.

5.7.7.3 Impact of Antibiotic-coated catheters (Bactiseal).

Figure 10: There has been a progressive increase in the use of antibiotic-coated catheters (Bactiseal) since their introduction in 2001 that has plateaued at about 65% for adults and 55% for children.

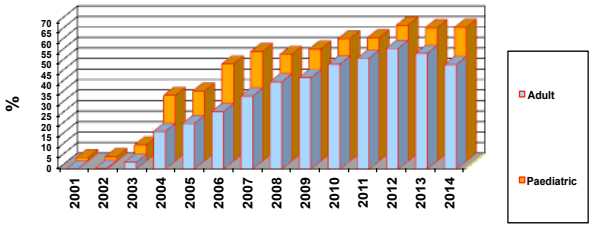
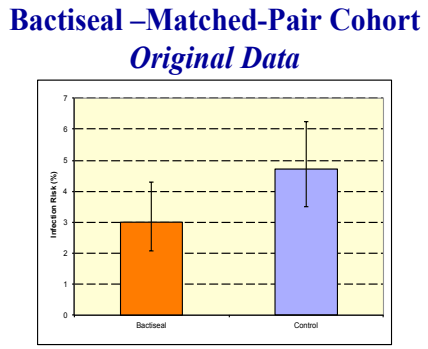
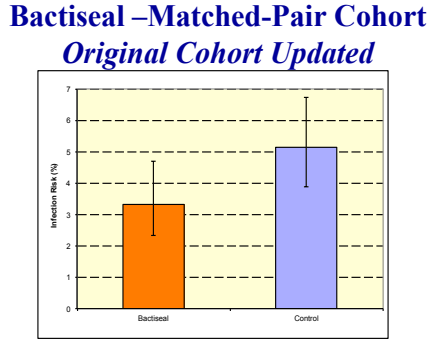


Figure 11: A matched-pair cohort design was used to assess the impact of Bactiseal catheters on subsequent infection risk. It was possible to identify 1463 procedures in which Bactiseal catheters had been used in ventriculo-peritoneal shunts up to the end of 2006 where the diagnosis, age, gender and revision status were known. 994 exact matches were found with a median difference in age between matched pairs of 0.6 years and median difference between dates of surgery of 0.3 years. The infection risk was reduced from 4.7% using conventional catheters to 3.0% using Bactiseal catheters (Richards, Seeley & Pickard J Neurosurg Pediatrics 2009;4:389-2009).



P=0.048 (Chi-square), n=994: Odds Ratio= 1.59

Figure 12: Follow up of this cohort reveals that there has been a small increase in infection risk in both groups due to late infections. The UKSR does not have access to the bacteriological findings so cannot comment on whether the use of antibiotic-coated catheters leads to a disproportionate increase in antibiotic-resistant organisms. Data from 2007 onwards has been used to construct a second matched-pair comparison. 11938 procedures were identified where patients could be defined by age, diagnosis, gender and number of previous revisions. 6302 antibiotic-impregnated catheters and 5636 conventional catheters were used. This data set yielded 4011 matched pairs. The calculated infection risk was 1.87% in conventional catheters and 1.12% in antibiotic-impregnated catheters (p=0.006).

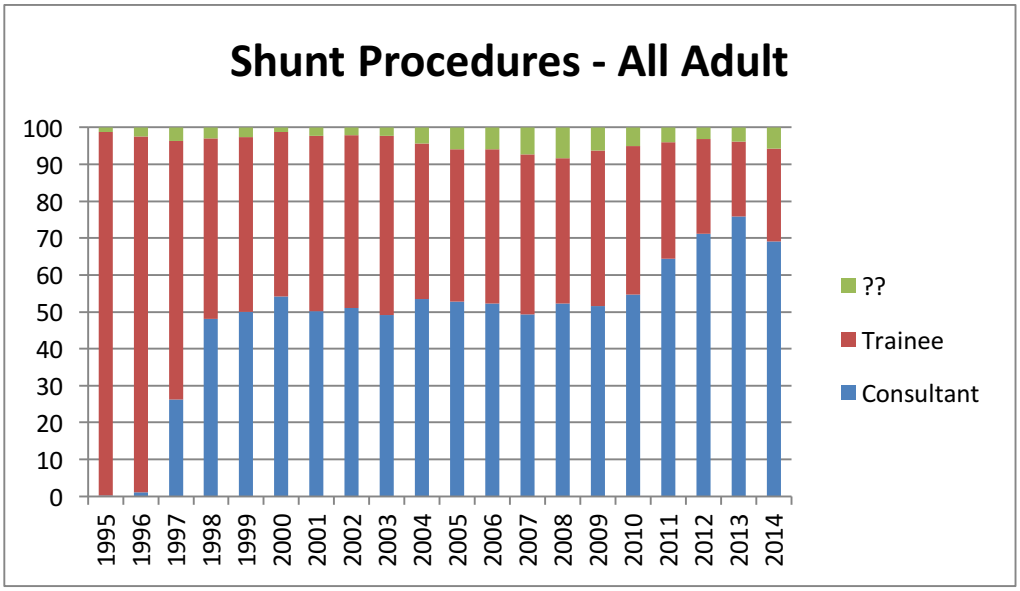


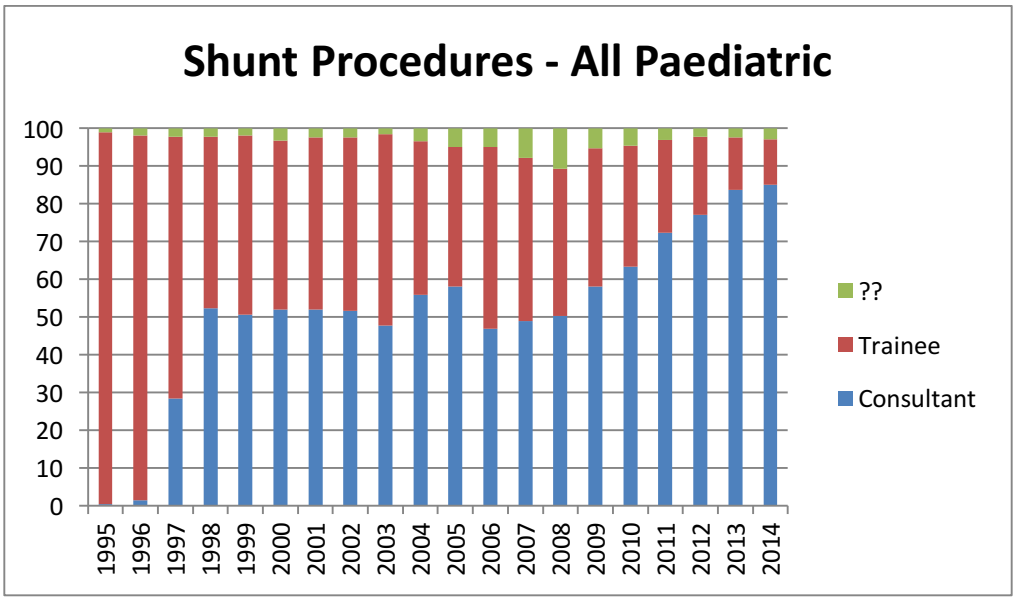
P=0.045 (Chi-square), n=994: Odds Ratio= 1.57

In summary, the overall risk of shunt infection at all ages has reduced over recent years (see figures 4a & 4b). Antibiotic-impregnated catheters have been associated with a significantly reduced shunt infection risk but other factors have probably also played an important role (eg seniority of the operating surgeon, theatre protocols, skin preparation, prophylactic antibiotics).

5.7.7.4 Seniority of the operating surgeon

There has been a profound increase in Consultant involvement during shunt surgery since 1995 from under 2% to 70% (adult) and to 80% (paediatric). Importantly, this has been associated with a reduction in infection rates over the past 5 years but no change in non-infection revision rates - Figure 13 (see also figure 19):





5.8 Timing of surgery

5.8.1 Month of the Year

The number of procedures reported per month from 1995 to 2013 are shown in Figure 14. Data from 2014 are not included as this would be biased toward earlier months in the year. There is some modest variation between months that may be a reflection of the varying length of months, public holidays and the impact of 'winter pressures' on elective procedures.

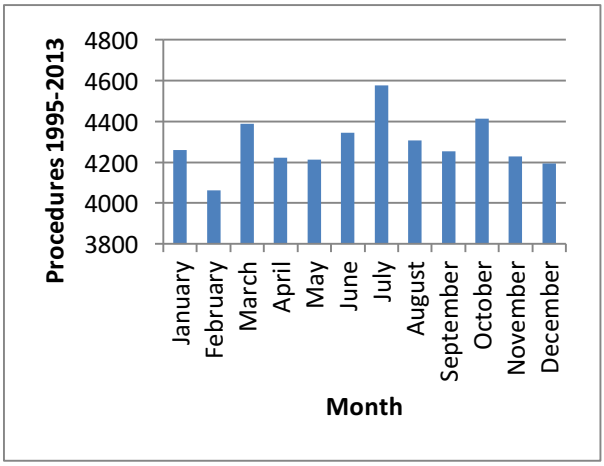
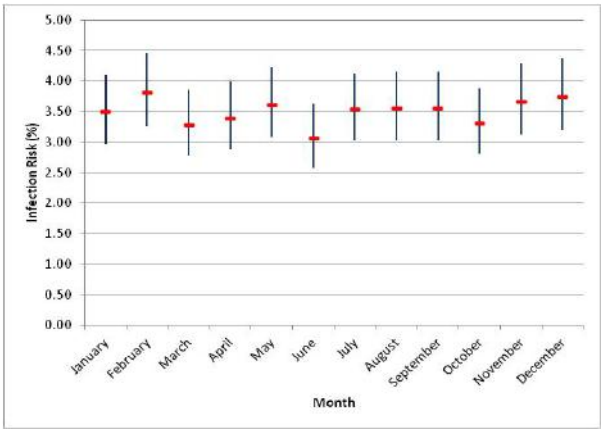


Figure 14: Reported Procedures per Month

The infection risk and one-year cumulative revision rate for each month are shown in Figures 6. The data shows very little variation in infection risk or revision rate throughout the year.



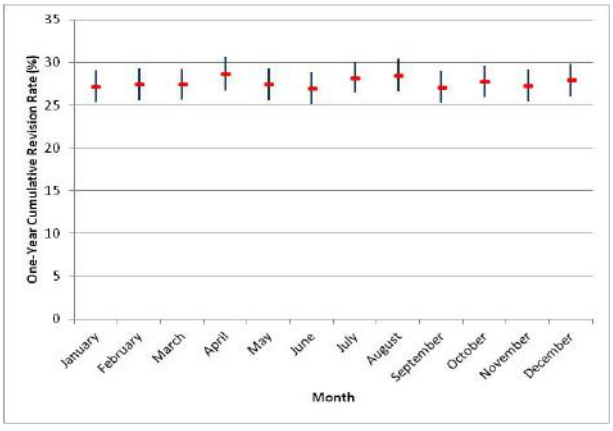


Figure 15: Infection Risk and One-Year Cumulative Revision Rate by Month

5.8.2 Day of the week and time of the day

The number of procedures reported by day of the week and out of hours from 1995 to 2014 are shown in figure 16. The data shows that there is variation in the number of reported procedures between days and out of hours. As expected far fewer procedures are performed at weekends and out of hours. During the working week, more procedures are performed on Friday than on Mondays.

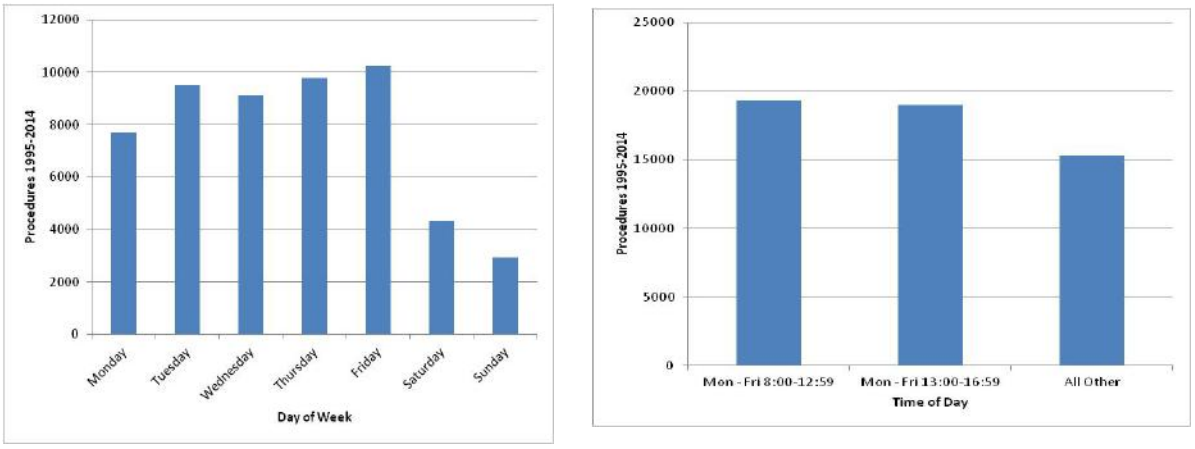


Figure 16: Reported Procedures by Day of the Week and by Time of the Day and out of hours.

The calculated infection risk and one-year cumulative revision rate for each day are shown in Figure 9. The data were further separated into procedures performed with a given starting time between 8:00 and 12:59, Monday to Friday, procedures performed with a given starting time between 13:00 and 16:59, Monday to Friday and all out of hours procedures (figure 10).

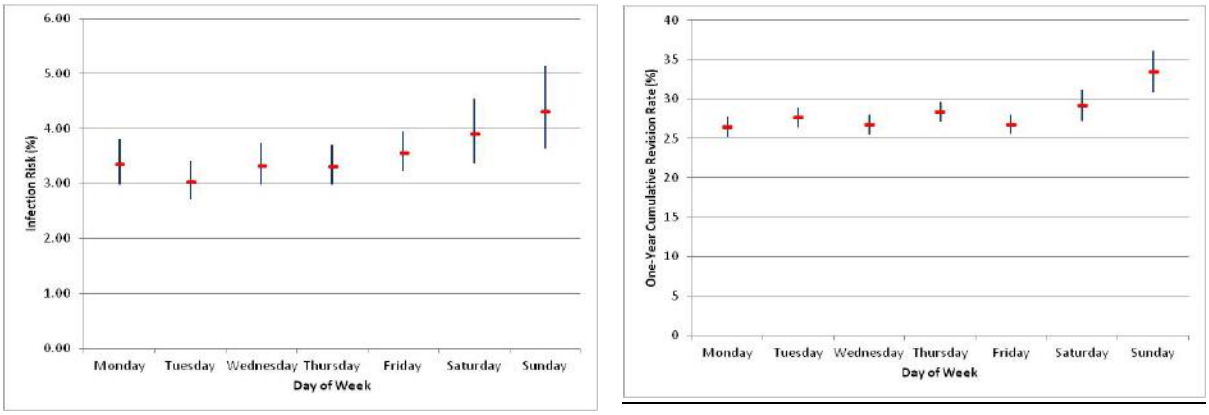


Figure 17: Infection Risk and One-Year Cumulative Revision Rate by Day of the Week (NB not corrected for case mix or proportion of primary versus revision procedures).

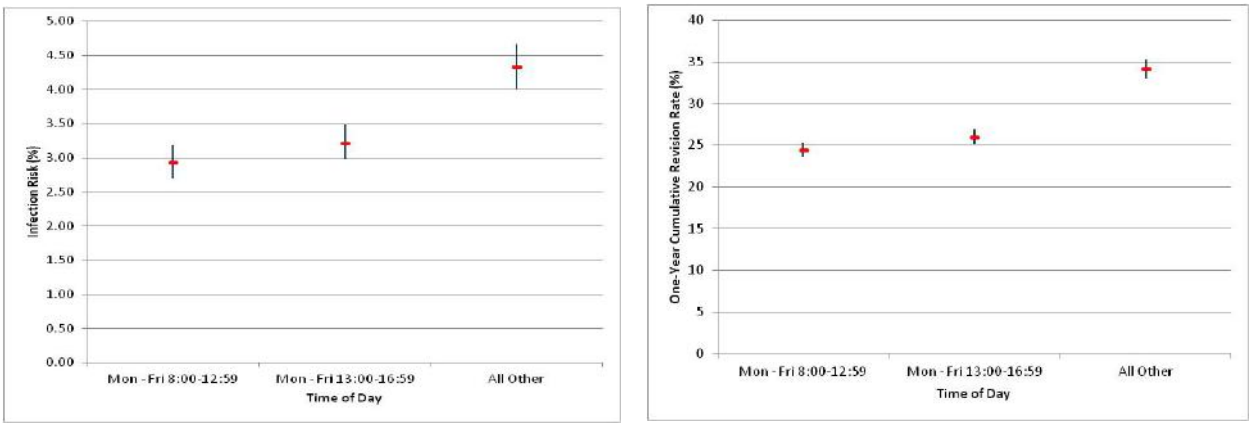


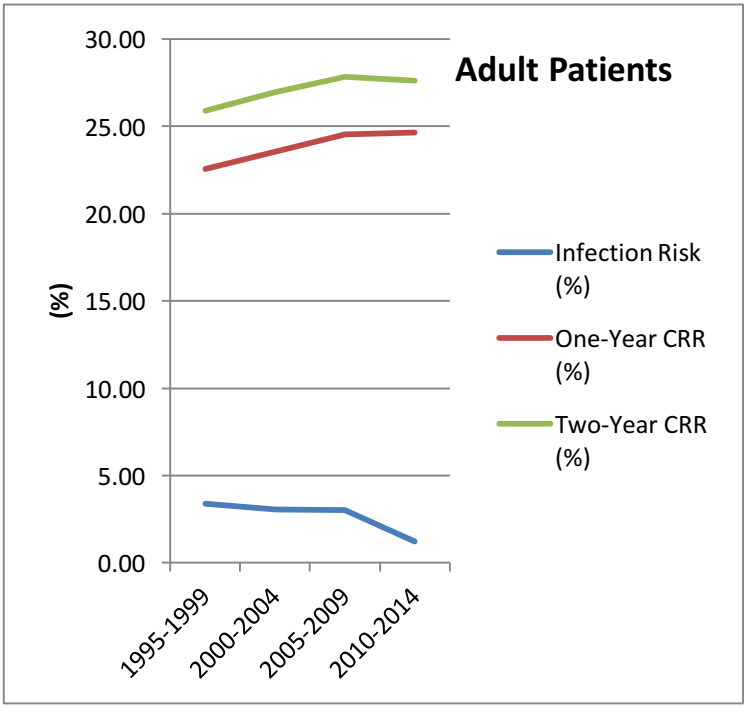
Figure 18: Infection Risk and One-Year Cumulative Revision Rate by Time of the Day (NB not corrected for case mix or proportion of primary versus revision procedures).

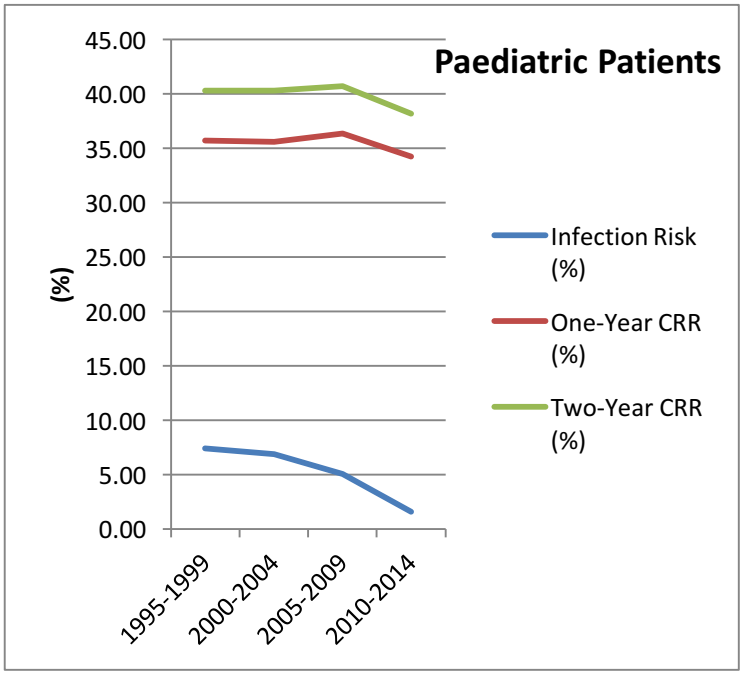
The data appear to suggest a higher infection risk and one-year revision rate at the weekend and out of hours. However, it is essential to correct for case mix and the proportion of primary procedures versus revisions. For example, there is as anticipated a greater proportion of shunt revisions performed out of hours (64.0%) than during the working week (48.3%). As figure 1a reveals, the one year cumulative revision rate for adults is 14% for primary procedures and 34% for revisions. The infection rate for adult primary procedures is 1.3% whereas it is 4% for adult revisions (table 10). The proportion of patients aged over 70 years is 13.0% during working hours and 8.1% out of hours. Both infection rate and cumulative revision rate is lower in the over 70's than in children and adults under 70 years of age. Further statistical modeling is in progress.

5.9 Variation in performance over time and between individual Centres

5.9.1 Variation in overall infection rate and cumulative revision rates over time

There has been a significant fall in infection rates over the past 5 years (figure 9) but otherwise no reduction in cumulative revision rate despite the increasing seniority of the operating surgeon (figure 13 and figure 19):





5.9.2 Performance of individual Centres

Infection risk in adults and children are shown in Figure 20 and one-year and two year revision rates in Figure 21a-d. Comparison between centres is problematic and league tables should not be published without confidence limits. It is salutary to remember the strictures of Goldstein and Spiegehalter in their authoritative paper on League tables and their limitations (J Royal Statistical Society 1996;159:385-443). Further statistical modeling is in progress. Centres vary in their size and case-mix and may also vary in the quality of the data returned. Centres may close or transfer to other sites and staff - surgical, nursing and administrative - can move between centres. Funnel plots are provided to highlight potential outliers. The SBNS Neurosurgical National Audit Programme (NNAP) defines performance to be of concern if it lies more than 2 standard deviations but less than 3 SD from the target performance. Performance is of serious concern if it lies more than 3 SD from the target performance. There were no centres that were a cause for serious concern and only one centre that was of potential concern (performance slightly more than 2 SD) but which was improving in the last 5 year epoch.

Figure 20: Centre Infection Risk in the Adult and Paediatric age groups

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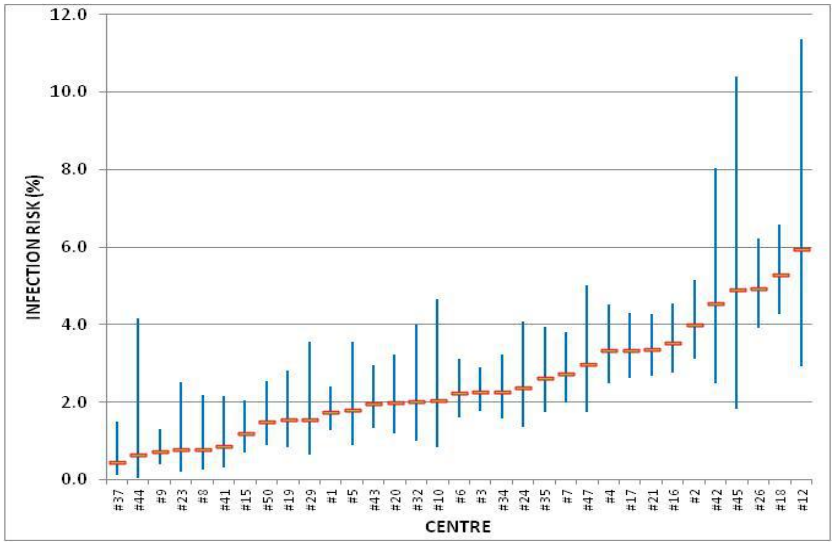


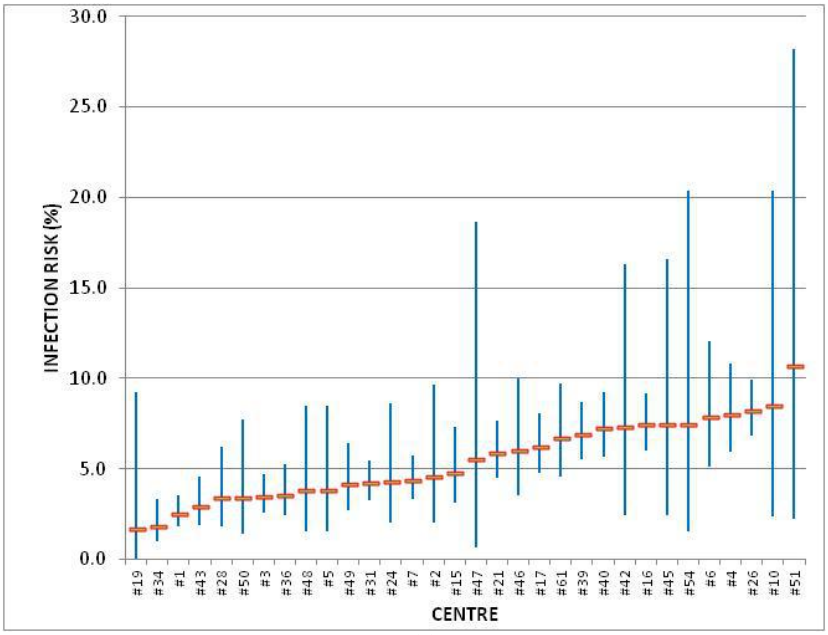
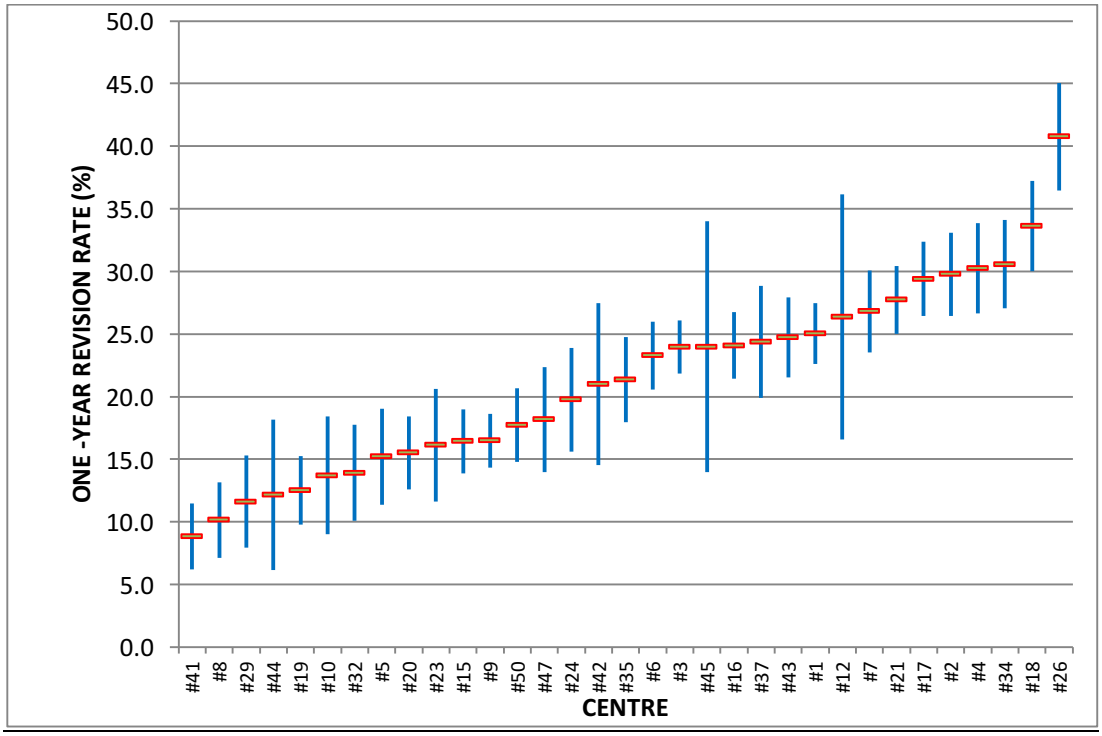


Figure 21a: Centre One-Year Cumulative Revision Rate – Adult including funnel plot



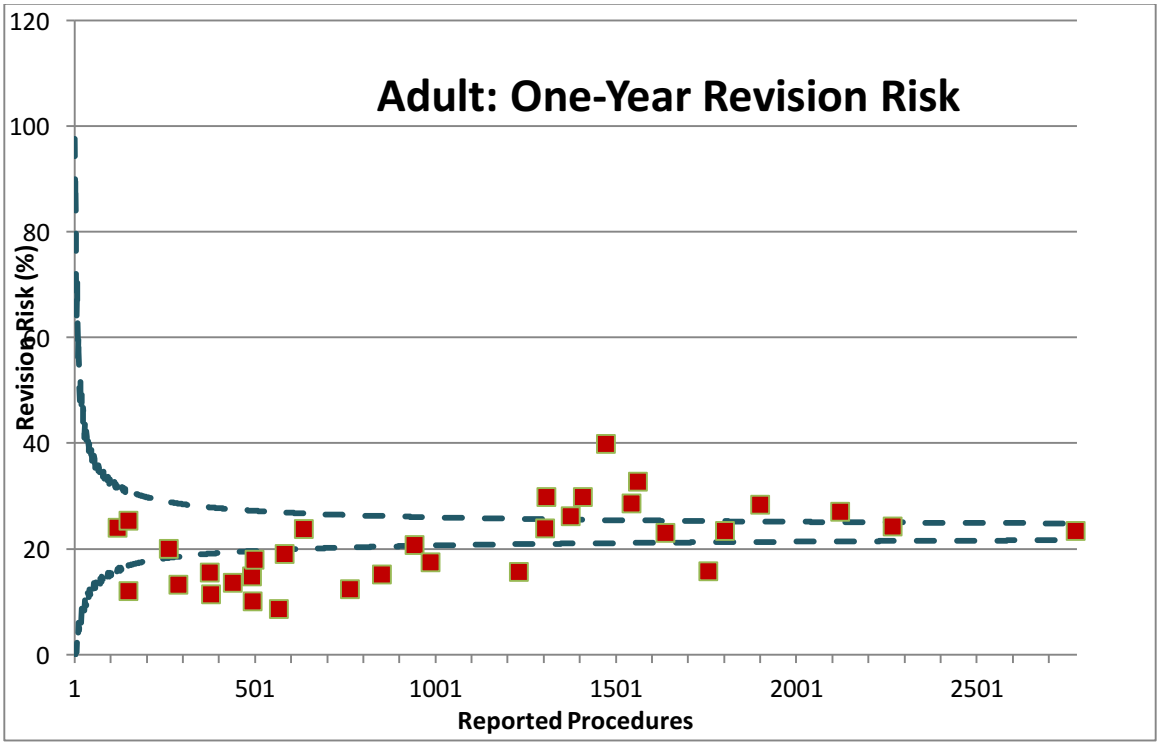
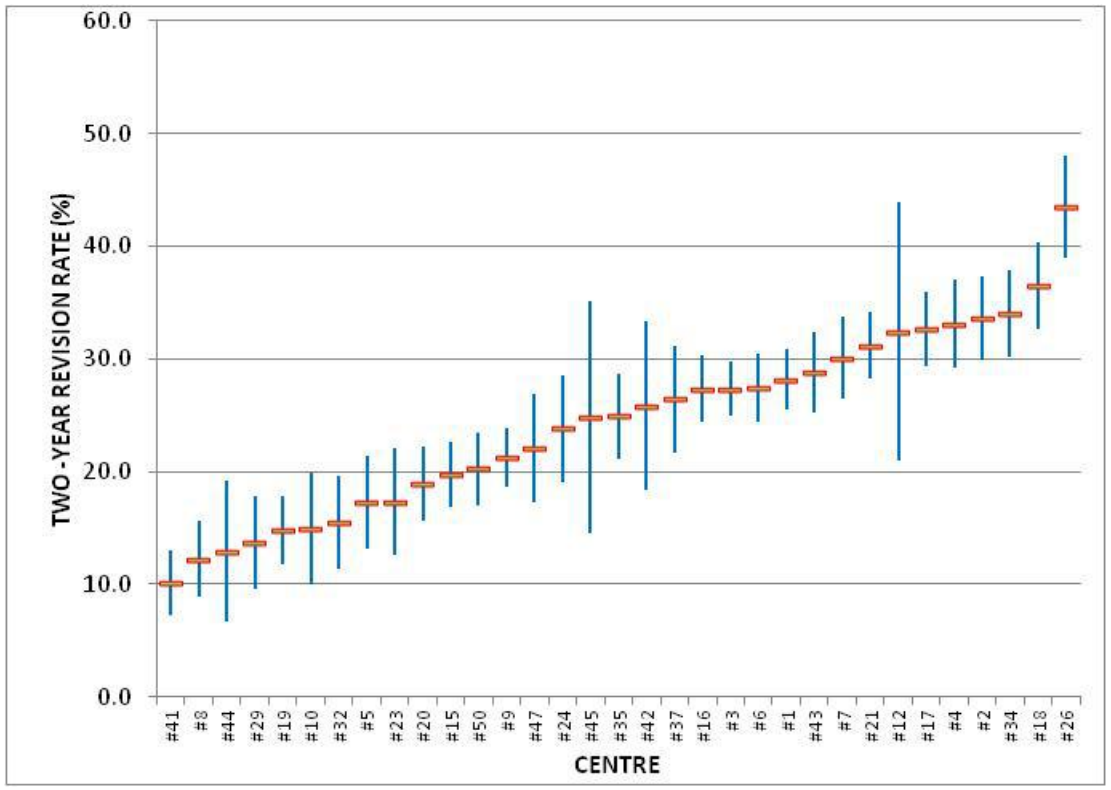


Figure 21b: Centre Two-Year Cumulative Revision Rate – Adult including funnel plot



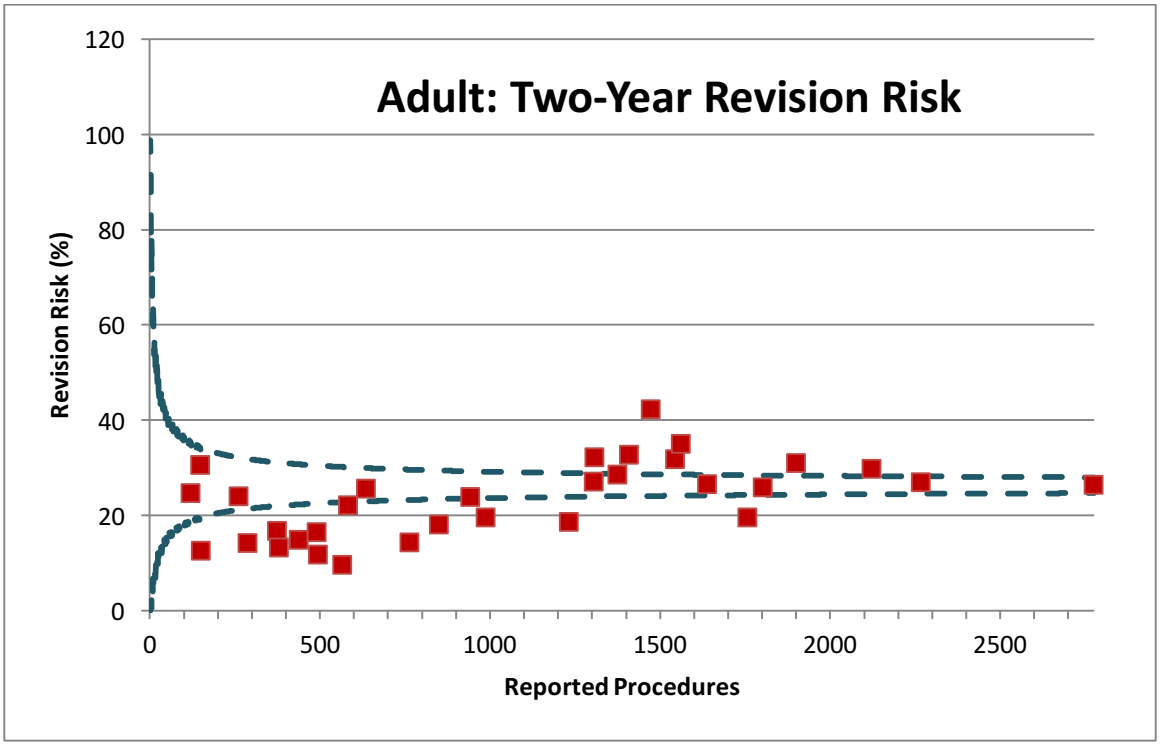
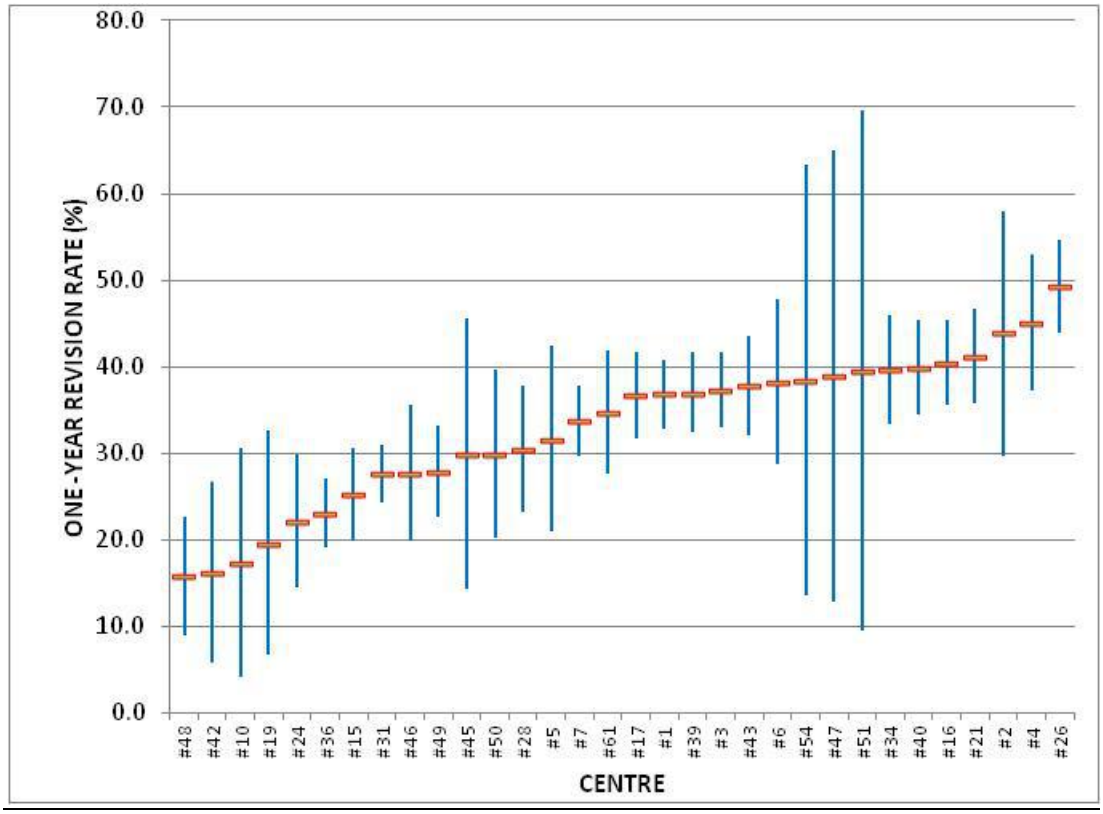


Figure 21c: Centre One-Year Cumulative Revision Rate – Paediatric including funnel plot



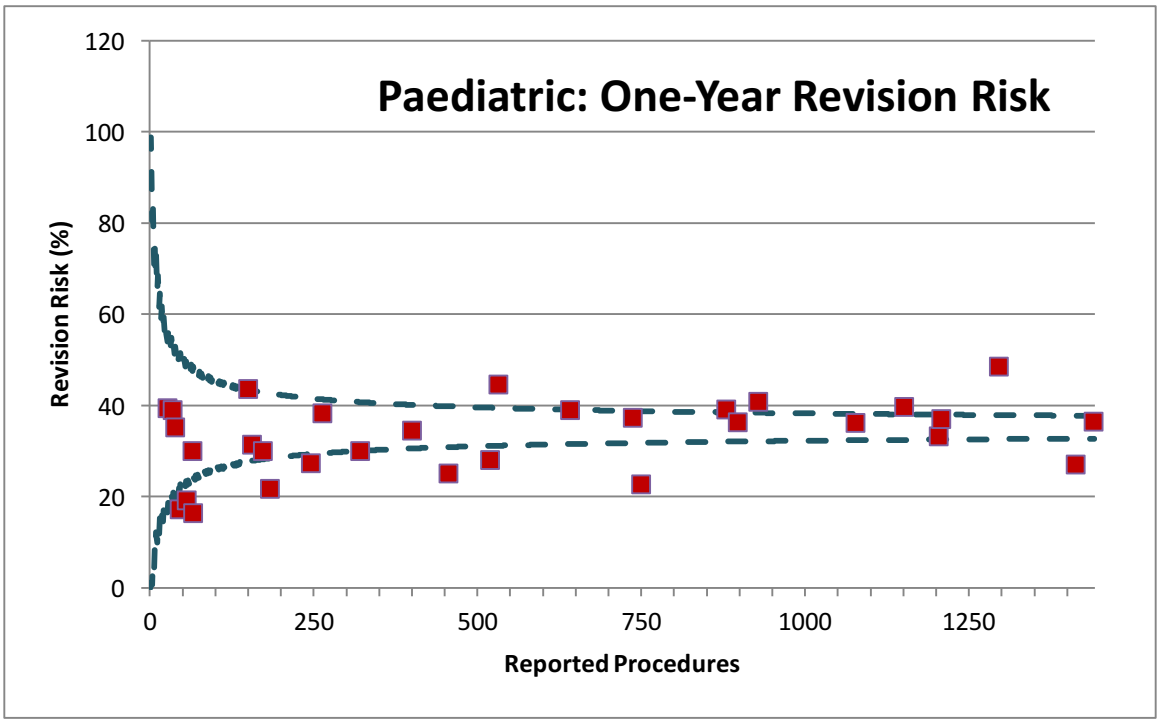
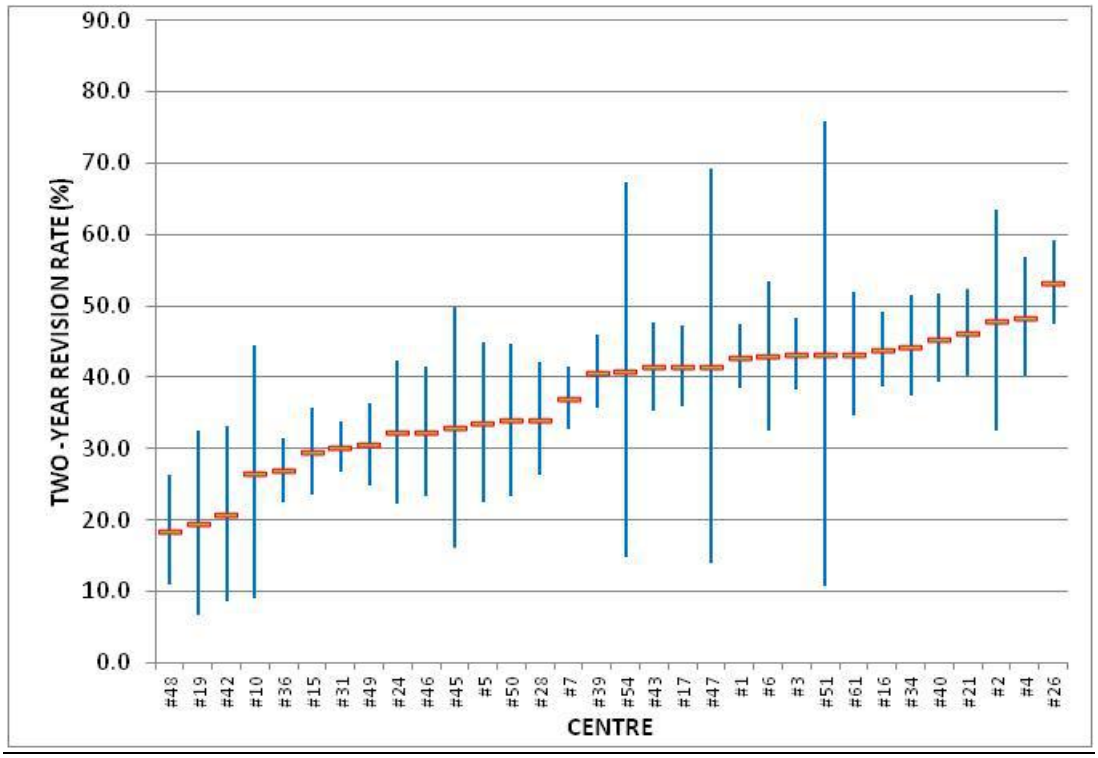
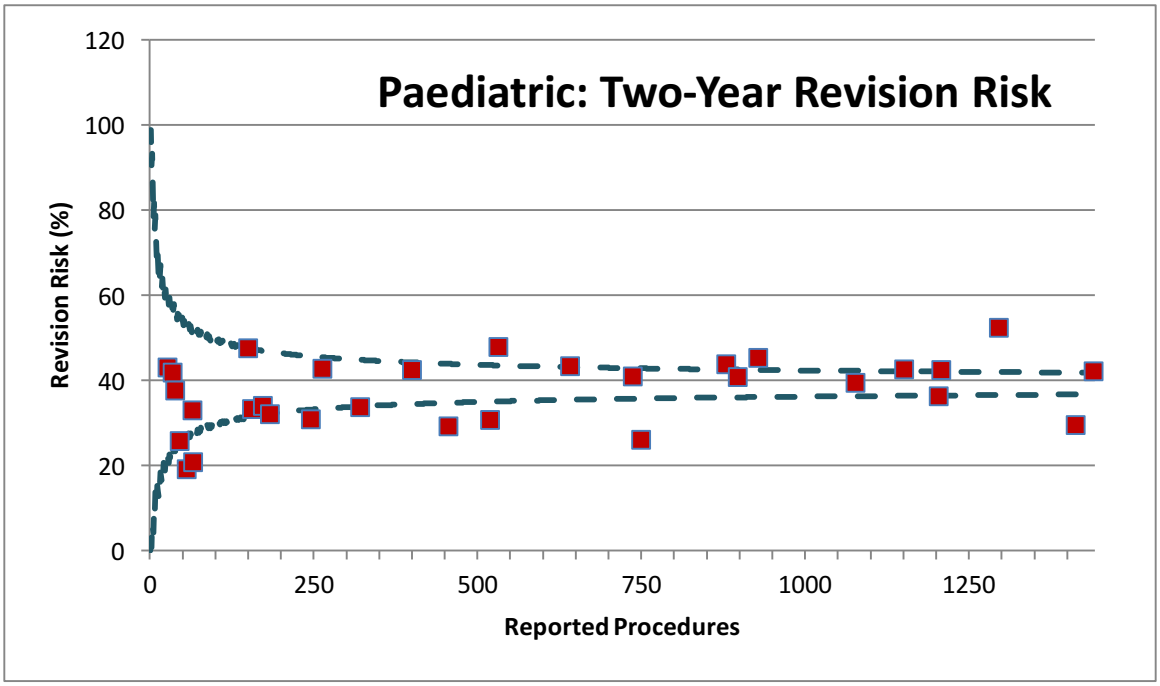


Figure 21d: Centre Two-Year Cumulative Revision Rate – Paediatric including funnel plot

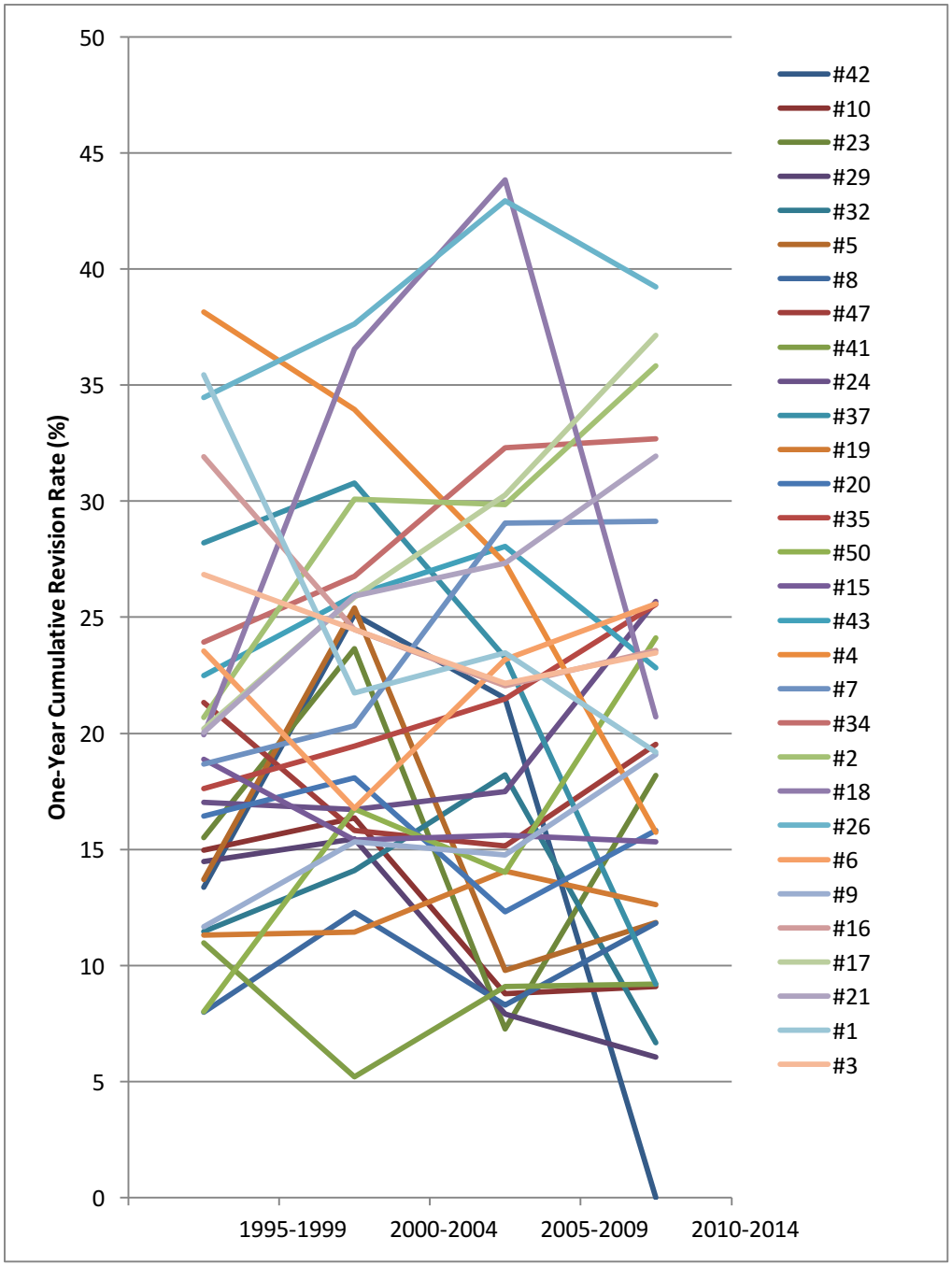




5.9.3 Cumulative Revision Rates and Infection Rates by Centre over time (in 5 year epochs)

In order to assess whether there have been any changes in performance in individual centres over time, the cumulative revision rates and infection rates have been split into five year epochs (figures 22 a - b) . Despite the substantial numbers of procedures involved, there was considerable variation between epochs such that it would be difficult to define when an individual centre's performance was trending towards becoming an outlier. Further statistical modeling is in progress.

Figure 22a: Adults - one year cumulative revision rate and infection risk.



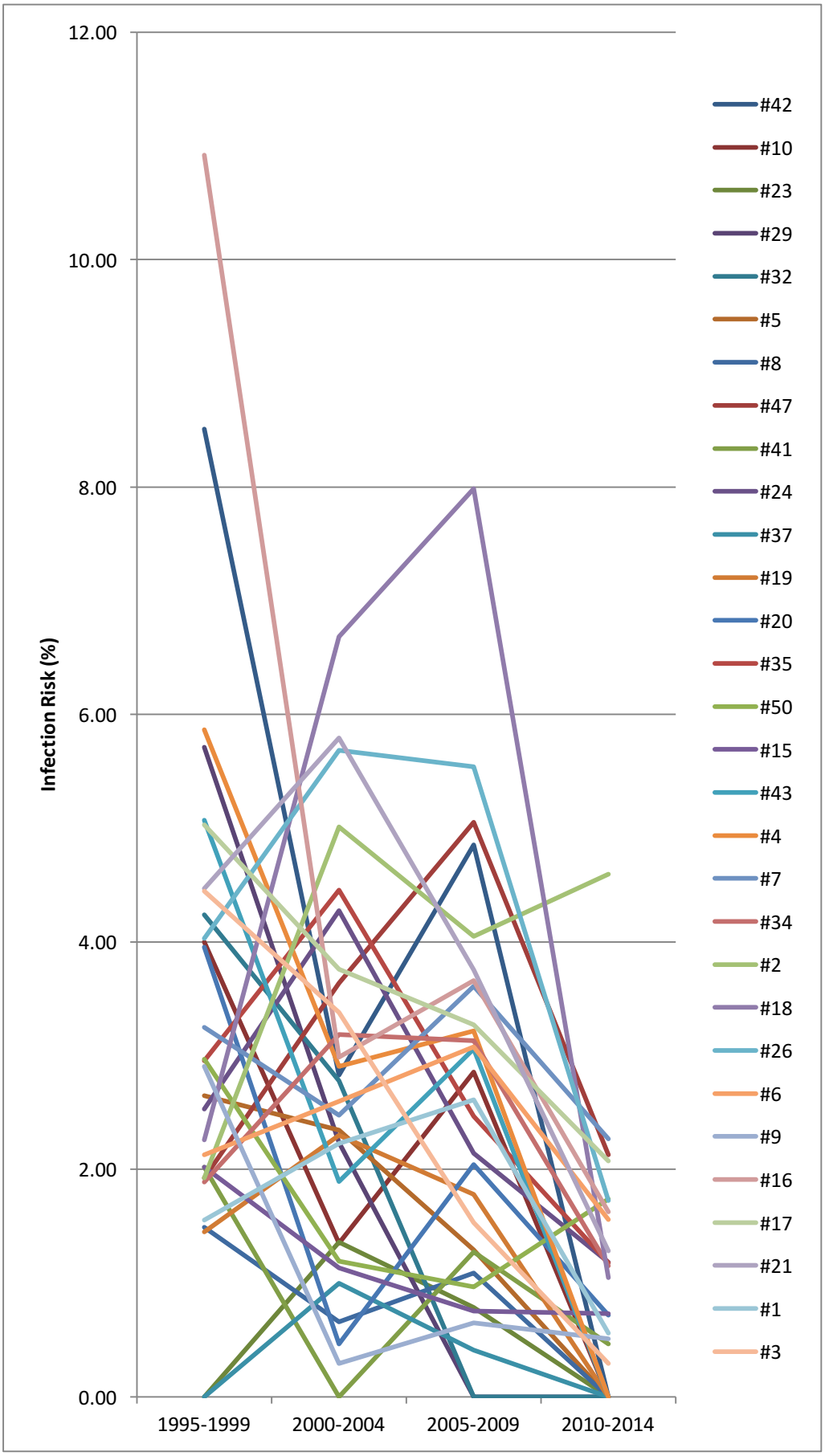
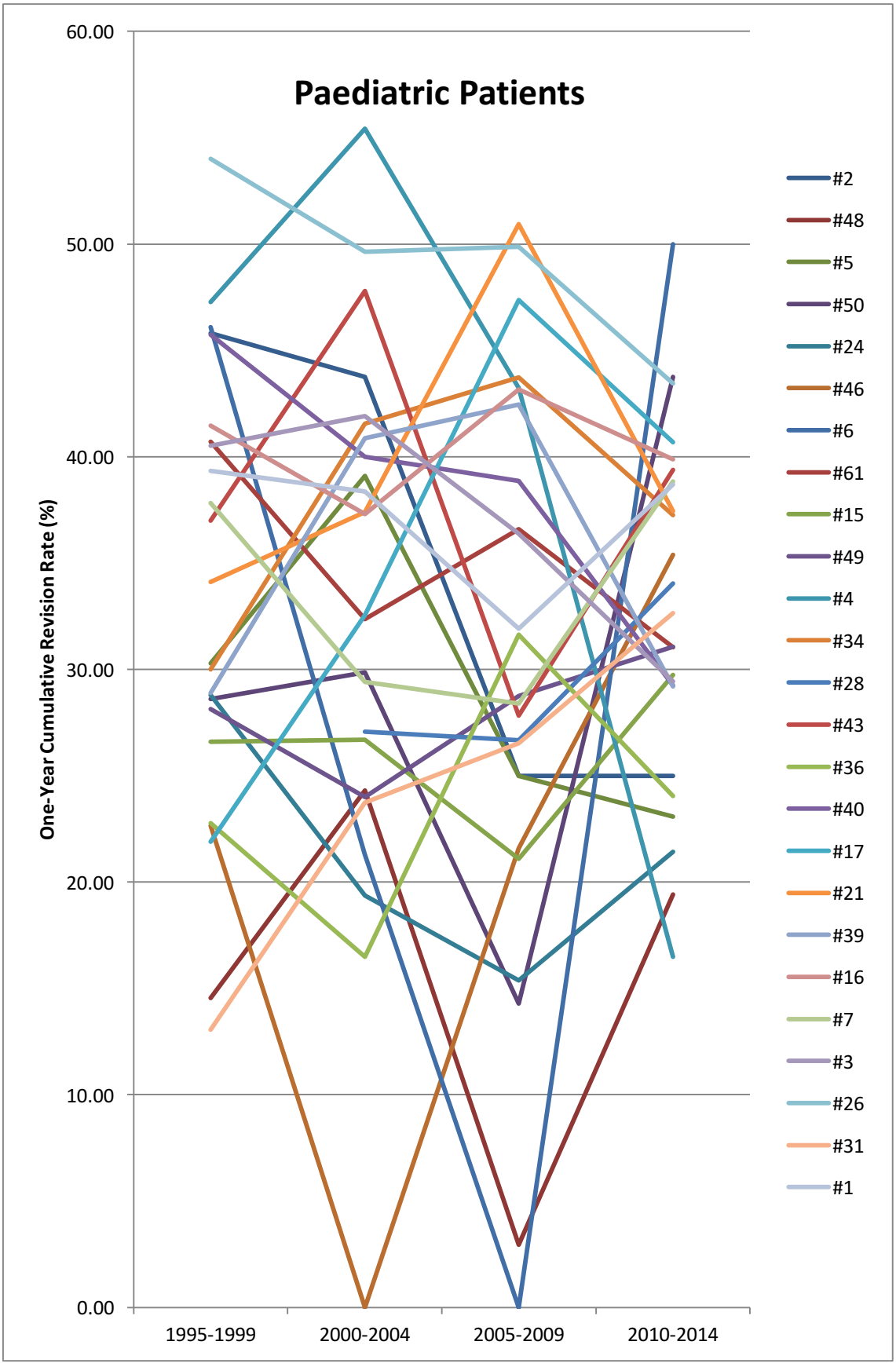
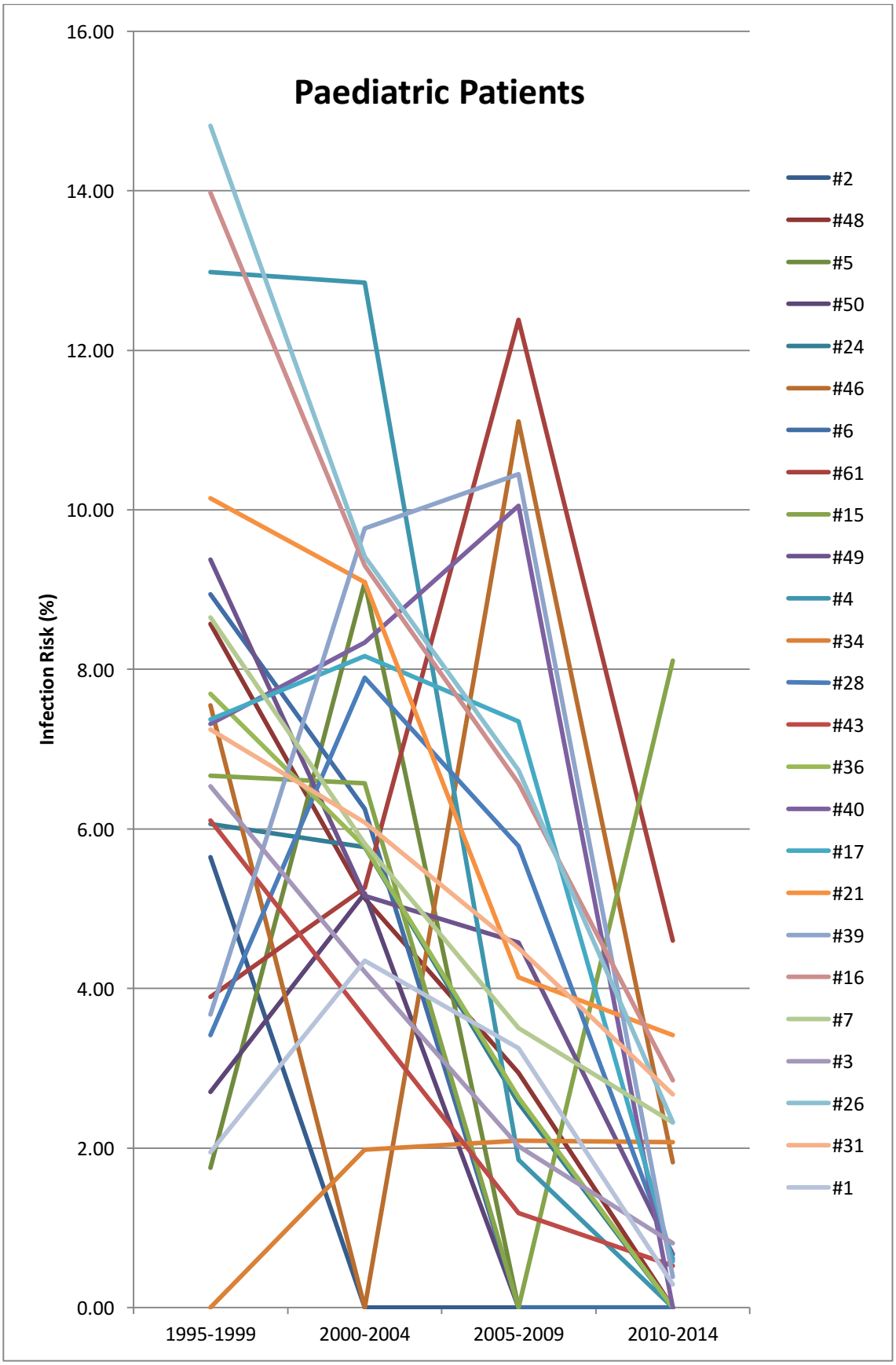

12.00
10.00
8.00
6.00
4.00
2.00
0.00
Infection Risk (%)
1995-1999
2000-2004
2005-2009
2010-2014
#42
#10
#23
#29
#32
#5
#8
#47
#41
#24
#37
#19
#20
#35
#50
#15
#43
#4
#7
#34
#2
#18
#26
#6
#9
#16
#17
#21
#1
#3

Figure 22b: Paediatrics – one year cumulative revision rate and infection risk.




Paediatric Patients
Infection Risk (%)
16.00
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
1995-1999
2000-2004
2005-2009
2010-2014
#2
#48
#5
#50
#24
#46
#6
#61
#15
#49
#4
#34
#28
#43
#36
#40
#17
#21
#39
#16
#7
#3
#26
#31
#1

7 The way forwards.

7.1 Objectives

Since 2014, the UK Shunt Registry has begun its transition to an electronic data collection and management platform, hosted within the Outcome Registry Intervention and Operation Network (ORION). As part of this transition, the strategic aims of the registry have been updated and expanded to include the following:

1. Define the current state-of-the-art in terms of long term management of different groups of patients with disorders of the CSF circulation and related disorders ['hydrocephalus'] using shunting, endoscopic third ventriculostomy and other related procedures including venous sinus stenting.

2. Provide an accurate picture of the use of different types of shunt.

3. Monitor in real time and through annual audit the outcomes of different groups of patients with 'hydrocephalus' achieved by types of operative intervention, type of implant, hospital and multidisciplinary team.

4. Inform patients, carers, clinicians, providers and commissioners of healthcare, regulators, and implant suppliers of the outcomes achieved in surgical interventions for 'hydrocephalus'.

5. Provide participating centres with a local reference and audit resource, including live data access and independent data for the shunt infection CQUIN measure.

6. Enhance patient awareness of outcomes after surgical interventions for 'hydrocephalus' to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations.

7. Support suppliers with the routine post market surveillance of implants and provide information to clinicians, patients, hospital management/procurement and the regulatory authorities.

8. Facilitate registry-based trials.

7.2 Key changes

Key changes in the updated registry, in line with the above aims, include:

Dataset update: a revised dataset consolidated to record key operative indicators within an adaptive data capture electronic form to enable fast and accurate submission. Procedure codes have been mapped to the standard ICD10-based coding adopted by the SBNS, and a complete live valve catalogue directory is now available on the system. Finally, acknowledging previous low submission rates, external ventricular drain insertion is no longer within the recorded registry procedures.

Baseline	Operative	Implants
Reason for shunting	Time and duration	Proximal catheter (type, site, image guidance)
EVD insertion in last 30 days	Surgeon grade	Valve (cat / serial number, setting)
Procedure type	Responsible consultant	Distal catheter (type, drainage site)
Reason for revision	Level of supervision	Reservoirs and other implants
Additional procedures (ETV, plexectomy, s/t decomp)	Number of surgeons	Implants removed
Ventricular size	*Operative note*	
Concurrent chemo	*BASICS (+/- other studies)*	
Existing CSF infection		
CSF infection in 6 months		

Local data access: individual centres have ongoing access to their submitted data, with the ability to filter procedures based on operation type, underlying CSF diagnosis and responsible consultant. It is also possible to export local operative data in spreadsheet format and in individual printable form. When clinically required, access to a patient's entire recorded shunt history across units can be provided.

7.3 Progress with implementation

Thirty-two out of thirty-five neurosurgical units have now been successfully set up on the electronic registry, of which 12 are now submitting data on an ongoing prospective basis. The transition has been supported by 29 on-site training visits to date, updating clinicians and theatre staff on the updated data submission process. We are working towards a target of all units submitting prospective data by the next financial year, in preparation for the new annual reporting cycle.

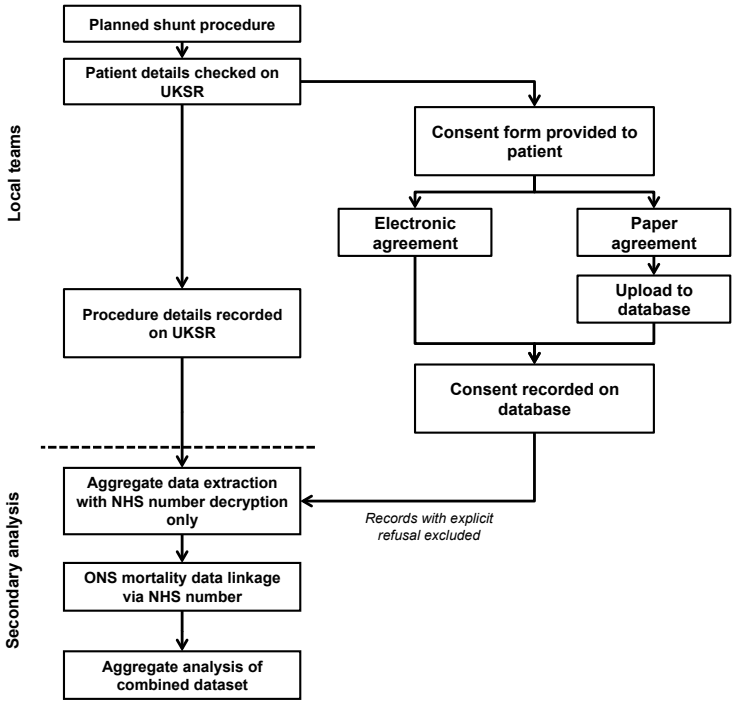
We are particularly grateful to the neurosurgical trainees participating in the national external ventricular drain audit for catalysing the early phase of the electronic transition. The audit, conducted through the newly implemented electronic registry, recorded 669 procedures in 21 units over a 5 month period (Nov 2014 – April 2015), demonstrating the feasibility of the electronic data capture process.

Whilst parallel paper submissions were accepted during the transition period, this was finally discontinued in June 2017, prompted by potential security concerns on outdated systems following the May 12th NHS cyber attacks. All the data from the old shunt registry server has been extracted and is in the process of being mapped and imported within the new electronic platform.

7.4 Data Management and Patient Consent

Participating units remain data controllers for the information submitted to the UK Shunt Registry, with a provision that aggregate data may be used by the registry on an ongoing basis for reporting and surveillance. This procedure is in line with all other registries hosted within ORION.

In order to use identifiable information for linkage with mortality data from the Office of National Statistics (ONS) and procedure information from Hospital Episode Statistics (HES), the Registry submitted an application for a Section 251 exemption from the NHS Health Research Authority. S251 final approval was granted in June 2017. As a condition of this approval, it is now necessary for patients to be informed - whenever feasible - of their data being submitted to the UK Shunt Registry, and consent recorded within the registry.



7.5 Annual reporting and Governance

Reporting from the UK Shunt Registry will be overseen by the SBNS CSF subspecialty group, and a data monitoring committee established for publishing an annual report in line with other established national audits. In line with the registry's objectives, the annual report will publish unit-level data on procedure volume and case-mix, and outcome stratified by types of intervention and implant. We anticipate the first annual reporting cycle to commence from 1st April 2018, to provide an opportunity for remaining units to fully engage with prospective electronic data collection.

8 Acknowledgements

The UK Shunt Registry is very grateful to Professor Ken Taylor (Emeritus Professor of Cardiac Surgery, Hammersmith Hospital), Professor Sir David Spiegelhalter and Dr Peter Walton (Dendrite) for their invaluable advice during the UKSR's set up phase in 1994 and to the MHRA for their long term support including initial funding and continuing intellectual input. We are very grateful to all those Centres and personnel who have contributed data. Particular thanks are due to Colette O'Kane & Evelyn Kamau for visiting the centres and to Meryl Madakbas, Beryl Ripsher, Liz Fahie & Elizabeth Tabone for their long suffering data logging in to the database and much else. The project has been supported by annual contributions from individual units, the NIHR Brain Injury Health Technology Co-operative and an NIHR Senior Investigator Award.

Correspondence should be directed to Professor John Pickard (jdp1000@cam.ac.uk) or Dr Alexis Joannides (aj238@cam.ac.uk).

9. Appendices

9.1

UK Shunt Registry PATIENT INFORMATION LEAFLET

What is the UK Shunt Registry (UKSR)?

The UKSR is a national database for recording all shunt-related procedures and other procedures related to the cerebrospinal fluid (CSF) circulation (endoscopic third ventriculostomy, choroid plexectomy and cranial venous stenting). It was established in 1993 and is currently adopted by all UK neuroscience units. Its purpose is to improve the health of patients with hydrocephalus (build of fluid in the brain) and other CSF-related conditions through monitoring of national practice.

You have been contacted as you are about to undergo, or have recently undergone, a shunt operation or related procedure.

What are the benefits of the UKSR?

- It provides accurate independent information to patients, carers, healthcare regulators and implant suppliers about the use of different types of shunts and outcomes from surgical interventions. It can therefore be used to identify substandard shunt systems, informs best practice and enhances patient choice.
- It helps the medical team to monitor the outcome of different groups of patients with hydrocephalus, and drive improvements in best practice for treatment of hydrocephalus.
- It can prompt investigation and follow-up support where there has been an unexpected outcome or where practice is below the expected standard.
- It helps give up-to-date information on mortality in patients with hydrocephalus.

How will the UKSR benefit me?

- It enables continuous monitoring of your type of implant including any episodes of infection.
- It allows access to your shunt record by neurosurgical units across the UK if you need to be treated in a different centre.
- It allows prompt notification should there be a fault alert on your type of implant.

Who will have access to my information?

Your treating team will record basic demographic information such as your name, date of birth and NHS number to reliably identify your record over different operations. We will collect data on the type of surgery you had, the reason for your operation, and details of the operation itself, including any shunt equipment used or removed.

Data will be kept confidential at all times. Your personal data will only be accessible to your local team(s) to support your treatment. Authorised persons working for the shunt registry will have access to your shunt data in anonymised form for data analysis.

The shunt registry may also use your NHS number to contact you promptly should we gather information suggesting you require a follow-up appointment urgently. Your NHS number may also be used to enable general analysis to monitor quality and efficacy of different implants across different age groups.

Is my information safe?

Keeping your information safe is of the highest importance. All those involved in the UKSR comply with the requirements of the Data Protection Act 1998 and NHS Act 2006. Only your medical team and authorised persons working for the UKSR will have access to your information. All personal information is securely stored in encrypted form, and there are strict procedures in place to ensure only those authorised will be able to view your records. Your personal information will not be shared or passed onto any third party unless required by law.

What if I have further question about the UKSR?

Your treating team should be able to provide you with information about the UKSR. If you would like to find out more information, please contact The Outcome Registry Intervention and Operation Network, Department of Neurosurgery, University of Cambridge, Box 167, Addenbrooke's Biomedical Campus, Cambridge, CB2 0QQ.

9.2 British CSF Group Constitution

1 Title

The Group will be known as the *British Cerebrospinal Fluid Group (BCSFG)*

2 Status

The BCSFG has been recognised by the Society of British Neurological Surgeons (SBNS) and acts as a forum to promote clinical, research and training aspects of Cerebrospinal Fluid and related venous disorders *(Abb. CSF disorders)*.

3 The aims of the group will be:

a) To provide a forum for discussion of issues relating to the management of CSF at all ages in the UK and Ireland
b) The group will be inclusive and multidisciplinary and will bring together medical, paramedical, nursing and other health care professionals in the UK and Ireland with an interest in the field of CSF disorders.
c) The group will focus primarily on CSF disorders and related venous pathology
d) The group's activities will cover clinical (e.g. co-ordination of service delivery, feedback on NICE guidelines), patient and public engagement, research (e.g. networks, facilitation of multicentre trials and ROSERI) and training (e.g. lifelong learning, CSF fellowships) aspects of CSF disorders.
e) The group will meet annually in the form of a scientific meeting. At the scientific meeting there will be a business meeting and minutes of this meeting will be maintained. Extraordinary meetings may take place as required. Funds will be sought to encourage trainee involvement through travel bursaries and prizes.
f) The group will liaise with and provide the SBNS and its council with evidence-based advice when issues regarding CSF disorders are under discussion.
g) The group will link with other organisations including the British Paediatric Neurosurgery Group, the UK Shunt Registry, the UK Shunt Evaluation Laboratory. Commissioners, Industry and relevant voluntary organisations (such as the relevant charities, Shine, IIH UK, Brain & Spine Foundation and the British Syringomyelia-Chiari Society).

4 Officers of the group

The group will be administered by a Chair and a Secretary/Coordinator who will be nominated by the members of the Group for a two-year term of office and be jointly responsible for organising the group's scientific meeting with a local organiser.

At the scientific meeting, the Secretary will call on members of the group to nominate candidates for Chair and Secretary-elect. If there is more than one nominee for either post a confidential postal ballot will be arranged by the secretary and the candidate with the most votes will be appointed to the post of secretary at the next meeting of the Group.

5 Membership

Membership will be open to all health care professionals with a clinical interest in the field of CSF disorders.

6 Fees

There are no membership fees but this will be reviewed as appropriate. Meeting finances will be audited by the SBNS Council.