Conclusion
Quetiapine and rivastigmine seemed of no benefit in patients with dementia and agitation in institutional care, and quetiapine was associated with greater cognitive decline than placebo. Our results suggest that quetiapine should not be used in people with dementia and highlight concerns regarding the long term use of antipsychotics in these patients.

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Ethical approval: The study was approved by a properly constituted local research ethics committee.

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A feasibility study of signed consent for the collection of patient identifiable information for a national paediatric clinical audit database

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Abstract

Objectives To investigate the feasibility of obtaining signed consent for submission of patient identifiable data to a national clinical audit database and to identify factors influencing the consent process and its success.
Design Feasibility study.
Setting Seven paediatric intensive care units in England.
Participants Parents/guardians of patients, or patients aged 12-16 years old, approached consecutively over three months for signed consent for submission of patient identifiable data to the national clinical audit database the Paediatric Intensive Care Audit Network (PICANet).
Main outcome measures The numbers and proportions of admissions for which signed consent was given, refused, or not obtained (form not returned or form partially completed but not signed), by age, sex, level of deprivation, ethnicity (South Asian or not), paediatric index of mortality score, length of hospital stay (days in paediatric intensive care).
Results One unit did not start and one did not fully implement the protocol, so analysis excluded these two units. Consent was obtained for 182 of 422 admissions (43%) (range by unit 9% to 84%). Most (101/182; 55%) consents were taken by staff nurses. One refusal (0.2%) was received. Consent rates were significantly better for children who were more severely ill on admission and for hospital stays of six days or more, and significantly poorer for children aged 10-14 years. Long hospital stays and children aged 10-14 years remained significant in a stepwise regression model of the factors that were significant in the univariate model.
Conclusion Systematically obtaining individual signed consent for sharing patient identifiable information with an externally located clinical audit database is difficult. Obtaining such consent is unlikely to be successful unless additional resources are specifically allocated to training, staff time, and administrative support.

Introduction

The paediatric intensive care audit network (PICANet) was established in 2001 in collaboration with the Paediatric Intensive Care Society. This prospective clinical audit database of all admissions to paediatric intensive care units in England and Wales aims to identify evidence based best practice, facilitate resource planning, and study the epidemiology of paediatric critical illness (see www.picanet.org.uk). The Data Protection Act requires that patients give their consent

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for the disclosure of patient identifiable information for purposes not directly related to treatment, including external clinical audit.

In 2002-3, under section 60 of the Health and Social Care Act 2001 for England and Wales[1] the independent statutory Patient Information Advisory Group granted PICANet temporary support for the collection of patient identifiable data without consent, on the condition that the viability of taking consent was assessed. We studied the feasibility of obtaining signed consent for submission of patient identifiable information to a national clinical audit. We tried to identify the characteristics of patients that might influence the likelihood of consent being given.

Methods and participants

During May to July 2003 we collected the details of consecutive patients admitted to seven paediatric intensive care units in England that agreed to take part in the study. Staff in the units approached participants (parents or guardians) in a two stage process to obtain consent: first they provided a short oral explanation and an information sheet, then 24 hours later (or before discharge) they asked for signed consent. (For 12-16 year olds, the protocol allowed staff to approach either the parents/guardians or the children themselves, but none of the staff did approach the children.)

We linked the data from returned consent forms to the PICANet database so that we could assess the proportion of admissions for which signed consent was given, refused, or not obtained for some reason (form not returned or form partially completed but not signed). To estimate the likelihood of gaining consent according to 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 (score on the paediatric index of mortality), and length of hospital stay (days in paediatric intensive care). We calculated odds ratios with 95% confidence intervals using logistic regression.

Numbers and proportions of patients for whom consent was obtained from parents or guardians of children admitted to five paediatric intensive care units in England in May and June 2003, by age, sex, level of deprivation, and illness severity

	Total	Consent obtained (%)	Odds ratio (95% confidence interval)	P value
All patients	422	182 (43)		
Age (years):				
<1	173	80 (46)	1.00	
1-4	116	51 (44)	0.91 (0.56 to 1.46)	0.703
5-9	62	25 (40)	0.79 (0.44 to 1.42)	0.422
10-14	60	19 (32)	0.54 (0.29 to 1.00)	0.051
≥15	11	7 (64)	2.03 (0.57 to 7.20)	0.271
Sex:				
Male	234	102 (44)		
Female	188	80 (43)		
Ethnicity:				
Not South Asian	382	168 (44)	1.00	
South Asian	40	14 (35)	0.69 (0.34 to 1.35)	0.277
Deprivation*:				
1 (most affluent)	52	20 (38)	1.00	
2	49	21 (43)	1.20 (0.54 to 2.66)	0.653
3	74	35 (47)	1.44 (0.70 to 2.95)	0.326
4	77	28 (36)	0.91 (0.44 to 1.89)	0.809
5 (least affluent)	160	78 (49)	1.52 (0.80 to 2.88)	0.198
Illness severity†:				
<1%	151	49 (32)	1.00	
1-<5%	157	76 (48)	1.95 (1.23 to 3.10)	0.005
5-<15%	74	36 (49)	1.97 (1.12 to 3.48)	0.019
15-<30%	20	10 (50)	2.08 (0.81 to 5.33)	0.127
≥30	20	11 (55)	2.54 (0.99 to 6.54)	0.053
Length of stay (days):				
≤1	66	21 (32)	1.00	
2	148	51 (34)	1.12 (0.61 to 2.09)	0.706
3	49	21 (43)	1.61 (0.75 to 3.46)	0.225
4	37	18 (49)	2.03 (0.89 to 4.64)	0.093
5	27	13 (48)	1.99 (0.80 to 4.97)	0.141
6	21	15 (71)	5.36 (1.82 to 15.76)	0.002
≥7	74	43 (58)	2.97 (1.49 to 5.95)	0.002

*Address was missing for 10 patients so no Townsend deprivation score could be calculated.
†According to the score on the paediatric index of mortality (the higher the score, the higher the probability of death).

Results

Owing to lack of staff resources, one unit did not start to implement and one did not fully implement the protocol. We excluded these two units from the analysis. All five remaining units reported that the process of gathering consent was labour intensive and they received no additional financial support for staff time. The table shows that consent was obtained for 182/422 admissions (43%) (range by unit 9% to 84%); of these, almost half (88) had some data missing but never the signature. Most (101/182; 55%) consents were taken by staff nurses. One refusal (0.2%) was received. For 239 admissions no approach for signature was made; 75 forms were returned unsigned and 164 forms were not returned. Consent rates were significantly better for children who were more severely ill on admission (≥ 1% on the paediatric index of mortality) and for hospital stays of six days or more, and significantly poorer for children aged 10-14 years. Long hospital stays and children aged 10-14 years remained significant in a stepwise regression model of the factors that were significant in the univariate model.

Discussion

Our findings show that systematically obtaining individual signed consent for sharing patient identifiable information with an externally located clinical audit database is difficult. We suggest that obtaining such consent is unlikely to be successful unless additional resources are specifically allocated to training, staff time, and administrative support.

The hospital most successful at gaining consent "missed" 16% of admissions, a level of incompleteness that would severely compromise the effective functioning of the Paediatric Intensive Care Audit Network as a tool for clinical governance and monitoring the effective delivery of care. The gaining of consent was unrelated to ethnicity or level of deprivation but was better for those who had longer hospital stays and was poorer for older children. The separate consent forms and leaflets that were available for children aged 12-16 may have been confusing for staff and may explain why no patients were approached. The extremely low refusal rate (< 1%) suggested that parents were willing to share patient identifiable data; no comparable information on parental consent seems to have been published.

Our results endorse the view that the logistics of obtaining consent in large multicentre studies presents substantial challenges requiring new approaches to the issue.[2] The authors believe that, to ensure the best delivery of care and the benefits of audit and research, patients should be made aware of the important ways in which patient identifiable information gathered by the NHS is used.[3 4]

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Contributors: PAMcK, ESD, and GP are the principal investigators on the paediatric intensive care audit network (PICANet). PAMcK established the PICANet Consent Study Group and with SJ, ND, MD, BC, and CS organised the ethical approval and data collection and management. RP conducted the statistical analysis. PAMcK wrote the first draft of the paper and her coauthors provided comments. PAMcK is the guarantor.

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What is already known on this topic

Little empirical evidence exists either on the feasibility of systematically obtaining individual signed consent for collecting patient identifiable information for non-therapeutic purposes or on patient characteristics that might affect whether consent is gained

What this study adds

The process of gaining consent is difficult and time consuming, and success varies widely across paediatric intensive care units

The process is unlikely to be successful unless extra resources are allocated to training, staff time, and administrative support

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Operative delivery and postnatal depression: a cohort study

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Abstract

Objectives To assess the association between elective caesarean section and postnatal depression compared with planned vaginal delivery and whether emergency caesarean section or assisted vaginal delivery is associated with postnatal depression compared with spontaneous vaginal delivery.
Design Prospective population based cohort study.
Setting ALSPAC (the Avon longitudinal study of parents and children).
Participants 14 663 women recruited antenatally with a due date between 1 April 1991 and 31 December 1992.
Main outcome measure Edinburgh postnatal depression scale score ≥ 13 at eight weeks postnatal on self completed questionnaire.
Results Albeit with wide confidence intervals, there was no evidence that elective caesarean section altered the odds of postnatal depression compared with planned vaginal delivery (adjusted odds ratio 1.06, 95% confidence interval 0.66 to 1.70, P = 0.80). Among planned vaginal deliveries there was similarly little evidence of a difference between women who have emergency caesarean section or assisted vaginal delivery and those who have spontaneous vaginal delivery (1.17, 0.77 to 1.79, P = 0.46, and 0.89, 0.68 to 1.18, P = 0.42, respectively).
Conclusions There is no reason for women at risk of postnatal depression to be managed differently with regard to mode of delivery. Elective caesarean section does not protect against postnatal depression. Women who plan vaginal delivery and require emergency caesarean section or assisted vaginal delivery can be reassured that there is no reason to believe that they are at increased risk of postnatal depression.

Introduction

The prevalence of depression in the postnatal period is similar to background population rates of depression and affects about 8-15% of women.[1] Postnatal depression is similar to depression occurring at other times in life and only distinguishable by the timing of onset. Depression at any time is associated with negative sequelae. What makes postnatal depression of particular concern is its possible detrimental long term effects on subsequent child development. Infants of depressed mothers have been found to perform less well on object concept tasks and be more insecurely attached to their mothers.[2] Other studies have found higher rates of intellectual deficits at 4 years of age,[3 4] behavioural disturbances up to 5 years,[4 5] and increased rates of special educational needs at 11 years.[6] If labour is complicated and the delivery unexpectedly performed as an emergency procedure it could potentially be stressful to the mother. In such scenarios there may be an association between emergency operative delivery and postnatal depression. Several studies have investigated this association, though the current evidence is conflicting. There may

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