A Review of Congenital Anomaly Surveillance in the Republic of Ireland

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List Of Abbreviations

CDC	Centers for Disease Control and Prevention
ERHA	Eastern Regional Health Authority
HIPE	Hospital Inpatient Enquiry System
HRB	Health Research Board
ICBDMS	International Clearing House for Birth Defects Monitoring Systems
MHB	Midland Health Board
MMWR	Morbidity and Mortality Weekly Report
MWHB	Mid Western Health Board
NDSC	National Disease Surveillance Centre
NEHB	North Eastern Health Board
NUI	National University of Ireland
NWHB	North Western Health Board
PHIS	Public Health Information System
SEHB	South Eastern Health Board
SHB	Southern Health Board
UCHG	University College Hospital Galway
UK	United Kingdom
WHB	Western Health Board
WHO	World Health Organisation
WWW	World Wide Web

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Summary

The public health importance of congenital anomaly surveillance should not be underestimated, as they are major causes of childhood morbidity and mortality. In 2000, 131 infants aged less than 1 year died from congenital anomalies. In the three-year period 1997-1999 there were over 25,000 hospital discharges for congenital anomalies.

In addition the last number of years has also seen an unprecedented demand from laypersons, medical professionals and policy makers for information on the potential impact of environmental pollutants on births in this country. It may relate to Chernobyl, Sellafield, Askeaton, an incinerator or a landfill site but the fact remains that without a comprehensive population based congenital anomaly surveillance system in place these questions cannot be answered with any degree of certainty. Congenital anomalies are clearly an important public health event in this country.

The ERHA, NEHB, SEHB, SHB and WHB currently operate congenital anomaly surveillance systems and all are either full or associate members of EUROCAT, a European wide, and European Commission funded surveillance programme. A critical review, principally of the ERHA Registry-the largest and longest operating in the Republic of Ireland-has led this Review Group to conclude that the EUROCAT model of congenital anomaly surveillance is a strong one and is the model that all existing and any future registries in this country should aspire to.

A National Centre for Congenital Anomaly Surveillance should also be established to work in partnership with individual health board registries. It would be responsible for the collation, analysis and publication of national reports and act as a resource center for collaborative research, training, expertise and advice. It would also serve as a national forum for discussion of 'new' or 'emerging' issues such as additional congenital anomalies and high-risk population subgroups (e.g. travelers, asylum seekers).

Registration of congenital anomalies is not obligatory in this country. Rather, the success of existing registries to date has been based on a very high level of multidisciplinary co-operation and good will towards this important public health issue. This is now being seriously threatened with the absence of specific legislation governing the operation of disease registers in this country. Already this has resulted in the withdrawal of some traditional sources of data absolutely vital to the production of accurate and reliable statistics without which surveillance is pointless.

It is the opinion of this Review Group that the only workable solution lies with an immediate need for specific legislation that tackles the issue of disease registers and informed patient consent. As a precedent, the UK Government has chosen this solution with Section 60 of the Health and Social Care Act 2001. It must be acknowledged that legislation by itself should only be a transitional measure whilst consent or suitable anonymisation procedures are developed in this country. The challenge therefore is twofold: to change any culture of paternalism within the medical profession and to move to systems of using patient identifiable information based upon the informed consent of patients.

The recently published health strategy 'Quality and Fairness-A Health System For You' emphasised a people-centred health system. Congenital anomaly surveillance will allow our health system to identify and respond to the needs of these individuals and their families and will also allow appropriate preventive, treatment and rehabilitation services to be planned and delivered in a coordinated way. But it has to be emphasised that this cannot be done without addressing the deficiencies governing the operation ofdisease registers and the issue of patient consent in the Republic of Ireland.

1. Introduction

In the summer of 2001, the Directors of Public Health established a Review Group to undertake a review of congenital anomaly surveillance in The Republic of Ireland. The terms of reference given to the working group were as follows:

- To undertake a review of the strengths and weaknesses of the congenital anomaly surveillance system in the Republic of Ireland
- To make recommendations for the future direction of congenital anomaly surveillance in the Republic of Ireland
- To report within 3 months

The Review Group held its first meeting in September 2001. It met on four occasions, three times in Dublin and once in Galway. As the Review Group required information from external sources it was not possible to meet the initial deadline imposed.

2. History of Congenital Anomaly Surveillance

2.1 The Success Of Congenital Anomaly Surveillance

Birth defect surveillance has become an established public health activity in many parts of the world [1 2 3]. The public health importance of birth defect surveillance should not be underestimated, as birth defects are a major cause of childhood morbidity and mortality[4].

Over the last 20-25 years surveillance has produced important epidemiological data on the distribution of birth defects in various populations [5]; has contributed data for case-control and family studies to assess risk of birth defects [6 7]; has identified long term trends in prevalence, such as that seen for neural tube defects in the Republic of Ireland [8]; has allowed for the planning and evaluation of interventions such as folic acid intake[9 10]; has allowed for more rational planning of services based on the incidence and survival of children with congenital defects [11].

Congenital anomaly surveillance also has the potential to evaluate the impact of exposure to possible environmental risk factors. Chernobyl in the 1980s, Askeaton in the 1990s and Sellafield continue to cause concern amongst laypeople and professionals alike. It is very difficult for any single register in the Republic of Ireland to do this given the size of the population, the incidence of congenital anomalies and the resultant limitations of statistical power. Extending coverage to all health boards and participation with international organisations can allow us to respond to queries on potential environmental risk factors.

2.2 Congenital Anomaly Surveillance-International Collaboration

Founded in 1974 to provide a forum for a rapid exchange of information among the various birth defects monitoring or surveillance programs around the world, the International Clearing House for Birth Defects Monitoring Systems (ICBDMS) is an independent non profit making organisation that was originally sponsored

by the March of Dimes Birth Defects foundation and has been affiliated since 1986 to the World Health Organisation (WHO) as a non-governmental organisation. The Eastern Regional Health Authority (ERHA) EUROCAT registry is an ICBDMS member.

The Concerted Action on Congenital Anomalies (and Twins), named EUROCAT, was officially established in 1979 by the Directorate General XII. EUROCAT was a prototype for European surveillance aiming to assess the feasibility of pooling data across national boundaries, in terms of standardisation of definitions, diagnosis and terminology, and in terms of confidentiality. In 1991 the funding of the EUROCAT Registries was transferred to the Directorate General V. Since November 2000 EUROCAT has been funded under the Rare Diseases Programme of the European Commission.

The EUROCAT Central Registry is currently based at the University of Ulster, Northern Ireland, in collaboration with the London School of Hygiene & Tropical Medicine, London. All existing registries in operation in the Republic of Ireland are either full or associate members of EUROCAT.

BINOCAR is the British Isles Network of Congenital Anomaly Registers. It was established in 1996 at the Glasgow Registry of Congenital Anomalies. The aim of this informal network is to bring together all those working in the field of monitoring and reporting on congenital anomalies in these islands.

There are considerable benefits in being affiliated with such international organisations. It allows exchange of routine information on the prevalence of congenital malformations; it allows for collaborative epidemiological research; it allows expert consultation and assistance for existing monitoring systems; the analysis of combined datasets can act as an early warning system to investigate possible outbreaks of congenital defects; it can also facilitate the establishment of new registers.

3. Critical Evaluation of Congenital Anomaly Surveillance in the Republic of Ireland

In order to address the terms of reference the Review Group undertook a formal review of the congenital anomaly surveillance system using internationally accepted criteria, published by the Centers for Disease Control and Prevention (CDC), for evaluation of a surveillance system [12]. All of the Irish registries were examined but specifically that of the ERHA, as this is the longest established EUROCAT registry in operation in the Republic of Ireland.

The MMWR guidelines[12] set out several steps in the evaluation process:

(a) Engage the stakeholders in the evaluation

(b) Describe the surveillance system to be evaluated

- Public Health Importance of the health event
- Describe the purpose and operation of the system
- Describe the resources used to operate the system

(c) Gather credible evidence regarding the performance of the surveillance system

(d) Justify and state conclusions, and make recommendations

(e) Ensure use of evaluation findings and share lessons learned

3.1 Engaging Stakeholders In The Evaluation

For the purpose of this evaluation stakeholders were defined as those who were, at the time of this report, either actively involved in the surveillance of congenital anomalies or who were interested in establishing a surveillance system in their health board area.

Health boards that currently operate a congenital anomaly surveillance system include the Eastern Regional Health Authority (ERHA), South Eastern Health Board (SEHB), Southern Health Board (SHB), North Eastern Health Board (NEHB) and Western Health Board (WHB).

The three remaining health boards, Mid Western Health Board (MWHB), North Western Health Board (NWHB) and Midland Health Board (MHB) have expressed strong interest in establishing a congenital anomaly surveillance system.

3.2 Describing The Surveillance System In Operation

3.2.1 The Public Health Importance of Congenital Anomaly Surveillance

Health events that affect many people, that requires large expenditure or that cause severe disability clearly have public health significance. The public health importance of congenital anomalies can be measured in several ways.

In 2000, 131 infants (< 1year) died as a result of congenital anomalies. Congenital anomalies were the single leading cause of mortality in infants aged less than one year, accounting for 41% of all infant deaths. The proportional contribution of birth defects to infant mortality has increased as other causes have diminished [13].

Morbidity and disability experienced by children who survive are equally important. Each year in the Republic of Ireland approximately 20 congenital anomalies are identified per 1000 total births. Ninety-five percent (95%) of these are live births. In the period 1997-1999 there were 25,275 hospital discharges for congenital anomalies[13].

Congenital anomalies are clearly an important public health event.

3.2.2 The Objectives of Congenital Anomaly Surveillance

The objectives of congenital anomaly surveillance as described by EUROCAT are:

1. To provide epidemiological information on congenital anomalies
2. To detect and investigate trends in the frequency of congenital anomalies in order to assess the impact of known or suspected risk factors

3. To evaluate the effectiveness and efficiency of health services in terms of primary prevention, prenatal diagnosis and treatment
4. To act as an information and resource center for the population, health professionals and managers regarding clusters or exposures or risk factors of concern, and to contribute to training of professionals
5. To provide a collaborative network and infrastructure for aetiological and clinical research related to the causes and preventionof congenital anomalies and the treatment and care of affected children.

3.2.3 The ERHA Registry (Dublin EUROCAT Registry) is a population based register of congenital anomalies that commenced in 1979. The subject population consists of babies born to all mothers resident at birth in the geographical area of counties Dublin, Kildare and Wicklow. Average number of births per year is approximately 20,000 with approximately 500 congenital anomaly notifications per year. Data is collected from the time of diagnosis up to 5 years after birth.

The ERHA is a EUROCAT register and as such congenital anomalies refer to structural defects (congenital malformations, deformations, disruptions and dysplasias), chromosomal abnormalities, inborn errors of metabolism and hereditary diseases. As a EUROCAT registry the common nomenclature and coding system of the British Paediatric Association Classification of Diseases [14], which is a five-digit code being an extension of the 9th revision of the International Classification of Diseases is used. Up to eight congenital anomalies may be coded for each baby and in addition a syndrome, if recognised can be coded.

The ascertainment of congenital anomalies and the precise diagnoses are based on the use of active case finding and ofmultiple sources of information such as birth notifications, death certificates, Hospital In-Patient Enquiry System (HIPE), pathology reports, karyotyping reports, cardiologists, paediatricians, special care baby units, long term illness and domiciliary care allowance records.

Information is collected on a standard form with standardised coding. In the absence of unique patient identifiers an index card system is used. Whenever a potential case is identified this index is searched to see if the patients name, address and date of birth are already present on the database. All information on the ERHA registry is held locally and an anonymised copy is sent to the central EUROCAT registry

Data are analysed locally and also at the central registry. Local data analysis provides birth prevalence rates for all congenital anomalies and birth prevalence rates for each congenital anomaly, in addition to providing information for specific research projects.

Internal reports are run regularly internally for the registry.Specific research is published usually submitted as papers in peer-reviewed journals.

Resources required in operating the system include:

- Nurse researcher (Full time)
- Specialist in Public Health Medicine (1 day/week depending on other commitments but $2^1/_2$ days per week would be more appropriate considering the size of the registry)
- Clerical staff/part-time secretarial support
- Travel to sources of data
- Computer time

3.2.4 The NEHB Registry is a population based register of congenital anomalies that commenced in 1997. The subject population consists of babies born to all mothers resident at birth in the geographical area of counties Cavan, Monaghan, Meath and Louth. Average number of births per year is approximately 4,500 with approximately 100 congenital anomaly notifications per year. Data is collected from the time of diagnosis up to 5 years after birth. The NEHB congenital anomaly register operates as a branch of the ERHA registry in that EUROCAT

methodology is employed and all anomalies registered in the NEHB are entered onto the ERHA central database. Data are pooled and analysed with ERHA data.

The ascertainment of congenital anomalies and the precise diagnoses are based on the use of active case finding and of multiple sources of information including birth notifications, death certificates, HIPE, paediatricians, all hospital admissions to each of the paediatric units and domiciliary care allowance records. Much time is spent cross-referencing to avoid duplication of cases

Information is collected on a standard form with standardised coding. In the absence of unique patient identifiers a manual register is used. Whenever a potential case is identified this register is searched to see if the patients name, address and date of birth are already present on the database. All information on the registry is held locally and an anonymised copy is sent to the ERHA registry. To ensure confidentiality only the Congenital Anomaly Register Nurse has access to both the manual register and the database.

With approximately 4,500 births per year in the NEHB the statistical power of the data collected on a yearly basis is low. It has been estimated that it would require 10-15 years of pooled NEHB data before a meaningful statistical analysis could be conducted.

Resources required in operating the system include:

- Nurse researcher (1/2 time)
- Travel to sources of data/Travel to ERHA registry
- Computer time
- Specialist in Public Health Medicine (1/2 day/month)

3.2.5 The SEHB Registry is a population-based register of congenital anomalies with data collection backdated to 1997. The subject population consists of babies born to all mothers resident at birth in the geographical area of counties Wexford, Waterford, Carlow, Kilkenny, and South Tipperary. Average number of births per

year is approximately 6,100 with approximately 200 congenital anomalies per year. Data is collected from the time of diagnosis with no specific cut-off age. The SEHB congenital anomaly register operates as a branch of the ERHA registry in that EUROCAT methodology is employed and all anomalies registered in the SEHB are entered onto the ERHA central database.

With just over 6,100 births per year in the SEHB the statistical power of the data collected on a yearly basis is low. By pooling with a larger database in the ERHA, this also helps with discussing rare anomalies.

The ascertainment of congenital anomalies and the precise diagnoses are based on the use of active case finding and of multiple sources of information including birth notifications, death certificates, HIPE, paediatricians, all hospital admissions to each of the four paediatric units and domiciliary care allowance records. Much time is spent cross-referencing to avoid duplication of cases.

Information is collected on a standard form with standardised coding. In the absence of unique patient identifiers a manual register is used. Whenever a potential case is identified this register is searched to see if the patients name, address and date of birth are already present on the database. All information on the registry is held locally and an anonymised copy is sent to the ERHA registry. To ensure confidentiality only the Congenital Anomaly Register Nurse has access to both the manual register and the computerised database.

Data is analysed regionally and also after merging with the ERHA. Reports are produced every 6 months for the regional steering committee (This committee is made up of a representative group of health professionals consisting of a Specialist in Public Health Medicine, Paediatrician, Obstetrician, Pathologist, Senior Area Medical Officer, Director of Public Health Nursing, Congenital Anomalies Register Nurse and Regional Disability Manager. The initial aim of the steering group was to establish a Congenital Anomalies Register for the SEHB, which would be compatible with data collected on the other Congenital Anomaly

Registers in the Republic of Ireland. However it now oversees the work of the register and ensures that the data collected is used appropriately.

Resources currently employed in operating the system include:

- Nurse researcher (1/2 time)
- Travel to sources of data/travel to ERHA registry
- Computer, printer, software (Word, Excel, SPSS)
- Specialist in Public Health Medicine (1/2 day/month)

3.2.6. The SHB Registry is a population-based register of congenital anomalies with data collection backdated to 1996. The subject population consists of babies born to all mothers resident at birth in the geographical area of counties Cork and Kerry. Average number of births per year is approximately 7,500 with approximately 180 congenital anomaly cases recorded. Data is collected from the time of diagnosis with no specific cut-off age. The SHB congenital anomaly register operates using the EUROCAT protocol and definitions.

The ascertainment of congenital anomalies and the precise diagnoses are based on the use of active case finding and of multiple sources of information including birth notifications, death certificates, HIPE, Community Care Staff, labour ward registers, orthopaedic outpatient letters, paediatric secretaries and domiciliary care allowance records.

Information is collected on a standard form with standardised coding. In the absence of unique patient identifiers a manual register is used. Whenever a potential case is identified this register is searched to see if the patients name, address and date of birth are already present on the database. All information on the registry is held locally on an Epi-info database.

Data is analysed regionally and the first report is ready for circulation at local level. A steering group while planned is not yet in operation.

Resources currently employed in operating the system include:

- Nurse researcher (1/2 time)
- Travel to sources of data
- Computer, printer, software
- Specialist in Public Health Medicine (1/2 day/month)

3.2.7 The WHB Registry is a community-based registry with data collection back dated to 1981. The subject population consists of babies born to all mothers resident at birth in the geographical area of County Galway. Average number of births per year is approximately 3,000 with approximately 60 to 70 congenital anomaly cases recorded. The WHB congenital anomaly register operates using the EUROCAT protocol and definitions.

The ascertainment of congenital anomalies and the precise diagnoses are based on multiple sources of information including birth notifications, death certificates, in-patient discharge summaries, out-patient diagnostic indices, labour ward registers, post mortem reports, Our Lady's Hospital for Sick Children Cardiology Department, UCHG Cardiology Department, Temple Street (metabolic disorders) and NUI Galway (Cytogenetics).

Information is collected on a standard form with standardised coding. In the absence of unique patient identifiers a manual register is used. Whenever a potential case is identified this register is searched to see if the patients name, address and date of birth are already present on the database. All information on the registry is held locally. Confidentiality is retained within the Galway Registry and information submitted to EUROCAT by local ID number and date of birth.

Resources currently employed in operating the system include:

- Consultant Paediatrician
- UCHG Department of Paediatrics Neonatal Secretary

3.2.8 Evidence Of The Performance Of Congenital Anomaly Surveillance

Under the MMWR guidelines[12] a system is useful if it contributes to the prevention and control of adverse health events including an improved understanding of the public health implications of such events.

The ERHA registry does identify the birth prevalence of congenital anomalies and is capable of identifying changes in trends in prevalence. The registry identified a large decrease in the prevalence of neural tube defects. A rise in prevalence of congenital anomalies of the diaphragm and gastroschisis has also been identified. A congenital anomaly surveillance system can and does identify rises in rare events that would not be picked up clinically.

The register has also been used as a database in determining the longterm survival of Down's syndrome children and therefore of use for health services planning. The register has also been used to provide a populationbased database of children with neural tube defects and other anomalies for research on the role of folic acid and vitamin B12 in the causation of neural tube defects and other anomalies.

Data on risk factors for congenital anomalies is requested on the EUROCAT registration form. One of EUROCAT's objectives is *"To act as an information and resource center for the population, health professionals and managers regarding clusters or exposures or risk factors of concern, and to contribute to training of professionals"*. However this information is often missing and the emphasis to date has been on accurate identification of the anomalies rather than on risk factors.

The register also aims to respond to specific queries and concerns as to the toxic effects of the environment in relation to birth defects. It is very difficult for any single register in the Republic of Ireland to do this given the size of the population, the incidence of congenital anomalies and the resultant limitations of statistical power.

3.2.9 Attributes of the Surveillance System

(a) Simplicity

The simplicity of a surveillance system refers to both its structure and eæse of operation. Surveillance systems should be as simple as possible while still meeting their objectives.

The structure is characterised by manual data collection and follow up from many sources. This can be complex, time consuming and heavily reliant onthe researcher's detailed knowledge and working relationships with many data sources. The structure is currently being seriously affected with the increasing uncertainty concerning data protection and patient confidentiality and the operation of disease registers. The data is manually coded and then manually entered onto a VAX mini-computer. In 2001 the ERHA EUROCAT Registry began to pilot an MS Access based data management system.

(b) Flexibility

A flexible surveillance system is one that can adapt to changing information needs or operating conditions with little additional time, personnel of allocated funds. Flexible systems can accommodate new health related events, changes in case definitions or technology and variations in funding or reporting sources. Flexibility is best evaluated retrospectively by observing how a system has responded to a new demand. Such an evaluation has not been undertaken.

(c) Sensitivity

This refers to the proportion of congenital anomalies in the population that are detected by the surveillance system. This is affected by the likelihood that the condition is occurring in the population under surveillance, that those with such conditions will seek medical care, that the congenital anomaly will be diagnosed and that the case will be reported to the system. In order to measure the sensitivity of the system the information collected must be validated and

information must be collected externally to the system so as to determine the frequency of the condition in the population. See also (d) below.

Sensitivity can be assessed through estimations of the total cases in the population under surveillance by using capture-recapture techniques [15 16] and was a method of quality assurance previously suggested for the ERHA registry [17]. In epidemiology capture-recapture techniques allow the number of cases of disease in a defined population to be estimated using two or more sources of cases. Taken alone each source may considerably undercount the actual number of cases. However by using information provided by duplicate cases an estimate of the number of uncounted cases, that is, an ascertainment corrected rate can be derived. Because this method always evaluates and corrects incidence and prevalence estimates for the efficiency of registration one can be more confident that rising rates of disease over time and reported geographical differences in the frequency are not the result of an increase in the efficiency of registration. Capture-recapture techniques have many characteristics that are appealing to registries: they need no non-registry data to come up with an estimate of completeness of registration and once set up they can automatically be incorporated into ongoing quality control procedures. Registries could then report corrected as well as calculated rates for birth defects.

(d) Data Quality & Validation

Data quality reflects the completeness and validity of the data recorded in the public health surveillance system. Quality of data is influenced by the performance of the screening and diagnostic tests (i.e. the case definitions) for the health related event, the clarity of records, the quality of training and supervision of persons who complete these surveillance forms and the care exercised in follow up and data management. A review of these facets would provide an indirect measure of data quality but such a review has not been undertaken.

Where at all possible the patients chart is currently reviewed prior to entry onto the register. There is no routine system for validating cases after their entry onto the register although regular updating is carried out. Data are sent to the European central registry and cases are reviewed by a geneticist there to check that the associations noted are likely and communication with the local registry follows where unusual associations are noted.

Comparison of information collected independently of the registry with registry data is difficult as the registry is using all known data sources and the register is population based. Ad hoc surveys[17] such as a case review can give an estimate of sensitivity for individual congenital anomalies but the sensitivity is likely to vary by anomaly given that sensitivity may change as a result of heightened awareness of a disease, the introduction of new diagnostic tests or changes in the method of conducting surveillance.

(e) Acceptability

Acceptability reflects the willingness of persons and organisations to participate in the surveillance system. Up until recent times there has been a great willingness to cooperate in the collection of data by the registry nurse. This is further supported by those health boards that want to establish new congenital anomaly surveillance registers.

However, the willingness to participate is being compromised by the increasing uncertainty concerning data protection and patient confidentiality issues and the operation of disease registers.

(f) Representativeness

A representative surveillance system accurately describes the occurrence of a health event over time and its distribution in the population by placeand person. Those registries operating under EUROCAT methodology are population based, use multiple sources of information and until recently has had the cooperation of all relevant specialties. In this regard it is likely to be representative.

(g) Timeliness

Timeliness refers to the speed or delay between steps in a surveillance system. Congenital anomaly surveillance is, until the stage of data entry, totally reliant on manual collection of data. Unsurprisingly for the major sources of data there are significant delays in receiving or obtaining information.

(h) Resources

Resources in the operation of existing registers are as previously described.

(i) Dissemination of information

There have been seven EUROCAT reports, the seventh of which was published in 1997 with an update in 1999. The ERHA registry produces internal and external reports principally targeted at the medical professional community. The ERHA registry is also about to publish a report on 20 years of congenital anomaly surveillance in the ERHA region. There is no regular newsletter at either local or central level although research papers on scientific topics are published in peer reviewed journals on a regular basis.

3.2.10 Conclusions and recommendations following evaluation

(a) The absence of specific legislation specific to public health disease registers addressing data protection and patient confidentiality issues is a serious and immediate threat to their continued operation.

(b) A partnership approach between clinicians and Departments of Public Health is essential to ensure the success of population based congenital anomaly surveillance in the Republic of Ireland

(c) The use of common nomenclature and the coding system of the British Paediatric Association Classification of Diseases [10] for the coding of congenital anomalies is a strong feature of the surveillance system currently in place and should continue

(d) The ascertainment of congenital anomalies based on the use of active case finding and of multiple sources of information is a strong feature of the surveillance system currently in place and should continue.

(e) A more automatic means of reporting cases to the register would lead to a simpler and timelier surveillance system and would also lead to a reduction in the potential for error.

(f) EUROCAT registries are currently piloting an MS Access database format. All Irish registries, to ensure consistency and compatibility, should adopt this software.

(g) A quality assurance system is required in the operation of a congenital anomaly surveillance system e.g. capture-recapture methods. A random sample of registry records should also be regularly reviewed for accuracy of diagnosis and for accuracy of coding of anomalies on computer.

(h) A unique patient identifier and geocoding of data would allow easier tracking and follow up of cases.

(i) Information should be disseminated more widely in the form of a periodic newsletter/suitable website to both professional and lay person

(j) The association with EUROCAT and other international organisations is of immense value and should continue.

4. Public Health, Data Protection And The Issue Of Consent

4.1 Legislation in the area of Data Protection

The legislation governing data protection in the Republic of Ireland are (1) Data Protection Act, 1988, (2) EU Data Protection Directive 95/46/EC (3) Data Protection (Amendment) Bill, 2002 (yet to be enacted) and (4) European Communities (Data Protection) Regulations, 2001 which will take effect in the Republic of Ireland on 1st April 2002.

- **Data Protection Act, 1988**

This is the law governing data protection in the Republic of Ireland. The Act was passed on the 13th July 1988, and came fully into force on the 19th April 1989. The Act gives effect in the Republic of Ireland to the 1981 Council of Europe *Convention for the Protection of Individuals with Regard to the Automatic Processing of Personal Data*, sometimes referred to as "Convention 108".

- **EU Data Protection Directive 95/46/EC**

In 1995, the European Union adopted a Data Protection Directive, *Directive 95/46/EC*.

- **Data Protection (Amendment) Bill, 2002**

When enacted, this Bill will amend the existing Data Protection Act, 1988 and give effect to the provisions of Directive 95/46/EC of the European parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

- **European Communities (Data Protection) Regulations, 2001**

The Republic of Ireland has given effect to Article 4,17,25 and 26 of Directive 95/46/EC in Irish law through the European Communities (Data Protection) Regulations, 2001, introduced by the Minister for Justice, Equality & Law Reform in December 2001, which will take effect from 1 April 2002.

4.2 EU Data Protection Directive 95/46/EC and Consent

- **Consent**

Under the 1988 Data Protection Act, there is no specific requirement to obtain people's consent before using their personal data within the organisation collecting it. There is a requirement to obtain and use people's data fairly, and in many contexts this requirement does entail the consent of the individual. Article 6 of the EU Directive preserves the requirement to obtain and use personal data fairly but in addition Article 7 adds a number of clear requirements, at least one of which must be met before personal data can be used.

Article 6

1. Member States shall provide that personal data must be:

(a) Processed fairly and lawfully;

(b) Collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards;

(c) Adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed;

(d) Accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified;

(e) Kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use.

Article 7

Member States shall provide that personal data may be processed only if:

(a) The data subject has unambiguously given his consent, or

(b) Processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract, or

(c) Processing is necessary for compliance with a legal obligation to which the controller is subject, or

(d) Processing is necessary in order to protect the vital interests of the data subject, or

(e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed, or

(f) Processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection under Article 1(1).

Comment: In general terms the EU Directive and the Data Protection (Amendment) Bill, 2002 will, in many circumstances, shift the balance in favour of obtaining clearer, more unambiguous consent from individuals than has been the case up to now.

4.3 Congenital Anomaly Registers And Data Protection

Obtaining data from multiple sources is absolutely crucial to the operation of congenital anomaly registers. This raises the issue of transferring data between different agencies e.g. clinicians in hospitals and those operating congenital anomaly registers.

1. The Office of the Data Protection Commissioner states that you can pass patient details on to another health professional for clinical purposes

However

- The operation of a congenital anomaly register is not for a clinical purpose

2. The Office of the Data Protection Commissioner states that you can disclose patient data to others for research or statistical purposes

However

- Data transfer can only happen if the individuals involved work for the same agency e.g. data can be transferred from hospitals within the NEHB to the Department of Public Health in the NEHB but this cannot happen if the hospitals or other agencies are outside the NEHB. Data sources for any health board's congenital anomaly register will not be confined to its own region. The situation is more complex in the ERHA as the ERHA is a separate agency to all hospitals even within its own region.
- Data if passed on must be in an anonymous or aggregate format from which individual patients cannot be identified. This is not practical for the operation of a congenital anomaly register as firstly validation of data is crucial as the

register is counting rare events. Missed cases or over counting can lead to the calculation of the wrong rate. Secondly, data collection on patients can take place over a long period (often years) of time. In the absence of a unique patient identifier personal/identifying data is an absolute and necessary requirement for the operation of congenital anomaly registers

- If you pass on identifying data you must obtain informed consent in advance. The Data Protection Commissioner is quite clear on this. See the comments of the Data Protection Commissioner below and Appendix 2 Case Study 1/97.

"I am of the opinion that for personal data to be fairly obtained, a data controller must make the data subject aware, directly and at the time his or her data are being obtained, of how such data may be used and to whom they may be disclosed, in order to get the person's informed consent to the uses and disclosures described."

".....there is a special need for the data controller to satisfy itself that any uses of the data which are unlikely to be anticipated by the data subject are fully explained."

The logistics of obtaining full consent from all expectant mothers in a manner that would meet data protection requirements would be significant.

Obtaining consent from parents after the birth is likely to be problematic given the enormous sensitivity of the situation. Even if consent was sought and obtained it could be argued at a later date that the parent(s) were in no reasonable state to give proper informed consent. There is potential for harm here not only to the parents but also to the professional relationship between patient and doctor.

4.4 Conclusions on legislation

This Review Group is of the opinion that the immediate solution lies with legislation but acknowledges that the issue of informed patient consent must be addressed.

In the UK Section 60 of the Health and Social Care Act 2001 (See Appendix 3) provides a power to ensure that patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can only be used to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice.

Ministers propose to establish class regulations that will provide support for broad classes of activity, reducing the number of individual projects that require consideration to the minimum.

One of the class regulations proposed is to permit disclosure of identifiable information to maintain disease registers, their analysis and research uses.

However, that said legislation by itself should only be a transitional measure whilst consent or suitable anonymisation procedures are developed. Data Protection and Human Rights legislation, guidance from the UK General Medical Council [18] the UK Medical Research Council, the British Medical Association and the Office for the Data Protection Commissioner here in Ireland reflect the evolving legal position and reinforce the requirement for consent.

The challenge here is twofold: to change any culture of paternalism within the medical profession and to move to systems of using patient identifiable information based upon the informed consent of patients.

As it stands existing congenital anomaly registers in the Republic of Ireland meet neither data protection requirements nor informed consent requirements. This is resulting in the gradual withdrawal of some traditional sources of data absolutely vital to meeting the objectives of the register.

5. Congenital Anomaly Surveillance-Review Recommendations

5.1 The Way Forward

- There is an urgent and immediate need for legislation concerning the operation of disease registers to ensure that the requirements of data protection can be met. Given present circumstances
  - The operation of existing registers is being seriously threatened
  - Establishing new registers in the absence of legislation is not recommended
- There must be a move to a culture of using patient identifiable information based upon the informed consent of patients

Assuming data protection/informed consent requirements have been met:

- A EUROCAT style of register should be the template adopted
  - Common nomenclature and the coding system of the British Paediatric Association of Diseases
  - Use of active case finding and multiple sources of information
- There is a need for a comprehensive surveillance system in each health board

  - Day to day operation (data collection/data validation) of the register to be done locally involving designated staff
  - Operation of local register to be overseen by a local multidisciplinary steering committee which could include representatives from: Specialist in Public Health Medicine and/or Director of Public Health, Consultant Paediatrician, Consultant Obstetrician, Consultant Pathologist Senior Area Medical Officer, Director of Public Health Nursing and Congenital Anomalies Register Nurse.

- A single national centre should be responsible for coordinating the operation of a National Congenital Anomaly Surveillance System working in partnership with individual health board registries.

  - Collation of regional data from individual health board registers
  - Analysis of data at national level
  - Production and dissemination of reports at national level for both professional and lay person
  - Forwarding of national data to the EUROCAT central registry
  - Resource center for collaborative research, training, expertise and advice
  - Act as a forum for discussion for 'new' or 'emerging' issues e.g.additional congenital anomalies, population subgroups (travelers, asylum seekers)
  - Overseen by a National Steering Committee with nominated representatives from Regional Steering Committees

- Computer hardware and software should be consistent throughout all registries to avoid data compatibility problems
- Data transmission between the regional and national centers needs to comply with data protection laws and maintain patient confidentiality.

5.2 Options For A National Centre for Congenital Anomaly Surveillance

Public health surveillance includes not only data collection and analysis but also the application of data to control and prevention activities by disseminating information to practitioners of public health and to others who need to know. These are the important criteria by which a national center should be judged. This Review Group recommends the following organisations to be considered as the national center.

1. National Disease Surveillance Centre (NDSC)

The NDSC was established in 1998 by the (then) eight health boards working conjointly and with the approval of the Minister for Health and Children. Since

then, the NDSC's initial priority has been surveillance of infectious diseases, in keeping with its mission statement *"To improve the health of the Irish population by provision of the best possible information on disease including infectious diseases through surveillance and independent advice, epidemiological investigation, research and training"*. NDSC now envisages broadening its surveillance activities, including the surveillance of congenital anomalies, and would be ready to do so assuming approval for funding and staffing are obtained from the Department of Health and Children. This model operates successfully in other countries, such as CDC in Atlanta, USA. The benefits of hosting surveillance activities nationally in one organisation include optimising surveillance, data protection and legislation, information systems and informatics expertise. It also encourages the promotion of integrated information systems for health, a key requirement if electronic patient record and electronic health record are to be advanced.

- **Proven track record in infectious disease surveillance**
  - Collation/Analysis/Dissemination of data
  - Weekly Infectious Disease Reports
  - Epi-Insight (Monthly)
  - SARI/ TB Reports/Meningitis Reports
  - Working in partnership with health boards
  - Extensive use of the World Wide Web (WWW) to disseminate information for action

NDSC has been very active in using information to inform the public, policy makers and professionals so that appropriate action can be taken to improve the population's health. This advocacy role is a vital aspect of surveillance, and NDSC has been very effective in this regard

NDSC is also working to improve access to information by all involved in infectious disease surveillance and control and is developing a national electronic

computerised infectious disease reporting system (CIDR) This will be a single data repository with access by partners, according to right or need to know the information contained. This will be an enterprise strength open standards based system, thereby allowing for future development and integration. It would be possible to add other conditions such as congenital anomalies at a later stage, thereby providing seamless timely high quality information to those at health board level and other partners in surveillance.

- **Expertise in surveillance methods and designated staff on a single site**
  - Specialists in Public Health Medicine
  - Information Technology
  - Health informatics
  - Surveillance Scientists

2. Health Research Board (HRB)

- The HRB together with its predecessor, The Medico-Social Research Board, has vast experience of operating national health databases. The HRB currently operates:
  - National Psychiatric In-patient Reporting System
  - National Drug Treatment Reporting System
  - National Physical and Sensory Disability Database
  - National Intellectual Disability Database
- Experience of initiating the EUROCAT register for the Eastern Health Board and running it for the first eight years of its existence
- Great breadth and depth of experience among HRB staff on all aspects of operating health databases including initiation, development, day to day operation, surveillance and data protection legislation
- High quality information technology systems in place to service the databases and the many clients who use them
- Excellent track record in research on aetiology and prevention of congenital anomalies

- Extensive network of experts in surveillance of and research on congenital anomalies in the Republic of Ireland and internatbnally
- Extensive experience of working with persons with congenital anomalies plus their families and support organizations
- In the research strategy published recently by the Minister for Health and Children a key role outlined for the HRB is to continue through intramural information activities (i.e. health databases) and research to building a research culture and the evidence base for decision making in the health services
- A strategic objective in the Corporate Strategy of the HRB for the period 2001-2006 is to impact on health and social policy and services through high quality information and research
- A core value of the HRB is responsiveness to clients' needs. In the context of the Board's health databases there is an excellent track record of working with and responding to the needs of clients throughout the health boards.

3. ERHA Registry

The ERHA Registry (Dublin EUROCAT Registry) is the largest congenital anomalies registry in the country. It was originally set up in 1979 and run by the Medico-Social Research Board until 1989 when the operation of the registry was transferred to the ERHA under the leadership of the late Dr. Zachary Johnson, and now under Dr. Bob McDonnell. In the early 1980s the system was computerised. The registry has been the main source of information on congenital anomalies in the state since then, with coverage of approximately 20,000 births per year, or almost 40% of those in the country. In the past four years, the ERHA registry has provided guidance and advice to the SouthEastern and the North Eastern health boards on setting up a congenital anomaly surveillance system. Both these registries are now in operation and because of their smaller size have requested that the ERHA registry act as the coordinating registry for the data for all three registries in the east of the country. This year, the data of the registries is being pooled to provide an analysis of congenital

anomaly surveillance for the three health board regions (ERHA, SEHB, NEHB) with coverage of almost 60% of births in the country.

The ERHA has 13 years experience in operating a large congenital anomaly surveillance system during which time a significant body of experience has been built up particularly in terms of personnel. This would be invaluable in the operation of a national centre.

- Staff with much experience in running a large computerised and manual congenital anomaly surveillance system with knowledge of its complexities, including the difficulties in obtaining data, manipulation and analysis of large amounts of data and data protection issues.

- Is an active member of the EUROCAT network and the International Clearinghouse for Birth Defects Monitoring Systems network, with whom it has in the past, and currently participates in joint projects e.g. limb defects, prevention of neural tube defects, congenital anomalies of the diaphragm.

- The ERHA registry provides congenital anomaly surveillance for almost 60% of births in the country in co-operation with the SEHB and NEHB registries.

- Has produced a number of papers published in peer-reviewed journals, including work on Down syndrome and Neural Tube Defects.

- Is about to publish a report on 20 years of congenital anomaly surveillance in the ERHA region.

- Involved in research projects to investigate changing trends in specific anomalies e.g. gastroschisis, diaphragm anomalies and research related to other anomalies e.g. folic acid and neural tube defects.

- Has a large informal network of contacts with staff in other European registries and internationally.

- Currently operates from the Health Information Unit of the Department of Public Health with access to a number of other databases including births, mortality, HIPE and census.

It is the opinion of this Review Group that whichever option is chosen t should be done so with due regard to the implementation of Quality and FairnessA Health System for You, the pending Health Information Strategy, the future development of the Health Board Executive and the invaluable experience of those who have been working in congenital anomaly surveillance to date.

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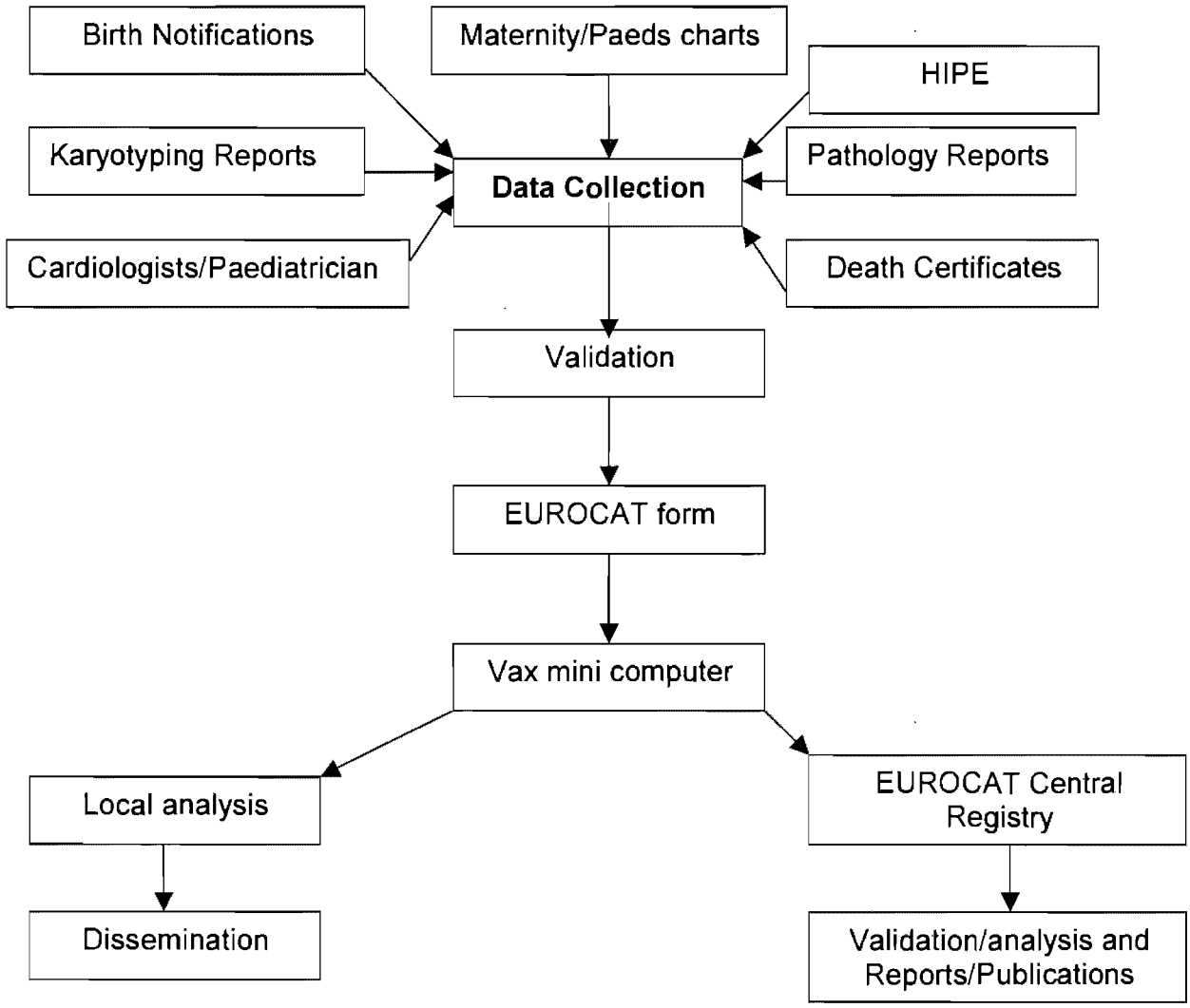
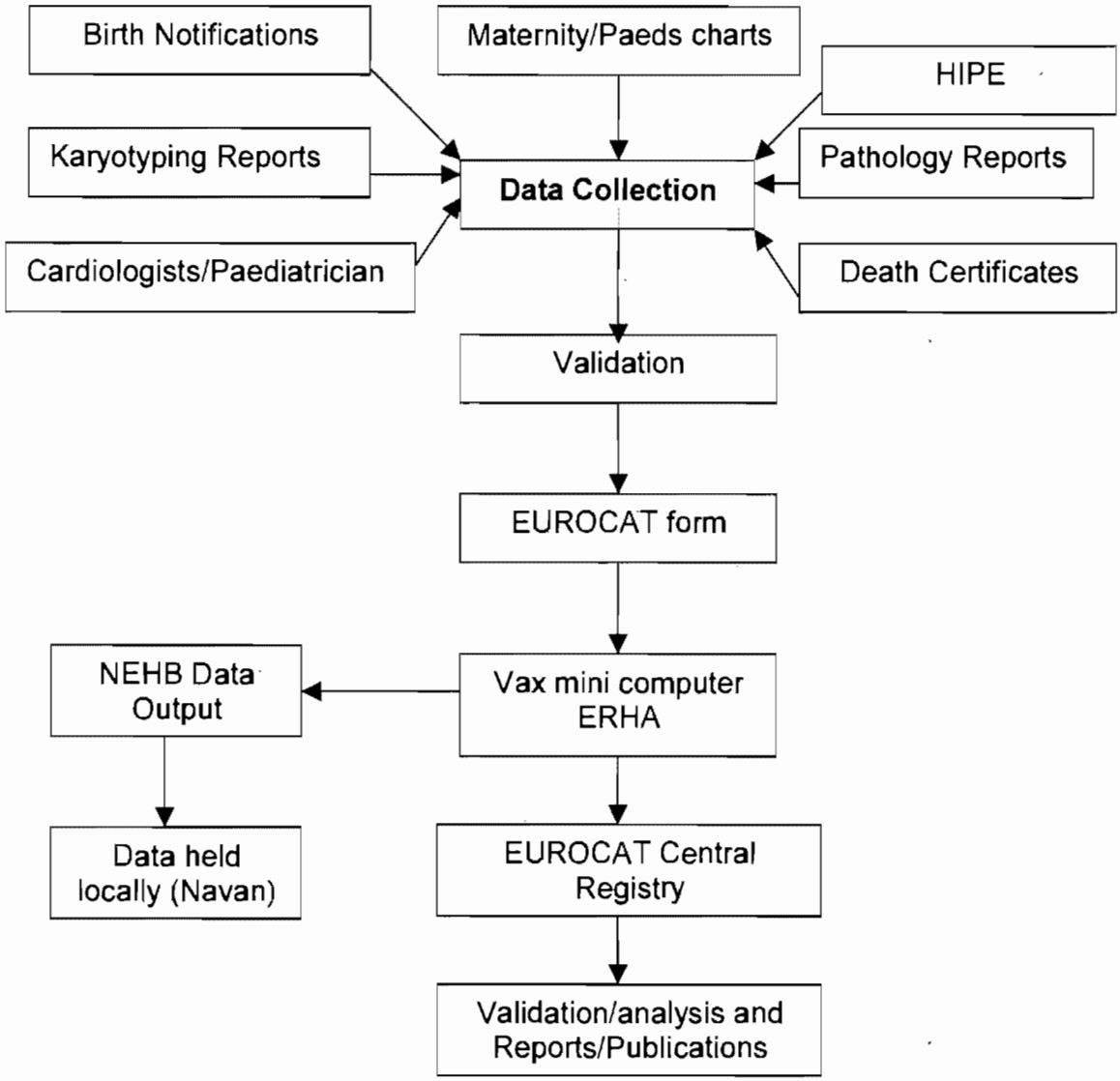
Appendix 1 **Registry Flow Charts**

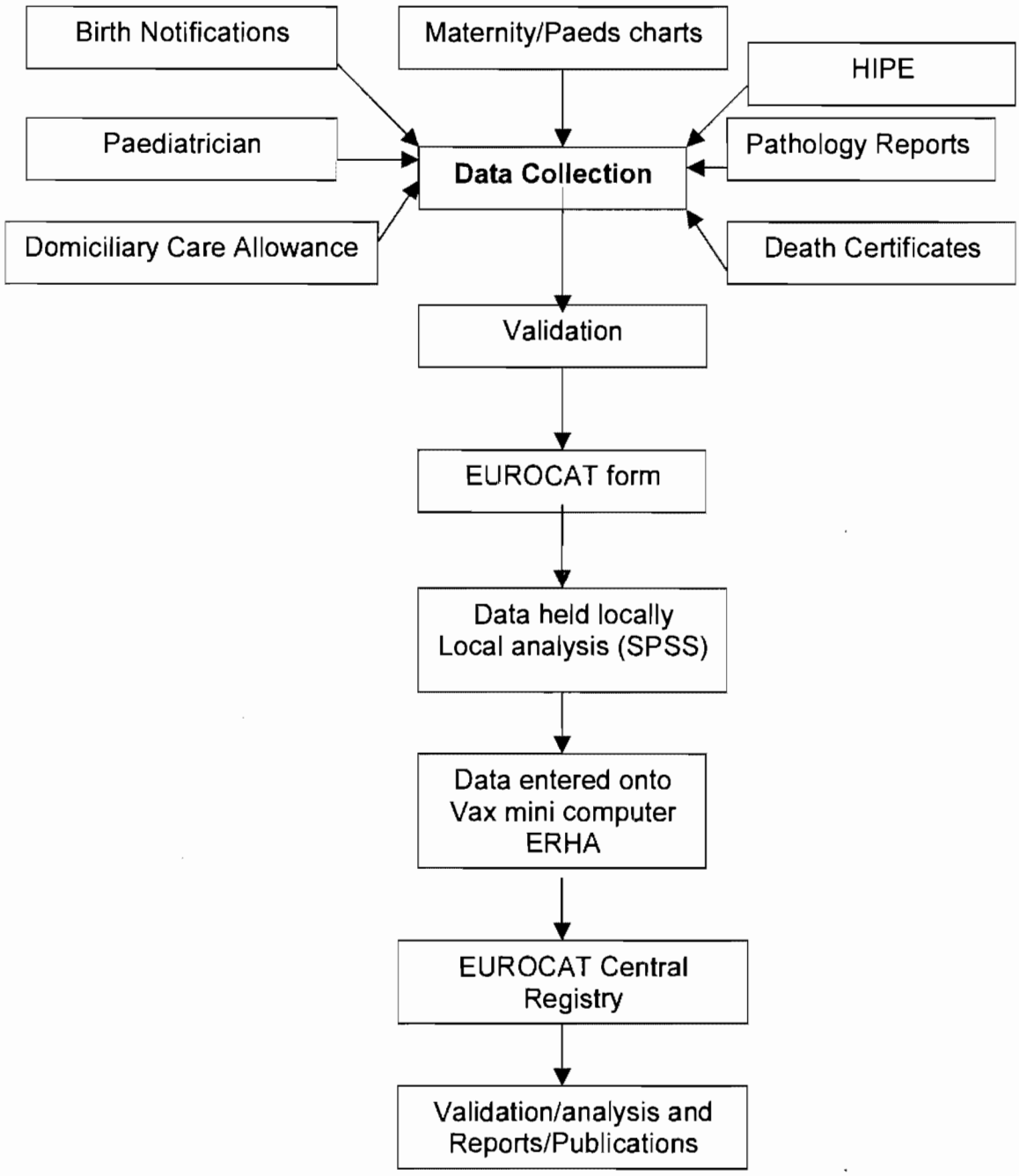
ERHA Flow Chart



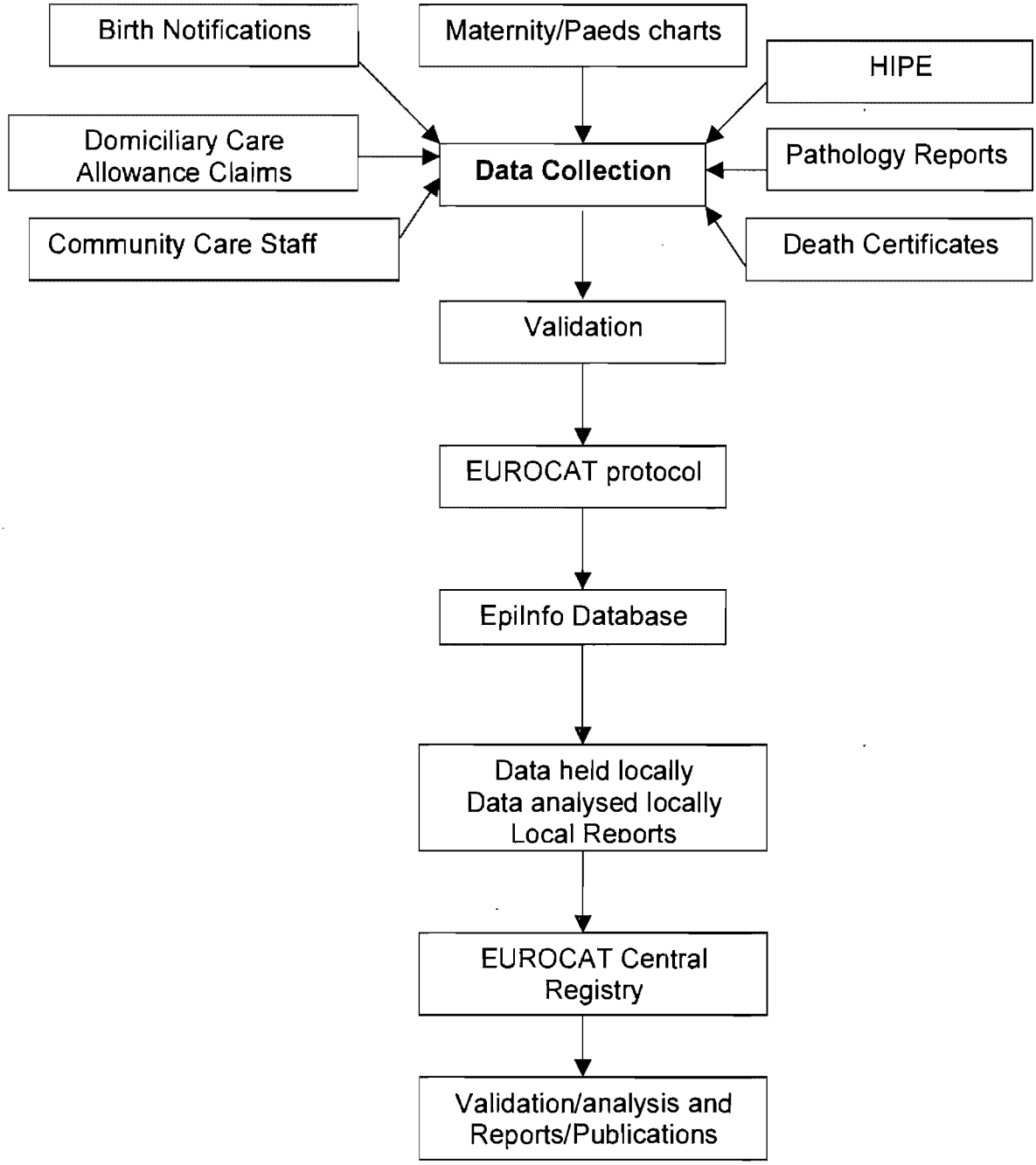
NEHB Flow Chart



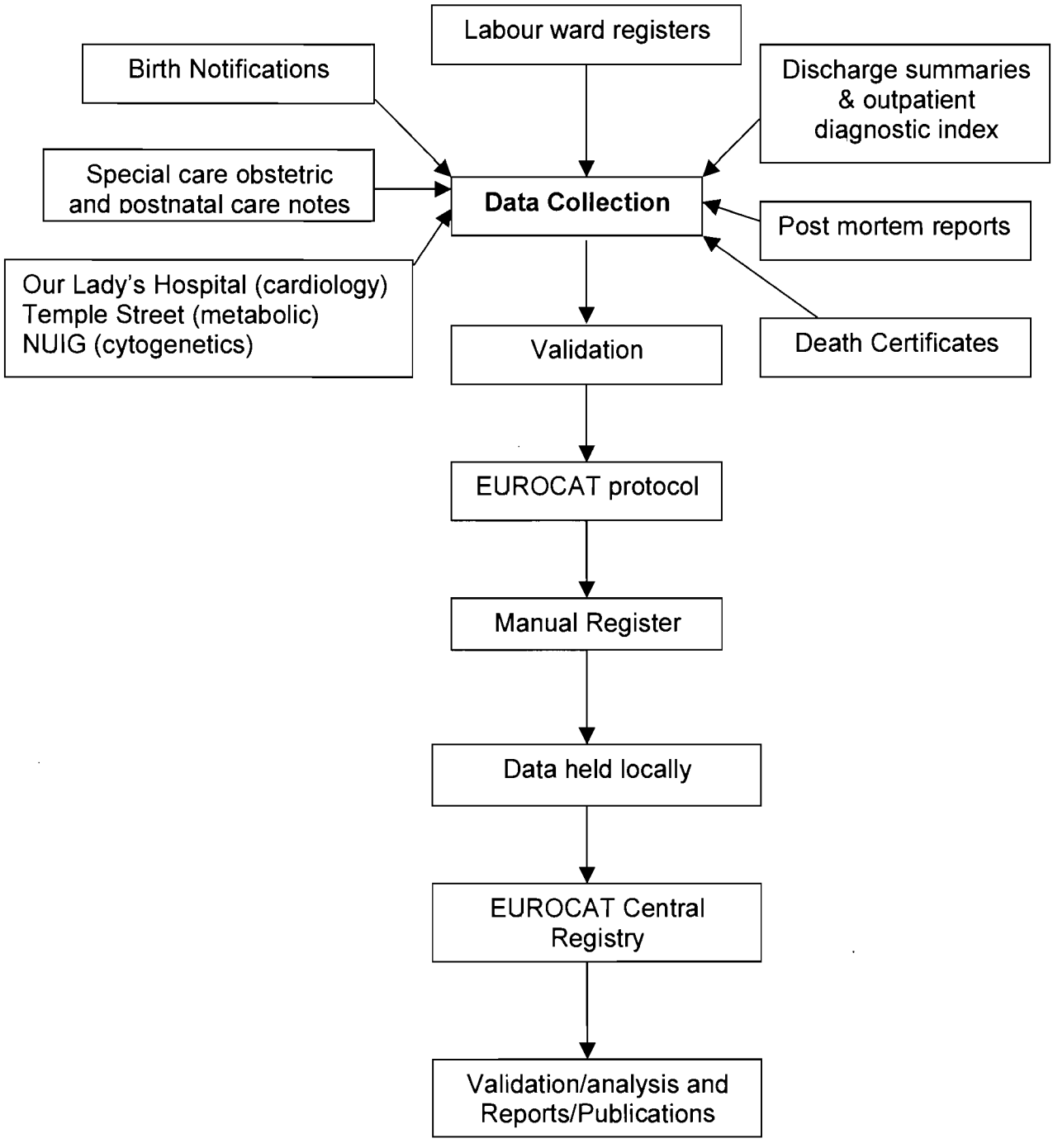
SEHB Flow Chart



SHB Flow Chart



WHB Flow Chart



Appendix 2 CASE STUDY 1/97

Hospital patient's data disclosed for research – data not obtained fairly for this purpose

The complainant attended the accident and emergency department of a public hospital. A few months later, she was contacted by an organisation carrying out research. The researchers knew when she had attended the hospital and why, and they asked her to answer some questions.

The complainant objected to the fact that the hospital had told the researchers about her visit. She took this up herself with the hospital, but was not happy with the response and she complained to me. She said she had not been informed, when she attended the hospital, that her personal data would be used in this way.

I identified the data protection issue in this case as one of fair obtaining. **Section 2(1)(a)** provides that *"data or, as the case may be, the information constituting the data shall have been obtained ... fairly"*. I set out to establish whether, and if so in what way, the complainant's personal information had been fairly obtained for the purpose of the research. I sought the hospital's observations.

The hospital was in fact aware of its obligations under the Data Protection Act, but it contended that it had met these in two ways. First of all, it had listed "personnel engaged in medical research" as disclosees in its entry in the Public Register of Data Controllers, which is maintained by my Office. Secondly, it had sought to make patients aware of the research project by putting a notice in the waiting area of the accident and emergency department. This notice told patients that the hospital intended to disclose their information to theresearchers, and invited them to let the receptionist know if they objected.

I was unable to accept the hospital's arguments. A data controller who must register with my Office under section 16 of the Act is legally obliged to provide details of the uses and disclosures of data. However this is a separate obligation

from that of obtaining data fairly. I am of the opinion that for personal data to be fairly obtained, a data controller must make the data subject aware, directly and at the time his or her data are being obtained, of how such data may be used and to whom they may be disclosed, in order to get the person's informed consent to the uses and disclosures described.

The hospital's second argument related to the notice, which it had placed in the waiting area. In my view, the issue to be decided was whether this was an adequate way of informing patients that their information would be disclosed to the researchers. In different circumstances, it might have been. In this case, however, account ought to have been taken of the particular environment in which patients' data were obtained. Many patients presenting themselves at the casualty department of a hospital may be expected to be in a state of some anxiety or discomfort. Consequently, they may not be expected to be alert to matters not relating directly to their condition. In such circumstances there is a special need for the data controller to satisfy itself that any uses of the data, which are unlikely to be anticipated by the data subject, are fully explained. For this reason, I took the view that the intention to disclose should have been brought to the specific attention of the complainant before data relating to her were obtained. This was essential to ensure that she was in a position to make an informed choice whether or not to furnish her information for such a purpose.

I upheld this complaint on the grounds that the measures taken by the hospital did not adequately fulfill its obligation of fair obtaining under section 2(1)(a).

Appendix 3 Background to the UK Health and Social Care Act 2001

The UK Government has made it clear that informed consent is the fundamental principle governing the use of patient identifiable information by any part of the NHS or research community. The NHS Plan proposed to develop a patient centered service where information is shared between all those involved in delivering or developing care presents an opportunity to make the best possible use of patient information. But the informed consent of patients must underwrite that objective. Alternatively, and this may be a better solution in many cases, information which no longer identifies individual patients must be used.

Ministers have taken a very public stand on the issue. In response to the Royal Liverpool Children's Inquiry they said that,

> "*The traditional paternalistic attitude of the NHS, that the benefits of science and research are somehow self-evident, was no longer acceptable*"

The challenge to the NHS was twofold: to change the culture and to move to systems of using patient identifiable information based upon the informed consent of patients.

The Law

Although this policy direction has an ethical basis, there are important legal considerations. Patients provide information about themselves in confidence and where information is held in confidence, common law provides no other reliable justification other than informed consent for use of the information in a patient identifiable form. Further, the NHS must comply with the Data Protection Act 1998, which requires certain information to be provided to patients and the Human Rights Act 1998, which subjects any invasion of the private life of an individual to a test of necessity. Guidance from the General Medical Council, as outlined earlier, the Medical Research Council, the British Medical Association

and draft guidance from the office of the Information Commissioner reflect the evolving legal position and reinforce the requirement for consent.

The Problem

There are also situations where informed consent cannot be obtained. For example, important research projects may involve tens of thousands of patients where contact would be impracticable. The essential nature of some of this research means that the public good outweighs issues of privacy. Some patients are not capable of giving consent, but the health service still needs to know about them and their conditions. Sometimes excluding those who refuse consent might bias data collection to the extent that it loses all value.

The Solution

Section 60 of the Health and Social Care Act 2001 provides a power to ensure that patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can only be used to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice. It is intended largely as a transitional measure whilst consent or anonymisation procedures are developed, and this is reinforced by the need to review each use of the power annually.

How It Will Work.

Proposals will be developed by the Department of Health or by those wishing support in law for the processing of information. A standard approach to presenting proposals is being developed and will be communicated to interested parties over the summer. The Act requires proposals to be considered by the Advisory Group termed the Patient Information Advisory Group and for many proposals will also require wider consultation.

The Patient Information Advisory Group's (PIAG) key responsibilities will be:

- To advise the Secretary of State on regulations which should be made under Section 60 of the Health & Social Care Act
- To advise the Secretary of State as required on the use of patient information and other NHS information

The advice of the PIAG must be published. Resulting regulations must be laid under affirmative process (debated in Parliament by each House).

It is worth noting that the passage of the Health and Social Care Bll provided clear evidence of the strength of feeling, particularly within the House of Lords, about the perceived erosion of patient rights. PIAG's role, therefore, will be to scrutinise carefully applications to use patient identifiable information made under section 60 to ensure the criteria are met.

Issues

It is estimated that there are over 250 disease registers, probably more than 50 public health related initiatives, and possibly several thousand research projects that potentially require some degree of support. Clearly the PIAG would not be able to consider a volume of individual applications numbering in the thousands. Ministers therefore propose to establish class regulations that will provide support for broad classes of activity, reducing the number of individual projects that require consideration to the minimum. There is a balance to be struck between the pragmatic need to support activity and the need to sustain pressure for change. Further, whilst key activity must be supported, overuse or misuse of the power is likely to draw considerable criticism, media attention and opposition in parliament.

Proposals for broad class support are being developed with the aim of providing a limited measure of support in law for a large number of activities. Initial proposals for class regulations are as follows:

- To support activities within a single care organisation where patient information is shared outside the normal care team to assist research and audit activities;
- To support disclosure of information outside the normal care team and care organisation to enable suitable patients to be approached for consent for participation in clinical trials or research and epidemiological studies;
- To permit an approach to patients for consent to re-use stored identifiable data or human tissue, organs or samples.

Initial soundings from the GMC, BMA, MRC and patient organisations suggest general acceptance of the need for class actions. Additional class actions are likely to be developed to cover other types of activty. For example, a fourth class is proposed to permit disclosure of identifiable information to maintain disease registers, their analysis and research uses.