Establishing a registry of children and young people with diabetes in north east England and north Cumbria

Karen Blakey
BSc, Cert Ed (HE), Registry Co-ordinator

Gillian Johnson
BSc, Programme Manager, NHS Diabetes

Richard JQ McNally
BSc, MSc, DIC, PhD, Reader in Epidemiology

Simon Court
MBChB, BSc, DCH, MSc, MRCP, FRCPCH, Associate Clinical Lecturer

Adam Potts
Medical Student

Carolyn Stephenson
Yorkshire Register of Diabetes in Children and Young People Manager, Paediatric Diabetes Network, Co-ordinator

Bill Lamb
MBBS, MD, FRCP(Ed Lon), FRCPCH, Consultant Paediatric Diabetologist

Timothy D Cheetham
BSc, MBChB, MD, MRCP, MRCPCH, Senior Lecturer in Paediatric Endocrinology and Consultant Paediatrician

Abstract
The incidence of type 1 diabetes and type 2 diabetes in children and adolescents is rising. The associated public health burden is substantial with major implications for those involved in health care provision at all levels. The aetiology of diabetes in this age group is poorly understood, although both genetic and environmental factors are likely to be involved.

Clinicians involved in the management of diabetes in the young in the Northern Region have wanted to establish a diabetes registry for more than two decades. With input and financial support from NHS Diabetes we have finally been able to establish a population-based registry of all prevalent cases of diabetes diagnosed in children and young people (0–17 years) in north east England and north Cumbria. There are several unique features of the study region. Most notably, compared with other areas, it has little general outward migration and only includes a small ethnic minority community. We anticipate that the registry will provide an important regional data source for research, audit and service provision planning.

The importance of regional registries is now being recognised, and we hope that a description of our recent experience will be useful to individuals involved in registry development elsewhere. Copyright © 2013 John Wiley & Sons.

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Key words
NHS Diabetes; development; registry; children; young people; diabetes, north east England; north Cumbria

Background
The prevalence of all types of diabetes in all age groups is rising in many parts of the world and is projected to have an ever-increasing impact on health service provision.1  The incidence of type 1 diabetes (T1D) in children and adolescents is growing at a rate of around 3% per annum and presents a considerable public health burden.2  T1D is associated with a range of complications and a reduction in life expectancy of around 15–20 years.3,4  The aetiology of T1D in young people is poorly understood, although both genetic and environmental factors are likely to play a role.5  One recent study has demonstrated that class II human leucocyte antigen (HLA) was strongly associated with T1D in both Asian and Caucasian populations, but haplotypes differed between the two ethnic groups.6

Despite this background and the associated implications in terms of health care provision and health economics, there are still many regions of the UK that do not have accurate information regarding diabetes incidence in the young. Following the St Vincent declaration in 19807 and the development of the National Service Framework for diabetes in 2001,8 there was much talk of developing a national registry of children with diabetes. The value of such illness registries has been proven in the fields of childhood disabilities, congenital anomalies, and particularly with childhood cancer where highly significant improvement in clinical outcomes and the development of greater equity of care have been achieved.9

Registries allow the demographic description of a condition and identification of any change in patterns of presentation or incidence. With accurate information which describes when and where a condition is occurring, service provision can be managed more effectively, economically and can be audited accurately. In addition, it opens up the opportunity for epidemiological and health services research.9  Unfortunately, early attempts to develop a national registry of children with diabetes
were only partially successful and were discontinued. However, a new initiative is being progressed by the Royal College of Paediatrics and Child Health which would involve the amalgamation of regional registries (personal communication, Ruth Gordon).

A registry of diabetes diagnosed in childhood has been established in Yorkshire and has been collecting case data for more than 20 years. This registry has generated a lot of interesting data, but it is important to note that the Yorkshire region comprises an ethnically heterogeneous population and information regarding disease incidence in this locality may not apply to other areas. There is therefore a strong argument for data collection in all areas of England.

We have recently established a population-based registry which will include all prevalent cases of diabetes in children aged 0–17 years, who were resident in north east England or north Cumbria at time of registration. There are several unique features of the study region, including the small proportion of the population from an ethnic minority and the low rate of outward migration. North east England is an area of high socioeconomic deprivation with a mix of rural and urban areas, and there is evidence to suggest that associations between where and how people live and the risk of diabetes development may be different from other parts of the UK. Intriguing patterns in incidence and relationships with socio-economic status, that warrant further investigation, have previously been identified in some of the census areas within the former Northern Health Region of England (NHRE). Another NHRE study found that there was a twofold increase in incidence from 7.7 per 100 000 persons per year in 1973 to 13.5 per 100 000 persons per year in 1988, but a registry that could explore patterns in more detail in subsequent years did not exist.

In this article we provide information about the various steps involved in the development of our regional registry. It is envisaged that, in due course, the registry will provide an important regional data source for research, audit and service provision planning.

**Aims and objectives**

We aimed to establish a specialist diabetes registry covering the geographical region comprising north east England and north Cumbria. We were interested in registering all forms of diabetes under review in regional paediatric diabetes units and not just T1D.

The short-term objectives were to:

- Establish the registry within an appropriate ethical framework.
- Construct a dataset that complemented the geographically proximal Yorkshire regional registry.
- Collect data from all patients currently under the care of paediatric diabetes teams.
- Support all paediatric units in the consenting and data collection process.
- Regularly engage with all units within the region, thus ensuring high rates of ascertainment.

The long-term objectives were to:

- Provide units with informative descriptive statistics to assist in planning effective patient care.
- Facilitate set-up and maintenance of registries in other regions of England by sharing our experience and documentation of the processes involved.
- Use the data for regional epidemiological research, health care audit and service improvement.
- Facilitate national diabetes audit submissions.

**The process**

Initial support for the new registry was provided by a grant from NHS Diabetes and subsequently by Sanofi Diabetes. Diabetes care, within the NHS, is supported by Regional Paediatric Diabetes Networks. These structures provide a platform for strategic development, good practice, improved clinical outcomes for children with diabetes and a forum for shared learning for all health care professionals caring for children with diabetes.

The North East Paediatric Diabetes Network (NEPDN) is one of 10 regional networks working across England supported by NHS Diabetes. The networks are led and assisted by a number of experts working in front-line diabetes services including clinicians, dietitians, psychologists, podiatrists and paediatric diabetes specialist nurses. The focus is to bring together health communities to reduce inequalities in health care and deliver better outcomes for people with diabetes, families and carers.

The NEPDN is based within a geographically well-defined area (formerly known as the NHRE). The NHS boundaries set in 1972 are still followed, even though there has been considerable re-structuring over the years. NHRE comprises the north eastern counties of Tyne & Wear, Durham (including Darlington, Hartlepool and Stockton-on-Tees unitary authorities [UAs]) and Northumberland, along with the UAs of Redcar & Cleveland and Middlesbrough. In addition, it also encompasses north Cumbria in north west England.

The total population of the region is approximately three million with approximately 17% aged 0–14 years. There were approximately 1500 patients living with diabetes who were diagnosed before their eighteenth birthday during the financial year 2010–2011. The majority of these children are treated in one of 13 paediatric diabetes units. We are not aware of young people being managed by paediatricians outside these diabetes services. The care that is provided from each unit is administered by nine NHS foundation trusts.

**Ethical and regulatory requirements**

Protecting patient confidentiality and anonymity was the cornerstone of the planning process, ensuring the registry was developed within a robust ethical framework. One of the long-term objectives was to use the registry data for regional epidemiological research. With this in mind, the registry was classified as a research database according to Integrated Research Application System (IRAS) definitions. There were three main components involved in the process of an IRAS research database application. These were ethical approval, Caldicott Guardian approval and...
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Reference Group
Includes all registry stakeholders. Members have been divided into smaller sub-groups according to their function in the registry.

| North East Paediatric Diabetes Network (NEPDN) |
| Funding bodies |
| NHS Diabetes – also supports NEPDN |
| Other funding bodies, e.g. Sanofi Diabetes |

Individuals with an interest in paediatric diabetes or data/registry issues from the local community
User group that includes patients, their families and carers
Colleagues with registry experience from other regions, e.g. data manager from Yorkshire & Humber

Registry Steering Group
This could be the network steering/executive group where one exists

Data Advisory Group
Mandated group to deliver data governance – will be convened by and will include members from the steering group together with user group members and other ‘experts’ in this field or people with a relevant interest

Project Delivery Team
Some members may also be part of the steering group. Their role is to deliver (and possibly maintain) the registry and take their lead from the steering group

Figure 1. Diagrammatic representation of the registry delivery framework

NHS Foundation Trust Research and Development (R&D) approval.

Even though ethical approval was not compulsory within the IRAS, it became necessary when registering the database with the Trust R&D offices operating within the registry catchment area. It is considered best practice to seek ethical approval and a number of Trust R&D offices will refuse registration without this. Research passports or honorary contracts were also required for all participating researchers to ensure full legal compliance with regulations. All ethical and regulatory approvals were granted, resulting in five-year generic ethical approval which is renewable.

Registry delivery framework
The project delivery team included representatives from Newcastle University and NHS Diabetes with the necessary clinical and research skills to drive the set-up process. One of its initial key tasks was to form a registry delivery framework for the establishment, development and maintenance of the registry in line with ethical requirements. This involved setting up a number of stakeholder groups as highlighted in Figure 1.

The project delivery team formed a steering group to oversee and provide directional guidance on all aspects of registry establishment, development and maintenance. Some of the project delivery team joined the steering group to ensure two-way communication channels with all relevant constituent groups. Additional members could be co-opted onto the steering group for specific periods of time as and when required.

Steering group members were drawn from a reference group, which included all registry stakeholders divided into smaller sub-groups. These sub-groups provided the registry with a broad base of expert and lay members and ensured that those providing or using paediatric diabetes services in the region were involved in all parts of the registry process. There was representation from both the paediatric units and the patients. Patients in this registry were recruited when they were less than 18 years of age. Therefore, user representation also included parents and carers as well as the children and young people with diabetes themselves. The reference group also provided knowledge in key areas such as database management and clinical experience in childhood diabetes.

Finally, the steering group set up a data advisory group to ensure a transparent and rigorous approach when dealing with data issues. It consisted of patients, lay members and professionals and included a number of steering group members. It had the same broad base of professional and non-professional members such as patients, families and carers.
**Practice point**

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**Data item selection**
The choice of data items was made after extensive discussion and feedback from the reference group; for example, through discussion at NEPDPN meetings and liaising with colleagues from the Yorkshire diabetes registry. The northern border of Yorkshire diabetes registry catchment area links to the southernmost border of the former NHRE. The data items that were collected by Yorkshire diabetes registry and the rationale for each of them were considered carefully at steering group meetings. In order to create a consistent dataset across the two regions it was decided to collect similar data in our area. This way, each region could form the building blocks for a national dataset. It was recognised that some data items would be easier to collect than others, particularly as data would have to be retrieved manually in many cases. Therefore, two categories were created: (1) First level data items, which were considered easy to collect and enable calculation of T1D incidence; (2) Second level data items, which were considered more time consuming to collect, for example, patient medical history. The full set of data items is given in Table 1.

**Post-approval planning**
On completion of the ethical and regulatory process all participating units were sent an information pack that included: a copy of the study protocol; copies of consent forms; copies of age-specific consent forms; parent/carer information leaflets; and age-specific information leaflets. In cases where consent was not obtained an anonymous dataset was collected to enable: calculation of ascertainment levels; health care planning and delivery for all patient groups; and to assess whether the group not providing consent is demographically different from the group that does consent. The anonymous dataset consisted of a more restricted dataset comprising age, sex, part postcode and date of diagnosis. Any health professional involved in obtaining informed consent from the parents or patient was required to have undertaken informed consent training. This could be web-based or, if necessary, this was offered through the regional network. Individual units developed different methods of obtaining consent. These could be shared at network meetings. Once informed consent had been obtained, the clinical notes could be flagged indicating permission had been obtained to extract clinical information. The prospective element of the registry could occur in a more considered way with consent and data being added at the time of diagnosis.

The case load varies in size with between 50 and 300 patients aged less than 18 years being treated in the paediatric diabetes units across the region. The retrospective element of data collection can appear quite daunting, particularly for the larger units because of the need to extract data manually from the patients’ clinical records. These data have to be entered onto an Excel spreadsheet before being sent in an encrypted format via a dedicated NHS.net email address to facilitate secure data transfer. Submitted data then need to be cleaned and screened before being imported into the registry database.

**Discussion and conclusion**
Our principal aim was to develop a registry of children and young people (aged 0–17 years) with diabetes across a geographically large and varied region. Our experience while achieving this objective has highlighted a number of issues. The development of this registry has proved more complex and time consuming than anticipated, and a committed project delivery team has been a crucial component of this process. Our enthusiasm for a regional registry was bolstered by the views and experience of a number of authors. For example, Donaldson in 1992 said 'Without a more widespread use of disease registers it is difficult to see how health authorities can meet the responsibility to assess their populations’ needs,' and Cheales and Howitt in 1996 said ‘In considering the management of patients with chronic disease, an accurate well maintained register is a pre-requisite to providing comprehensive and coordinated care.’

There has been significant learning regarding the resources required to establish a registry, including identification of appropriate personnel who can ensure ongoing sustainability. We have provided an estimate of the time required for staff and processes involved in the registry in Appendices 1 and 2 (available online at www.practicaldiabetes.com). In our experience, the importance of establishing an appropriate implementation and management strategy with ongoing supervision from professionals and users can conflict with busy schedules. Organising meetings takes time and is not cost neutral. Indeed, the overall running costs required are considerable but obtaining a longer-term funding stream is difficult. This is an issue that will hopefully be addressed in part by regional and national budget holders. Historically, registries have been funded through short-term grants and there is a need to establish a more appropriate funding stream so that less time is spent trying to sustain them from one year to the next.

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**First level data**
- Surname
- Previous surname
- First name
- Date of birth
- NHS number
- Sex
- Ethnicity
- Date of diagnosis
- Type of diabetes
- Address at diagnosis
- Address at birth
- Address at registration
- GP at registration
- Date of data collection

**Second level data**
- Date of first insulin injection
- Change in diagnosis
- Clinical results at diagnosis, e.g. pH, glucose, ketones
- Other results, e.g. Hba1c
- Hospital consultant
- Hospital Number at registration
- Hospital admissions
- Family history of diabetes
- Birth weight
- Height and weight at first clinic appointment
- Care planning appointment details
- Record of the biomedical indicators shared with the patient prior to appointment

**Table 1. Details of registry data items**

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<table>
<thead>
<tr>
<th>Issue</th>
<th>Top tips for issue resolution</th>
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<tbody>
<tr>
<td>Ethical and regulatory approvals are time consuming. Indeed, we are not aware of anyone who has ever overestimated the time taken to obtain the necessary approvals. All Research &amp; Development (R&amp;D) offices in the region need to be notified of the registry. Gaining ethical approval before R&amp;D approval is considered best practice and some R&amp;D offices will not allow registration without it.</td>
<td>Establish a robust ethical framework. This will encourage a transparent approach and ensure the registry is fit for purpose. It will also promote competence in management of unavoidable and complex information governance issues. Submit the registry for ethical approval as a research database and follow the National Research Ethics Service (NRES) guidelines. This is time consuming but gaining renewable five-year generic ethical approval limits the number of re-applications and saves time. Begin the ethical and R&amp;D applications in parallel. R&amp;D requirements are not uniform and all R&amp;D offices within the region will need to be contacted to ensure the correct procedure is followed.</td>
</tr>
<tr>
<td>The issues involved in establishing a registry need to be aired with all interested parties from the beginning. A sense of ownership needs to be encouraged. Setting up a robust communication framework that enables both service user and provider involvement is an ethical requirement.</td>
<td>Form groups that will enable communication between all stakeholders and maintain regional sign-up (Figure 1). We recommend that you start with a steering group. In our experience, the reference group extended the North East Paediatric Diabetes Network (NEPDN) to include others from the local community with an interest in paediatric diabetes or generic registry issues. We found that the NEPDN meeting was a valuable forum for encouraging a sense of ownership and airing registry issues, particularly during set-up. This facilitated the agreement of data items and the sharing of information and experience (consenting, data collection etc). Getting users to become more involved in service delivery and planning processes may become easier if the proposed national parents’ reference group is created. To set up a user group, we recommend referring to the Making Involvement Happen resources available through the Diabetes UK website: <a href="http://www.diabetes.org.uk/Professionals/Making-Involvement-Happen/About-this-resource/">www.diabetes.org.uk/Professionals/Making-Involvement-Happen/About-this-resource/</a>.</td>
</tr>
<tr>
<td>Re-consenting patients at 18 years of age to allow them to withdraw their data from the database (if they so wish) is another ethical requirement. Our registry recruits patients with diabetes when they are less than 18 years. However, data from previous cohorts are potentially useful and so further permission must be sought to enable their data to remain on the database.</td>
<td>Consider what will happen when individuals reach 18 years of age. Re-consenting patients so that their data can remain on the registry is a logistical challenge. Current ethical guidelines will not allow an ‘opt-out’ strategy to be put in place. Therefore, we have created an alert system within the registry database so that we are aware when patients are approaching 18 years of age. The system flags patients at 17 years and 6 months and again 3 months later. This way, patients can be contacted by the paediatric units before they move to other services.</td>
</tr>
<tr>
<td>The registry needs to be adequately resourced (Appendices 1 and 2 [available at <a href="http://www.practicaldiabetes.com">www.practicaldiabetes.com</a>]). This will usually involve a centrally-funded individual with associated costs. Additional resources may be needed for travel and meetings. Registry development is not a funding priority so there is a need to develop innovative funding solutions.</td>
<td>We have tried to link the registry to other pieces of work or groups already in place and in particular to the local network. We have developed a newsletter to inform staff from the paediatric units of progress, and also have a registry update section in the NEPDN newsletter. The Payment by Results (PbR) tariff may provide a mechanism for ongoing support funding where a percentage can potentially be top-sliced by each unit on a per trust basis.</td>
</tr>
<tr>
<td>Unit support – units will be different in size, ways of working and also have different information systems. Some units will inevitably find it much easier to consent and submit data than others.</td>
<td>Think about how you can help the units where data collection is proving to be a particular burden. One of the project delivery team can be the main point of contact for each of the units. As well as telephone and email communication, face-to-face meetings were found to be valuable so that staff from each of the units could discuss practical issues. The staff also shared their own experience so that successful strategies could be communicated to other units. Be flexible with data format requirements to ensure timely data transfer.</td>
</tr>
</tbody>
</table>

Table 2. Illustrates some of the main issues involved in setting up a registry with corresponding top tips for resolution

Those registries already in existence are coming under increasing financial pressure because of the need for centrally-based coordinators or personnel who can retrieve data from around the region. To maintain a registry there needs to be a dedicated officer with associated salary and additional, inherent costs. The Payment by Results (PbR) tariff, however, may provide a mechanism for ongoing support funding where a percentage can potentially be top-sliced by each unit on a per trust basis.  

The importance of service user representation in health care service delivery and planning is well recognised. However, there are a number of barriers to successful service user involvement. Although we tried a number of ways of recruiting service users on the steering group and data advisory group, we found it was very difficult to maintain service user representation, particularly with the teenage group. If the PbR tariff does provide a financial support for regional registries in the future, we recommend that some of the funds...
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Key points

- The existing UK diabetes registries have generated important information about disease incidence. Unfortunately, many regions are still without registries and therefore unable to assess patterns of disease in their own locality.
- Our experience of establishing a registry and negotiating the associated ethical and administrative steps will hopefully be of value to other areas of the UK.
- Setting up, developing and maintaining a registry is time consuming and requires financial resource. The PnR Tariff may help to provide an appropriate funding stream.

...are used to cover user involvement costs, for example, travel expenses. Further detail on the issues that can be faced when starting up a registry alongside top tips for issue resolution can be found in Table 2.

The strength of this registry lies within its foundations; that is, a robust ethical framework that protects patient confidentiality and anonymity while ensuring the involvement of the paediatric diabetes service user, their families or carers. This registry meets all the requirements of an IRAS research database application. It has been approved by a Research Ethics Committee that has been flagged as having the appropriate expertise to deal with complex data issues that registries can raise. Although the application process is time consuming, submitting a registry application through IRAS as a research database is recommended given five-year generic ethical approval can be granted and can also be renewed.

Approximately two-thirds of the current patient population in the paediatric units have been consented (January 2013). Overall, the unit staff have reported excellent feedback, particularly from parents who consider the registry an integral part of children’s health care. We have collected data on one-third of the total patient population. Data collection has been slower than first anticipated because of central and local resource issues and other factors such as the time taken for the registries to become an integral part of clinical team activity.

National Research Ethics Service guidelines for research database applications20 and the set-up templates for this registry (available from the authors) have the potential to save other regions time. Collection for the National Paediatric Diabetes Audit (NPDA) has taken priority over the registry, which has also slowed progress. We recommend following NPDA data item definitions in order to increase data collection and prevent duplication of effort. In the future, once data are available electronically rather than through manual trawling of patient records, data collection will become quicker and easier. The long-term sustainability of the registry will depend on continued resource to provide financial support. It is envisaged that the registry will provide a unique and important resource that will have multiple uses in research, audit and planning of service provision.

Acknowledgements

This registry has been made possible through a concerted effort by all staff working in the paediatric units within the catchment area. We are very grateful for their continuing help and support. Likewise, we would like to thank all members of the groups that have been formed (reference, user, steering and data advisory) and the NEPND for their insightful contributions to discussions and processes.

We are also extremely grateful to: NHS Diabetes and Sanofi Diabetes (Sanofi UK, One Onslow Street, Guildford, Surrey, GU1 4YS) who funded this work; Mr Richard Hardy, Institute of Health and Society, Newcastle University for IT and database support; Dr Peter James, Institute of Health and Society, Newcastle University who calculated NHRE population figures that were based on ONS data;18 and Miss Katie Milburn, Newcastle-upon-Tyne Hospitals NHS Foundation Trust, Royal Victoria Infirmary, for additional administrative support.

Declarations of interests

There are no conflicts of interest declared.

References

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Appendix 1. Details of personnel required for set-up and running of a paediatric diabetes registry

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Year number (time in hours/week)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year 1</td>
</tr>
<tr>
<td>Academic</td>
<td></td>
</tr>
<tr>
<td>Principal investigator</td>
<td>8</td>
</tr>
<tr>
<td>Research assistant</td>
<td>40</td>
</tr>
<tr>
<td>Administrative and secretarial support</td>
<td>16</td>
</tr>
<tr>
<td>Information technology (IT) support</td>
<td>8</td>
</tr>
<tr>
<td>– Hardware</td>
<td></td>
</tr>
<tr>
<td>– Data entry and processing</td>
<td>8</td>
</tr>
<tr>
<td>– IT support for units (including collecting data and dealing with registrants re-consenting at 18 years)</td>
<td>8</td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
</tr>
<tr>
<td>Clinician</td>
<td>2</td>
</tr>
<tr>
<td>Clinical network representative</td>
<td>2</td>
</tr>
</tbody>
</table>
Establishing a registry of children and young people with diabetes

**Practice point**

### Ethical and regulatory approvals

<table>
<thead>
<tr>
<th>Process name</th>
<th>Details and estimates of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical and regulatory approvals</td>
<td>The process of submitting for approvals of the registry as a research database may take approximately 9 months to complete. However, even though this process is time consuming, it saves time in the long run as the resulting 5-year generic ethical approval limits the number of re-applications in subsequent years.</td>
</tr>
</tbody>
</table>

#### Producing protocol
- Selecting and finalising data items
- Designing age-ranged information leaflets
- Designing age-ranged consent/assent forms
- Submitting ethical approval application
- Submitting research and development approval applications

#### Selecting and finalising data items
- Designing age-ranged consent/assent forms
- Submitting research and development approval applications

### Project delivery framework

<table>
<thead>
<tr>
<th>Meetings</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Project delivery/registry set-up management team</td>
<td>2 hours per week</td>
<td>1 hour per week</td>
<td>1 hour per week</td>
</tr>
<tr>
<td>– Steering group</td>
<td>2 hours every 3 months</td>
<td>2 hours every 3 months</td>
<td>2 hours every 3 months</td>
</tr>
<tr>
<td>– Reference group (tied in with North East Paediatric Diabetes Network meetings)</td>
<td>4 hours every 3 months</td>
<td>4 hours every 3 months</td>
<td>4 hours every 3 months</td>
</tr>
<tr>
<td>– Data advisory group</td>
<td>2 hours every 3 months</td>
<td>2 hours every 3 months</td>
<td>2 hours every 3 months</td>
</tr>
</tbody>
</table>

### In paediatric units

<table>
<thead>
<tr>
<th>Process name</th>
<th>Details and estimates of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Informed consent training</td>
<td>For members of staff who have no informed consent training in place (can also be gained through Good Clinical Practice [GCP] training). Time dependent on number of staff requiring training.</td>
</tr>
<tr>
<td>– Taking informed consent</td>
<td>Feedback from units suggests that the process of taking informed consent (including providing patient with information about the registry) takes on average 20 minutes</td>
</tr>
<tr>
<td>– Collecting data items from patient records</td>
<td>Time to collect data items depends on whether data are available electronically or a manual trawl of patient records is required</td>
</tr>
<tr>
<td>– Securely transferring data items from patients’ records over to registry</td>
<td>Feedback from units suggests that, once the data transfer through NHS.net is set up, sending the data takes approximately 1 hour, regardless of the amount of data being sent</td>
</tr>
</tbody>
</table>

### Registry set-up and process

<table>
<thead>
<tr>
<th>Process name</th>
<th>Details and estimates of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Database design</td>
<td>40 hours</td>
</tr>
<tr>
<td>– Hardware support</td>
<td>8 hours per week</td>
</tr>
<tr>
<td>– Data entry and processing</td>
<td>8 hours per week (including cross-checking of data with other sources such as national audit results and General Register Office records supplied through the NHS Information Centre)</td>
</tr>
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</table>

**Appendix 2:** Details of processes involved in setting up a registry with associated estimates of time