**Airway Intervention Registry (AIR):**

**a research database to capture safety and efficacy outcomes of balloon dilatation in the treatment of airway stenosis and any intervention in the treatment of respiratory papillomatosis**

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| **Chief Investigator:** | Dr Andrew Sims, Head of Department, Medical Physics and Clinical Engineering (NCCC Level 2), Freeman Hospital, Freeman Road, High Heaton, Newcastle upon Tyne, NE7 7DN. Tel: 0191 244 8738 Email: [andrew.sims@nuth.nhs.uk](mailto:andrew.sims@nuth.nhs.uk) |
| **Investigators:** | Steven Powell, Consultant ENT Surgeon, Freeman Hospital, Freeman Road, High Heaton, Newcastle upon Tyne, NE7 7DN. Tel: 0191 213 7629 Email: [steven.powell@nuth.nhs.uk](mailto:steven.powell@nuth.nhs.uk)  Adam Donne, Consultant in Paediatric Otolaryngology, Alder Hey Children's NHS Foundation Trust, Eaton Road, West Derby, Liverpool, L12 2AP. Tel: 0151 551 2080 Email: [adam.donne@alderhey.nhs.uk](mailto:adam.donne@alderhey.nhs.uk)  Gavin Morrison, Consultant Otolaryngologist, Head of Service Paediatric Otolaryngology, Evelina London Children's Hospital, Guy's & St. Thomas' Hospitals NHS Foundation Trust, London, SE1 7EH. Tel: 020 7188 2194 Email: [gavin.morrison@gstt.nhs.uk](mailto:gavin.morrison@gstt.nhs.uk) |
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| **Chief Investigator Signature:**  **Date of signature:** |  |

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# BACKGROUND AND RATIONALE

The National Institute for Health and Care Excellence (NICE) has produced guidance as part of the Interventional Procedures (IP) programme related to two specific procedures: *Endoscopic balloon dilatation for subglottic or tracheal stenosis* [IPG425, 2012] and *Radiofrequency controlled ablation for respiratory papillomatosis* [IPG434, 2012]. However, due to the small evidence base for these procedures, the guidance recommended that the procedures be undertaken under special arrangements and that data should be collected on their use in the NHS, to inform future guidance on their long-term safety and efficacy.

The Newcastle and York NICE External Assessment Centre (EAC), a partnership between The Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) and the York Health Economics Consortium (YHEC), has been commissioned by NICE to facilitate the development of a procedural registry to include information about these two procedures, to encourage and monitor data submission and to analyse and publish observational studies to inform future guidance.

Favourable ethical opinion was received on 29th December 2014 (REC reference 14/NE/1200; IRAS 164160) with version 1.1 of this protocol. Following this, the Airway Intervention Registry (AIR) platform was developed to host the balloon registry (AIR-balloon) for recording balloon dilatations in paediatric airway stenosis. The AIR-balloon registry opened for recruitment April 2015, and currently has 66 registered surgeons from 20 centres with entries for 73 procedures on 41 patients. It is expected to achieve its target of 100 procedures by March 2018.

Development of a registry for the second intervention considered within 14/NE/1200 (radiofrequency controlled ablation for respiratory papillomatosis) was paused following discussions among the project team, and the funder (NICE), centring on uncertainties over the prevalence of RRP, the use of other forms of treatment, and the likelihood of a registry being suitable to inform national guidance on one specific intervention. To address these questions, the research teamconducted a survey of 283 ENT consultants across the UK and identified a cohort of 918 RRP patients currently being managed in the UK acute hospital sector [Donne et al, 2016]. Of this cohort, 479 patients had received treatment within the preceding 12 months; however of all RRP procedures conducted, radiofrequency ablation was used in only 3.3% of cases. The results of this survey indicated that micro-debridement (used in 37.5% of all RRP procedures), laser (16.5%) and cold steel surgery (12.0%) were other interventional procedures which were used more frequently, with alternative treatment options being used in 1.1%. Due to the rare nature of RRP, the short- and long-term efficacy and safety evidence of these other treatments of RRP is also lacking in the literature. NICE has also expressed interest (but not issued formal guidance) in other interventions for respiratory papillomatosis, for example: intra-lesional cidofovir for laryngeal papillomatosis, and Helica Thermal coagulator for the treatment of benign laryngeal tumours.

Due to the low prevalence of use of RF ablation in RRP, NICE felt that they could not justify financial support for an RRP registry specific to RF cold ablation, and that a registry collecting data on all forms of treatment for RRP was outside of NICE’s scope. The research team, with the support of NICE, therefore applied for research funding to NIHR to develop and host an RRP intervention registry. The funding application was successful, and this protocol has been revised to add a second registry to the existing online platform, AIR, to record information from all interventions in the treatment of respiratory papillomatosis in the UK.

Due to the low incidence of airway stenosis and extremely low incidence of respiratory papillomatosis, observations from all hospitals within the UK (including adults and paediatrics)will be required to inform future guidance.. The AIR platform, developed and hosted by NUTH, currently collecting information from respiratory hospital visits from all consented paediatric patients where balloon dilatation procedures for airway stenosis have been conducted will be expanded to include information from adults and paediatrics on any interventional procedure in the treatment for RRP.

# OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

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| --- | --- |
| **Objectives** | **Outcome Measures/Endpoints** |
| To collect short- and long-term safety and efficacy evidence (which is currently lacking) from both balloon dilatation procedures for the treatment of airway stenosis in paediatric patients and any intervention in the treatment of RRP being conducted across the UK in both adults and paediatric patients | Short-term safety outcome measures will include peri-procedural complications, in-hospital mortality and length of stay. Long-term safety outcome measures will include number of hospital admissions, outpatient/A&E attendances, complications, and mortality.  Efficacy outcome measures for balloon dilatation will include the Cotton-Myer grading system for degree of stenosis and the paediatric Voice Handicap Index (pVHI). Efficacy outcome measures for all RRP treatments will include the Derkay scoring system for degree of papillomatosis in the airway, the pVHI and VHI (adult alternative). Parent/guardian/patient surveys of patient general health, including aspects of breathing, swallowing and speech will also provide an additional measure of efficacy. |
| 1. To identify how widely the balloon dilatation and RRP procedures are being applied in the UK 2. To identify the patient groups where balloon dilatation and RRP procedures are most/least effective and identify potential confounding factors which may influence outcomes of both balloon dilatation and RRP procedures 3. To survey patients or their parent(s) /guardian(s) to capture patient related outcome measures and test for association with efficacy outcome measures | 1. Number of procedures and number of patients receiving balloon dilatation, or treatment for RRP. 2. Conduct multivariate analysis on efficacy outcome measures taking into account patient demographics (e.g. age, gender, comorbidities, previous treatments used, medications etc.). 3. Results from patient surveys will comprise of the following: paediatric Voice Handicap Index (pVHI) (0-17 year olds), Voice Handicap Index (VHI) (18 years and over), general questions of quality of life covering aspects of breathing, feeding/swallowing, speech and overall health, frequency of health care visits (GP, inpatient, outpatient & A&E). |

The above objectives and outcome measures have been peer-reviewed by the already established Steering Group committee (which comprises of respiratory professional societies, clinicians involved in diagnosis and/or treatment of either airway stenosis or respiratory papillomatosis, and members of the National Institute for Health and Care Excellence and its External Assessment Centre (NUTH – which is also the developer and host of AIR) and the NIHR as part for the successful Research for Patient Benefit (RfPB) funding application.

Due to the observational nature of the data collection additional research objectives may be retrospectively applied to the collected data where deemed necessary by the established Steering Group committee.

All of the above required information to meet the objectives will be prospectively collected in the online registry and completed by the treating clinician taking information from patient notes, medical examination(s) results and from parent/guardian surveys. The data will also be verified, where possible, with information gathered from national databases including Hospital Episode Statistics (HES) and Office for National Statistics (ONS).

# STUDY DESIGN

The Airway Intervention Registry (AIR) is a prospectively designed online platform which aims to capture observational information from all consented patients undergoing balloon dilatation treatment for airway stenosis, and any interventional treatment for respiratory papillomatosis. Balloon dilatation treatment for airway stenosis and one specific treatment for respiratory papillomatosis (radiofrequency cold ablation) have received NICE IP Guidance under ‘special arrangements’, therefore patient/parent/guardian consent should already be requested prior to conducting either procedure. Additional consent will be sought, at the same time, for submission of data to the AIR registry.

Data extracted from the registry will form the basis of a prospective single arm cohort study, which could also be described as observational disrupted time series design, without a parallel control. Due to the low incidence of airway stenosis and extremely low incidence of respiratory papillomatosis, this registry is intended for data collection from all hospitals across the UK. The strength of this study design is that it will capture information from all patients undergoing these respiratory interventions with no selection issues or bias. The limitation of this study design is the lack of comparator groups for balloon dilatation (however this is intrinsic to the registry being designed as a focused procedural audit rather than a wider disease registry capturing outcomes from all interventions). This limitation is not apparent for the RRP subset, in which we aim to collect information from all interventions for RRP.

Patient demographics, clinical history, medical assessment, procedural details, and post-procedural outcomes will be obtained from patient notes and recorded in the online registry by data field completion by the treating clinician. Quality of life measures will be obtained from patient/parent/guardian completed surveys. Patients/parent/guardian will either complete a hard copy, which will be transcribed to the online registry by the treating clinician or research nurse or patients/parent/guardians can submit online from the patient study website.

Data collection of balloon dilatation in AIR has been extended to 30 June 2018 (with possible extension beyond this period if deemed necessary by clinical community and established Steering Group committee, which will be informed by registry uptake and data completeness). Data collection of RRP interventionsinAIR has been funded until end of August 2020 (due to the successful NIHR RfPB grant application). Information from eligible patients will be recorded from all respiratory related hospital visits; however no additional hospital visits will be required in order to participate in this registry. The only deviation from standard clinical care would be the provision and completion of patient/parent/guardian surveys at each hospital visit.

The proposed Airway Intervention Registry (AIR) timeline for balloon dilatation is as follows:

Setup - 6 months (Sept 2014 – Feb 2015)

IRAS approvals (overarching REC and R&D approvals)

Development of online registry

Publicising of registry at national conferences

Publicising of registry on professional society websites

Gathering expressions of interest to participate in registry

Pilot – 1 month (Feb 2015 – March 2015)

Pilot online registry

Gather consultation comments and revise registry

Data collection –36months (April 2015 – June 2018)

Comment patient recruitment and data collection

Monitor patient recruitment and data completion from individual centres (comparison with HES)

Regular interim reporting (monthly for first year, quarterly for second year) to participating centres

Report submitted to REC of initial findings at 12 months

Analysis – 3 months (July 2018– September 2018)

Data cleaning

Detailed statistical analysis (univariate, multivariate, time series analysis)

Write up – 3 months (September 2018 – November 2018)

Anonymised results from all UK shared with all participating centres

Manuscript drafted for publication in a peer-reviewed journal

We have been awarded NIHR Research for Patient Benefit (RfPB) funding to develop the AIR to add all interventions RRP. The funding has been awarded from 01 September 2017. The duration of the award is 3 years (to 31 August 2020), which is of benefit to the RRP data collection due to the extremely low incidence of RRP.

The overarching schedule is similar to balloon dilatation, i.e.

Patient diagnosed with recurrent respiratory papillomatosis (RRP)

↓

Patient indicated for RRP intervention

↓

Eligibility Criteria Fulfilled

↓

Informed Assent/Consent

↓

Data Collection from RRP procedural admission

↓

Data collection from all subsequent respiratory related hospital visits (fixed data collection period of 2 years)

↓

Study End

The proposed Airway Intervention Registry (AIR) timeline for RRP interventions is as follows:

Setup - 6 months (Sept 2017 – Jan 2018)

IRAS amendment approvals (overarching REC and R&D approvals)

Development of online registry

Publicising of registry at national conferences

Publicising of registry on professional society websites

Gathering expressions of interest to participate in registry

Pilot – 2 months (Jan 2018 – March 2018)

Pilot online registry

Gather consultation comments and revise registry

Data collection –36 months (April 2018 – March 2020)

Patient recruitment and data collection

Monitor patient recruitment and data completion from individual centres

Regular interim reporting (monthly for first year, quarterly for second and third years) to participating centres

Report submitted to REC of initial findings at 12 months

Analysis – 3 months (April 2020– June 2020)

Data cleaning

Detailed statistical analysis (univariate, multivariate, time series analysis)

Write up – 3 months (June 2020 – August 2020)

Internal report drafted for NIHR

Anonymised results from all UK shared with all participating centres

Manuscript drafted for publication in a peer-reviewed journal

PARTICIPANT IDENTIFICATION

## Study Participants

The Airway Intervention Registry (AIR) will be designed to capture information from all consented patients aged 18 years or less (i.e. neonates, infants, children, adolescents and young adults) undergoing balloon dilatation treatment for airway stenosis, or patients of any age undergoing any interventional treatment of recurrent respiratory papillomatosis (RRP).

## Inclusion Criteria

* Patient/parent/guardian written informed assent/consent
* Patient/Parent/guardian able to complete paper surveys of patient health
* Patient (male or female) aged 0-18 years diagnosed with airway stenosis who are indicated for balloon dilatation treatment, or patients (male or female) of any age diagnosed with respiratory papillomatosis and are indicated for any interventional treatment

## Exclusion Criteria

* Patient/parent/guardian unable/unwilling to provide written informed assent/consent

# STUDY PROCEDURES

## Recruitment

Eligible patients identified prospectively, will be approached during assessment by the Ear, Nose and Throat (ENT) team in the inpatient or outpatient setting. The patient/parent/guardian will be introduced to the study by a member of the local clinical or research team, usually the treating clinician and have the opportunity to discuss participation of data to the registry with the clinician and/or research nurse.

Eligible patients who have already had at least one procedure will be approached by the local Ear, Nose and Throat (ENT) clinical team or research team via telephone call or at a follow-up visit. The patient/parent/guardian will be introduced to the study and have the opportunity to discuss participation of data to the registry. If willing to participate, the local clinical team or research team will send a patient information sheet and consent form to the patient/parent/guardian via the post.The patient will receive no financial benefit for participation in the registry. Patients will be followed up through the existing routine hospital/clinical visits and therefore no additional hospital visits will be required to participate in this registry. The registry will be held open for data collection of information from balloon dilatation procedures until June 2018 (i.e. the first purpose of this amendment application - an extension from the original planned completion date of October 2017), and data collection of information from RRP interventions for a fixed term of 3 years from opening, due to extremely low incidence of RRP (however this may be extended if deemed necessary by the clinical community and depending on data completeness of the registry). All data entered into the registry will be gained from patient notes, results from medical examination(s) occurring during a hospital visit and from parent/guardian survey completion at the time of the hospital visit. Thus participation in this registry will not require additional hospital or home visits.

## Informed Assent/Consent

Each patient/parent/guardian will be informed of the aims, methods, anticipated benefits and potential hazards of the study, both through the Patient Information Sheet (PIS) and verbally (either face to face where patients are recruited prospectively, or by phone or face-to-face at follow-up for retrospective recruitment). The participant/parent/guardian’s right not to participate in the registry and the right to withdraw at any time, without the need to give an explanation and without detriment to their overall treatment will be clearly stated. Whilst it is ethical best practice for patients/parents/guardians to be given a cooling off period of at least 24 hours between receiving the Patient Information Sheet (PIS) and providing their written informed assent or consent, due to the urgency of respiratory intervention in this patient population, where the airway is occluded, this length of time is not feasible for this study. We therefore propose that patients/parents/guardians be given a cooling off period of at least 1 hour between receiving the Patient Information Sheet (PIS) and providing their informed consent to participate data to the AIR registry.

Confirmation of the written informed assent or consent may then be taken by clinicians or suitably qualified nurses according to local practice. For retrospective cases, confirmation of the written informed assent or conset can be sent back to the local clinical or research team via post. Written informed assent requires eligible patients under 16 years of age to personally write and date the latest approved version of the Informed Assent form before data can be entered onto the registry. Written informed consent requires the eligible patient or parent/guardian of the eligible patient to personally sign, initial and date the latest approved version of the Informed Consent form before data can be entered onto the online registry.

All assent and consent forms will be stored at recruiting hospital in accordance with local requirements and copies given to the participant parent/guardian, entered into the patient’s hospital notes and kept in the site study file. Patient participation to the registry will be logged through data completion of the NHS number and date of birth data fields on the on-line registry.

## Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. Patient participation in the registry will be discontinued if any of the following apply:

* the patient/parent/guardian withdraws assent or consent
* the patient/parent/guardian opts to discontinue participation
* the patients is withdrawn from the trial by the treating physician or medical researcher due to loss to follow up

If patients wish their entire data set to be withdrawn from the trial, they may notify the local research team, or the registry host (NUTH – contact details will be provided in the Patient Information Sheet).

## Definition of End of Study

The data collection period of the balloon dilatation data set is extended to June 2018 from October 2017 in this amendment application. The data collection period of the RRP dataset will be open for a fixed period of 36 months from opening (extended data collection due to extremely low incidence of RRP). This data collection period may be extended if deemed appropriate by the clinical community, and will depend upon data completeness of the registry. The proposed data collection periods will be reviewed at 18 months and discussed with the Steering Group committee which has already been established.

# STATISTICS AND ANALYSIS

Due to the observational nature of this registry, no power calculation has been applied. The registry will instead recruit as many eligible patients as possible within the definedperiods.

The results of the registry will be reported according to the STROBE guidelines for observational data [Vandenbroucke et al, 2007]. Demographic data from participants (e.g. sex, age, comorbidity and diagnosis distributions etc.) and treating hospital information (e.g. total number of participants, total number of procedures) will be presented in tabular form. Data will be summarised using descriptive statistics.

Most of the analyses will be based on time series analysis for individual patients (e.g. change in degree of stenosis over time, change in degree of respiratory papillomatosis over time) using area under the curve (AUC) analysis. Patient anatomical and physiological parameters assessed before and after the balloon dilatation or RRP intervention will be assessed using paired t-test (if data are normally distributed) or a suitable non-parametric test (such as Mann Whitney U test) if assumptions of normality are violated (Shapiro-Wilk = *p* < 0.1).

Multivariate analysis will also be conducted to determine the influence of additional variables (such as gender, age, comorbidity score) on the outcome variables (e.g. complication, mortality etc).

In some cases, it may be possible to compare different device manufacturers/models (and different interventions in the case of the RRP dataset) for differences in outcomes. Parametric data of this type could be analysed using the unpaired t test, ANOVA analysis (for multiple comparators) or multiple regression analysis. Dichotomous outcomes such as incidence of complication or death, could be tested for significance using the chi squared test or Fischer’s exact test.

Expert statistical advice will be sought from a medical statistician on all aspects of data analysis.

All scripts for data extraction, cleaning, and analysis will be written in the statistical programming language R (R Foundation for Statistical Computing).

# DATA MANAGEMENT

Access to the registry will require approval from the established Steering Group committee, and secure password and username access provided by the registry developer (NUTH). The password provided will require updating every 12 months. Clinicians participating data to the registry will be able to see identifiable information entered into the registry from all patients involved in their care. Only anonymised high level information collated from all participating centres will be shared with participating clinicians. Only anonymised data will be shared in any subsequent publication of results. Only the registry developer will have access to all identifiable information from all participants. This identifiable information (e.g. NHS number and date of birth) will only be used for the purposes of linking records from individual patients over time (where patients have multiple hospital visits recorded) in order to track clinical progress over time. This identifiable information will also be used to link to national administrative databases such as Hospital Episode Statistics (HES) and the Office for National Statistics (ONS), where possible, to gain additional data and to verify the registry content.

Data analysis will be performed on the password protected NHS network account of the registry developer and host, NUTH, as an ongoing process during the study. As the online registry will be developed and internally maintained by NUTH, no transfer of information via email or removal optical media will be carried out.

Data collection for balloon dilatation is intended to be open until June 2018 (extending the original fixed period of 24 months). Data collection for RRP interventions is intended to be open for a fixed period of 36 months (due to extremely low incidence of RRP).Data collected from the registry will be stored by the registry host for a minimum of 5 years to allow for retrospective auditor inspection of the data, and to ensure publication of results is finalised.

## Regulatory

All staff from NUTH involved in the data analysis, have undertaken Good Clinical Practice (GCP) training and will adhere to Caldicott and generic Research Governance principles to ensure that there is no breach of confidentiality.

**Legal compliance:**

* NUTH (which will conduct all the data analysis on behalf of the Steering Group committee) regards all personal information of patients as confidential.
* NUTH regards all personally identifiable information relating to staff as confidential except where national policy on accountability and openness requires otherwise.
* NUTH undertakes at least annual assessments and audits of its compliance with legal requirements. This includes assessment of compliance with Information Governance Toolkit requirements and IG toolkit submissions.
* NUTH has in place policies to ensure compliance with the Data Protection Act 1998, Freedom of information Act 2000, Human Rights Act 1998 and the common law of confidentiality.
* NUTH has established policies for the controlled and appropriate sharing of patient information with other agencies, taking account of relevant legislation (e.g. Health and Social Care Act 2008, Crime and Disorder Act 1998, Protection of Children Act 1999).

**Information security:**

* NUTH has policies for the effective and secure management of its information assets and resources.
* NUTH undertakes annual assessment and audits of its information and IT security arrangements.
* NUTH promotes effective confidentiality and security practice to its staff through policies, procedures and training.
* NUTH has in place explicit incident reporting procedures and will monitor and investigate all reported instances of actual or potential breaches of confidentiality and information security.
* NUTH’s IG framework is detailed below, outlining the Trust's structure for the management and reporting of Information Governance.

**Governance Framework:**

* Information systems are recorded within the NUTH Service catalogue and Information Asset owners identified within the catalogue.

**Training & Guidance:**

* Information Governance training for all staff is mandated through IG Training Tool.
* All staff sign confidentiality code of conduct and acceptable use declaration. All policies are available to all staff.
* Incident reporting and risk management policies and training are provided.

**Access Policy Control:**

* NUTH has full auditing on all patient level systems and any breaches are reported to the privacy officer.

## Approvals

The protocol, informed assent and consent form, participant information sheet (all of which have been peer-reviewed by the established Steering Group committee) has already been submitted to an appropriate NHS Research Ethics Committee (REC), and The Newcastle upon Tyne Hospitals NHS Foundation Trust for written approval.

For adult RRP patients, we intend to use the exact content of the information sheet and consent forms designed for 16-18 year olds. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents. Due to the observational nature of the registry in capturing data from respiratory interventions, participating sites will be identified (from manufacturer liaison and active surveillance of the HES database) and recruited on a rolling basis. The addition of new data collection centres participating to the registry will be highlighted to REC, via email, on an annual basis.

## Reporting

An annual progress report will be submitted to the REC which gave the favourable opinion 12 months after the date on which the favourable opinion was given and again at 24 months according to the Health Research Authority (HRA) website [HRA, 2014].

Anonymised high level results will be shared by the registry host to participating centres on a monthly basis (for the first 12 months) and a quarterly basis (for the remaining 12 months of data collection). The registry host will also prepare an internal report summarising the main findings to NICE at data collection completion. The registry host, with the support of the Steering Group committee, will also summarise findings from the registry in a manuscript which will be submitted to a peer-reviewed open access journal. Authorship of manuscripts will follow the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals [ICMJE, 2014]. Where any lead clinicians from provider sites express an interest in co-authorship, then their contribution will also be negotiated and agreed at outset. Full acknowledgement will be given to clinical leads at all other sites contributing patient data to the ‘AIR’.

# FUNDING

This online registry in capturing data from balloon dilatation procedures is financially supported by the National Institute for Health and Care Excellence (NICE) and the registry host, The Newcastle upon Tyne Hospitals NHS Foundation Trust. If data collection is extended beyond the June 2018 completion date, additional financial support will be sought from relevant professional societies and device manufacturers, where applicable.

External funding has been secured from NIHR to support the development of the RRP registry pages for all interventions and conduct data collection for a 36 month fixed period.

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