RESEARCH PROTOCOL FOR DEAN LANE FAMILY PRACTICE STUDY

Version 1, 29 March 2005. Dr Gillian Rice

BACKGROUND

In September 2005 the Dean Lane Family Practice in Bedminster, Bristol, will be moving from its current location (in a converted Victorian house) to new, purpose-built premises (in a multi-use development site). The new premises have been carefully designed with considerable input from architects, artists and interior designers, in an attempt to produce a supportive and therapeutic environment for patients and staff. Building on evidence from a number of 'arts in healthcare' projects, especially at the Chelsea and Westminster Hospital, London, we are keen to incorporate the arts into our new surgery in order to produce better health outcomes for patients. We have three artists and one poet producing specially commissioned art works for the new surgery and we have already developed links with other community organisations such as Bedminster Library and Dance Voice (a local dance movement therapy centre), and a local primary school, to provide ongoing arts activities for patients and local people, including children, in the new premises.

AIMS AND OBJECTIVES

Existing evidence suggests that the built environment can affect clinical outcomes but most work has been done in hospitals and there is little research examining the impact of therapeutic aspects of the built environment in primary care. This project will examine the effects that our current unenhanced premises and the new, enhanced surgery environment have on patients and staff. We aim to assess the effect of enhancements to the surgery premises, particularly the reception and waiting areas and doctors' consulting rooms, on patient satisfaction and on levels of anxiety in patients while they are in the surgery building. We will also assess the effects of enhancing the surgery premises on staff job satisfaction and well being.

If we can identify elements of building design that have beneficial (or detrimental) effects on patients and staff we will be able to add value to the advice available to others involved in the design of new primary care facilities. They will be able to use this information to help produce built environments that improve doctor-patient interaction, patient satisfaction, concordance and clinical outcomes, as well as improved staff well-being, retention and job satisfaction. As we will have the same patient population before and after the surgery moves to new premises, we will have a rare opportunity to study the same individuals, and mostly sample the same population, in unenhanced and enhanced primary care environments.

METHODS

There are several distinct groups to be studied in the planned research, and there are two phases to the research study – the first while the Dean Lane Family Practice remains in its current premises and the second after we have moved to our new premises.

Group 1 - Patients completing questionnaires only – While we remain in our current premises we aim to recruit 800 patients to complete a customised questionnaire assessing their satisfaction with various aspects of the current building. This questionnaire will also incorporate the validated 6-item short-form of the state scale of the Spielberger state trait anxiety inventory (STAI), to assess how anxious patients feel a) while sitting in the waiting area before their appointment with a doctor and b) immediately after their consultation with a doctor.
On one further occasion, at about six months after moving to our new premises, we aim to recruit 800 patients to complete the same questionnaire (also including the short-form of the STAI) with a few additional questions about aspects of the new premsises that did not exist in the old building. On both occasions the patients will be offered a questionnaire to complete when they attend the surgery for an appointment with a doctor. The first part of the questionnaire is completed while they sit in the waiting area until they are called by a doctor for their appointment. The second part of the questionnaire is completed immediately after their consultation, and before they leave the surgery building. The 800 patients on each of these occasions may be different individuals or there may be some overlap.

Group 2 - Patients being interviewed – 15 patients will be selected to take part in one-to-one semi-structured interviews to discuss in detail their views on various aspects of the building design and interior d cor of the surgery premises (focusing particularly on the reception and waiting areas and the consulting room in which they saw a doctor) and the effect these may have had on their anxiety level while in the surgery and their satisfaction with the consultation.

Patients telephoning reception to book an appointment at least three days in advance will be asked if they are happy to be interviewed immediately after their consultation with a doctor. If they express interest the receptionist will ensure that an information sheet is posted to them the same day. When the patient arrives at the surgery for their appointment, the interviewer will meet them, ask if they are still happy to be interviewed, go through the information sheet, answer any questions and get them to sign their consent form. The interview will then take place immediately after the patient's consultation with a doctor. The patient's computer record will have a code added to notify that they have been interviewed in the old surgery premises. This will aid us in identifying these patients once we move to the new building.

Starting six months after the move to the new surgery premises, we aim to re-interview the same 15 patients immediately after another booked appointment with a doctor, to obtain further qualitative data about their views on the design and interior d cor of the new surgery building. If it is not possible to re-interview any of the original 15 patients, we will recruit others (in the same way we recruited the original group). The same procedure will be carried out (as outlined above) before conducting these interviews.

Group 3 - Patients having physiological measurements (pulse rate and galvanic skin response)

Pulse rate and galvanic skin response (GSR) may reflect levels of anxiety experienced while in the surgery building which is why we aim to measure these in a group of patients attending the surgery for an appointment with a doctor.

While we remain in our current premises, patients who phone in to surgery requesting an appointment with a doctor at least 3 days in advance of the appointment, or who are seen by a doctor and identified as needing to return for a follow up appointment within the next six weeks, will be asked if they would be happy to complete a questionnaire and have physiological measurements taken during their next visit to the surgery. We aim to recruit 105 patients for this part of the study. If the patient expresses interest, the receptionist will post an information sheet to them the same day or the doctor will give them an information sheet for them to read, either while they remain in the surgery or to take away with them. The receptionist or doctor will add an 'alert message' to the front of the patient's computer record which identifies the patient as having been given an information sheet about the physiological measurements.

If the patient wishes to take part in the physiological measurements, the information sheet asks them to inform a receptionist when they book their next appointment. If the patient forgets to tell the receptionist, she will be prompted by the alert message to check with the patient whether they do, or do not, wish to have physiological measurements taken during their next visit to the surgery. If the patient agrees to the physiological recordings the receptionist will note the patient's name and the date and time of their next appointment and pass these details on to the research assistant who will greet the patient when they come to the surgery for that appointment.

When the patient arrives at the surgery the research assistant will go through the information sheet, answer any questions and, if the patient is happy, will get them to sign their consent form. The pulse monitor and GSR sensor will then be attached to the patient. The pulse sensor is a simple wristband device and the GSR sensor consists of small finger pads attached to two wires which connect to a small, lightweight, portable box. There are no known risks or side effects from wearing this equipment. The patients will be given the same questionnaire as that given to patients in Group 1. Patients in Group 3 will need to add their name to the questionnaire so we can compare their responses on the anxiety part of the questionnaire with the results from their pulse and GSR recordings. The information sheet makes it clear that although the patient's results may be referred to in the final report, their name will not be used.

The patient will then book in at reception and wait in the waiting area until the doctor calls them for their appointment. While the patient sits in the waiting area they will complete the first part of the questionnaire. Immediately after their consultation with a doctor they will fill out the second part of the questionnaire. The research assistant will then remove the pulse and GSR sensors and the patient will be free to leave the surgery. The research assistant will change the 'alert message' on the front of the patient's computer notes to record the fact that they have completed the first set of physiological recordings.

Six months after we move to the new surgery premises we will begin to repeat the physiological recordings on the 105 patients who were involved in this part of the study before the move. We wish to delay this part of the study for six months after the

move in the hope that all the patients will have attended the new premises at least once before the second physiological recordings are done. Their first visit to the new building may be associated with unusually elevated anxiety due to unfamiliarity with the layout of the building and initial difficulties with way finding.

When any one of these 105 patients phones, or attends the surgery in person, to book an appointment with a doctor, the receptionist will be prompted by the alert message on their computer notes to ask if they would be willing to have the pulse and GSR sensors applied during their next visit to the surgery. If the patient is happy, the receptionist will pass their name and the details of their next appointment to the research assistant so she/he can greet them when they arrive at the surgery. From this point on the procedure will be exactly the same as during their first set of physiological recordings (except that the questionnaire the patient completes will have a few extra questions relating to additional features in the new premises that were not present in the old surgery building).

Group 4 – Staff completing questionnaires

While we remain in our current premises we aim to get all members of reception, administration and managerial staff, and all health professionals working at the surgery, to fill out a customised questionnaire assessing their satisfaction with various aspects of the current building (including their work areas and public parts of the surgery). The questionnaire will include questions about job satisfaction, and psychological symptoms will be measured using the 12-item General Health Questionnaire (GHQ-12) which has high reliability and validity.

Four and twelve months after the move to our new premises we will ask all staff to fill out the same questionnaire again. These questionnaires will contain a few extra questions relating to features of the new building that did not exist in the old building.

Group 5 – Staff taking part in focus groups

All staff will be asked if they would be willing to take part in focus groups before the move, and again four months and twelve months after moving to the new surgery premises. The focus groups will be split into one for administration, reception and managerial staff, and one for health professionals working at the surgery. About eight people will be included in each focus group and the participants will be representative of the age range and genders currently working at the surgery.

Focus groups will be held during the working day and every attempt will be made to hold the groups at times that are convenient for participants. Each group will last for a maximum of one hour. Where staff need to be excused from normal duties to attend a group, the practice manager will arrange suitable cover and the surgery will pay any expenses incurred in providing that cover.

Staff will be given an information sheet at the start of the study that gives details about the focus groups. At the start of each group each participant will sign their consent form.

Audiometric measurements

Noise levels around the reception desk, in the waiting area and in specific consulting rooms, will be measured using simple audiometric provided and operated by MEMO (medical equipment management organisation). Measurements will be taken on five occasions, at varying times of the working day, both in the current surgery premises and in the new surgery. Audiometric measurements and scores from specific parts of the patient and staff questionnaires will be analysed to see if there is a correlation between a) actual noise levels and b) perceived noise levels mentioned by patients and staff.

SAMPLE SIZE CALCULATIONS

Patient questionnaires

We will be using two unmatched groups of patients – those who attend before the move and those who attend afterwards.
A sample size of 800 in each group will have 80% power to detect a difference in means of 1.33 in the Stait Trait Anxiety Inventory (STAI) (the difference between the group seen in the old practice 33.00 and the group seen in the new premises 31.67) assuming that the common standard deviation is 9.50, using a two group t-test with a 5% two-sided significance level.

Physiology group.

We are looking at changes in skin conductance using the same patients before and after the move. A sample group of 83 patients will have 80% power to detect a difference in mean skin conductance of 1.5, assuming a standard deviation of differences of 4.8 (taken from T Margrain data), using a paired t-test with a 5% two-sided significance level.
To ensure that we have 83 sets of data to analyse we need to recruit 105 patients to allow for 20% drop-out.

ETHICAL CONSIDERATIONS

As the lead investigator, Dr Gillian Rice, is a GP principal in the practice where the research study will be taking place, and will be the ‘usual GP’ for some of the patients being approached to take part in the project, it is possible that this relationship might exert pressure on patients to become involved in the study. The provision of information sheets to patients, and time away from the practice (a minimum of 48 hours) in which to decide whether or not to take part in the research study, should provide a counter to the fact that Dr Rice is one of the GPs in this practice.

TIMESCALE FOR RESEARCH PROJECT

We aim to start the research study in June 2005 which will be at least three months prior to the move to the new surgery premises. We aim to have 800 questionnaires completed, the first 105 sets of physiological measurements recorded, 15 patient interviews conducted and the first staff focus groups and staff questionnaires completed before the move to the new surgery takes place. Once we are in the new surgery building the remaining questionnaires, physiological measurements, interviews and focus groups will be organized, starting with the second set of focus groups and staff questionnaires at four months post-move, the interviews and physiological measurements at about six months post-move and the third set of focus groups and staff questionnaires at 12 months post-move.

PUBLICATION

We hope to publish and disseminate the findings of this research study in a peer reviewed journal.