



The feasibility of signed consent for the collection of patient-identifiable information for the Paediatric Intensive Care Audit Network (PICANet):

SUMMARY

Methods

Ethical approval was given by the Northern and Yorkshire Multi-Centre Research Ethics Committee. Details of consecutive patients admitted to 7 volunteer PICUs in England were collected over 3 months (May-July 2003). Participants (parents/guardians) were approached in a 2 stage process to obtain consent, initially with a short verbal explanation and an information sheet followed by an approach to collect signatures 24 hours later (or before discharge). Data from returned consent forms were linked to the PICANet database to assess the proportion of admissions where signed consent was given, refused or not obtained. To estimate the likelihood of gaining consent associated with characteristics of the patient, each of the following were considered separately in a univariate approach - age, sex, level of deprivation (Townsend score derived from residential postcode), ethnicity (south Asian or not), illness severity (PIM score), length of hospital stay. Odds ratios with 95% confidence intervals were calculated using logistic regression.

Results

One unit did not start and one did not fully implement the protocol through lack of staff resources. Consent was obtained for 182/422 admissions (43.1%) (range by unit 8.7% - 84.2%). One refusal (0.2%) was received. Consent rates were significantly positively associated with illness severity and hospital stays of longer than 6 days and negatively with older children (10 - 14 years). Long stays and older children were retained as significant in a stepwise regression model of the factors significant in the univariate model.

Conclusion

Our findings show that systematically obtaining individual signed consent for sharing patient-identifiable information with an externally located clinical audit database is unlikely to be successful without resources specifically allocated to training, staff time and administrative support. The most successful hospital at gaining consent 'missed'



15.8% of admissions, a level of incompleteness which would severely compromise the effective functioning of PICANet as a tool for clinical governance and monitoring the effective delivery of care. The success of gaining of consent from this cohort was unrelated to ethnicity or level of deprivation but was increased for longer in-patient episodes and reduced for older children. The extremely low refusal rate suggested that parents were willing to share patient-identifiable data; no comparable information on parental consent appears to be published. Our results endorse the view that the logistics of obtaining consent in large multi-centre studies presents substantial challenges requiring new approaches to the issue.³ The authors believe that patients should be made aware of the important ways in which patient-identifiable information gathered by the NHS is used to ensure the best delivery of care and the benefits of audit and research^{4,5}

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References

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