Challenges of undertaking a retrospective cohort study

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Abstract

Aim. To highlight challenges and lessons learnt from using a retrospective cohort design and historical birth records to determine whether infants born growth restricted achieve the same health-related quality of life in adulthood as infants born at normal birthweights for gestation.
Study design. The cohort consisted of 50-year-old adults who were born between 1954 and 1956 in the Royal Maternity Hospital, Belfast. The exposure in this defined population group was intrauterine growth restriction (IUGR). The study group were born at term (≥37 weeks' gestation) with IUGR (birthweight <10th centile) and the comparison group were born at term without IUGR (≥10th centile). A very personal journey is presented, addressing issues such as identifying appropriate resources to use, access and retrieval of historical birth records, sample selection, tracing the sample 50 years on, with discussion around the decision-making process involved.
Conclusion. The key message from these lessons learnt is the irreplaceable contribution of data from good quality historical birth records, which give a privileged insight and detailed picture of maternity care provision over half a century ago.

Key words: Challenges, historical birth records, intrauterine growth restriction, reflections, retrospective cohort study, term infants, evidence-based midwifery

Background

Intrauterine growth restriction

The title of my research was 'Infancy to adulthood: a 50-year follow-up of those born growth restricted'. Intrauterine growth restriction (IUGR) is defined as a failure of the fetus to achieve the expected weight for a given gestational age (Arulkumaran et al, 2004). The fact that some fetuses will not reach their optimal growth potential thus presents a challenge for midwives and obstetricians involved in antenatal care provision. Issues around identifying those at risk and planning appropriate surveillance thereafter, add to this challenge. Antenatal care in developed countries such as the UK, place great emphasis on prediction, detection and treatment of mothers and babies potentially at risk of adverse outcome in pregnancy. IUGR is one of the two major conditions that account for most cases of adverse perinatal outcome, yet unfortunately there has been no substantial progress globally in its prevention, detection and treatment (Sankaran and Kyle, 2009). IUGR is associated with increased perinatal mortality and morbidity, with significant mortality caused by 'unexplained' stillbirths, many of whom are small for gestational age. These often present in what may be classified as 'low-risk pregnancies', with most deaths involving IUGR occurring after 36 weeks' gestation (Bricker et al, 2009). This places huge responsibility on midwives, as the key professionals providing antenatal care for the majority of this group of women.

Recent decades have seen the introduction of some of the most innovative therapies in the history of fetal medicine and neonatal intensive care, resulting in an increased survival rate of a heterogeneous group of babies, including those with IUGR (Saigal and Rosenbaum, 1996). It is therefore important to assess if the associated problems with these babies who do survive, impact on health-related quality of life long term. The primary question addressed in my study was: do infants born growth restricted achieve the same quality of life in adulthood as infants born with normal birthweights for gestation? Study objectives were to compare health-related quality of life, general health, health service use, socio-economic status, blood pressure and anthropometric measures in adulthood in a group born with IUGR and a group born with normal birthweight for gestation, using a retrospective cohort design.

This paper focuses on the challenges of a retrospective cohort study and the use of historical birth records, which I encountered throughout the course of my research.

Retrospective cohort design

This was a retrospective cohort study, which received ethical approval from the local research ethics committee, Queen's University Belfast (QUB) reference number 56/00. Research indemnification was also obtained from the Royal Group of Hospitals Trust Research and Governance Office. The cohort consisted of babies born in the Royal Maternity Hospital (RMH), Belfast between 1954 and 1956, who were traced and assessed in adulthood, after a period of almost 50 years. The cohort was assembled from historical birth records on exposure status. The exposure in this defined population group was IUGR. In all retrospective cohort studies, the investigation begins at a point in time when both the exposure and disease have already occurred (Hennekens et al, 1987). The study group comprised babies born at term (≥37 weeks' gestation), who were growth restricted (<10th centile) (Arulkumaran et al, 2004; Kliegman, 1997). The comparison group was babies born at term (≥37 weeks' gestation) and not growth restricted (≥10th centile).

Description of experience

This section of the paper outlines some of the challenges and lessons learnt throughout my research journey. It discusses some of the issues faced and the subsequent decision-making process.

Doctoral fellowship

I was privileged to be awarded a doctoral fellowship by the Research and Development Office for the Health and Personal Social Services in Northern Ireland. It also provided funding for equipment used in the study, under the Small Equipment Scheme. The preparation required for this application was one of the initial challenges I encountered. However, having been successful in this selection process, I would unreservedly recommend the route of a full-time funded PhD, as it certainly reaps rewards on numerous fronts for a postgraduate research student.

Identifying appropriate resources

To undertake this type of study, I required access to a wide range of resources to enable a wider understanding of the Belfast this cohort were born in, and childbirth as experienced at that time over half a century ago. Resources such as historians, libraries including the History of Medicine Library (Wellcome Trust) in London, past and present staff of RMH (medical records staff, midwives, neonatologists, obstetricians, physicians) were invaluable. Informal interviews with such staff, in particular, the retired obstetrician Professor Harley who provided historical background information on RMH and secondly, gaining access to hospital reports and health reports for Belfast at that time, made it possible to build a very accurate picture of life, health and childbirth in Belfast for the study period. Support from current staff was crucial in terms of access and retrieval of the actual historical birth records required to carry out such a challenging, but very rewarding study.

Study in context

Study setting

The first maternity unit in Belfast was established in 1793 by 'benevolent ladies' who created a charity entitled 'The Humane Female Society', which was for the relief of 'lying-in' women. Their 'hospital' was opened with six beds in January 1794 at Donegall Street to serve poor women of Belfast. A larger replacement hospital was constructed at Lancaster Street in 1830 and, in 1904, a new hospital was opened at Townsend Street. It was replaced by the present RMH in 1933, the setting for this study.

Belfast in the 1950s

This cohort was born into Belfast, which in the 1950s had become a city with a population of 440,000 by 1951. Of the total number of persons employed in manufacturing in Northern Ireland (NI), 58% worked in factories in Belfast. The main occupations at that time were in shipbuilding, tobacco products, linen and specialised engineering of various kinds. The total number of women employed in 1951 (last census available relevant to the study period) was 76,473, which was 42.4% of females in the city aged 14 years and upward (Northern Ireland General Register Office, 1953). It was post World War II and the effects of the blitz were still very evident with overcrowding, lack of amenities and poverty. There were huge public health concerns with tuberculosis rife and maternal mortality rates higher than anywhere else in Great Britain or Ireland. Although the NHS had been introduced in 1948, there were

clearly major problems detrimental to the health of those living in the city of Belfast throughout this study period of 1954 to 1956. By 1955, the estimated population was 453,900 and the continuing emigration to seek employment from rural areas to Belfast, combined with low incomes and periodic high unemployment, had created extensive areas of sub-standard back-to-back housing, a substantial percentage of which were slums.

The 1950s may not seem so long ago, yet, these data available, which provide a microscopic and detailed sense of the health in Belfast then, is undoubtedly very different to the Belfast of today, over half a century later (Swann, 1954; 1955; 1956).

Historical birth records

Having established that historical birth records were stored on the hospital's site, the challenge was then to access and retrieve them. On the surface this may seem a relatively simple task, however, the experience was somewhat testing.

Consecutive obstetric records exist for every birth occurring at the RMH Belfast in the 1950s and have been kept in bound volumes. A three-year period was selected, with the years 1954 to 1956 chosen because records were mostly complete. There were only two missing volumes, one from 1955 the other from 1956, which equated to 200 births. The records were 'stored' in a building separate to RMH, which required a risk assessment, resulting in a delay in obtaining access while a health and safety report was compiled. Medical records staff were not allowed into this building and permission had to be sought from the directorate and medical records managers for the researcher to be granted access. Having overcome that hurdle, negotiating a six-foot high overgrown yard to unlock a door secured by five varieties of locks, seemed relatively simple! When inside there were more surprises, the 'filing system' lacked organisation and numerous boxes piled high and in no particular order, had to be negotiated. With a lot of effort and assistance from colleagues, the numerous volumes of birth records were eventually retrieved and transferred to RMH. It was certainly worth all the hard work and was most satisfying to see all these volumes eventually on shelves in RMH ready for use.

It was with great excitement and awe that the first volume was opened. The records were of extremely good quality, handwritten and legible. They were fascinating to read and many long hours were spent going through page-by-page each individual birth record, initially abstracting all relevant details and transferring these on to a hard copy and finally entering the details onto an electronic database. For the three-year study period, there were a total of 6366 birth records.

Sample selection

The next challenge was to begin the search for IUGR babies. Birthweight was converted to grams, and gestational age was calculated based on the first day of the last menstrual period (Hyppönen et al, 2003; Strauss, 2000; Kiserud and Maršál, 2000), as ultrasonography was not used in the 1950s. All modes of delivery and onset of labour (spontaneous or induced) were included. Inclusion criteria were singleton, live births at term. Exclusion criteria were multiple pregnancies, those with major congenital abnormalities, and those

individual potential participants whom their GP deemed inappropriate to include in the study.

The issue then arose as to what growth reference chart was appropriate for use in this cohort who were born in the 1950s. Advice was sought from a variety of organisations and experts in this field. Researchers involved in the Thousand Families Study, which is a prospective cohort study of babies born in May and June 1947 in Newcastle upon Tyne, compared birthweight standard deviation scores by gestation among Tanner et al (1966), Gairdner and Pearson (1971) and the UK 1990 reference standards (Freeman et al, 1995). It was concluded that the UK 1990 reference standard was superior and could be used in the 1947 cohort (Wright and Parker, 2004). In view of this, the same was used for the RMH cohort born in the 1950s. Software provided by the Child Growth Foundation, London – which summarises the UK 1990 growth reference from infancy to adulthood, and is already in evidence and readily available – was thus used in sample selection for this study.

Use of this software made it possible to adjust birthweight for gestation and gender and to convert these to a standard deviation score. The study and comparison groups were selected from n=4667 who met the inclusion criteria. Using Statistical Package for Social Sciences version 11 (SPSS, 2001), a syntax was run to identify the study group (n=491). A random selection of the non-study group was then chosen (n=491). A one-to-one ratio for study group and comparison group was used. A check was done using the Tanner and Whitehouse and Gairdner and Pearson programmes to ensure the study and comparison groups identified were similar to those selected using the UK 1990.

The total sample including study and comparison groups was 982. The overall groups (each n=491) were similar in terms of available birth characteristics. Actual study participants were also similar in terms of birth characteristics and, in addition, social class at time of study. Sociodemographic and lifestyle characteristics such as education, employment, marital status, diet, smoking and alcohol intake, recorded at the time of study did not differ significantly between groups. Losses to follow-up, dropouts and non-participation were recorded at the various stages to enable the researcher to examine potential sample bias.

Tracing the sample selected
Tracing potential participants proved to be a huge challenge and involved three main phases, namely the Central Services Agency (CSA), GPs and participants. The success of the entire study hinged on this aspect of the research process and as a researcher, I had little control over the outcome. The most I could do was to provide as accurate information as possible and continually follow progress. At this stage I was solely relying on others, particularly GPs, therefore the ability to pass on my enthusiasm and highlight the value of such a study was crucial.

Central Services Agency
The Family Practitioner Services Information and Research Branch of the CSA for NI provide a range of support functions to health and personal social services organisations. When the study and comparison groups were selected, maternal and birth details were forwarded to the branch for tracing. CSA was able to use these details recorded in the birth records of infants born in the 1950s to trace this cohort 50 years on, and identify the GP CSA records indicating who they were registered with. Electronic matching was done for the majority of records and for those traced, CSA provided the GP reference code (n=591) they had linked to individual potential participants, now aged 50 years. The researcher then used a current GP practice reference code list from the four health boards in NI to identify the name and address of these GPs.

Although this service is charged per trace, regardless of whether it is successful, lack of personnel and continuity at CSA compounded the difficulties surrounding the tracking process. One example of the problems encountered is that the first batch returned from CSA did not provide forenames for any individuals or current surnames, which are needed to contact females who are married. It would not have been feasible to send a letter to a GP with no first name for either gender or only a maiden name for married females, as patients with duplicate names and dates of birth can be and were registered in the same practice.

General practitioner
The information returned from CSA was then sorted by health board, GP code and practice. Individual GPs, or where appropriate practice managers were posted a pack consisting of a cover letter, study information leaflet, structured sheet for the GP to complete and a stamped addressed envelope (SAE). Assistance from GPs was essential and this phase required a lot of personal input by the researcher. Some GPs had no record of individual patients, which suggests that CSA records are incomplete or not updated if patients change GP practice. A minority of GPs were not happy to assist with the study and this may be related to data protection issues, or volume of work. Overall however, response from GPs was good.

Participants
When participant information was returned from GPs (n=515), a pack containing a cover letter, information leaflet, consent form and an SAE was posted to potential participants, inviting them to take part in the study. In total there were 235 who participated in the study, three of which completed the questionnaire only, but were unable to attend for testing. Some members of the original cohort now live abroad and completed questionnaires were returned, for example, from Australia, Germany and Hong Kong. Of those who could be contacted, 45% were followed up, which is comparable to a study by Barker et al (1990), also involving follow-up 50 years after birth. It was interesting that some individuals who were born in RMH at that time but were not selected, contacted the research office offering to take part after a friend or relative had received information about the study.

On a small number of occasions, the wrong individual may have been traced or had an incorrect address. One person contacted said she was born in the Republic of Ireland, although had lived in NI at one stage. Another person thought she was born in England and abandoned there and had no information about her early childhood until she went into

care in Belfast. In light of the human organs enquiry, a female participant who had experienced a stillbirth several years ago requested information regarding this. All these unforeseen discrepancies created a totally new set of challenges for the researcher that had to be investigated and resolved appropriately. It should be highlighted that no contact had been made with the cohort since they were born in RMH in the 1950s. As it transpired many of the study group were not aware they had been 'born small', nor indeed did they know their actual birthweight. This is quite a contrast to deliveries now in this century, where birthweight has such a focus and is one of the first details parents like to know about their newborn baby.

The importance of an efficient administrative database established at an early stage could not be stressed enough. Keeping track of each individual cohort member at each individual stage of the research process, from the original historical birth record entry to tracing through to response, certainly posed a huge challenge.

Reflection on learning

As I wrote this paper, which provides insight into my personal journey of my research experience, I recounted key challenges. These were to the fore as I considered what lessons I had learnt from the experience and how these may help other researchers embarking on such a study as this in the future. To attempt to summarise these presents a challenge in itself. However, key points include retaining your belief in the immense value of your research and the substantial benefits of using data from historical birth records to share with others. Access to such records unlocks the door to give a privileged insight and accurate picture of maternity care over half a century ago. As time passes and midwifery and obstetric colleagues from this era also pass on, these detailed birth records are all we will have to understand what birth was like in the 1950s and also reinforce what progress has been made, particularly in terms of improving outcomes for mothers, babies and their families in the present day arena of maternity care. Yet, to undertake such a long-term follow-up study in the current research climate would continue to pose difficulties regarding data protection and confidential policy, particularly tracing individuals and accessing records. However, many additional challenges may arise, such as the impact of lack of resources. Obstetric records must be kept for 25 years and within RMH as in many healthcare Trusts, there are enormous pressures in terms of available space and associated storage costs of records prior to that period. It is incredibly difficult to contemplate destroying historical birth records and the loss of a wealth of irreplaceable data that provide such an accurate and detailed sense of birth in the previous century.

More generally, establishing goodwill with various key players, often over a series of contacts, was crucial to the overall success of this research. Having worked as a midwife in Royal Jubilee Maternity Service, Belfast also helped considerably, particularly in the early stages of my research. Many challenges were encountered, requiring me to use a diversity of skills and many lessons were learnt along the way and I hope sharing some of what are very personal experiences, will be thought-provoking and perhaps helpful in future research within the maternity care environment. My journey was by no means a solo effort and I am appreciative of all those who contributed to the completion of this ambitious, but very rewarding retrospective cohort study.

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