CURRENT TOPIC

Follow up studies: a case for a standard minimum data set

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A vast amount of information is collected on the subsequent health and development of babies who are born early or small, as well as about babies who are ill around the time of birth, or who have had a particular treatment or intervention. This information is collected for different reasons and in several different ways. Some data are collected as part of prospectively planned follow up studies, and some in hospital based, follow up, and specialist clinics. Data are also collected routinely by people providing care in the community, including community paediatricians, general practitioners, and health visitors. Although such information is of great potential interest to parents, to providers of obstetric and neonatal care, to those responsible for purchasing care and to the public at large, much of it is inaccessible and never used. This is because there is no central focus for collecting together data on childhood morbidity; the diversity of purposes means there is little agreement on which data should be collected and definitions are not standardised There are also wide local differences in the ways in which data are collated, tabulated, and reported.

Broadly, there are two reasons for following up children. First, an assessment can be done as a continuing service for the children and their families after an acute illness, and this focuses on the health and development of the individual child. This is done to identify the child's health and other needs, and provide reassurance, advice, and information for parents. The information from the assessment can be fed back to nursing and medical staff who treated the baby, albeit at an anecdotal local level. This type of follow up may be hospital or community based. The information obtained can also form part of a continuing record of the child's status—for example, on the district based computerised child health systems.

The second reason for follow up is to obtain a more systematic overview of the long term effect of events at or around birth on particular groups of babies. These can be, for example, those who have needed neonatal intensive care, or those within a particular birthweight group, or those who have had an intervention within the context of a controlled trial. The underlying questions are to do with evaluation of care, cost effectiveness issues, the impact of changing mortality rates on morbidity, or monitoring differences in rates of morbidity over time or between areas. Here the outcomes sought may be very detailed and targeted to specific areas of function. Follow up of this type is usually funded as a research project and some of the observations and findings are to be found in medical publications.[1]

All this activity undoubtedly addresses many research issues related to specific interventions or categories of care, and provides a good continuing service for individual children, but other questions remain unanswered. For example, it is difficult at present to answer questions about trends over time on the rate of disability in extremely preterm babies, or the numbers of low birthweight survivors who may need additional health and educational services in later childhood. This is because the numbers of children included in any one study or report are usually small, and fluctuations over time in the number of children with an adverse outcome cannot be distinguished from random variations. The way to overcome this is to pool study findings, but this is difficult because in study reports, groups of babies are defined in different ways, the children are seen at different ages, and their outcomes described in a variety of ways.

So how can we tap this vast pool of unused information? One way forward might be to collect an agreed simple common core of data on each child seen at follow up, for whatever reason. This would describe his/her health and development at a specific age and be collated at district level. When appropriate, it could be available in published reports.

Two years ago, the first steps were taken towards this goal. Two national working groups agreed a standard core of data to describe the health and functional status of children at the age of 2 years.[2] This focused on describing the level of function of the child within a number of domains, clearly defining those with a severe level of functional loss. The underlying impairment or disease was stated secondarily. Three identifiers were also suggested: the NHS number of the mother and of the child, and the date of birth of the child. These would facilitate linking with other data sets, particularly if the NHS number of the baby were allocated as soon as possible after birth. In view of the

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interrelation of socio-demographic factors and the subsequent health and development of children, four further measures were suggested. These were postcode, age of the mother, her age when last in full-time education and her support status at birth. A simple set of perinatal variables was suggested to provide baseline data. These were place of birth, presence or absence of congenital malformation, gender, birthweight, gestational age, and plurality. (Appendix).

A number of concerns immediately emerge. First, there are issues about the reliability of data on functional loss which are collected in different ways. We need to know more about the convergent validity of information on disability provided by health visitors, paediatricians, or by parents themselves, perhaps using the parent held record. Secondly, there is a wide range of functional ability among the children included in the group defined as "severe." Thirdly, the data provide a snapshot of the child at one age. These will not provide all that needs to be known—for example, about morbidity in low birthweight babies—when follow up into school years may reveal learning difficulties, behavioural problems, and minor movement disorders.[3] Although the early ascertainment of the level of severe disability in groups of children provides information which is perceived as relevant to current practice by those providing care, a further small dataset at school entry or in early school years would be useful in understanding the full extent of morbidity.[4] Fourthly, this is clearly a minimalist approach. Having this common core would not preclude the collection and reporting of much more detailed information appropriate to particular purposes and on smaller groups of children. Indeed, the working group recommended that if the data were to be used as part of audit, or as a basis for comparison over time, or for monitoring changes in policy or practice, further information—for example, measures of severity of neonatal illness, would be needed.[5]

The standard minimum dataset may well need refinement. For example, clear definitions of neonatal variables need to be agreed, and sources of imprecision recognised—for example, the effect of the availability of specialist and imaging services on the frequency of congenital malformations. Feedback is welcomed. If a common core of data could be agreed, however, these could be collected for each child at district level, preferably using the child health computer systems as a framework. There are a number of advantages to using existing databases rather than new free standing systems. First, much of the information in the common core dataset is already available on the child health system as part of the health visitor's routine checks, although there are issues in quality assurance which need to be addressed.[6] Secondly, all children resident in an area are included on the database, and so the status of subgroups of children—for example, those with a low birthweight—can then be set in the wider context of the whole population. This is important given that most children with a serious disability at the age of 2 years were not born with a low birthweight. Thirdly, if the family moves, the child's health records follow the child across district boundaries, thus reducing the problem of loss to follow up.

Using such a district based system it then becomes possible, at the very least, to tabulate rates of severe disability within domains, by birthweight group. As with birthweight specific mortality, interpretation of trends and variations and comparisons between areas would need careful interpretation. Nevertheless, such tabulations would be a useful first step towards providing information on the numbers and characteristics of children with severe disability within the population. It might even stimulate sufficient interest to direct the same level of commitment and resources towards understanding the origins of severe disability as is currently directed to studying stillbirths and infant deaths. CESDI in England will cost over £2.3 million in the financial year 1995-96 and involves 30 staff at regional level as well as a national secretariat.[7]

Another way of making better use of existing data is to improve the consistency of reporting follow up studies in journals. Anyone who has tried to collate information on specific groups of babies from published material knows that the lack of consistency in grouping babies and describing outcome places severe limitations on any attempts at meta-analysis.[8–10] Perhaps editors could ask authors to provide their follow up results against the following background information: the total number of stillbirths and live births in the population being described (if possible set in the wider framework of the geographic area from which the babies are drawn), the number of neonatal and postneonatal deaths, the number of surviving children at the age of assessment and the number of children assessed. The birthweight groups and gestational age groups would need to be agreed, the lower cutoff for birthweight and gestational age, and international differences in the definitions of live birth and stillbirth stated. Then as well as describing the other outcomes appropriate to the study, where possible, the numbers of children who meet the criteria for severe functional loss at the age of 2 years could be tabulated by birthweight, gestational age, gender and plurality.

In the four countries of the United Kingdom considerable resources are already expended in maintaining child health computer systems, in funding research studies, and in providing health care for the childhood population. The resulting information on the health and abilities of children is not at present available in a form which enables questions about the subsequent outcome and needs of groups of children who have been ill in the early days after birth to be answered. In comparison, the funds needed to access and collate what is already known about these children are minimal. This approach would, however, require collaboration between health professionals, those responsible for information systems and journal editors.

1 Mutch LMM, Johnson MA, Morley R. Follow-up studies: design, organisation and analysis. *Arch Dis Child* 1989;**64**;1394-402.
2 National Perinatal Epidemiological Unit. *Disability and perinatal care: measurement of health status at two years.* A report of two working groups convened by the National Perinatal Epidemiology Unit and the former Oxford Regional Health Authority. Oxford: National Perinatal Epidemiology Unit, 1994.
3 Ornstein M, Ohlsson A, Edmonds J, Astalos E. Neonatal follow-up of very low birthweight/extremely low birthweight infants to school age: a critical overview. *Acta Paediatr Scand* 1991;**80**:741-8.
4 Sanderson C, Hall DMB. The outcomes of neonatal intensive care. *BMJ* 1995;**310**:681-2.
5 International Neonatal Network. The CRIB (clinical risk index for babies) score: a tool for assessing initial neonatal risk and comparing performance of neonatal intensive care units. *Lancet* 1993;**342**:193-8.
6 Wearmouth EM, Lambert P, Morland R. Quality assurance in protocol surveillance. *Arch Dis Child* 1994;**70**:565-11.
7 Hansard. December 11 1995. Column 531. December 18 1995. Columns 946-7.
8 Aylward GP, Pfeiffer SI, Verhurst SJ. Outcome studies of low birth weight infants published in the last decade: a meta-analysis. *J Pediatr* 1989;**115**:515-20.
9 Escobar GJ, Littenberg B, Petitti DB. Outcome among surviving very low birthweight infants: a meta-analysis. *Arch Dis Child* 1991;**66**:204-11.
10 Escobar G. Prognosis of surviving very low birthweight infants: still in the dark. *Br J Obstet Gynaecol* 1992;**99**:1-4.

Appendix
Standard minimum dataset
Patient identifiers
NHS number of mother
NHS number of infant
Infant's date of birth

Social and demographic measures
Postcode of mother's residence at time of birth
Mother's date of birth
Age (in years) last in full time education
Maternal support status at birth

Perinatal data items
Place of birth (home or name of delivery unit)
Presence of a congenital malformation
Gender
Birthweight (g)
Gestational age at birth (weeks)
Plurality (number of fetuses and birth order within multiples)
Death before discharge from maternity services (with date of death and cause of death)

Criteria for "severe disability" at age 2 years:
Malformation
Any malformation which despite physical assistance impairs the performance of daily activities

Neuromotor function
Unable to sit
Unable to use hands to feed self
Unable to control head movement without support or no head control

Seizures
Seizures more than 1/month despite treatment

Auditory function
Hearing impaired, uncorrected even with aids

Communication
Unable to comprehend word/sign in cued situation
Unable to produce >5 recognisable sounds or no vocalisation

Visual function
Blind or sees light only

Cognitive function
About 12 months behind at 2 years or more
More than 3 standard deviations below mean on standardised assessment.

Other physical disability
Respiratory
Requires continual oxygen therapy
Requires mechanical ventilation

Gastrointestinal function
Requires tube feeding
Requires parental nutrition

Renal function
Requires dialysis

Growth
Height or weight more than 3 standard deviations below mean for age

From: *Disability and Perinatal Care: measurement of health status at two years*. A report of two working groups convened by the National Perinatal Epidemiology Unit and the former Oxford Regional Health Authority, March 1994. Oxford: National Perinatal Epidemiology Unit.