# Changes in consent procedure improve uptake of school based dental epidemiology

Dr Iain A Pretty BDS, MSc, MPH, PhD, MFDSRCS(Ed)

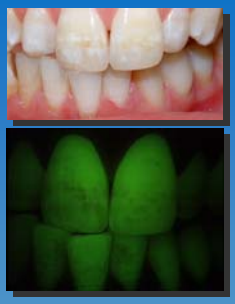
National Oral Health Conference, Portland, OR. 2009

## Introduction

- A survey of 2000 school children in Newcastle and Manchester (12 years)
- Designed to develop a more objective means of assessing enamel fluorosis
- Based on QLF imaging
- Schools selected on % FSM


## Introduction

- Undergo:
  - ICDAS Caries exam
  - Intra-oral photographs
  - 35mm photographs
  - QLF images of central incisors



## Consent procedure - original

- Standard positive consent model
- Letter sent home with child
- Returned with form to say could participate or not permitted
- No letter taken as de facto no
- 57% consent rate
- On days of examination many children requested to take part with variety of reasons for no consent form…

## Consent procedure - revised

- Discussed study with the ethical committee
- Felt that we needed to work within current framework
- School meetings, parent teacher events
- All attempted with modest to no improvement
- Committee accepted that study was not ethical given the low consent rate and agreed to consider another model

## Consent procedure - revised

- Children can consent to take part in research – always asked even under previous model
- Need to engage children in their participation
- Legislative guidance – the Gillick test
- Competent, autonomous, medical treatment
- In research this is risk based…

## Consent procedure - revised

- Risk of current study determined to be minimal therefore appropriate for 12 year olds
- Therefore parental opt out (two mailings)
- Positive consent obtained from children at the time of examination following scripted information procedure
- 200 questionnaires sent to parents following examinations

## Results

- Consent rate increased dramatically to a mean of 78%
- Some of these schools had been in previous consent model and the de facto "no's" were not realised
- Still large variations:
  - Low deprivation – higher parental opt out
  - High deprivation – higher child opt out
  - Therefore still response bias

## Results

- Questionnaires – 113 returned
- No parent objected to the system
- Many wanted information on the results
- All felt that the system has presented them with ample opportunity to remove their child and had provided sufficient information to base this decision on

## Errors

- At this stage 16 children have been examined (positive consent obtained) and later a parental opt out was received
- Postal issues need to be considered
- Number of incorrect addresses held by schools
- Address not that of the primary care giver
- Telephone contact with each immediately followed by letter

## Conclusion

- Epidemiological research in the UK is becoming increasingly difficult
- This system employed in NHS dEpi
- However, our study was more involved
- Worked with the IRB to determine a satisfactory conclusion
- Consent bias is still a significant issue and one that is difficult to address without some form of incentive

# Thankyou & Questions

MANCHESTER 1824
The University of Manchester