The role of the nurse health and social care essay

The impact of " do not disturb" tabards worn by nurses on medicines administration rounds on the safety and quality of patient care. 4th year project, submitted to the University of Manchester in partial fulfillment of the MPharm degree

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Executive Summary

Medicinal errors are a problem across the UK with the National Patient safety Agency receiving an increased number of error reports each year. Although errors may occur at any stage during the medicines process, those which are of greatest concern to nurses are administration errors; as nurses are often seen responsible for this task. Each error carries the potential of a serious adverse effect and so the NHS is under pressure to improve safety. Previous research has identified potential factors which may contribute to the error rate; one factor identified is the interruption rate. Literature has found nurses who encounter interruptions during medicines administration have an increased risk of error. It is due to this that the " do not disturb" tabards were consequently introduced in 2011. The limited research available does suggest tabards reduce administration errors due to fewer interruptions. However, some patient groups have raised concerns regarding tabard use, suggesting they may reduce the quality of patient care, as the patient would feel as though nurses look unapproachable. At a present there are a number of hospitals that use such tabards on a regular basis; nevertheless this number is relatively low. As such, limited degree of research has been carried out to test the impact of the tabards on the quality of patient care.

The research presented here aims to identify the impact of the " Do not disturb" tabards on both the safety and quality of patient care. The research will be conducted through the use of a cluster randomised trial will be used to test this aim, with the use of eight hospitals randomly allocated to either the tabard wearing intervention cluster or the control cluster. In order to measure the impact on safety, the number of administration errors will be recorded via observations. To identify the impact on the quality of patient care, questionnaires will be given to patients discharged from observed wards. The trial period will last 6 months, at the end of this period researchers will analyse data collected and compare the results of the intervention and control cluster. Patient safety is a major concern within the NHS. Therefore this research aims to evaluate whether the tabards will act as an innovative cost effective idea to improve patient safety outcomes. As a result of this research the use of tabards may be implemented in hospitals across the UK. Contents

Declaration

I understand the nature of plagiarism and understand that it is a serious academic offence. I confirm that no material in this project has been plagiarised. Signed: 71852841Date: 08/02/2013

Acknowledgments

This project is made under the sincere guidance of Dr. Mary Tully.

1. Introduction

1. 1 The role of the nurse

The Royal college of Nursing states " Nursing involves providing care and clinical judgment to help improve, preserve or recover a person’s health, in order to achieve the best quality of life regardless of the person’s condition or disability until death".(1)Since 2001 the number of qualified nursing staff employed by the NHS has increased by 16% to over 315, 410. (1) This accounts for over 8% of the total NHS staff and suggests the importance of the role of the nurse. Nurses are usually seen at the forefront of the provision of patient care and regularly carry out tasks such as the administration of medicines, changing beds, feeding patients and administration rounds. (2) Although nurses can be found working throughout different sectors of health, they are required to work alongside other healthcare professionals to ensure positive patient outcomes.

1. 2 Medication administration

A fundamental nursing role is the administration of medicines. On average a nurse may carry out this task 4-6 times per day depending on the type of ward and patients present. (3) As this task is often seen as high risk due to the complex nature of certain medicines, the Nursing and Midwifery Council (NMC) has in place strict guidance detailing the step by step process which must be followed.(3) This aims to reduce the number of clinical errors, and also ensure that the quality and care delivered during this process is of a high standard. The simplified version of this process is called " The Five Rights": Giving the right drug, at the right dose, via the right route, to the right patient at the right time. (3) Nurses are professionally accountable to

the Nursing and Midwifery Council for their actions when administrating or assisting self-medication, therefore records of medicines administered or omitted doses must be completed.(3, 4)

1. 3 Medication error

A medication error is an incident which occurs at any stage during the prescribing, dispensing, preparation, drug administration and monitoring process. (5) In practice, nurses and healthcare workers are advised to report errors to the National Patient Safety Agency. Since this was set up in 2001, over 4 million medicine errors have been reported. (6) Medication errors are the single most preventable cause of patient harm with approximately 1 in every 250 prescriptions in UK hospitals containing an error. (7)

1. 3. 1 Medication administration error

Errors made during the administration process are of particular concern to the nursing profession, as a key outcome when measuring the safety and quality of nurse care is the number of administration errors.(1) . Statistics from the National Patient Safety Agency revealed that 59. 3% of all medicine errors occur during the administration process. (8) The most common administration error is the omission of medicines, where the drug is not administered to the patient for a number of reasons. Other errors during this stage include: the wrong route, wrong time, wrong dosage form and wrong strength. (9)In order to gain a better understanding of the nature of administration errors in the UK, a Meta analysis was carried out. A total of nine healthcare databases were searched for the results of observational studies measuring the administration error rate in UK hospitals. The results for non iv administrations revealed an overall medicines administration rate

of 5. 6% of the total 21533 opportunities for error.(10)The results of this Meta analysis also found that error rates were higher in IV administrations with a 35% error rate out of a total 154 administrations. This is five times greater than the error rate in non IV administrations, and could potentially be due to the complex nature of the medicines involved and the multiple steps required during their preparation. However as errors are voluntary recorded, it is difficult to obtain the true administration error rate in practice, as research has shown that nurses are less likely to report errors due to fears of manager and peer reactions.(11)Research carried out by Tang et al looked specifically at the nurse error rate through focus groups. Findings revealed that 80% of the 72 female nurses experienced an administration error. The most common places for errors were medical wards and intensive care units due to the complexity of medicines involved.(12) Nurses also believed that they were less likely to report an error due to fear of professional disclosure. The literature suggests that administration errors commonly occur in practice with medicine complexity i. e. intravenous doses increasing the potential risk of error. In order to improve patient safety the cause of these errors must be identified.

1. 4 Approaches to administration errors

Although administration errors in practice are common, it is often difficult to identify the root cause of the problem. One approach suggested by Reason, describes errors as the result of active and latent factors. Active factors are those which produce immediate effects and consist of the operator; who in this case is the nurse, as the " faulty" component. A lack of knowledge, non-adherence to protocols and poor calculation skills increases the risk of errors

made by nurses. Latent factors such as staffing levels and interruptions are a result of the environment and conditions under which individuals work and it is these factors which over time may trigger the active factors resulting in error. (13)

Nursing knowledge

Administration errors can be linked specifically to a nurse's professional attributes and competencies.(14, 15) Mc Mullan et al suggest that an error may be caused due to a lack of knowledge regarding the medication such as incorrect formulation, calculation of dose or route of administration. Although basic mathematical skills are essential when calculating drug percentages and dosage forms, this research found that 89% of44 nurses failed a dose calculation test approved by the NMC.(15) The calculations provided were similar to those in practice, suggesting lack of nurse knowledge contributing to error rates. However, a possible explanation of this high fail rate could be the use of calculators, as during these studies they were not used; yet in practice they are used frequently, therefore lacking external validity.

Medicine administration Interruptions

The number of interruptions during the administration process has been identified as a contributory factor to administration errors. (16, 17) When an individual is interrupted it is thought to have a negative impact on memory, as they are required to switch their attention from one task to another. (18) Previous research findings have indicated that nurses who experience a high number of interruptions are more prone to errors.(19, 20) This is especially important during the medicine administration round, which is considered a high risk activity. During this procedure nurses are often stationary at the

medication trolley for long periods of time making them more prone to interruptions. (20)This theory is supported by findings of an 18 month direct observational trial, carried out in 6 hospital wards in 2010. The numbers of clinical errors identified were compared to both observational data and medication charts. An interruption was classed as anything which resulted in the nurse having to deviate from the administration process, such as having to answer a phone call or stopping administration to speak to relatives. From the 4271 medicine administrations, it was found that an interruption occurred in 53. 1%, with each interruption associated with a 12. 1% increase in clinical error. (16) The researchers therefore concluded these results as significant due to the correlation between number of interruptions and errors. These findings are fully supported from the results of a literature review which analysed 23 studies measuring the nurse interruption rate. An average rate of 6. 7 interruptions was recorded per hour. The major cause of interruption was found to be through nurse to nurse communication, whereas a lower proportion of interruptions were caused by system failures e. g. not having the correct medicine on the trolley at the time. The findings from this review also stated there was a strong association between the number of interruptions and the error rate. (21)

Nurse staffing levels

Adequate staff levels are essential in maintaining patient safety.(22-24) The risk of medication errors, falls, infections and overall mortality is thought to increase when appropriate staffing levels are not provided.(22) Currently, there is a shortage of nursing staff in the NHS; an explanation of this could be due to the decreased nursing school capacities, low salaries and an

increase in patient expectations. Although the recession has motivated many older nurses to return to fulltime work, the demand for nurses still outweighs the supply. (22, 25)Research by the Royal college of Nursing suggests that appropriate staffing levels are met when the nurse: patient ratio is at a minimum of 1: 5.(25) These figures were based on a questionnaire completed by over 55% of NHS employed nurses who felt care was compromised when the number of patients per nurse increased.(25) Although this is not a true representation of all nurses in the NHS, the results are supported by Aiken et al, who found there was a 7% increase in mortality, for every additional patient per nurse.(22) A more recent study with similar results carried out in England, found that the mortality rate increased by 26% in hospitals who experienced higher nurse: patient ratios (above 1: 6). (26)This was also found to decrease the quality of care provided as nurses showed more dissatisfaction and higher levels of burnout. (26, 27)Despite these findings, current research (2012) suggests that working extended hours (more than ten hours), will influence the rate of errors rather than the number of staff present, as then nurses are two and a half times more likely to experience fatigue and burnout, therefore risking patient safety. (27)

1. 5 The use of tabards

In 2010 the NHS received over 162, 129 written complaints regarding poor patient care, with 21. 7% of these directed at the nursing and midwifery profession.(28) Due to this high number of complaints, the NHS is under increasing pressure to develop innovative and cost- effective plans to improve patient care. The 2011 introduction of the " do not disturb tabards"

was set to improve patient safety by reducing the number of interruptions nurses experienced during the administration process, thus reducing medicine administration errors.(17)

1. 5. 1 Tabard product information

A tabard is a short, loose sleeveless garment worn above clothing. They are available in a variety of colours including red, royal blue and burgundy and have the wording " Do not disturb nurse on drug round" on the front and back. (29) They are available as disposable or non-disposable, which cost approximately 17. 5 pence and 41-43 pence respectively per use. (30) Several hospitals including Cardiff and Vale NHS trusts in Wales and The Christie in Manchester have introduced the use of tabards with many more set to follow in the upcoming months.

1. 5. 2 The impact of tabards on patient safety

Although limited research is available, two studies carried out suggest the use of tabards may result in decreased administration interruptions, which carry the potential risk of administration errors. (17, 31) A one month trial conducted at the Colchester hospital, analysed the number of interruptions, and time taken on the 08: 00, 12: 00 and 18: 00 medication rounds both before and after the introduction of the tabards. It was found that the tabards reduced the number of interruptions by 28%. These positive results provided the basis for a 3 month extended trial, where the rate of interruptions and time taken to complete medicine rounds was again measured. Results found a further 71% reduction in the number of interruptions, and the time taken to administer medication at the 08: 00 round was reduced significantly from an average of 108 minutes to 70

minutes. (17) As a result of this research, the hospital has implemented the use of tabards on all medical and elderly wards. These findings are further supported by the results of a 3 month observational study which explored whether the use of tabards reduced the number of interruptions during administration rounds. Data was collected both pre and post intervention and results found that on average the number of interruptions per medicines round reduced from six to five. There was also a slight decrease in the number of administration errors when compared to the previous year.(31) Although this research may not have been long enough to provide robust evidence, the results do suggest that the use of tabards will reduce the number of interruptions, which in turn may lead to a decrease in error rate.

1. 5. 3 The impact of tabards on quality of care

Although the tabards were introduced to increase patient safety, reports published suggest they may have a negative effect on the quality of patient care.(32, 33) This concern is related more towards the wording of the tabards, as patients groups such as patient concern believe that the " Do not disturb" makes staff look unapproachable. (32) Although no robust evidence is available to suggest this is the case, the actions taken by East Kent hospital to remove the " Do not disturb" from the tabards implies that the tabards may well have a negative impact on the quality of care. (33)However, conflicting research suggests that the use of tabards may in fact have a positive effect on care quality. As mentioned in section 2. 5. 2, tabards have shown to reduce the time taken to administer medication, thus allowing nurses to carry out other tasks and care duties. (17) This will allow nurses to carry out simple tasks such as comforting and talking to patients

which has been found to improve the quality of care. (24, 34)Nevertheless this information is based purely on concerns and reports from individuals and no study has yet looked directly at the impact of tabards on the quality of patient care. Due to this it is not possible to form a cause and effect relationship. What’s more, is the fact that quality is a complex aspect to measure, as it is based on both patient and staff perceptions which will differ in what they believe is good quality.

1. 6 Rationale

From the research available it is apparent that medicine errors are a problem throughout the UK. Errors may occur at any point during the medicines process, yet those which are of greatest concern to nurses are those which occur during the administration process. The complex nature of these errors suggests that they cannot be simplified down to one cause, but more a number of contributing factors. Conflicting research has suggested that low staffing levels and poor nurse education may increase the error rate, yet a common factor found throughout the literature suggests that the interruption rate plays a key role in increasing errors. Whilst much research has been carried out to identify these factors, little has been done to suggest innovative ways to overcome them. The introduction of the " Do not disturb" tabards worn by nurses during the administration process, was set to reduce the administration error rate, thereby improving patient safety. Although research carried out by two independent NHS hospitals has confirmed that the tabards do reduce the level of interruptions, concerns have been raised by patient groups over the impact of tabards on the quality of patient care. These concerns suggest that the tabards may in fact reduce care quality by

making staff look unapproachable. However these are only concerns and the impact on quality has not yet been studied. What’s more, the literature available measuring the safety of the tabards has lasted no more than 3 months, with small sample sizes, use of single hospitals and lack of study details published questioning the reliability of results. It is therefore apparent that more robust, reliable research is needed in order to show the impact of the tabards on both the safety and quality of patient care, taking into account a greater nationwide sample size. The research presented will act as the basis for the following investigation.

2. Aims and Objectives

2. 1 Aim

The aim of this study is to determine the impact of the " do not disturb" tabards on both the safety and quality of care when worn by nurses during medicines administration rounds.

2. 2 Objectives

The objectives of the following study are: Observe medicines administrations to identify error ratesCompare error rates from intervention and control groupsIdentify possible causes of errorMeasure the effect of tabards on drug administration timeMeasure the difference in quality of care between a control group and an intervention (tabard wearing) group.

3. Research Design

3. 1 Cluster Randomised Controlled trial

The research method chosen to study the impact of tabards on the safety and quality of patient care will be a cluster randomised controlled trial (CRT).

The clusters will consist of 8 NHS hospitals located in the North West of England, which will be randomly assigned to either the intervention cluster (tabard wearing), or the control cluster (non tabard wearing). Each cluster will therefore consist of 4 hospitals. This method was chosen as CRT's typically focus on the effectiveness of interventions targeted at groups of health professionals rather than individuals. It is due to this, they are often used in therapeutic settings under conditions of actual use. The use of clusters ensures all individuals within the intervention cluster will wear the tabards during medicines administrations. As a result nurses within hospitals will work under the same conditions, therefore increasing the generalisability of results. (35)

3. 2 Methodological Justification

Although a cluster randomised trial is considered the most appropriate for this piece of research, other methodological approaches may also be considered.

3. 2. 1 Randomised controlled trial

Randomised controlled trials are considered to provide the most reliable form of scientific evidence when analysing the effectiveness of an intervention.(35, 36) This method prevents researcher bias, as the research has no control over allocation of hospitals to either cluster therefore methods used can be replicated in order to validate results. However this particular method is not suitable for this research, as studying both intervention and control groups within the same hospital may lead to contamination of results. Patients may experience confusion and question why some staff wear the tabards and others do not, this may affect their perception of care

quality. The results would also lack external validity, as in practice staff within a hospital would adhere to the same guidelines and procedures. (35)

3. 2. 2 Focus Groups

This method would allow small groups of nurses to share their thoughts on why they believe errors occur and whether the use of tabards has affected the number of errors made by individuals. As this would take place as an open discussion, previously unidentified factors contributing to error rates may be identified allowing researchers to gain a better understanding of the issue. However as this is a sensitive issue, nurses may not wish to disclose information regarding errors they have made, thus resulting in low contribution rates. This method would not produce any statistical figures, as all data would be based purely on nurses opinions, therefore a definite cause and effect relationship cannot be derived. Instead it may be more appropriate to use nurse focus groups to identify factors which contribute to administration errors. When used to measure quality of care, a focus group would allow small groups of patients to discuss the care they experienced whilst in hospital. The group moderator present could prompt patient responses and ensure all participants engaged and contributed to the discussion. Unlike a questionnaire, those questions not fully understood by participants could be reworded by the moderator to ensure an appropriate response. Although this method has the ability to provide a rich source of qualitative data, due to the nature of the study the responses from patients may be low. Patients recently discharged from hospital may not want to participate, resulting in low participant numbers. Also unlike the use of a questionnaire, patient consent would be required along with data collection

methods e. g. video recorder, therefore increasing research costs. Due to these reasons, the use of a focus group is not suitable for measuring the safety or quality of the tabards.

3. 2. 3 A before and after study

This non experimental method would involve carrying out the study before the introduction of the tabards, and then during the introduction of the tabards. The findings would be compared and a difference in pre and post intervention results would suggest an impact of tabards on safety. This method would allow comparisons of results within wards.(37)However this non experimental method has many drawbacks, the lack of control group decreases the ability to find a definite cause and effect relationship, thus reducing the validity of results. Also unlike a cluster controlled trial, there will be no randomisation, which could potentially introduce researcher bias. The fact that the data is collected twice, suggests that the cost of the overall research will increase due to increases in research/resource requirements. It is due to these reasons, a before and after study is not considered suitable for this research. (37)4. Hospital recruitmentThere are 29 NHS hospitals within the northwest of England; these will be asked to participate in this study. Of those which agree, 8 will be randomly selected to take part. As this is over a quarter of the hospitals, it will ensure a representative sample size. More than this may overcomplicate data collection and analysis. Each hospital will be made aware of the importance of this research and how the findings could affect future practice. A table of numbers; each representing a hospital, will be used to randomly allocate hospitals to either the intervention cluster or the control cluster. This will be carried out by an independent

researcher who has no previous knowledge of hospital error rates in order to prevent bias. A meeting will be held with hospital and ward managers to reveal which cluster they have been assigned to. This will allow any necessary changes to be made to hospital guidance to ensure all nurses in the intervention group wear tabards during administration. Details regarding the number of research observers and length of the study will be provided beforehand along with safety information sheets. Nurses will therefore be fully aware of the details of the study in advance and will have the opportunity to ask any questions or fears regarding the research.

5. Research Procedures

5. 1Data Collection

During the study those in the intervention group will wear the tabards as agreed with hospital managers. The tabards provided will be disposable as they are more cost effective than the reusable tabards.(30) Those in the control cluster will carry out administration under normal working conditions.

Measure of safety

The number of administration errors will be recorded via observations of nurses during ward rounds. In order to reduce interobserver variability, observers will meet before the study and define a medicines administration error. This will be based upon the National Patient Safety Agency definition: The wrong dosage formThe wrong route of administrationThe wrong timeThe wrong formThe wrong strengthObservers will refer to patient medication charts in order to recognise errors. When an error is identified, the drug involved will also be recorded. This will allow researchers during data analysis to categorise errors into mild, moderate or severe depending on the

implications the error could have on the patient. Please see Appendix 2 for more informationDuring administrations, observers will remain at a distance where they are close enough to observe administration without causing any distress to both patients and nurses. The records made will remain anonymous and only the time and ward number will be noted. The record card will also have a section to record the number of interruptions. This will identify whether or not the tabards reduce the number of interruptions which result in errors. An interruption will be defined as anything which causes the nurse to deviate from the administration process. The time taken to complete administration rounds will also be recorded, as reducing this potentially allows nurses to carry out other care duties. If the tabards are effective in improving safety, the number of errors in the intervention group will decrease compared to the control group. Observations will take place during the week and on weekends at different times each day for approximately 3 hours. The time of day will be randomly assigned using a number generator, where each number will represent a specific 3 hour time period during the day. This will ensure data collected represents all nurses working on the observed wards. Although all staff nurses in the intervention group will be required to wear the tabards, only the following will be observed during this study: Inclusion criteria: Fully qualified nursing staff (diploma/degree)Permanent ward baseProvided written consentExclusion criteria: Non nursing staff as they will not be required to wear the tabardsNurse Managers as it is unusual for them to carry out medicines administration therefore may not reflect true practiceNon permanent staff (bank/agency staff) as it is not feasible to gain written consent. An advantage of this method is that it allows for data collection in the

participants' natural environment therefore increases the internal validity, also data does not depend on the subjects' ability to report results, therefore increasing reliability of results.

Number of observations

In order to determine the number of administrations required to be observed, a simple sample size calculation is required. This will ensure the sample is large enough to detect a significant change in the two groups, and will ensure that resources and time is not wasted. The NPSA does not classify medicine errors into types during the medicine process; therefore the exact proportion of administration errors cannot be truly established. The rate of medication errors in the UK is approximately 1-2%; this will act as the basis for the sample size calculation. The following equation will be used:

n = p1(100-p1) + p2(100-p2) x f(α, β)

(p2 - p1)2

Key: n = sample sizeα = significance level (in this case this will be 0. 05)Δ Effect size = the smallest difference worth detecting (in this case 2%)p1 and p2 = percentage success in the two groupsTable 1: Sample size calculation

f(α, β)

P1 (%)

P2 (%)

Δ (%)

n calculatedn rounded upn each arm7. 92112331233211667. 921. 50. 5108631086454326. 221. 50. 5852585264263

6. 2

2

1

1

1829

1830

915

Table 1: For f(α, β) values of 7. 9 and 6. 2, the power is 80% and 90% respectively. The sample size which will be used (534 administrations) will have a significance level (P-value) of 0. 05, thus suggesting that 90% of results will not be due to chance. Table 1 suggests that a minimum of 915 medicines observations are required per arm. However, due to similarities amongst subjects in clusters, the responses may not be as varied as those from a simple random selection of participants. This similarity is expressed as the intracluster correlation coefficient, which compares the variance within clusters to the variance between clusters. This often results in a smaller effective sample size therefore a larger sample size is often required during a CRT. To overcome this, 915 observations will be carried out per hospital. The length of the study period ensures sufficient time to carry out this number of observations. This also reduces the need to employ multiple wards within hospitals, which may further complicate the research process. For this particular study, only one ward per hospital will be required, this will be a general medical ward as these tend to provide a range of acute medical services to patients.

Measure of quality

The second part of this study will measure the impact of the tabards on the quality of patient care. As mentioned previously, tabards may decrease the quality of care experienced, if this does occur the intervention group will have a lower quality average than the control group. As quality is a difficult aspect to measure, a quantitative questionnaire consisting of 10 questions will be used to analyse this aspect. The questionnaire will be designed so that it takes approximately 5-10 minutes to complete and answers will be provided via a tick box method. Patients will have up until one month after the final observation to complete questionnaires. A number of questions targeted at nurses will be used from the HCAHPS (Hospital Consumer Assessment of Healthcare providers and systems) survey. This will allow valid comparisons to be made between groups based on patient perspective. (38) The following questions have been selected from the HCAHPS survey for use in this research: During this hospital stay, did you get help when required? During this hospital stay, did you have confidence and trust in the nurses? During this hospital stay, do you think nurses provided enough information regarding ward routine? Please see appendix 5 for more informationBefore the research is conducted, the questionnaire will be piloted to ensure the layout; language and flow of the questions are appropriate. Factors such as unfinished questionnaires, low response rates or incorrect completion may indicate that changes need to be made. The questionnaire will be distributed to all discharged patients in both clusters. This will be provided in a sealed envelope containing a return envelope with stamp and a participant information sheet. Inclusion criteriaPatients who were administered at least one drug during hospital stay. Patients admitted,

treated and discharged on observed wards- Patients moved from one ward to another may base their results on the level of quality experienced in other non-observed wards. 18 years or olderPatients who had at least one overnight stay on the ward as those who did not may have a limited experience. Exclusion CriteriaStaff members who may have been admitted during this research, as they are likely to have a different perspective than patients. Patient unable to fully speak, read or understand EnglishPatients with a decreased mental capacity as they may be unable to make decisions for themselves or complete questionnaires.

Questionnaire sample size

Based on the HCAHPS, a minimum of 150 surveys during the 6 months must be completed per cluster for results to be reliable. However as data is based upon patient perceptions, the more data gained will provide a clearer insight into this area, therefore a minimum of 150 questionnaires per hospital will be completed. Although this may seem unrealistic, due to the length of the study period, this target is achievable.

5. 2 Data Analysis

Analysis of observational Data:

The error rate will be calculated using the Total Opportunities for Error (TOE- The sum of all doses administered). This is the number of administration errors divided by the TOE and multiplied by 100. This will find the percentage of administrations associated with an error. A t-test may be used to identify whether there is a significant statistical difference between the two groups. A comparison of the average interruption rate will identify whether the tabards do in fact decrease the interruption rate. Each error will be independent of

the other, so one medication may have more than one error. The average time taken per administration round will be calculated and compared in both groups using the following equation: n= (Time ward administration started - Time ward administration ended)n + n2 + n3 + n4 + n5 +n6……. etc = Average time per administration roundTotal number of administrationsAverage time per administration round = Average time taken to administer medicineNumber of patients administered per patient. This will identify whether the use of tabards will decrease the time taken to complete the administration process.

Analysis of Questionnaire Data:

Analysis of questionnaire data will not be as complex due to the use of closed questions. This will therefore produce categorical data so a statistical test such as a Chi squared test will be used to compare data from the control and intervention group.

5. 3 Time Scale

Once ethical approval is granted, a literature review will be carried out to provide basic background knowledge in this area. This will be followed by training of observers which will take around 2 weeks; this is an important step in ensuring that errors are defined correctly and consistently. During this two week period the pilot questionnaire will be tested and the results analysed in case of change. Following this, hospitals will be randomly allocated to either cluster, and managers and staff will be made aware of which cluster they have been allocated to. Participant information leaflets will be made available on wards to raise awareness of the research. This will allow sufficient time before the observational period for any questions or

concerns to be raised. Please see appendix 1 for more details. The observation period of this study will last approximately 6 months. Although previous studies have lasted 3 months they have not taken into account the impact of the tabards on quality, therefore in order to gain the minimum data required, this time period is adequate. Questionnaires will be handed to patients on discharge, as leaving this to late may result in the patient forgetting the quality of care experienced. Once data has been analysed, findings will be published and made available to those involved in the study. Please see the table 1 for more informationTable 1- Project Research timelineMonth: Task: 12345678910Ethical approval from hospitals and ethics committeeLiterature ReviewTraining observersPilot questionnaireAssignment to clustersInformation sheets sent to hospitalsCarry out observationsQuestionnaire data collectionAnalyse dataPublish findings

5. 4 Impact of Research

The findings of this research could potentially impact all NHS hospitals. Medicines' administration errors are problematic across the UK and so if findings show a reduction in errors, the tabards may become an essential component of hospital guidelines during the administration process. This will improve patient safety, and reduce the number of adverse effects caused by errors. A reduction in adverse effects will reduce the number of complaints against the NHS, thus reducing costs. Measuring the rate of interruptions will confirm the scale of the problem allowing further research into finding alternate ways alongside the use of tabards to try and tackle this issue. Alternatively research may find that the tabards have a negative impact on the quality of care received. Although this may be the case, if the tabards

are found to reduce error rates it may not be practical to not use the tabards, therefore changes regarding the wording e. g. removing the " Do not disturb", may be a more suitable option. However further research may be required to test the quality of care once this wording has been altered.

6. Ethics

Ethical approval will be required from the local NHS and ethics committee due to the use of NHS patients. Each hospital will also need to agree to the study. Ethical consideration will be required during both the observational and questionnaire aspects of this research.

6. 1 Observation

Observing administration errors may be considered unethical as preventable harm may be caused to patients. To overcome this issue, observers will record the error and if nurses have not realised their mistake observers will intervene before drug administration. The intervention will consist of the observer quietly suggesting that the nurse refer back to the medication chart, this will ensure that the nurse does not feel undermined and the patient is not alarmed. Written consent is required by individual nurses to allow observation. After nurses are made fully aware of what their participation involves they will be asked to sign a consent form. Nurses who do not wish to participate in this research will still be required to wear the tabards as part of hospital guidelines. Observers will distinguish between the two, as a register will be provided beforehand with names of nurses who have consented to being observedTo maintain confidentiality individual nurse names will not be recorded at any point throughout the trial. The errors recorded will remain anonymous, this way error rates cannot be

associated to individual nurses. To emphasise this point nurses will be shown the error recording chart before hand to alleviate any worries.

6. 2 Questionnaire

All discharged patients on the research wards will be provided with questionnaires from ward staff. In order to distinguish between cluster groups, questionnaires will contain the hospital name. Patient names will not be recorded and to maintain this confidentiality, questionnaires will be sent back in sealed envelopes. This will ensure that researchers have no control over which patients complete the questionnaires which will prevent bias. Alongside the questionnaire, patients will receive the participant information sheet in order to help them understand what is expected and the purpose of the questionnaire. Individual consent forms are not required as consent is implied if the questionnaire is completed. All data collected from both the observations and the questionnaire will be protected, and results will not be made available until the results have been analysed and published.

7. Resources

Observers approximately 2 per hospitalStamp and sealable envelope to send questionnaire backDisposable Red tabardsStopwatch for observers to record time takenData analysis softwareStationary: pens/ error record charts/photocopying and printing forms. Cost of the data analysis and posters/patient information sheets distributed

8. Study Limitations

As hospital clusters are used instead of individuals the intra cluster variation is increased, thus reducing the effective sample size. To overcome this, the

sample size will be increased during both the observation and questionnaire data collection. A possible methodological problem associated with observational studies is the fact that subjects may alter their behaviour when observed. This is known as the Hawthorne effect.(39) Nurses may carry out procedures with more caution, thus reducing the number of errors, which would not reflect normal practice. However this theory has been dismissed from research carried out by Savage, who found that during a two week study comparing the number of dispensing errors in community pharmacies there was little difference between the observed group and non observed group.(39) This suggests that perhaps during this study the fact the nurses are being observed will not affect the error rate and errors recorded will reflect those in practice. The questionnaire used to measure quality will provide quantitative data; this may result in a lack of in-depth data and understanding of the quality of care. However as the patients completing questionnaires will have recently been discharged from hospital, they may not feel well enough to want to fill out a long questionnaire. Due to this a tick box questionnaire is considered a more practical option and is more likely to increase the questionnaire completion rate. Although a reduction in quality may initially be assessed, the long term effects of the tabards may not be seen during this study, as the data collection will last no longer than 6 months. The tabards may in fact increase the quality of care, as overtime the numbers of adverse effects resulting from errors will reduce which may increase the quality of care received. To overcome this issue, a follow up study may be considered a year after the initial study to find any differences in quality using the same questionnaire. However this would only apply if nurses continued to wear the tabards after the study. This research focuses

on the administration errors made by nurses, however in practice physicians' also carry out medicines administration. Further research may be required to investigate their rate of error in order to suggest alternate ways of improving practice. Additional research may be necessary in order to provide a better understanding of the long term use of the tabards. Issues such as infection control and long term costs may require further examination in order to find the true benefits/ limitations of the tabards.