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# **Comprehension and recall of informed consent among participating families in a birth cohort study on diarrhoeal disease**



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# Background

- ◆ Informed consent:
  - enables to make an *educated* decision
  - ensures *voluntary* participation
  - protects from *exploitation* or *harm*
  
- ◆ *Comprehension* of informed consent *poor* among research participants from *developing countries*
  
- ◆ Participant's *recall* of certain elements of informed consent *deteriorate* over time



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# Study objective

- ◆ To assess the *comprehension* and *recall* of informed consent process among participating families in a birth cohort study on diarrhoeal disease
- ◆ **Rationale:** use the data to *improve* the content and conduct of the informed consent process in future studies



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# Study area

- ◆ Three *urban slums* of Vellore district:
  - Ramnaickanpalayam, Chinnallapuram and Kaspā
  - Population: ~ 33,390 ; 8.7% <5 years of age
  - Commonest occupation: *Beedi work*
  - 23% infant deaths attributed to diarrhoea
  
- ◆ Physician run *urban health centre* within the area;  
*government hospital* approximately 5 kilometers away
  
- ◆ **Study population:** Participating *family members* of children recruited in the Childhood Rotavirus Infection (CRI) study



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# CRI Study

- ◆ *Cohort study recruiting children at birth and following them till 3 years of age to investigate the natural history of rotavirus diarrhoea*
- ◆ *452 children recruited between March 2002 and August 2003; 82.5% completed the 3-year follow up*
- ◆ *Informed consent obtained by the study supervisor or recruiting doctor*
- ◆ *Twice weekly field worker visit*
- ◆ *Stool sample collected every two weeks or whenever the child had diarrhoea*
  - *Surveillance samples collected at scheduled intervals in 87% of collection*
  - *Diarrhoeal stool samples collected during 98.2% episodes*
- ◆ *Free immunization provided to each child*
- ◆ *Clinic set-up in the study area to provide free and accessible healthcare*





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# Data collection

- ◆ *Parents or guardians* of children participating in the CRI study interviewed by two *independent* interviewers
- ◆ Questionnaire aimed at assessing *awareness* about:
  - disease under study
  - purpose of study
  - voluntary nature of participation
  - freedom to withdraw
  - feelings and concerns at end of study
  - stakeholders in decision to participate
- ◆ *Verbal consent* obtained prior to administration of the questionnaire



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# Statistical analysis

- ◆ Data analysed using *STATA 9.0* software (StataCorp, College Station, TX, USA)
- ◆ Associations between variables assessed by:
  - $\chi^2$  test for categorical variables
  - *two-tailed independent t-test* for continuous variables
- ◆ *P*-value <0.05 considered *statistically significant*
- ◆ *Multivariate logistic regression* to identify significant determinants of awareness about disease under study



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# Key findings

- ◆ 81.4% families interviewed between November 2006 and March 2007
  - *Inability to contact family members* was major reason for *non-response*
- ◆ 93.8% of respondents were *mothers*; 31.3% without any *formal education*
- ◆ Respondents *more likely* to have *completed 3 years of follow-up* ( $\chi^2$  test,  $P < 0.001$ )
- ◆ *No difference* in *socio-demographic characteristics* between responders and non-responders



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## Key findings (contd.)

- ◆ 82.4% respondents stated that the study was *explained properly* at time of enrolment
  - 70.6% said that *subsequent* queries were always adequately explained
- ◆ 92.1% expressed their desire to *join similar studies* in future
- ◆ 43.2% correctly recalled the *disease under study* to be *diarrhoea*
- ◆ 25.5% correctly mentioned *at least one* of the study purposes; 2.2% could mention *both*



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## Key findings (contd.)

- ◆ 98.3% respondents stated that they *joined the study voluntarily*
  - 13.6% knew that they could *leave the study freely at any point*
- ◆ *Provision of free treatment* was the principal motivating factor for 60.9% respondents to remain in the study
- ◆ 55.6% respondents feared that their child will *no longer get proper healthcare*, since the study was over
- ◆ 82.9% respondents considered *approval of spouse* to be most important in their *decision to participate*



## Multivariate logistic regression analysis results for lack of awareness about the disease under study in respondents who were mothers

Variable	Number (%) (n=345)	Crude OR	Adjusted OR	95% CI	P-value
<b>Maternal education</b>					
Secondary school and higher*	61 (17.7)	1	1	-	-
Middle school	81 (23.5)	2.99	2.49	1.19–5.22	0.016
Primary school	95 (27.5)	3.74	2.84	1.33–6.04	0.007
No formal education	108 (31.3)	4.77	3.59	1.65–7.82	0.001
<b>Religion: Muslim</b>	167 (48.4)	2.10	1.48	0.92–2.39	0.110
<b>Gender: Female</b>	175 (50.7)	0.72	0.76	0.48–1.18	0.218
<b>SES:</b>					
Low *	214 (62.1)	1	1	-	-
Middle	114 (33.1)	0.72	0.91	0.56–1.48	0.700
High	17 (4.9)	0.37	0.69	0.22–2.14	0.517
<b>Completed 3 year follow-up</b>	319 (92.5)	1.24	1.37	0.59–3.19	0.458

\* Reference category



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# Conclusions

- ◆ Despite informed consent, *retention of understanding* about a research study *low* over a long period of time
  - Underlines the need for *reinforcement* of the key elements of informed consent *periodically* in long-term studies
- ◆ Maternal education *positively associated* with *increased awareness* about the disease under study
- ◆ Spousal consent *important* for studies involving children
- ◆ Provision of free healthcare cited as an important reason for participation, highlighting the need for *health equity* before true informed consent can be administered



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