# Randomised Control Trial Evaluating the Efficacy of an Information Sheet in Improving Parental Consent

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## Introduction

The cornerstone of a medical student's paediatrics training is that of repeated history and examination of children. One is always aware of the sensitivities and protectiveness of parents towards their children. Students are often refused permission to visit certain children, one of the reasons cited being parental refusal. It is a widespread belief that many parents do not like or want to be visited by students.

It is the role of every healthcare professional, not only doctors, to provide the best care possible for patients whether it be in the short or the long term. The importance of patient education has surfaced and risen into prominence over the last decade with an emphasis on allowing patients to make an informed decision with regard to their care. The aspect of informing patients (or their parents in the case of minors) as to why medical students need to visit them has been largely neglected. It is imperative that this problem be rectified to preserve and perpetuate a high standard of care. In this study simple educational measures such as provision of an information sheet explaining the reasons for student visits are postulated to be the first prophylactic steps in this direction.

## Objectives

- Determine if the use of a specifically designed information sheet will improve rate of parental consent to medical students visiting their child.
- Obtain evidence to confirm or refute the belief that many parents do not want or like to be visited by students.
- Identify patient groups which have a low rate of consent to student visits.
- Determine if the recommendation of visiting patients in pairs is in line with parental preferences.

## Design

- Randomised controlled trial.
- Outcome data collected by method of a survey.
- Setting: National Children's Hospital Tallaght, Dublin, Ireland.
- Subjects: Parents of paediatric patients admit ted to the 3 main wards in the hospital.

## Methods

All in-patients who were admitted to one of three wards in the National Children's Hospital were viewed to be potential candidates for this study. The study period was from the 30th of September 1999 to the 18th of October 1999. Patients in the intensive care unit and neutropoenic children were excluded and the study was only performed on weekdays to simulate the actual patient population available to students for visiting.

## Randomisation Methods

The ward register on each of the three wards: Beech, Maple and Oak were used to identify the total number of in-patients on the respective wards. This was performed each day during lunchtime (12.00 pm to 1.00 pm). All patients who had already been surveyed were excluded from the pool. Ten patients were selected at random and the survey administered to their parents. The information sheet was administered to the parents together with the survey on alternate days.

*NB. Although the study period was 13 days long and the recruitment rate at 10 per day, the total number of subjects was only 124. This was due to the reduced number of available subjects on the last day (18th October) in view of the nursing strike that was to commence the day after. The study was aborted on this day as the sample population was not felt to be reflective of the normal pool available to students as hospital admission was restricted to emergency cases only.*

Consent to participate in this survey was obtained in all cases and all subjects were willing participants. No one declined to participate when approached. Non-parental guardians were excluded from the study. A single investigator administered the survey to the subjects. At this point, the information sheet was given to the subjects who were randomised. A medical student visit was explained to comprise of taking a history (from the child directly or a collateral from the parents) and completing a physical examination. Subjects were specifically

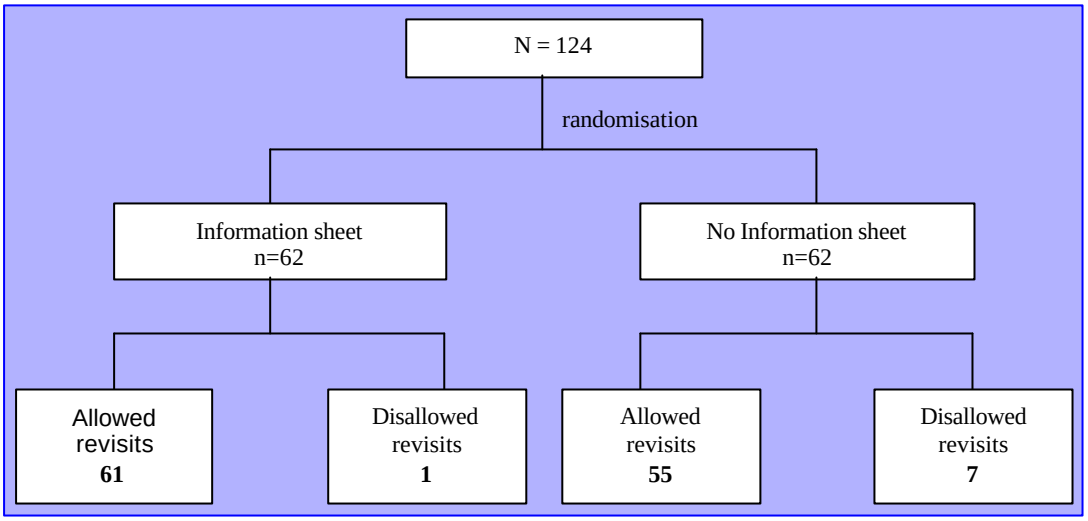



***Figure 1:*** *Flow diagram of parent consent of student visits*

told that all information provided was strictly confidential and to be solely used for research purposes. It was also stressed that in no way would the information they provide affect the care of their child. The subjects were encouraged to be as truthful as possible. The survey form was then administered. No names were recorded on the survey itself. The survey forms were collected after 30 minutes. Any queries were addressed and clarified. The diagnosis of the child was confirmed by reference to his or her chart. The data obtained from the survey was completed using the Mircosoft Excel 97™ computer program. Data was stratified to categories for analysis of proportions.

## Data Stratification

- *Age of patient*

*The ages of the patients were stratified into the four recognised developmental categories. (see Table 1)*

- *Free parental comments on concerns or worries with student visits (see Table 2)*

*This was included in the survey for the purpose of obtaining a qualitative perspective to the binary variable of parental consent to student revisits. This data when stratified into the following categories was felt to have a higher sensitivity to the response in the actual situation.*

The Fisher's Exact test was performed with degrees of freedom on the data where a probability of rejecting the null hypothesis whereby the difference between the observed and expected values were zero. A $p$ value of $< 0.05$ was taken to be statistically significant.

***Table 1***

| Age Category | Actual Age |
|---|---|
| Infant | 0-1 year |
| Toddler | 1-3 years |
| Adolescent | 3-13 years |
| Teenager | 13-19 years |

## Results

A total of 124 parents of children were recruited and randomly assigned to the study group (62 subjects) or the control group (62 subjects). All of the potential parents who were approached consented to participate in the study. Analysis was performed on the subjects in their randomly assigned groups (see Figure 1). Parents were found to be more likely to consent to student visits if the information sheet had been administered first ($p$=0.03). The risks of a medical student being refused in the study group and control group were 1.6% and 11.3%, respectively. The absolute risk reduction was 9.7% (95% CI 1.2%-18.1%), translating to a number needed to treat of 10.3 (95% CI 5.5-83.4). The relative risk reduction was 85.7%.

For a qualitative analysis of the willingness of the subjects to allow visits by students, the subjects were broken down as illustrated in Figure 2. Stratification of the free comments was performed. There was no statistically significant difference in

***Table 2:*** *Parental opinion on previous student visits*

| | |
|---|---|
| **Positive** | ·Encouraging statements such as understanding the need for medical students to visit their child.<br>·The concerns and worries column was left blank.<br>·'No worries or concerns' was written down. |
| **Negative** | ·Parents who felt that student visits were unnecessary.<br>·Parents who imposed restrictions of any kind e.g. only if a doctor was present. |

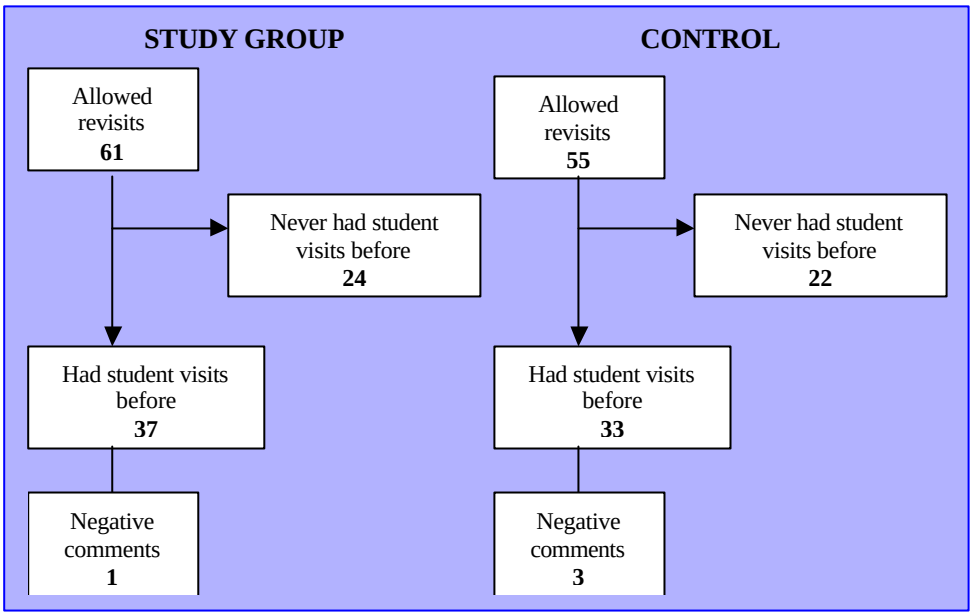



***Figure 2:*** *Qualitative analysis of parent comments on student visits*

the study and control group with respect to having negative comments ($p$=0.22).

***Analysis of the willingness of parents to allow student visits at the moment***

This was performed with the 62 subjects in the control group only. As they were randomly picked, it is reasonable to assume that their opinions are reflective of the current situation. Sub-analysis of the subjects showed that age of the child, gender of the child or the ward the child was in, was independent of the willingness to allow student visits (Table 3).

***Table 3***

| Variable | p Value |
|---|---|
| Age of child | >0.05 |
| Gender of child | >0.05 |
| Ward | >0.05 |

***Parental opinion on previous student visits***

The full complement of the 75 subjects who had students visit their child before was used in the analysis, as the information sheet should have no bearing on the opinions of previous visits. None of the subjects disliked previous visits. Fifty six percent of them enjoyed the visits, the remaining 44% being neutral (see Figure 3).

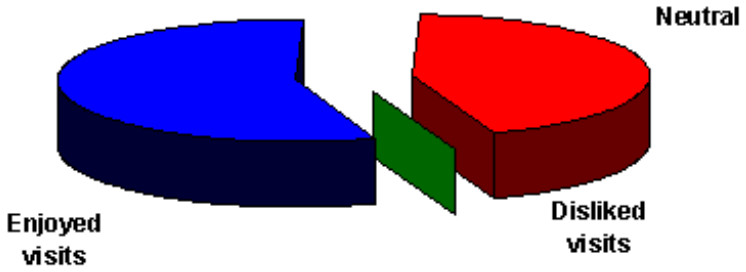
***Parental preference for gender of the visiting student***

All 124 subjects were included in the analysis. 98.4% (122 subjects) of parents did not have a preference for student gender. The remaining 2.6% (2 subjects) recorded a preference for female students.

Parents who refused medical students were excluded from this analysis, hence the total number of subjects involved was 116. It was found that 58% of parents preferred 2 students per visit, 26% preferred 1 student, the remaining 16% opting for greater than 2 students per visit. There was no significant difference observed between the randomised groups, wards or age groups of the patients (see Figure 4).

***Correlation of number of visits per day to parental willingness to allow student visits***

Subjects included in this analysis were naturally restricted to those who had allowed student



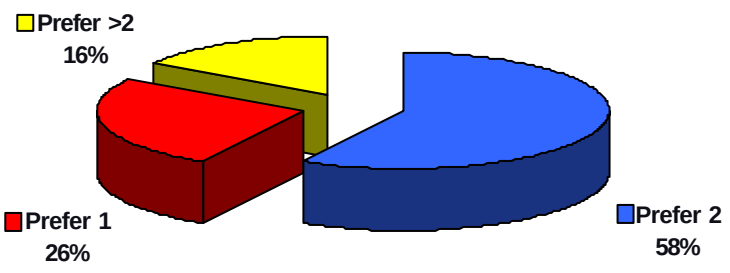




***Figure 3*** *(above): Parental opinion on previous student visits*
***Figure 4*** *(right): Parental preference for number of students per visit*

***Table 4:*** *The number of visits and length of stay of the 7 subjects who refused student visits*

| Absolute Number of Visits | Length of Stay | Rate of Student Visits |
|---|---|---|
| 1 | 1 | 1 per day |
| 1 | 1 | 1 per day |
| 1 | 1 | 1 per day |
| 1 | 4 | <1 per day |
| 1 | 4 | <1 per day |
| 1 | 9 | <1 per day |
| 1 | 9 | <1 per day |

visits before. Subjects who were randomised to receive the information sheet were also excluded, as it would have changed parental willingness. The 40 subjects were analysed. Seven of the subjects refused student visits (Table 4). All of them had only been visited once previously. The number of visits per day was calculated dividing the absolute number of visits to date by the current length of stay. Hence there was no evidence in this study found to suggest that a high average rate of student visits per day or a high absolute number of visits decreased parental willingness to allow student visits.

***Willingness of parents who had never experienced student visits to allow them***

All subjects who had never experienced students visiting their child were willing to allow student visits regardless of whether an information sheet was provided (100%).

***Concerns or worries of parents with student visits***

In general, of those parents who expressed concern with student visits, the consistent theme was that students should be supervised during visits and that it may distress the child if his or her condition is discussed too frequently. Some parents feared that the students might hurt the child. However, there were very encouraging comments from the parents, the majority understanding the need for students to learn.

## Discussion

Student complaints of not having enough patients to visit never fails to plague the Department of Paediatrics. There is an average of 50 patients distributed between the 3 wards: Beech, Oak and Maple on any one day. Even after exclusion of those unfit for student visits, there should be an ample supply of at least 1 patient per student as there are only 37 students at any one time. However, this is not the case as there are various obstacles in the path between the students and the patients, one of which are the parents. It is imperative that a solution be found in the view that the discordance between the increase in the medical student population and the expansion of resources to accommodate this. The paediatric class size in 3 years is estimated to be 25% bigger than the current one, the extrapolation based on the current total class size of 120 and the 2nd medical year class size of 150 as of 1999.

This study shows that the intervention significantly decreased the rate of parental refusal to student visits by 85.7%. For every 10.3 information sheets given out, one extra parent would consent to student visits. The extra financial burden is minimal at a cost of £0.31 per extra patient assuming a cost of £0.03 per sheet. The benefits however, are huge. Increasing a patient pool of 50 by 10% alone will solve 60% of the patient supply problem anticipated in 3 years.

Contrary to popular belief, this study shows that medical students are not an unpopular crowd in the eyes of the parents. In fact, more than half of the parents actually enjoy medical students visiting their children. Concerns that parents have a bias toward the gender of medical students are unfounded. The results of this study which show a 58% parental preference for 2 medical students per visit is in line with the current recommendations of the Department of Paediatrics. Students should have an equal success rate in obtaining parental consent to visiting patients regardless of the ward, age or gender of the patient.

The evidence supports the statement that parental refusal is usually in the early stages of their child's stay in hospital. Students have been frequently told that certain patients are off-limits; some of the reasons cited being that they have been visited too frequently. This study does not support parental refusal being the governing factor in these cases.

As a medical student administered this survey, the subjects may have felt compelled to answer in a fashion thought to be more in the students' favour. There was also the fear that the subjects would be afraid to express negative comments in case it had a bearing on their child's care. Hence the number of subjects who indicated that they would allow student visits obtained in this survey may be an overestimate. Similarly, the subjects would have been more inclined to not state any worries or concerns they may have. An attempt to reduce this problem was made by explanation that the survey had no bearing on the care of the child and that frank answers were needed to better student-patient skills. Some of the free comments made were grammatically ambiguous. These had to be clarified personally. Interpretation

of the comments in this manner may have been more positive than actually intended. Subjects filled out the survey in the absence of the investigator. There is a high probability that the patients themselves were involved in the answers provided, especially the free comments and consent to future student visits portions. This was only thought to be possible in the adolescent age groups and above.

## Conclusions and Recommendations

- All parents should receive the information sheet.

This is not only for the immediate educational benefit of the students but also paves the way for patient education and the ability to make an informed decision. It is important that they understand that medical students will be the doctors directly responsible for their child's care in the future and that history and examination is the prime ingredient of the training.

- Many parents enjoy student visits.
- Two students per visit is preferred by slightly more than half of parents.
- Parents who refuse student visits usually do so after the first visit.
- There is a wide variation with regard to parental understanding of the importance of student visits.

The average patient pool of about 55 per day after administration of the information sheet can be maximised by pairing students up and allocating them to visit 2 specific patients everyday. Patient allocations can be rotated daily, e.g. by cubicle or bed number. Daily lists of patients suitable for visiting can be easily compiled and placed on the notice board in each ward, the patients who have been visited ticked off for the benefit of everyone else.

## Acknowledgements

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