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# Survey of informed consent for registration of congenital anomalies in Europe

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Eurocat is a network of population based registers of congenital anomalies in Europe covering about a quarter of the birth population in 19 countries ([www.eurocat.ulster.ac.uk](http://www.eurocat.ulster.ac.uk)). We surveyed registries with regard to the requirement for informed consent and its implementation.<sup>1</sup>

## Participants, methods, and results

We sent a questionnaire on ethics and confidentiality developed by the Eurocat Working Group to 35 registries in 2003 and updated June 2004; 29 registries from 15 countries replied (table). Eight registries reported experience of opt-in informed consent.

Five registries depend on medical records and notification from clinicians. One experienced a fall in registration (less than 10 written consents in the entire year in which opt-in consent was instituted, compared with 249 cases in the year before opt-in) such that an exemption was negotiated enabling a switch to opt-out consent. Currently 0.1% of parents opt out. A second registry, in which notifying clinicians ask for consent by post, is permitted to keep a reduced, anonymous set of documentation on cases without consent (about 18%). A third registry gives administrative help for clinicians obtaining consent by post (amounting to 1-3 hours a case) but still estimates 15-20% loss of cases through non-response, although only 0.5% of parents actively refuse to participate. A fourth registry is not fully operational because of low notification levels related to the consent requirement. All these registries reported difficulties persuading busy clinicians to undertake the additional work of obtaining consent for the registry, or convincing clinicians of the value of collecting registry data. Healthcare professionals have also to coordinate consent procedures to avoid parents being

approached multiple times. A fifth registry does not yet know how ascertainment is affected but reports less than 1% parental refusal.

Of the other three registries operating opt-in consent, one registry covering a small population has research paediatric staff who examine all babies (malformed or not) born in participating hospitals, for which consent is obtained at booking. This registry reports only two parental refusals since 1990. One registry is based on interviews of cases and controls shortly after birth by clinicians who then notify the case to the registry; this registry is not aware of problems, although it has little information from clinicians on parental refusals. One registry is a voluntary association of clinicians who obtain verbal consent from their patients when registering the case and is not aware of serious problems, although this has not been formally evaluated.

## Comment

Eurocat experience shows that informed consent is a serious threat to the operation of registries relying on clinician notification or access to medical records. Despite extremely low parental refusal, opt-in informed consent poses logistical problems, as other types of registry have found.<sup>2-4</sup> Although much has been written about the right of the individual to be adequately informed and to give consent (the parents in the cases of newborns), further research should evaluate parents' desire to participate in activities that may lead to the protection of the health of children in the community and the subsequent ethical duty on the part of the clinician to inform and to request consent. However, this places a further burden on clinical workload.<sup>5</sup>

Discussion about opt-in informed consent seems to have eclipsed discussion about effective forms of opt-out

## National legislation on informed consent for congenital anomaly and other clinical registers

Country	National legislation regarding informed consent as of June 2004*
Austria	Has not yet enacted new legislation which may lead to a consent requirement, but does not currently require consent
Malta	
Finland	Exemption from informed consent for health care registers
Italy	Exemption from informed consent for healthcare or disease registers the data from which are officially included in regional health statistics
Belgium	The relevant supervisory body can provide an exemption from the requirement for consent for individual registries on a case by case basis for a specified period. In Belgium, France, and England and Wales this exemption requires some level of "opt-out" consent
Denmark	
England and Wales	
France	Consent is required depending on the statutory position of the organisation from which data is sought; a total restructuring of the health services in 2005 will likely further change the requirement for consent
Spain	
Ireland	
Germany	
Luxembourg	National legislation requires informed consent without exemptions for registries
Poland	
Netherlands	
Portugal	One registry is able to operate without consent since they do not hold name and address†

\*For those registries operating consent procedures we define "opt-in consent" as the situation in which parents of children with a congenital anomaly are specifically asked for consent to place their children on the register. We define "opt-out consent" as the situation in which information is generally available to all parents to advise them of the existence of the register and the option to remove their child from the register.

†In some countries—for example, Germany—informed consent is required even if name and address are not retained by the register.

### What is already known on this topic

Although European Directive 95/46/EC allows national law (or a national supervisory body) to exempt healthcare or disease registries from the requirement to obtain informed consent for the processing of personal medical data, many countries have not legislated for any exemptions and there is much debate about the effect of the consent requirement on epidemiological research and surveillance

### What this study adds

The logistical difficulties in obtaining informed consent is a serious threat to the operation of registries that rely on clinician notification or access to medical records, despite extremely low parental refusal

Debate about the right of the individual to be adequately informed and to give consent has eclipsed discussion about research governance and confidentiality procedures that might obviate the need for individual consent

**Contributors:** All authors are members of the Eurocat Working Group on Ethics and Confidentiality (chair AR; cochair AB) and were involved in the development of the questionnaire and commented on drafts of the paper. AB and HD drafted the paper. AB and NC coordinated data collection. AB analysed the questionnaire data. AR, HDW, IRG, MG, RM, and VN completed questionnaires giving information on ethics and confidentiality in their registries. All authors are guarantors.

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consent and also about data confidentiality and research ethics procedures that would be acceptable to the public. The primary concern of most patients is not the use of their data for research but inappropriate access to medical data, and there is insufficient debate about what safeguards to ensuring confidentiality and the appropriate use of personal data would be sufficient to replace the requirement for individual consent.

## Lifetime intellectual function and satisfaction with life in old age: longitudinal cohort study

Alan J Gow, Martha C Whiteman, Alison Pattie, Lawrence Whalley, John Starr, Ian J Deary

What is successful ageing? Current opinion is that "cognitive vitality is essential to quality of life . . . in old age."<sup>1</sup> This depends substantially on people's cognitive ability from early life,<sup>2</sup> and on how much they decline from their cognitive peak in young adulthood. Early cognitive ability also affects physical health and even survival to old age.<sup>2</sup> But surely happiness and satisfaction with life are also key indices of successful ageing. Happiness was described as "the highest good and ultimate motivation for human action"<sup>3</sup>; this does not seem to be related to current cognitive ability.<sup>3</sup> Cognitive level in youth and the amount of cognitive change across the lifespan are important indicators of cognitive vitality in old age. We examined a unique data set to investigate whether these factors are associated with people being happier.

### Participants, methods, and results

The Lothian birth cohort 1921 is a relatively healthy group of 550 older people (mean mini-mental state examination 28.2 (standard deviation 1.7), range

18-30). They were given the same test of mental ability (a version of the Moray House test number 12) at mean ages 10.9 (0.3) and 79.1 (0.6) years old,<sup>2</sup> giving three cognitive measures: early life ability, late life ability, and lifetime cognitive change. Moray House test scores were converted to IQs (standardised to a mean of 100 (15) and adjusted for age at testing. To compute lifetime cognitive change we used the following process. IQ at age 11 was the independent variable in a linear regression with IQ at age 79 as the dependent variable; the standardised residual produced from this equation was used as the measure of lifetime cognitive change.

Participants were mailed<sup>4</sup> the widely validated satisfaction with life scale.<sup>5</sup> This scale has five statements requiring a response from strongly disagree (score 1) to strongly agree (score 7), which we summed to give a

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