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**Developing a medicines management intervention in older patients with
dysphagia**

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Abstract

Background

Administering medication to patients with dysphagia (PWD) is a challenging process for patients and healthcare professionals (HCPs). This study aimed to improve those administrations by focusing on the development of the elements of a pharmacy service providing individualised guidance on the administration of medication to older PWD in care homes. The objectives were to:

- assess the feasibility of a pharmacy service promoting guidance on the administration of medication to PWD,
- identify and develop theory on the elements that affect the administration of medication to PWD in care homes,
- identify outcomes for the modelling process previous to a large scale intervention.

Methods

A questionnaire was designed to evaluate the acceptability by HCPs of a pharmacy service for PWD in hospital wards. Qualitative interviewing was used in care homes to explore the perceptions of nurses on the administration of medication to PWD and nurse's acceptability of a pharmacy service providing individualised medication administration guides (I-MAGs). Observational drug rounds were carried out in care homes to describe the quality, type and frequency of errors in the administration of medication to PWD.

Results

I-MAGs were well received on the hospital wards and nurses felt more confident and time efficient in their practice when the I-MAGs were present on the ward. Interviews identified the isolating environment of the care home, the importance of formulation choice, the lack of awareness of dysphagia and gaps in nurse's pharmaceutical knowledge as barriers in the medicines management of PWD. Observational drug rounds revealed that medicine administration errors (MAEs) in care homes (excluding time errors) are three times more frequent in PWD than in those without.

Conclusion

Medicines management for PWD requires a multidisciplinary approach from several HCPs and consequently PWD could benefit from interventions that overcome the practice barriers between those HCPs.

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Glossary

ADE	Adverse Drug Events
ADR	Adverse Drug Reaction
CI	Confidence interval
COO	Care Of Older people
CTA	Consent to Approach
DP	Dysphagia Pharmacist
EFT	Enteral Feeding Tube
HCP	Healthcare Professional
IDF	Inter Professional Dysphagia Framework
I-MAG	Individualised Medication Administration Guide
IP	Inappropriate Prescribing
IV	Intravenous
LTCF	Long Term Care Facilities
MAE	Medicine Administration Error
MCS	Mental Component Summary
MIOI	Medication-Induced Oesophageal Injury
MRC	Medical Research Council
NHDS	National Hospital Discharge Survey
NSAID	Non-steroidal anti-inflammatory drug
OMI	Older people Mentally Infirm
PCS	Physical Component Summary
POD	Patient's Own Medicine
PWD	Patient With Dysphagia
PWD	Residents With Dysphagia
QOL	Quality Of Life
SALT	Speech and Language Therapist
SIMS	Satisfaction with Information about Medicines Scale
SOP	Standard Operation Procedures
SD	Standard Deviation
TOR-BSST	Toronto Bedside Swallowing Screening Test
UK	United Kingdom
US	United States

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1. Introduction

The focus of this thesis is to explore the components involved in the development of a complex intervention in medicines management where a community pharmacist-led service provides individualised guidance on the administration of medication to patients with dysphagia (PWD) in care homes with nursing. This chapter describes why such an intervention is complex and reviews the literature that identifies the scope of the problems involved in the management of medication in older PWD. This chapter will also identify how those components of a complex intervention will be reflected in the research projects presented in this dissertation.

1.1. Development and evaluation of complex interventions: MRC guidelines

This section will outline the revised structure of complex interventions and some examples that illustrate the framework of the MRC for complex interventions.⁽¹⁾

In 2000, the Medical Research Council (MRC) defined complex interventions as those that include several components and its evaluation is difficult because of problems of developing, identifying, documenting, and reproducing the intervention.⁽²⁾ Complex interventions included a phased approach to the development and evaluation of the interventions that was proposed to help researchers define clearly where they were in the research process and that was followed by an evaluation combining the use of qualitative and quantitative research methods.

Post-publication several authors identified limitations in the framework and made the following recommendations:

- greater attention to early phase piloting and development work,⁽³⁾
- a less linear model of evaluation process,⁽⁴⁾ integration of process and outcome evaluation,⁽⁵⁾
- recognition that complex interventions may work best if they are tailored to local contexts rather than completely standardised,⁽⁶⁾
- and greater use of the insights provided by the theory of complex adaptive systems.⁽⁷⁾

These led to a review of the guidance in 2008 in which the MRC redefined complex interventions as those that contain several interacting components within the experimental and control interventions as well as:

- number and difficulty of behaviours required by those delivering or receiving the intervention,
- number of groups or organisational levels targeted by the intervention,
- number and variability of outcomes,
- degree of flexibility or tailoring of the intervention permitted.

The initial proposal by Campbell et al⁽²⁾ for complex interventions considered the process of development and evaluation of such interventions as having several distinct phases that could be compared with the sequential phases of drug development. However, this structure was criticised⁽⁸⁾ as it did not fit previous guidance on randomised controlled trials. The 2008 review of the guidance for complex interventions⁽¹⁾ provided a much more detailed but flexible structure on the ‘how to’ develop complex interventions. This structure will be described in this section.

The design of a complex intervention should be a cycle containing four main phases as indicated in Figure 1.

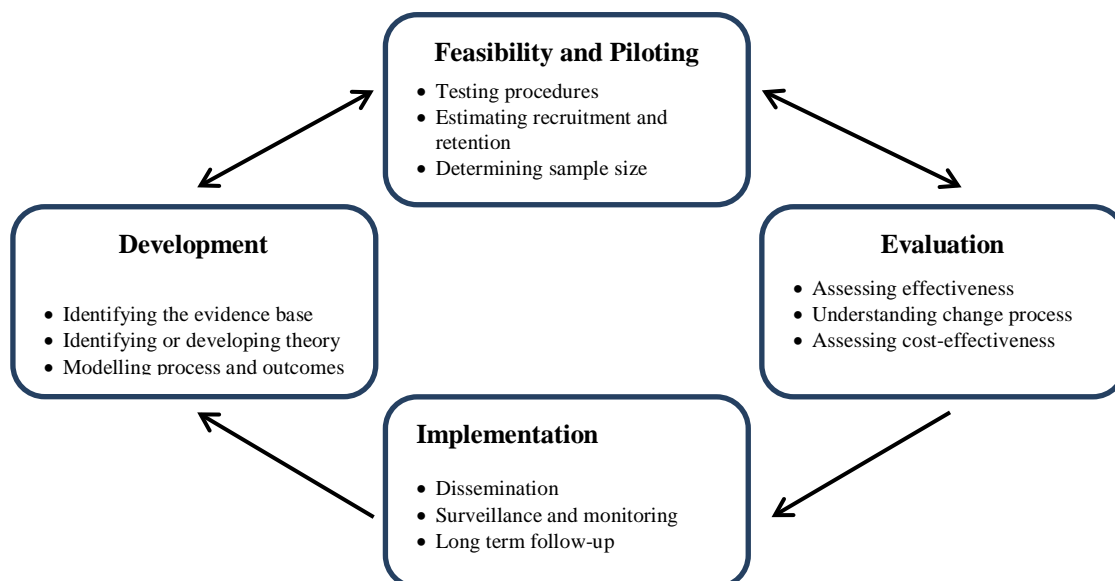


Figure 1: Key elements of the development and evaluation process (Craig et al. 2008, page 980)⁽¹⁾

1.1.1. Theoretical development

Before evaluating an intervention, it is essential to identify what is already known about similar interventions in order to avoid replication and to recognise the

validity of some of the elements of the intervention. This phase should be composed by three steps:

- identifying existing evidence: a thorough and high quality literature review about what methods have been used and the results obtained is essential at this stage. The MRC recommends that if there is no recent, high quality systematic review of the relevant evidence, one should be conducted and updated as the evaluation proceeds.⁽¹⁾ This evidence should help identifying an expectable effect,
- identifying and developing theory: this step is the theoretical understanding of the intervention and should explore any theories available, the changes that are expected when implementing our intervention and the interaction between those changes,
- modelling process and outcomes: as indicated in the MRC guides, modelling a complex intervention before a full scale evaluation can provide important information about the design of both the intervention and the evaluation. A series of studies may be required to progressively refine the design before embarking on a full scale evaluation.

The processes mentioned above are illustrated in the next example. In 2005, Eldridge et al⁽⁹⁾ developed a cost-effectiveness model of a complex intervention from pilot study data in order to inform the viability and design of a subsequent falls prevention trial. Two models were used to estimate the probability of falling over a 12-month period based on a probability tree and to assess the impact of the programme over time. The results showed that the intervention would only reduce the proportion falling by 2.8% over a 12-month period making the intervention not cost-effective due to its inability to reach those at risk of falling. However, this study highlighted the importance of the model-building approach when designing complex trials and where a trial is not possible.

1.1.2. Assessing feasibility

This phase explores any challenges that need to be considered with regards to the acceptability, compliance, delivery of the intervention, recruitment and retention, and smaller than expected effect sizes that could have been predicted by thorough piloting.

As an example, in 2009, Farquhar et al⁽¹⁰⁾ carried out a feasibility study on a novel service for patients with persistent breathlessness. It was evaluated using the

Medical Research Council's framework for complex interventions. A single-blinded fast-track pragmatic randomised controlled trial was conducted for patients with chronic obstructive pulmonary disease referred to the service. Patients were randomised to either receive the intervention immediately for an eight-week period, or receive the intervention after an eight-week period on a waiting list during which time they received standard care. Outcomes examined included: response rates to the trial; response rates to the individual questionnaires and items; comments relating to the trial functioning made during interviews with patients, carers, referrers and service providers; and researcher fieldwork notes.

The fast-track trial methodology proved feasible and acceptable. Although two of the baseline/outcome measures proved unsuitable, this study added to the evidence that fast-track randomised controlled trials are feasible and acceptable in evaluations of palliative care interventions for patients with non-malignant conditions. Reasonable response rates and low attrition rates were achieved. Furthermore, with adequate preparation of the research and the randomisation teams, clinicians and respondents, and effective liaison with the clinicians, single-blinding proved effective.⁽¹⁰⁾ However, pilot study results should be interpreted cautiously when making assumptions about the numbers required when the evaluation is scaled up. Effects may be smaller or more variable and response rates lower when the intervention is rolled out across a wider range of settings and this study did not consider any adjustments to the waiting time due to the skewed recruitment suggested by other authors when participants are more positive about the intervention.^(11, 12)

1.1.3. Evaluation of the intervention

There are many study designs to choose from and different designs suit different questions and circumstances.⁽¹⁾ Researchers should beware of blanket statements about what designs are suitable for what kind of intervention and choose on the basis of specific characteristics of the study, such as expected effect size and likelihood of selection or allocation bias.⁽²⁾ Awareness of the whole range of experimental and non-experimental approaches should lead to more appropriate methodological choices. Three essential parts of the evaluation are the assessment of effectiveness, determining outcome measures and the understanding of processes.

Assessing effectiveness

Randomisation should always be considered because it is the most robust method of preventing selection bias^(1, 13) balancing both known and unknown prognostic factors, in the assignment of treatments. If a conventional parallel group randomised trial is not appropriate, other randomised designs should be considered. As indicated in the guidelines,⁽¹⁾ if an experimental approach is not feasible, because the intervention is irreversible, necessarily applies to the whole population, or because large scale implementation is already under way, a quasi-experimental or an observational design may be considered.

Determining outcomes

Researchers need to decide which outcomes are most important, which are secondary, and how they will deal with multiple outcomes in the analysis. A single primary outcome and a small number of secondary outcomes are the most straightforward for statistical analysis but may not represent the best use of the data or provide an adequate assessment of the success or otherwise of an intervention that has effects across a range of domains.

The importance of identifying a variety of outcome measures is reflected in the following example. With the aim of estimating the extent to which a case-management intervention for persons newly discharged into the community following an acute stroke effected a change in stroke outcome in comparison with usual care, Mayo & Scott⁽¹⁴⁾ carried out an RCT in five acute care hospitals in Canada. The study targeted persons returning directly home within 28 days of an acute stroke who had one or more indicators of need for health-care supervision post-discharge: lives alone; mobility problem or need for post-discharge management for co-morbidity or social situation. For six weeks following discharge a nurse case manager delivered, depending on need, over 50 different nursing interventions, which targeted physical, emotional and psychological impairments, role participation restrictions and health perception. The primary outcome was the Physical Component Summary (PCS) instead of the Mental Component Summary (MCS) of the previously validated Measuring Outcomes Study 36 item Short-Form (SF-36).⁽¹⁵⁾ The results showed no statistically significant differences in average scores on the SF-36 PCS. The type of intervention described here did not have enough elements to impact on motor or physical function outcomes. This study failed to show an effect of a nurse case-management intervention for people discharged home after acute stroke despite debriefing sessions indicating the potential for response. Clearly the intervention

was complex but the analysis, may not have reflected the true benefit of the intervention.

Understanding processes

Process evaluation explores the way in which the intervention under study is implemented, can provide valuable insight into why an intervention fails or has unexpected consequences. It is a method used to monitor and document programme implementation and can aid in understanding the relationship between specific programme elements and programme outcomes. The scope and implementation of process evaluation has grown in complexity as its importance and utility have become more widely recognised. Several practical frameworks and models are available to practitioners to guide the development of a comprehensive evaluation plan, including process-evaluation for collaborative community initiatives. However, frameworks for developing a comprehensive process-evaluation plan for targeted programmes are less common.

Saunders et al⁽¹⁶⁾ presented a comprehensive and systematic approach for developing a process-evaluation plan to assess the implementation of a targeted health promotion intervention. They suggested elements for process-evaluation plans including fidelity, dose or data sources (delivered and received), reach, recruitment, and context and identified the questions and information required to complete the process (Table 1).

	Possible question	Information needed
Fidelity	1. To what extent was the intervention implemented consistently with the underlying theory and philosophy?	1. What constitutes high-quality delivery for each component of the intervention? What specific behaviours of staff reflect the theory and philosophy?
	2. To what extent was training provided as planned (consistent with the underlying theory and/or philosophy)?	2. What behaviours of trainers convey the underlying theory and philosophy?
Dose delivered	3. To what extent were all of the intended units or components of the intervention or programme provided to programme participants?	3. How many units/components (and subcomponents as applicable) are in the intervention?
	4. To what extent were all materials (written and audio-visual) designed for use in the intervention used?	4. What specific materials are supposed to be used and when should they be used?
	5. To what extent was all of the intended content covered?	5. What specific content should be included and when should it be covered? What is the minimum and maximum time to spend on the content?
	6. To what extent were all of the intended methods, strategies, and/or activities used?	6. What specific methods, strategies, and/or activities should be used in what sessions?
Dose received	7. To what extent were participants present at intervention activities engaged in the activities?	7. What participant behaviours indicate being engaged?
	8. How did participants react to specific aspects of the intervention?	8. With what specific aspects of the intervention (e.g., activities, materials, training, etc.) do we want to assess participant reaction or satisfaction?
	9. To what extent did participants engage in recommended follow-up behaviour?	9. What are the expected follow-up behaviours: reading materials, engaging in recommended activities, or using resources?
	Reach 10. What proportion of the priority target audience participated in (attended) each programme session? How many participated in at least one half of possible sessions?	10. What is the total number of people in the priority population?
Recruitment	11. What planned and actual recruitment procedures were used to attract individuals, groups, and/or organisations?	11. What mechanisms should be in place to document recruitment procedures?
	12. What were the barriers to recruiting individuals, groups, and organisations?	12. How will we systematically identify and document barriers to participation?
	13. What planned and actual procedures were used to encourage continued involvement of individuals, groups, and organisations?	13. How will we document efforts for encouraging continued involvement in intervention?
	14. What were the barriers to maintaining involvement of individuals, groups, and organisations?	14. What mechanisms should be in place to identify and document barriers encountered in maintaining involvement of participants?
Context	15. What factors in the organisation, community, social/political context, or other situational issues could potentially affect either intervention implementation or the intervention outcome?	15. What approaches will be used to identify and systematically assess organisational, community, social/political, and other contextual factors that could affect the intervention? Once identified, how will these be monitored?

Extracted from Saunders et al. 2005⁽¹⁶⁾

Table 1: Sample process evaluation questions for fidelity, dose delivered, dose received, reach, recruitment, and context

These articles also divided systematic process evaluation in six different steps:

1. description of the programme: the previously planned programme is described fully, including its purpose, underlying theory, objectives, strategies, and the expected impacts and outcomes of the intervention,
2. description of a complete and acceptable programme delivery: this includes specific strategies, activities, media products, and staff behaviours. The goal of this step is to state what would be entailed in complete and acceptable delivery of the programme,⁽¹⁶⁾
3. develop potential list of questions: the initial wish list of possible process-evaluation questions based on the programme (without full consideration of resources) needed is drafted,
4. determine methods: the team begins to consider the methods that will be used to answer each question in the wish list of process-evaluation questions,
5. consider programme resources, context and characteristics: the team considers the resources needed to answer the potential process-evaluation questions listed in step 3 using the methods proposed in step 4,⁽¹⁶⁾
6. finalise the process-evaluation plan: the final process-evaluation plan emerges from the iterative team-planning process described in steps 3 to 5.

In conclusion, the reviewers of the MRC guidelines for complex interventions acknowledged that many issues surrounding evaluation of complex interventions are still debated, that methods will continue to develop and that practical applications will be found for some of the newer theories. However, the revised guidance is aimed to help researchers, funders, and other decision makers to make appropriate methodological and practical choices. The key message for policy makers is the need to consider evaluation requirements in the planning of new initiatives and, wherever possible, to allow for an experimental or a high quality non-experimental approach to the evaluation of initiatives when there is uncertainty about their effectiveness.

As suggested by the MRC framework,⁽¹⁾ the literature review presented in the following chapter will introduce evidence supporting the management of medicines in dysphagia, starting from the normal swallowing function and moving onto the causes, consequences and challenges of dysphagia and other issues surrounding our research topic. Consecutive chapters will also be introduced outlining how the methodological approach contributed towards the design of our complex intervention.

2. Literature review

The delivery of a medicines management intervention in dysphagia required the exploration of the issues around dysphagia (such as causes, consequences, identification, management, etc.) and how those are related to a pharmacy intervention. Hence this literature review has been divided into two main sections that will identify the aims and objectives of the research presented in this thesis. These sections are:

- normal swallowing and dysphagia,
- medication and dysphagia.

2.1. Normal swallowing and dysphagia

2.1.1. Physiology of swallowing

The normal swallow allows an individual to manage a wide range of food and drink, of varying volumes, textures and consistencies.⁽¹⁷⁾ Swallowing normally occurs as an orderly physiological process that transports ingested material and saliva from the mouth to the stomach.^(18, 19)

There are numerous views on the number of phases in the process of normal swallowing. Whilst Logemann⁽¹⁷⁾ described this process as four different stages, other descriptions of the swallowing process like Leopold & Kagel (1997)⁽²⁰⁾ consider the inclusion of a fifth phase, opposite to others like Hendrix (1993)⁽²¹⁾ that divides this process in three main phases. From the anatomical point of view, dysphagia can appear in three different areas (oral cavity, pharynx and oesophagus) (Figure 2) and therefore the classification of normal swallowing in three phases will be the one explained.

The oral phase – preparation of the bolus

The preparatory phase consists of taking material into the mouth and preparing it for a swallow. In the case of solid or semi-solid food, the food is chewed, mixed with saliva, and usually positioned on top of the anterior tongue in anticipation of a swallow. The lips, tongue and soft palate are involved in retaining and controlling food and drink within the oral cavity. During the oral phase of swallowing, the tongue elevates and rolls posteriorly in a peristaltic motion, making sequential contact with the hard and soft palate, and thereby propelling the bolus into the

pharynx.⁽²²⁾ At the end of the oral preparatory phase the bolus is propelled towards the pharynx with a backward motion of the tongue.

Pharyngeal phase – airway protection

As the pharynx provides a shared passage for swallowing and respiration the pharyngeal phase provides a mechanism to prevent material entering the airway. This phase is initiated by the backward movement of the tongue and immediate detection of the bolus within the pharynx.

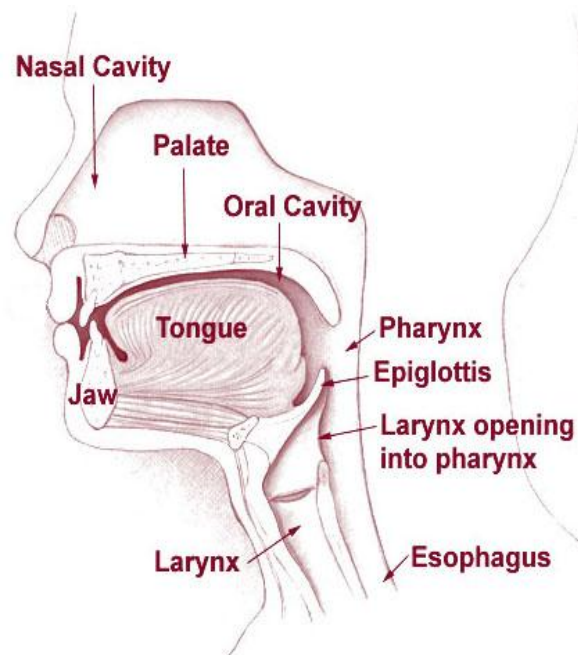


Figure 2: Midsagittal section of the head and neck (Wright 2011, page 6)⁽²³⁾

Timing and coordination are crucial. The main activities during the pharyngeal phase are the cessation of breathing and the closure of the airway. Closure is achieved by drawing together the vocal folds within the larynx. This is accompanied by the upward and forward movement of the larynx. The epiglottis closes over the larynx diverting the bolus towards the oesophagus. The upward movement of the larynx facilitates the opening of the upper oesophageal sphincter. The major mechanism preventing the entry of secretions of swallowed material into the larynx, the trachea and lungs (aspiration) is contraction of the intrinsic laryngeal muscles that approximate the arytenoids and epiglottis, close the false cords, and adduct the vocal cords.⁽¹⁷⁾ At the same time the pharyngeal musculature exerts pressure on the bolus pushing it into the oesophagus.

Oesophageal phase

The oesophageal phase describes the transport of the bolus through the oesophagus and consists of muscular contractions, in a series of peristaltic waves, which actively transport the bolus to the stomach with some help from gravity. The pharynx and proximal oesophagus are the only areas in the human body where striated muscle is not under voluntary neural control.⁽¹⁹⁾ While it is important to recognise the normal swallowing process, we also need to explore what happens when this function is compromised. Therefore, the following section will focus on describing dysphagia.

2.1.2. Definition of dysphagia

Dysphagia is a symptom that refers to difficulty or discomfort in swallowing a wet or dry bolus during the progression from the mouth to the stomach.⁽²⁴⁾ From an anatomical standpoint, dysphagia may result from oropharyngeal or oesophageal dysfunction:⁽²⁵⁾

- oropharyngeal or high dysphagia: the difficulties in swallowing are due to problems with the mouth or throat,
- oesophageal or low dysphagia: this is where the difficulties in swallowing are due to problems with the oesophagus.

Dysphagia may involve impairment in any or all phases of the swallowing process. Impairment involving the oral phases of swallowing may result in difficulty retaining the bolus in the oral cavity or in chewing or moving the bolus toward the oropharynx. Impairment involving the pharyngeal phase may result in the bolus being retained in the oropharynx and overflow aspiration after swallowing. The bolus may also be diverted and lead to nasal regurgitation. Impaired function in the oesophageal phase can result in ineffective movement and retention of the bolus in the oesophagus.⁽²⁶⁾

2.1.3. Prevalence of dysphagia

When estimating the prevalence of dysphagia, it is important to outline several components that describe the population explored. The prevalence of dysphagia varies in different age groups and settings and it may be related to the occurrence of other conditions that the patient may suffer from. For the purpose of our research topic, this section will explore the prevalence of dysphagia in an ageing

population, the conditions associated to it and the different rates found between institutionalised patients and those in their own homes.

Dysphagia in an ageing population

An increase in the percentage of older persons is one of the principal demographic characteristics of the population of developed countries. In Europe, more than 17% of the citizens are older than 65 years. In the last decade, this group has increased by 28% whereas the rest of the population has only grown by less than 1%.^(27, 28) In a study carried out in Sweden in a sample of ninety-one 55-year-olds, dysphagia was reported in 13% of the patients with normal oesophageal function and 27% of the patients with oesophageal dysfunction revealing an overall incidence of dysphagia of 22%.⁽²⁹⁾ In the same country, another study with 600 participants (300 men and 300 women) from 50 to 79 years old, identified signs of dysphagia in 35% of the population.⁽³⁰⁾ However, none of these studies identified significant differences between men and women. More recently, a study including 2,359 patients discharged from an acute geriatric unit between 2002 and 2009, with a mean age of 85 years, identified dysphagia in 47% of the sample after bedside assessment.⁽³¹⁾ Despite the variation of these figures, it is clear that dysphagia is a symptom that is more commonly found in older patients as reported by Murry & Carrau (2006)⁽³²⁾ who suggested that 70-90% of older people have some degree of swallowing dysfunction.

Conditions associated to dysphagia

The prevalence of oropharyngeal functional dysphagia is also dependant on other conditions suffered by the patients. A review by Kuhlmeier in 1994⁽³³⁾ in 889 patients from the Maryland Health Services in US identified that the most common condition associated to dysphagia was ‘diseases of the circulatory system’ (primarily stroke) with almost 17% of the sample suffering from both dysphagia and stroke. The following most common primary diagnosis is ‘diseases of the respiratory system’ (primarily inflammation of lung tissue) with 13% of the sample.⁽³³⁾ Current reported prevalence of dysphagia in stroke varies from 37% to 78% depending on the type of test used to determine the presence of dysphagia.⁽³⁴⁾

Recent studies in Europe identified that dysphagia affects more than 30% of patients who have had a cerebrovascular accident, 52%–82% of patients with Parkinson’s disease and 84% of patients with Alzheimer’s disease.^(25, 35) A study carried out in Southampton General Hospital, UK examined 53 patients with Parkinson’s disease with similar nutritional status. The authors reported that

dysphagia was present in 81% of the cases, but in the majority of them, this was mild.⁽³⁶⁾

Institutionalised patients and patients' own homes

Dysphagia in older people is also an important cause of morbidity and mortality. A study that examined the factors associated with loss of functional capacity to eat across 240 residents (average age of 82) in nursing homes, found that in nursing homes PWD had a higher six-month mortality rate than those without dysphagia.⁽³⁷⁾ Croghan et al (1994)⁽³⁸⁾ documented increased morbidity (due to recurrent pneumonia and repeated hospitalisations) and mortality in older patients with oropharyngeal dysphagia and associated aspiration in nursing homes. Due to the observational nature of these studies it is, however, difficult to determine whether the dysphagia caused the increased morbidity and mortality or whether it was an indicator of the patient's worsening condition.

A study by Smithard et al⁽³⁹⁾ confirmed that swallowing problems following acute stroke are common, and dysphagia may persist, recur in some patients, or develop in others later in the history of their stroke.⁽³⁹⁾ In this study 61 (51%) out of 121 consecutive patients admitted to hospital in the UK within 24 hours of the onset of their stroke were considered to have a compromised swallow.

A study from Mount Sinai School of Medicine⁽⁴⁰⁾ found that hospitalised PWD averaged a 40% longer hospital stay than patients without the condition. They also had a generally poorer prognosis. The researchers evaluated more than 77 million hospital admissions during 2005-2006, of which 271,983 were associated with dysphagia; the median number of days in the hospital for PWD was 4.04, compared to 2.40 days for patients without dysphagia. Mortality increased significantly in PWD and heart disease, and those undergoing rehabilitation had a greater than 13-fold increased risk of mortality. Patients aged 75 and older were twice as likely to have dysphagia.⁽⁴⁰⁾ Although this study seems to be establishing dysphagia as cause of longer stay in hospital, the authors actually concluded that dysphagia may be present as a consequence of other debilitating diseases that ultimately lead to these morbidities as, in fact, PWD had more diagnoses overall at the time of discharge than patients without dysphagia.

These studies and others like Steel et al (1997)⁽⁴¹⁾ and Lin et al (2002)⁽⁴²⁾ could be indicating not only higher prevalence of dysphagia in institutionalised patients compared to those in their own homes but also higher rates of admissions in

hospitals with longer stays. A summary of prevalence of dysphagia comparing different facilities is highlighted in Table 2.

Facility	Mean age	Prevalence of dysphagia	Studies
Own homes	87+	15-16%	Bloem, et al. (1990) ⁽⁴³⁾ , Chen, et al. (2009) ⁽⁴⁴⁾
Long term care facilities	77	51-68%	Lin et al.(2002) ⁽⁴²⁾ , Rofes, et al. (2011) ⁽²⁸⁾ , Steele et al. (1997) ⁽⁴¹⁾
Hospital /acute geriatric unit	79-85	47-51%	Cabré et al. (2013) ⁽³¹⁾ Smithard et al. (1997) ⁽³⁹⁾

Table 2: Prevalence of dysphagia in different facilities

Older PWD also have lower quality of life. Problems with dysphagia adversely affect social and mental health and lead to considerable isolation and meal-related anxiety.⁽⁴⁵⁾

The social and psychological impact of dysphagia has been limited in reported large studies. A study carried out by Ekberg et al⁽⁴⁶⁾ in 2002 sought to determine the effects of dysphagia on the quality of life of patients and to explore the relationship between the psychological handicaps of the condition and the frequency of diagnosis and treatment. The sample consisted of 360 patients selected on the basis of known subjective dysphagia complaints, regardless of origin, in nursing homes and clinics in Germany, France, Spain and the United Kingdom. The study participants were given a short questionnaire that was specifically modified to elicit problems related to dysphagia rather than to the ageing process.⁽⁴⁷⁾ While 36% per cent of patients acknowledged receiving a confirmed diagnosis of dysphagia, only 32% acknowledged receiving professional treatment for it.⁽⁴⁶⁾ Although these results varied greatly between countries, the study highlighted that patients' perceptions of treatment were usually referred to movement therapy with a SALT or surgery and excluded any pharmacological treatment. However, one of the main findings was the high psychosocial effect of dysphagia where the UK represented the highest rates of anxiety and reduced quality of life related to the disorder when compared to the participants of other countries. It needs to be considered that this study was limited by the fact that

participants identified themselves as dysphagic. Although a selection assessment was carried out, it was recognised by the study that the professionals involved in the assessment had different approaches and difficulties when identifying PWD. Conversely, the study provided results that highlighted the social and psychological impact of dysphagia in institutionalised patients.

In summary, it is important to identify the prevalence of dysphagia in order to estimate the proportion of patients that could benefit from a pharmacy intervention. The identification of the prevalence of dysphagia could also benefit from describing the conditions associated with dysphagia, the age of the population with that disorder and the differences in prevalence between the different levels of care provided (primary, secondary and tertiary care). This will be further explored in chapters 3 and 5.

2.1.4. Dysphagia and ageing

This section explains the normal development of the swallowing process in relation to age.

Developments in modern medicine have improved the diagnosis, prevention, and management of diseases. One visible result has been increased longevity and a greater number of older people. When considering the importance of nutrition on individuals of advanced age, it is essential to explore the physiological changes of swallowing affecting older people.

It is hard to define the boundary between middle age and older people in current society. Recent reviews on what age can be considered old, middle age and young revealed with reasonable consistency that individuals between the age of 40 and 60 are considered middle age while those over 60 are classified as old.⁽⁴⁸⁾ However, current literature has specified that there are age-related changes in the oral, pharyngeal and oesophageal functions and people over the age of 65 swallow slower than those under the age of 45.⁽⁴⁹⁻⁵²⁾

Changes in the oral cavity

While chewing itself does not change with age,⁽⁴⁸⁾ poor dentition and missing teeth cause problems of mastication.⁽⁵³⁾ Also, an increase in connective tissue in the tongue and a decrease in masticatory strength⁽⁵⁴⁾ result in smaller size of boluses and a longer oral phase duration in older individuals causing older people to prefer softer food.⁽⁴⁹⁾ A reduction in the amount of saliva output has also been associated with ageing.⁽⁵⁵⁾

Changes in the pharynx

Dysmotility of the pharyngeal muscles, epiglottic dysfunction, defective closure of the larynx, and cricopharyngeal dysfunction all occur with increased frequency with advancing age.⁽⁵⁶⁾ Pharyngeal webs are also more commonly seen with advancing age, especially in women above 75 years of age.⁽⁵⁶⁾ Neuronal degeneration, vascular compromise and tumour invasion are all common in the older population. These changes can interrupt the swallowing reflex at any point, causing abnormalities of deglutition.⁽⁵⁷⁾

As a consequence of these changes, it is often found that there is also an increased rate of second (bolus free) swallows in older individuals⁽⁴⁸⁾ employed as a second 'clearing swallow' to cleanse the oral and pharyngeal cavities of residue, after their primary swallow of a spoonful of food or a mouthful of fluid.

Changes in the oesophagus

Oesophageal transit and clearance are slower and less efficient in the ageing individual.⁽⁴⁸⁾ Delays in oesophageal emptying and dilatation of the oesophagus⁽⁵⁸⁾ are commonly seen in older people causing non-propulsive, repetitive contractions. These changes result in slower transit of the bolus, increased retention, and dilatation of the oesophagus.⁽⁵³⁾

In summary, it could be said that dysphagia is not a consequence but a symptom of ageing and when it appears caused by other diseases, it should be the cause that is treated rather than the swallowing problem. This section of the literature review is highlighting that further exploration of the awareness of dysphagia and the training required for the management of dysphagia is required. This will be explored in chapters 4 and 5. The perceptions of HCPs on the implementation of training will be covered in chapters and 3 and 4.

2.1.5. Causes of dysphagia in older people

This section explains the main reasons why dysphagia appears.

2.1.5.1. Conditions associated with dysphagia

In older people, central nervous system diseases such as stroke, parkinsonism, and dementia, as well as other factors, including prescribed medication, local oral and oesophageal physiopathology are common causes of swallowing dysfunction. Swallowing disorders in older people are associated with increased mortality and morbidity due to the rates of aspiration, dehydration, pneumonia, malnutrition and

functional decline.⁽⁵⁹⁾ There have been numerous attempts to classify the causes of dysphagia. Hurwitz et al (1975)⁽⁶⁰⁾ and Paterson (1996)⁽⁴⁵⁾ established some of the causes of dysphagia based on a structural and functional classification of the problem (Table 3).

	Structural problem	Neuromuscular problem
Oropharyngeal dysphagia	Neoplasms	Cerebrovascular accident
	Infection or abscess	Amyotrophic lateral sclerosis
	Postsurgical (e.g., laryngectomy)	Multiple sclerosis
	Zenker's diverticulum complication	Brainstem neoplasm
	Vertebral osteophytes	Bulbar poliomyelitis and post-polio syndrome
		Miscellaneous peripheral neuropathies
		Oculopharyngeal muscular dystrophy
		Polymyositis and dermatomyositis
		Myasthenia gravis
		Metabolic myopathy
		Idiopathic neuromuscular dysfunction
Oesophageal dysphagia	Peptic stricture	Achalasia
	Rings and webs	Diffuse oesophageal spasm and related disorders
	Neoplasm (intrinsic or extrinsic)	
	Vascular compression	Motility disorders
	Diverticula	

Table 3: Classification of causes of dysphagia from Paterson⁽⁴⁵⁾ and Hurwitz et al⁽⁶⁰⁾

A much more comprehensive classification of the causes of dysphagia was published in 2006 by Cichero and Murdoch. In this book⁽⁴⁸⁾, the author offered an anatomical classification of the conditions that caused, or were associated with, dysphagia (Table 4). However, due to the complexity of dysphagia and the wide range of conditions associated with it, there are overlaps between those disorders. Furthermore, it also explored medication as a cause of dysphagia.

Cause	Conditions associated
Stroke	Cortical and subcortical strokes Brain stem strokes
Neurological medicine	Cranial nerve lesions Bulbar and pseudobulbar palsy Myasthenia gravis Guillain-barre syndrome Multiple sclerosis
Burns	Thermal smoke and fire burns Caustic burns Thermal food and fluid burns
Palliative medicine	Motor neurone disease Parkinson's disease Progressive supranuclear palsy Alzheimer's disease
Infectious diseases	Poliomyelitis (polio) and post-polio Human immunodeficiency virus and aids
Gastroenterology	Gastroesophageal reflux disease (GORD)(hiatus hernia, Barrett's oesophagus and oesophageal adenocarcinoma) Laryngopharyngeal reflux (LPR) Mechanical oesophageal disorders Oesophageal motility disorders
Trauma	Head trauma Direct laryngeal trauma
Respiratory medicine	Chronic obstructive pulmonary disease (COPD)
Surgery	Head and neck surgery Oral surgery – general Radiation therapy and chemotherapy Cardiac surgery Anterior cervical spine surgery
General medicine	Chronic obstructive pulmonary disease (COPD) Sjogren's syndrome
Psychiatric medicine	Phagophobia
Tracheostomy	

Extracted from pages 237-298, Cichero (2006)⁽⁴⁸⁾

Table 4: Causes and conditions associated with dysphagia

2.1.5.2. Medication-induced dysphagia

It is not only medical conditions that can cause dysphagia but also its pharmacological treatment.

Stoschus & Allescher (1993)⁽²⁴⁾ described how dysphagia can be the consequence of the intake of medication in three different ways:

- as a normal drug side-effect (xerostomia, anticholinergic effects, etc.),
- as a complication of the drug actions affecting the pressure of the oesophageal sphincters,
- as medication-induced oesophagitis and injury.

Dysphagia caused by drug-induced xerostomia

Xerostomia is the medical term for the subjective symptom of dryness in the mouth and is a common side-effect of a large number of commonly used drugs. Dysphagia due to xerostomia can be caused by two general mechanisms. The dryness of the mouth can cause impaired oropharyngeal bolus transport, giving the patient the feeling of impaired swallowing and also a link between xerostomia and oesophagitis has been suggested due to the role of saliva in the deglutition.⁽⁶¹⁾

Most of the time, xerostomia is a reversible drug-induced side-effect and is frequent, particularly in elderly people and psychiatric patients with numerous medicines prescribed on a long-term continuous basis. It remains a neglected clinical problem. Besides the well-known antimuscarinics, antihistaminics and imipraminic antidepressants, many drugs may induce xerostomia. As an example, neuroleptics are commonly used for control of aggressive or disruptive behaviour in older patients with dementia.⁽⁶²⁾ Low potency neuroleptics, such as chlorpromazine, are associated with a low incidence of extrapyramidal side-effects, but frequently cause sedation, orthostatic hypotension, and dry mouth whereas high potency agents, such as haloperidol, are more likely to cause extrapyramidal side-effects, and less likely to cause anticholinergic effects.⁽³⁵⁾

Reduced lower oesophageal sphincter pressure

The smooth and striated muscle function of the oesophagus can be influenced by a variety of drugs. Substances that affect muscle tone and activity can be either inhibitory or excitatory.⁽⁴⁸⁾ Both mechanisms can increase the incidence and severity of gastroesophageal reflux which can subsequently cause dysphagia.

Drugs affecting the striated muscle portion of the oesophagus act mostly via the central nervous system; these substances include sedative and narcotic agents. A

direct effect on the striated muscle can be caused by muscle relaxants like the ones used in anaesthesia or intensive care units.⁽⁴⁸⁾

Antipsychotic or neuroleptics can cause dysphagia as a side-effect due to the extrapyramidal motor disturbances which can lead to an impaired function of the striated muscle of the oropharynx and the oesophagus^(63, 64) which presents as disorder of peristalsis that disrupt the propulsion of swallowed materials to the stomach.

Cancer therapeutic agents, mostly cytotoxic agents, can cause dysphagia through two different mechanisms: first, by predisposing patients to viral and fungal infections of the oesophagus (candida, herpes, cytomegalovirus, etc.) causing ulcers; and secondly by causing an oesophagitis in which no infectious agent can be identified.⁽²⁴⁾

A summary of drugs that have been identified to be the cause of dysphagia through different mechanisms is presented in Table 5.

Mechanism	Drug classification	Drug
Xerostomia	Anticholinergics	Atropine, pirenzepin, Hyoscine
	Antiemetics	Ondansetron
	Antihypertensives	Clonidine, terazosin
	ACE inhibitors	Captopril
	Antiarrhythmic drugs	Disopyramide, mexiletine, ipatropium bromide
	Diuretics	
	Opiates	
	Antipsychotics	
	Antidepressants	
	Muscle relaxants	
Reduced lower oesophageal sphincter pressure		Cholecystikin, sekretin, progesterone, glucagon, neurotensin, vasoactive intestinal polypeptide, dopamine, calcitonin gene related peptide, atropine, hyoscine, theophylline, nitrates, dopamin, calcium antagonists
Oesophageal injury	Antibiotics	Doxycycline, tetracycline, clindamycin, oxytetracycline, minocycline, phenoxymethylpenicillin, erythromycin, tinidazole
	NSAIDs and aspirin	Aspirin, ibuprofen Alprenolol, ascorbic acid, codeine, doxycycline, , ferrous sulphate or succinate, indomethacin, phenylbutazone, prednisolone, potassium chloride, quinidine, theophylline
Extrapyramidal effects	Antipsychotics	Haloperidol Metoclopramide, prochlorperazine, risperidone

Extracted from Stoschus & Allescher ^(24, 35, 65) Sokoloff ^(24, 35, 65) and Gallagher ^(24, 35, 65)

Table 5: Drugs that cause dysphagia ^(24, 35, 65)

Medication-induced oesophageal injury (MIOI)

MIOI is usually caused by local irritation of the oesophageal mucosa by orally ingested drugs. The clinical presentation is characteristic in most patients with MIOI. There is usually a sudden onset of dysphagia (20%), accompanied by retro-sternal chest pain within 4-12 hours after ingestion of the medication.^(24, 66) When swallowing small round tablets, the transit of these tablets can be transiently held up at the upper oesophageal sphincter, the aortic arch, and distal oesophagus immediately proximal to the lower oesophageal sphincter.⁽²⁴⁾ In addition, swallowing decreases during sleep, diminishing the frequency of peristalsis as well as the ability of saliva to dilute medications present in the oesophagus and to neutralise acidic substances.⁽⁶⁷⁻⁶⁹⁾

Acid-producing substances with a pH less than three, i.e. the antibiotics doxycycline, tetracycline and other acidic drugs can produce a moderate-to-severe injury of the mucosal layer.⁽⁷⁰⁾

In summary, the identification of medication used by PWD can help to identify conditions associated with dysphagia, as well as approaches when prescribing for these patients. The analysis of the drugs prescribed in PWD is reflected in chapters 4 and 5 of this dissertation.

2.1.6. Consequences of dysphagia

This section explains the physiological and psychological changes that may appear as a consequence of dysphagia.

There are numerous adverse consequences of dysphagia and these are generally underrated. They range from deterioration in the quality of life (QOL), dehydration, under nutrition, asphyxia, congestion, recurrent respiratory tract infections due to aspiration and death.^(35, 71) Literature has indicated that dysphagia is partly responsible for mortality in acute stroke and it can also lead to complications which hamper functional recovery.⁽⁷²⁾ Other minor complications were highlighted in a study where 796 older participants replied to a questionnaire concerning dysphagia and other chest symptoms. Chest pain, heartburn, and regurgitation occurred significantly more frequently in subjects with dysphagia during the ingestion of food ($p < 0.01$) making apparent that difficulty in swallowing in older people leads to physical problems that may reduce their quality of life.⁽⁷³⁾ Dysphagia is also a significant cause of morbidity of head-and-neck cancer treatment, and the severity of dysphagia is correlated with a compromised QOL, anxiety, and depression.⁽⁷⁴⁾

Aspiration pneumonia is the major cause of morbidity and mortality among older people who are hospitalised or in nursing homes.⁽⁷⁵⁾

2.1.6.1. Aspiration and aspiration pneumonia

Aspiration is defined as the misdirection of oropharyngeal or gastric contents into the larynx and lower respiratory tract. Aspiration pneumonia develops after the aspiration of colonised oropharyngeal contents. However, when the term *aspiration pneumonia* is used, it refers to the development of a pneumonia in the setting of patients with risk factors for increased oropharyngeal aspiration.⁽⁷⁶⁾ Approximately half of all healthy adults aspirate small amounts of oropharyngeal secretions during sleep.^(77, 78)

Clinical signs of aspiration include absent swallow, coughing when lying flat or sitting up quickly from a reclined position, choking, a hoarsened voice during or after eating or drinking, difficulty handling secretions or reflexive cough after water bolus.⁽⁷⁹⁻⁸³⁾ However, other authors have found no significant relationship between an abnormal, reflexive cough and aspiration.^(84, 85) While these signs can be detected at a bedside clinical swallow examination, videofluoroscopy techniques are still considered the gold standard when identifying aspiration.^(26, 81, 86, 87)

A study comparing clinical bedside examination with videofluoroscopy evidence of a swallowing disorder⁽⁸⁸⁾ identified dysphagia in 51% (95% confidence interval (CI) 42–60%) and 64% (95% CI 55–72%) of patients respectively, and aspiration in 49% (95% CI 40–58%) and 22% (95% CI 15–29%) of patients, respectively. However, the authors reported lower sensitivity and specificity in the clinical evidence compared to videofluoroscopy. This was also suggested by other authors as the reason for videofluoroscopy to remain the most accurate tool when evaluating aspiration.^(81, 86, 87)

It is estimated that aspiration occurs in approximately 40 to 50% of PWD and those who aspirate are at an increased risk of acquiring pneumonia.^(89, 90) There is an increased relative risk of pneumonia in stroke PWD (3.17 vs. individuals without dysphagia)⁽⁹¹⁾ and the development of pneumonia from seven times greater^(92, 93) to 11 (11.56)⁽⁹⁴⁾ in stroke patients who aspirate, as compared to those who do not. Despite the fact that dysphagia improves in most patients following a stroke, often dysphagia follows a fluctuating course, with 10 to 30% of patients continuing to have dysphagia with aspiration.^(39, 95) In 2000, Nakagawa et al⁽⁹⁶⁾ evaluated the cough reflex and swallowing in 143 stroke patients that were followed-up for one

year. Forty-three patients had a normal cough reflex and swallow; pneumonia developed in none of these patients. However, pneumonia developed in 24 of the 100 patients with abnormal cough reflex and swallow function. This study demonstrated that older post-stroke patients have a five-fold higher risk of developing pneumonia than older patients without.⁽⁹⁶⁾

The close link between dysphagia and aspiration and aspiration pneumonia indicates that changes in the signs of aspiration could be considered as a patient outcome when implementing interventions that affect the way that patients receive medication.

2.1.6.2. Psychological factors of dysphagia

An increasing number of studies have been carried out on the social importance of dysphagia and its consequences on the quality of life. Dysphagia is considered a disabling disorder for the individual from the functional point of view of swallowing, as well as the emotional-relational viewpoint.⁽⁹⁷⁾ Psychosocial problems in those with dysphagia were given as anxiety at meal times and the wish to eat alone.⁽⁷³⁾ It has a negative influence on the patient's life, worsening it qualitatively from both a social and an emotional point of view. In a survey carried out on 73 patients, with more than 50% over 60 years old, PWD after surgery were found to be more fragile, lacked self-confidence, with limited social relationships and consequently, a tendency to isolation. Most patients, who had previously considered meal times an opportunity to meet others and as a social gathering, no longer believed them to be a pleasant aspect of their day on account of the difficulty in swallowing. As a result, food consistency had to be changed and strategies had to be invented in order to make the meal less embarrassing.⁽⁹⁷⁾ The social 'handicap' is also worse after operations.⁽⁴⁷⁾ Denial and concealment of dysphagia are also common and in a study carried out on a small group of 19 patients it was found that dysphagia influenced a reduction in self-esteem, security, work capacity, exercise and leisure time.

In a European study that included PWD in nursing homes from the United Kingdom,⁽⁴⁶⁾ 84% of patients felt that eating should be an enjoyable experience but only 45% actually found it so. Moreover, 41% of patients stated that they experienced anxiety or panic during mealtimes. Over one-third (36%) of patients reported that they avoided eating with others because of their dysphagia. In a largely older population that might accept dysphagia as an untreatable part of the

ageing process, this study may be indicating that clinicians need to be more aware of the adverse effects of dysphagia on self-esteem, socialisation, and enjoyment of life as it was before dysphagia appeared. For the purpose of the research on PWD, these humanistic outcomes also should be considered.

This section of the literature review is highlighting the need of combining quantitative health outcomes such as aspiration, as well as other qualitative values such as the individual perceptions of the HCPs on the patient's health. Further research on these outcomes is, therefore, presented in chapters 4 and 5.

2.1.7. Screening and assessment of dysphagia

This part of the literature review will focus on current methods for identifying dysphagia.

Speech and language therapists (SALTs) are trained to assess and treat an individual's ability to swallow. A SALT will advise on the consistency required, foods and drinks that are suitable, the best sitting position to make swallowing easier, and certain techniques to aid swallowing.

Despite the range of procedures that can be used for swallowing screening, no specific guidelines for clinical dysphagia assessment have been published as there is currently insufficient evidence available to support their production.⁽⁹⁸⁾ Screening methods at bedside clinical examinations may include, but are not limited to, (a) water swallow tests, such as the Burke water swallow test⁽⁹⁹⁾ or the 3oz. (85mls) water swallow test;⁽¹⁰⁰⁾ (b) swallowing screening protocols including brief assessments of oral motor and sensory function as well as water swallow tests, such as the Toronto Bedside Swallowing Screening⁽¹⁰¹⁾ or the Simple Standardised Bedside Swallowing Assessment;⁽¹⁰²⁾ or (c) clinical (bedside) swallow examinations like the one described by Curfman⁽¹⁰³⁾ in Table 6.

-
1. Assess for alertness and control of secretions.

 2. Determine patient's ability to follow directions.

 3. Have the patient say 'ah' or count to ten to evaluate vocal quality.

 4. Have the patient smile or pucker to note facial symmetry.

 5. Have the patient puff cheeks out to determine lip seal.

 6. Have the patient protrude tongue to determine deviation and tongue mobility.

 7. Have the patient swallow saliva to note if ability to swallow is immediate or delayed.

 8. Observe oral hygiene.

 9. Have patient cough to determine strength.

Table 6: Steps for clinical bedside swallow evaluation extracted from Curfman (2005)⁽¹⁰³⁾

An alternative to bedside clinical examinations is videofluoroscopy. Videofluoroscopy of swallow is a modification of the standard barium swallow examination used in the management of oropharyngeal swallowing disorders. It is described in a number of sources as the 'gold standard' for the assessment of oropharyngeal dysphagia. ^(26, 81, 86, 87)

In a study that examined 128 patients with acute first-ever stroke,⁽⁸⁸⁾ clinical bedside examination, based on the steps indicated in Table 6, was compared with videofluoroscopy. This study found clinical and videofluoroscopy evidence of a swallowing disorder in 51% (95% confidence interval (CI) 42–60%) and 64% (95% CI 55–72%) of patients, respectively. This data was also explored in 2005 in a systematic review⁽⁹⁴⁾ that reported incidence of dysphagia was lowest using cursory screening techniques (37% to 45%), higher using clinical testing (51% to 55%)⁽⁸²⁾ and highest using instrumental testing (64% to 78%). However, the literature contained in this systematic review was limited to only post-stroke dysphagia omitting any other conditions such as Parkinson's disease that are also associated to dysphagia.

Although clinical bedside examination underestimates the frequency of swallowing abnormalities and overestimates the frequency of aspiration compared with videofluoroscopy, it may still offer valuable information for the diagnosis of swallowing impairment.

As part of the assessment, a complete physical examination should also be performed and include neurologic and muscular evaluation with full assessment of

mental status, head and neck position, oral sensory and motor function, protective reflexes, respiratory and laryngeal voice function status, cerebellar function, and weight. Assessment of cognitive and mental status is necessary because dysfunction in either may alter swallowing and nutrition. For example, patients with Alzheimer's disease may chew too quickly or completely forget to swallow, in addition to not recognising food or remembering how to use utensils. Patients with anxiety, severe depression, panic disorders, psychosis, and schizophrenia may present with a globus sensation, decreased attention spans, or poor muscular control, increasing the risk of dysphagia.⁽²⁶⁾

The goal of early assessment and diagnosis is to formulate an intervention plan that provides for safe, adequate nutrition. The interdisciplinary team, including patient and family, identifies interventions focused on correcting or moderating effects of swallowing abnormalities. Interventions include placing the patient in a relaxed, well-supported, anatomically correct position with head and trunk leaning slightly forward.⁽²⁶⁾

The assessment of dysphagia may require different skills and training depending on the HCPs delivering it and further research is required in identifying the different approaches of HCPs to the assessment and its impact on their usual practice. Chapter 4 of this dissertation will investigate those perceptions in the care home environment while chapters 3 and 5 will evaluate training provided by a pharmacist and potential improvements to that training.

2.1.8. Management of dysphagia in older people

This section will outline the strategies involved in the management of dysphagia in older patients.

The management of older PWD requires the coordinated expertise of a number of healthcare professionals, including the patients' primary care general practitioner, respiratory physician, SALT, clinical dietician, occupational therapist, physiotherapist, nurse, oral hygienist, dentist, as well as the primary caregivers.⁽⁷⁶⁾ The aim of the management of dysphagia is to improve the safety, efficiency and effectiveness of the oropharyngeal swallow, to maintain adequate nutrition and hydration, and to improve oral hygiene.

2.1.8.1. Compensatory strategies

The management of dysphagia may include techniques of compensatory strategies such as dietary modification, postural manoeuvres and postural adjustments therapy (exercises to strengthen swallowing musculature).^(17, 104, 105)

The consistency of the patient's food should be individualised according to the findings from clinical testing. Dehydration in older people is one of the leading problems in nursing homes and long-term care facilities.⁽¹⁰⁶⁾ Caution should, therefore, be taken with regard to the modification of fluids, as adherence with thickened liquids is often reduced. Small sips of cold water in patients with good oral hygiene may bring relief to thirsty patients and may reduce the resultant dehydration.⁽¹⁰⁷⁾

Swallow manoeuvres place aspects of the pharyngeal swallow under voluntary control.⁽¹⁰⁸⁾ The findings from the clinical bed examination and videofluoroscopy will direct which strategies and exercises are most beneficial for a specific patient; however, environmental strategies are often key in managing the dysphagia of older people.⁽⁷⁶⁾ These changes, which may include modifying the feeding environment or altering the feeding schedule, frequently improve nutritional intake. This implies that the right education, training, and counselling of the patient and/or their caregiver plays an important role on the management of dysphagia.

2.1.8.2. Enteral feeding tubes (EFT) and surgery

An enteral feeding tube (EFT) is a medical device which bypasses the oesophagus and is used to provide nutrition to patients who cannot obtain nutrition by mouth, are unable to swallow safely, or need nutritional supplementation. Various EFTs are available for delivering medications and nutrients to the patient. The tubes are typically classified by site of insertion (e.g., nasal, oral, percutaneous) and location of the distal tip of the feeding tube (e.g., stomach, duodenum, jejunum). Enteral tube feeding may be indicated in older patients with severe dysphagia and aspiration when improvement of swallowing is likely to occur.⁽⁷⁶⁾ However, tube feeding is not essential in patients who aspirate as, in fact, studies have found no data to suggest that tube feeding of patients with advanced dementia prevented aspiration pneumonia, prolonged survival, reduced the risk of pressure sores or infections or improved function.^(109, 110) While a study carried out in 143 dysphagic patients demonstrated that the incidence of pneumonia was significantly higher in stroke PWD who were fed orally compared to those who received tube feeding

(54.3% vs. 13.2%, $p < 0.001$) the study failed to recognise that the orally-fed patients had a higher functional status. Another study in the UK showed that intubation proved to be an effective method of relieving dysphagia in patients unsuitable for curative treatment; however, 44% of the patients involved in the study developed further dysphagia due to tube dysfunction, and 19 patients (37%) were readmitted for further procedures to restore swallowing.⁽¹¹¹⁾

The use of surgery and prosthetic devices is another more radical form of compensation for dysphagia. Together, these devices may be useful for the treatment of speech and swallowing disorders where the deficit lies with the soft palate region.⁽¹¹²⁾

2.1.8.3. Pharmacological management of dysphagia

There is limited literature in the management of dysphagia with medication as general swallowing treatment programmes are associated with a reduced risk of pneumonia.⁽¹¹³⁾

Swallowing reflex is known to be impaired in elderly patients with aspiration pneumonia⁽¹¹⁴⁾ and therefore it is important to explore whether drugs that improve the quality of the swallow may help to prevent aspiration pneumonia. In a study carried out in Japan, the use of ACE inhibitors was preferred when compared with other antihypertensive drugs. This study explored the incidence of pneumonia in 127 stroke PWD treated with ACE inhibitors compared with 313 PWD treated with other antihypertensive agents. During a two-year follow-up period, pneumonia was diagnosed in 7% of patients receiving an ACE inhibitor (antihypertensive drug) compared to 18% in patients receiving other hypertensive agents (relative risk, 2.65; 95% CI, 1.3 to 5.3; $p = 0.007$).⁽¹¹⁵⁾ The authors of the study could not specify at the time the reasons for the improvement on the swallowing disorder and the rate of pneumonia. However a recent review⁽¹¹⁶⁾ explained that patients taking ACE inhibitors often suffer from chronic cough associated with throat irritation. This coughing helps protect the respiratory tree from aspiration of pharyngeal contents and increases clearance of inhaled organisms.⁽¹¹⁶⁾

A consecutive study, demonstrated a significantly lower rate of pneumonia in older people hypertensive patients randomised to an ACE inhibitor compared to an angiotensin-II receptor antagonist. Although this study was aiming to identify the best antihypertensive treatment for patients with high blood pressure and stroke, the authors provided evidence that patients with oropharyngeal dysphagia should

be considered for treatment with an ACE inhibitor (even if normotensive) as the incidence of pneumonia in the ACE inhibitors-treated group was significantly lower ($p = 0.013$) than the one in the group treated with other antihypertensive drugs.⁽¹¹⁷⁾ However, these studies did not reveal the types of formulation compared (liquid medication, tablets, etc.) nor identified any association with any funders who could bias the research.

A UK study in four patients suggested that pharmacological agents such as nifedipine (calcium-channel blocker and antihypertensive drug) may have a role in the management of stroke-related dysphagia and merit further investigation.⁽¹¹⁸⁾ However, the small sample size and the fact that the participants were post-stroke patients may limit the validity of the results as dysphagia can rapidly resolve post-stroke.⁽⁴⁸⁾

One study has reported improvement of dysphagia with the use of cisapride,⁽¹¹⁹⁾ with three patients completely recovering their ability to swallow. This could be due to the biofeedback (psychotherapy used in conjunction with the drug) and further research was recommended as later studies have not been able to establish a therapeutic effect of cisapride on dysphagia.⁽¹²⁰⁾ The symptomatic improvement may possibly be due to increasing the number of peristaltic contractions and oesophageal emptying of solids.^(121, 122) However, the product license for cisapride (used to treat gastric and digestive disorders in adults and children) was suspended by the Medicines Control Agency after five deaths in the United Kingdom and 125 deaths worldwide that were thought to be associated with the drug.⁽¹²³⁾

It can be seen that evidence to support the use of medicines for the management of dysphagia is limited and treatment via this route is rare.

Summarising, the management of dysphagia may require different strategies and techniques and these may involve several HCPs with different expertise. This interaction between professionals can be seen as a challenge to the management of dysphagia and, therefore, the perceptions of that interaction need to be explored. The perceptions of nurses on the role of the prescriber, pharmacist, nurse and SALT and on the interactions between them are explored in chapter 4 of this thesis.

2.1.9. Dysphagia in acute and long-term care facilities

This section outlines some of the problems related to dysphagia in older patients in hospitals and care homes.

It is recognised that hospitalisation of older patients may result in functional decline despite cure or repair of the condition for which they were admitted. Hospitalisation can result in complications unrelated to the problem that caused admission or to its specific treatment for reasons that are often avoidable.⁽¹²⁴⁾

The use of acute-care hospitals by older people is rising rapidly, particularly in the age group 75 and older.⁽¹²⁵⁾ Hospital admission and bed rest commonly involve enforced immobilisation, reduction of plasma volume, accelerated bone loss, increased closing volume, and sensory deprivation.⁽¹²⁴⁾ These factors could trigger an irreversible functional decline as a consequence of the vulnerability of the older population.

It is also important to identify the different types of care provided in long-term care facilities as care homes for older people may provide personal care (residential) or nursing care. Residential care homes are registered to provide personal care and will offer support, ensuring that basic personal needs, such as meals, bathing, going to the toilet and medication, are taken care of. In some homes more able residents have greater independence and take care of many of their own needs. Some residents may need medical care and some care homes are registered to provide this. These are often referred to as nursing homes or care homes with nursing. In this type of facility, nurses are responsible for the care for all the patients assigned to them. Generally, the nurse is assigned a group of patients each day. For that group, the nurse must monitor vital signs, pass medications, change dressings, check the status of wounds, attend patient care-plan meetings, oversee carers, administer enemas and start intravenous (IV) medications and fluids. They may also counsel families and provide other personal hygiene care, depending on nursing assistant staffing levels. The number of patients varies according to the size of the facility and the type of shift. Generally, midnight shift nurses will be responsible for more patients as most of them sleep through the night and require little care. Some care homes with nursing also specialise in certain types of disability, for example, dementia and EFTs.

Through inspections and creation of policies, the Care Quality Commission (CQC) is in charge of making sure that hospitals and care homes (as well as dental and GP surgeries, and all other care services) provide people with safe, effective, compassionate and high-quality care according to national standards in England.⁽¹²⁶⁾

However, only a small amount of research is conducted in care home settings in the UK. In the last few years, the Dementia and Neurodegenerative Diseases Research

Network (DeNDRoN) and Enabling Research in Care Homes (ENRICH) have focused their efforts in providing information, tools, case studies and further resources for facilitating research in care homes and since 2012 a whole new network of care homes are ready to participate in research.

2.1.9.1. Hospital

Within healthcare institutions, it is estimated that 47% to 51% of older patients in hospitals have dysphagia during their stay and at the time of discharge. This is especially predominant after stroke.^(31, 39, 127) The consequences of dysphagia on hospitalised patients with heart disease⁽¹¹⁰⁾ and pneumonia⁽¹²⁸⁾ and its association with laryngopharyngeal abnormalities (particularly with intubation) have also been recognised.⁽¹²⁹⁾ Despite 15.2% of referrals of PWD to other departments being inaccurate (dysphagia is erroneously identified),⁽¹³⁰⁾ PWD are believed to benefit from a multidisciplinary dysphagia management programme that has the potential to enhance patient care while decreasing the cost of healthcare delivery for the hospital.⁽¹³¹⁾

In Norfolk, UK, a retrospective database study, including 1,330 stroke patients (median age 78) indicated that PWD have worse outcome in terms of inpatient mortality and length of hospital stay, odds ratios 12.5 (95% CI=8.9–17.3) and 3.9 (95% CI=3.3–4.6) respectively, than those without dysphagia. The presence of dysphagia appears to determine the likelihood of a poor outcome. However this study didn't clarify whether this effect is related just to stroke severity or results from problems related directly to dysphagia.⁽¹³²⁾

In the US, the National Hospital Discharge Survey (NHDS), 2005-2006, was evaluated for presence of dysphagia and the most common co-morbid medical conditions. A total of 271,983 hospital admissions were identified as associated with dysphagia, which was most commonly associated with fluid or electrolyte disorder, oesophageal disease, stroke, aspiration pneumonia or congestive heart failure. The median number of hospitalisation days for all PWD was 4.04 compared with 2.40 days for those patients without dysphagia. Mortality also increased substantially in PWD associated with rehabilitation, intervertebral disk disorders, and heart diseases.⁽⁴⁰⁾

These results indicate that dysphagia is related to hospital length of stay and is a poor prognostic indicator. Early recognition of dysphagia and intervention in the hospitalised patient is advised to reduce morbidity and length of hospital stay.⁽⁷⁶⁾

2.1.9.2. Care homes

When considering the high incidence of cerebrovascular and degenerative neurologic diseases in nursing home residents, it is not surprising that up to 75% of care home occupants are suffering from dysphagia,^(82, 133-135) and that those residents with oropharyngeal dysphagia and aspiration have a 45% 12-month mortality.^(38, 127) A variety of symptoms may indicate that a care home resident has a swallowing disorder.

A retrospective study⁽¹³⁶⁾ in Valencia, Spain collected information from 254 PWD across 107 care homes with nursing. The study identified that only 54% of nursing homes had a specific diet for the management of dysphagia and 51% used nasogastric feeding. The most frequent complications in these patients were lung aspirations (75%), dehydration (39%), malnourishment (32%) and pneumonia (31%).⁽¹³⁶⁾ This data correlates with other studies that indicated that PWD in care homes are not positioned properly, they were fed inappropriate food and/or liquid consistencies, or were given large, unmanageable bites of food and forced to eat quickly.⁽⁸²⁾ It is also concerning that only 22% of these residents had been referred to a SALT or an occupational therapist for evaluation.

Residents in long-term care facilities (LTCF), especially those orally-fed with dysphagia, are prone to dehydration. Dehydration was found to be very common amongst orally-fed patients but surprisingly was also common in those patients fed via nasogastric tubes.⁽¹³⁷⁾ Dehydration in older people is one of the leading problems in nursing homes and long-term care facilities.⁽¹⁰⁶⁾ Caution should, therefore, be taken with regard to the modification of fluids, as adherence to treatments with thickened liquids is often reduced.⁽¹⁰⁷⁾

Additionally, the magnitude of problems identified has implications for both resource and staff-training requirements in long-term care facilities.⁽⁴¹⁾ Clinicians who work in long-term care settings rely heavily on the clinical examination because instrumented examination procedures such as videofluoroscopy, endoscopy or manometry are difficult to obtain.⁽¹³⁸⁾ The research literature, however, does not support the use of clinical examination as a method of detecting aspiration or planning diet or management modalities.

Summarising, dysphagia is a debilitating condition but it may be reflected differently in primary care when compared to secondary care. Further research should describe the differences observed in the development of dysphagia between

acute and long-term care facilities. These differences are explored in chapters 3 and 5 of this thesis.

2.1.10. The role and interaction of healthcare professionals in dysphagia

This section outlines a brief description of the role of HCPs involved in dysphagia and describes the models of interaction between them.

A multidisciplinary approach to the assessment and management of dysphagia has been shown to be beneficial for the patients.^(139, 140) The SALT will assist with making an accurate diagnosis and may recommend oral muscular exercises and specific swallowing techniques. Muscle exercises to strengthen weak facial muscles and improve coordination may be recommended. The dietician can advise on the nutritional content of food and drink and the texture and temperature of the diet, as well as provide advice on foods that will suit the individual's ability to swallow and diets to help reduce the risk of aspiration.⁽¹⁴¹⁾ The physiotherapist can advise on the optimum positioning of the patient for eating and drinking (the patient should remain in an upright position while eating and drinking). The nurse can ensure that the patient is in a relaxed environment at meal times and is well-positioned⁽¹⁴²⁾ when administering food and medication. The prescriber has an important role in the diagnosis and treatment of swallowing disorders. However, it is currently expected that bedside clinical examinations to identify dysphagia are carried out by the SALT. While the role of the pharmacist is traditionally limited to the provision of medication, a complete description of this role is described broadly later on in this dissertation.

If dysphagia is suspected, the healthcare provider should involve an interdisciplinary team for additional diagnostic evaluation. Most of the time, an interdisciplinary team includes the carer, nurse, speech pathologist, dietician, patient, and family.^(75, 143) The interdisciplinary team, including patient and family, identifies interventions focused on compensating, moderating or correcting effects of swallowing abnormalities.⁽²⁶⁾

The literature has identified different models of interaction between the HCPs in their roles of identifying, assessing and managing dysphagia.⁽³⁴⁾ These are some examples:

- model A: the SALT trains nursing staff to conduct swallowing screenings. Nursing staff perform swallowing screenings and refer patients with identified swallowing problems to a SALT for a comprehensive swallowing assessment.

Given nursing staff turnover, training may need to be offered on a regular basis. In one study reported in the literature, the SALT maintained a presence in the emergency department for several months with the purpose of conducting swallowing screenings and, at the same time, demonstrating screening procedures to nursing staff who ultimately assumed the responsibility of conducting swallowing screenings for future patients.⁽¹⁴⁴⁾ This model may allow for senior nursing staff to become sufficiently skilled to train future nursing staff in screening,

- model B: the medical practitioner performs swallowing screening in the course of his or her regular medical evaluation. He or she requests further swallowing assessment by the SALT when he observes signs of swallowing difficulty. However, medical practitioner swallowing screening tends to be less structured than swallowing screening conducted by nursing staff,⁽¹⁴⁵⁾
- model C: model A or B followed by an automatic referral within a specific timeframe (often 24–48 hours) for swallowing assessment by SALT for all patients admitted with a specific diagnosis. This model may include an on-going in-service training module for nurses during annual education days or staff inductions, as well as frequent in-services/presentations to medical residents and/or attending doctors,
- model D: all patients are automatically referred to SALT for swallowing screening or assessment,
- model E: nursing staff contact the SALT on an on-call basis to request screening for patients who have presented to accident and emergency with conditions that are recognised to pose a possible risk of dysphagia.

Model A (in which nurses are trained to perform screening) has received the most attention in research studies probably due to the cost-efficiency of training nurses and extending their role in dysphagia. In Canada, Martino and colleagues designed an extensive training programme for nurses to perform screening procedures using a tool known as the TOR-BSST (Toronto Bedside Swallowing Screening Test).⁽¹⁰¹⁾ The accuracy of screening results was studied in comparison to videofluoroscopy. The TOR-BSST offered an accurate method to identify stroke PWD in the acute and rehabilitation setting with confidence that patients with a negative screen will not have dysphagia.

Cichero et al⁽¹⁴⁶⁾ in 2009, during the development of a dysphagia screening tool involving 38 nurses in a seven-week study where 442 patients were screened on two general medical wards, highlighted that improved quality of care and cost

savings are likely when training nurses in the management of dysphagia. Also an audit carried out in Heartlands Hospital, Birmingham, identified how a systematic approach to train nurses reduced the time patients wait for dysphagia screening from 35 hours to less than one hour.⁽¹⁴⁷⁾

By enabling non-specialist staff to screen and manage the more persistent dysphagia cases, practitioners with higher dysphagia management competence can be used in a more consultative role for the more complex and long-term cases.⁽¹⁴⁸⁾ However, no national guidance on developing these programmes or on the roles, responsibilities and competencies of the respective professions was available until recent years, leading to considerable variation of practice across the UK. In 2006, the National Dysphagia Competence Steering Group created the Inter Professional Dysphagia Framework⁽¹⁴⁹⁾ (IDF) with the aim of informing strategies or developing the skills, knowledge and ability of SALTs, nurses and other healthcare professionals/non-registered staff, to contribute more effectively in the identification of people with, and in the management of, feeding/dysphagia.

This nationally recognised framework refers to five levels of dysphagia practitioner:

- awareness: they need an awareness of the presenting signs and symptoms of dysphagia and will need to be aware of the associated health risks. Professionals at this level will need to know how and to whom the observed difficulties should be highlighted,
- assistant dysphagia practitioner: the assistant dysphagia practitioners can demonstrate basic skills that contribute to the care and treatment of individuals presenting with dysphagia. They will contribute to the implementation of dysphagia management plans prepared by others in the care team and report to foundation, specialist or consultant dysphagia practitioners. Assistant dysphagia practitioners may prepare oral intake for individuals and contribute to feeding and providing fluids,
- foundation dysphagia practitioner: the foundation dysphagia practitioners can demonstrate acceptable performance undertaking a protocol-guided assessment of swallowing. They will identify presenting signs and symptoms, and will undertake a protocol-guided assessment of dysphagia. They will be working to pre-defined criteria, which may include the use of liquids, semi-solids and solids, as appropriate to the individual's age and needs. They are able to initiate and implement the actions dictated by the protocol and disseminate this

- information to the individual, the carer and the team. They demonstrate knowledge and understanding of relevant policies, procedures, and guidelines,
- specialist dysphagia practitioner: the specialist dysphagia practitioners can demonstrate competent performance in the assessment and management of dysphagia, working autonomously with routine and non-complex cases. They will receive referrals from others in the care team, prioritise referrals in line with local risk assessment procedures, and conduct a comprehensive assessment of the feeding/swallowing function. In this comprehensive assessment they will utilise a range of assessment techniques based on current research/best practice and any relevant policies, procedures and guidelines. They will generate a working hypothesis, analyse the emerging information and they will provide advice and guidance to other care team members taking a holistic view of the individual. They will provide rehabilitation programmes and suggest interventions to manage the ongoing problems with feeding or swallowing,
 - consultant dysphagia practitioner: the consultant dysphagia practitioners can demonstrate skilled activity with advanced theoretical knowledge and understanding, based on current research/best practice and any relevant policies, procedures and guidelines. They will be able to determine the underlying cause of complex dysphagia problems, develop and test hypotheses, identify and trial interventions to rehabilitate or compensate for the presenting difficulties, and devise extensive dysphagia management plans. They will undertake specialist interventions, and/or alternative examinations, particularly for those individuals who present with unusual, complicated or co-existing difficulties. They may identify that further assessments are needed and refer for specialist assessments, interpreting the results and modifying dysphagia management plans accordingly.

Dysphagia still remains a shared field between professionals as a multidisciplinary approach is essential in its assessment and management. However, the roles of these HCPs are not always defined and it seems that the full responsibility of training and delivery of dysphagia services falls on the SALTs. With the role of the pharmacist in the management of dysphagia virtually non-existent in current literature, it is hard to identify the approaches towards other concerns in dysphagia such as the pharmaceutical care of PWD. Nurses still seem to be the focus of many studies on the implementation of assessment tools and training on dysphagia probably due to the cost-efficiency of nurse-led interventions.

In summary, numerous models can be identified to describe the interaction between HCPs. However, the impact of this interaction on the nurses' practice and ultimately on the care received by PWD needs to be explored. A theoretical model could benefit the implementation of pharmacy interventions on the administration of medicines and hence chapter 4 will apply a theoretical model to the current practice as perceived by nurses in care homes.

2.2. Medication and dysphagia

This section describes the physical, legal and technical challenges associated with the provision of medication to PWD.

2.2.1. Oral medication in older PWD

The use of medications is common in older people and this population has the highest risk of medication-related problems. The increasing number of older people in the population is leading to a growth in the amount of treatments prescribed for chronic diseases. As these diseases require treatment with a greater number of medicines, the problems of polypharmacy are becoming more important. In 2000 a systematic review exploring 143 articles tried to determine the extent and nature of polypharmacy in older people and to identify the morbidity and mortality which may result from polypharmacy in general practice.⁽¹⁵⁰⁾ While the study defined polypharmacy as the use of two or more drugs, the quality of the studies failed to draw conclusions about the extent to which polypharmacy is associated with health problems. However, further efforts in recent years to reduce unnecessary polypharmacy in older adults and updates in the literature have found that polypharmacy continues to increase and is now a recognised risk factor for important morbidity and mortality.⁽¹⁵¹⁾

Polypharmacy is associated with a number of harmful effects. The incidence of adverse drug reactions (injury caused by taking a medication)(ADRs) and drug interactions increases with advancing age,⁽¹⁵²⁾ partly due to changes in the pharmacokinetics and pharmacodynamics associated with ageing but also to the presence of multiple disease states and their consequent drug treatments. Drug adherence (the likelihood of patients taking their medication as expected) is known to decrease as the number of drugs prescribed increases.⁽¹⁵²⁾ Patients prescribed multiple medications are also more likely to be admitted to hospital, have a longer length of stay, an increased mortality rate and to be readmitted after discharge.⁽¹⁵²⁻

¹⁵⁴⁾ Polypharmacy may also be a predictor of nursing home placement, malnutrition, fractures and impaired mobility.⁽¹⁵⁴⁾

As previously discussed, dysphagia is more often found in older patients due to its relation with ageing and chronic conditions associated with advanced age such as dementia and Parkinson's.

A qualitative study carried out by Kelly et al⁽¹⁵⁵⁾ recruited 11 PWD over 60 years old. The study found in some of the participants that the adherence to medication in PWD was affected by the medicine's importance (as perceived by the patient), the number of medicines, the complexity of the regimen, the degree of respect for the prescriber, the ability to remember to take medicines and the medicine's formulation. Participants identified that the formulation can affect the ease with which patients are able to take their medications. They also generally preferred liquid medicines but found tablets more normal. This study also highlighted the lack of awareness of the availability of liquid medicines on the part of participants, resulting in some crushing their tablets and enduring the unpleasant taste and the concerns of PWD on how to take their medication. However, these results were limited by the self-selected nature of the interviewees, small sample size, the short length of the interviews and the similar demographic data of the participants and, therefore, they may not represent the experiences of the whole population.

A survey carried out nation-wide in the US in 2003 revealed that over 40% of adults (over 18 years old) in the general community experience problems swallowing tablets and capsules.⁽¹⁵⁶⁾ Of 679 adults who reported difficulty swallowing solid dose forms in a centre for swallowing disorders, 26% were older patients. In this group, 14% disclosed that they had delayed taking a dose of their medication, and 8% had skipped a dose completely. These findings indicate that some adults who have difficulty swallowing these forms of oral medications do not comply with prescribed regimens. Poor adherence to oral medication regimens may be elevated in the patient with dysphagia.⁽¹⁵⁷⁾ For example, 15% of all residents in surveyed long-term care facilities reported difficulty swallowing tablets and capsules. Of this group, 5% regularly expectorated this medication, while 27% did not even attempt to swallow these medications.⁽¹⁵⁸⁾ PWD who fail to comply with prescribed medication dosing are likely to encounter further increases in morbidity and mortality.

A survey carried out by Morris (2005),⁽¹⁵⁹⁾ which included 154 patients (most over 75 years of age) and received an overall response rate of 94%, reported problems

swallowing medications. Interestingly, 80% of those patients said that they did not inform their doctor or pharmacist if they could not take their medication and only 22% of patients said that their doctor or nurse asked them if they had problems swallowing before issuing a prescription. The survey was carried out based on a computer search that identified patients with one or more risk factors for dysphagia and receiving medications. The high recruitment rates may be due to the fact that the doctor and the research nurse approached the patients or carers in person or over the phone. Patient consent was taken on receipt of the completed questionnaire and no ethics committee approval was sought.

Evidence suggests that healthcare providers need to be more pro-active in identifying dysphagia and not assume ability to easily swallow solid dosage forms and when it is identified, methods to effectively deliver oral medications need to be improved to minimise non-adherence.⁽¹⁵⁷⁾ If a patient fails to take their medication this not only represents a waste of the medicines themselves but increased future costs to the health system due to poorer health outcomes.⁽¹⁶⁰⁾

In summary, the awareness of dysphagia by HCPs and the adherence to treatment can be compromising the management of the condition. Therefore, the prescriber's approaches to the management of dysphagia and the way that nurses administer medication need to be explored and described. The observations of drug rounds in care homes, as explained in chapter 5, provide an opportunity to identify these issues.

2.2.2. Prescribing for PWD

This section highlights some of the challenges faced by HCPs when prescribing medication for PWD.

2.2.2.1. Appropriateness of prescribing to PWD

Appropriate prescribing is a general phrase encompassing and compressing a range of values and behaviours to express in a simple term the quality of prescribing.⁽¹⁶¹⁾ Many other words are used to describe prescribing quality, such as good, poor, appropriate or inappropriate, optimal or suboptimal, and error. Not only quality but also quantity can compromise the appropriateness of prescribing. Under-prescribing refers to failure to prescribe drugs that are needed and over-prescribing refers to prescribing more drugs than are clinically needed.⁽¹⁶¹⁾

Mis-prescribing, or inappropriate prescribing (IP), refers to incorrectly prescribing a drug that is needed^(162, 163) and it can be described as the use of medicines where the risk of an adverse drug event outweighs the clinical benefit, particularly when safer or more effective alternatives are available.⁽¹⁶⁴⁾ For example, Cornish in 2005 described two cases in which PWD had been administered solid formulations orally and through the EFT where alternative liquid formulations were available.⁽¹⁶⁵⁾ This caused respiratory depression and loss of efficacy of the drugs, respectively.

Older people are particularly vulnerable to problems like inappropriate prescribing.⁽¹⁶⁶⁾ Parkinsonism and cerebrovascular disease commonly result in dysphagia requiring more creative prescribing methods to ensure that adequate serum-drug-concentrations are achieved.⁽¹⁶⁷⁾ As a consequence, PWD may be prescribed less medication than needed as highlighted in a recent study in the UK which reported that dysphagia is a factor to under-prescribe medication such as warfarin.⁽¹⁶⁸⁾

2.2.2.2. Prescribing and law

The legal framework in the UK which regulates the provision of medicines is formed by the Medicines Act⁽¹⁶⁹⁾ and the Consumer Protection Act.⁽¹⁷⁰⁾ Additionally, patients have redress through negligent practice in the UK via civil law courts.⁽¹⁷¹⁾

Consumer Protection Act 1987⁽¹⁷⁰⁾

This Act gives initial statutory protection for all products. The Consumer Protection Act 1987 also implements the Product Liability Directive issued by the European Union to protect consumers from harmful products, including medicines, and makes a producer liable for damage caused by a defective product. If harm is caused to a patient by an inherent defect in the medicinal product then liability would fall to the producer not the practitioner. This act is relevant to patients when medicines are supplied which are defective or if medicines are altered prior to administration and become defective.

Medicines Act 1968⁽¹⁶⁹⁾

The Medicines Act 1968 (now superseded by Human Medicines Regulations 2012) is the principle statutory framework that regulates the licensing, supply and administration of medicines in the UK. The legislation is interesting as it starts by prohibiting all activities associated with medicines and then provides a long list of

exceptions to this rule. Within this, the Medicines Act places a duty on the Secretary of State for Health to identify those medicines which represent a danger to the patient if their use is not supervised by an appropriate practitioner (registered medical practitioners, registered dentists, vets, independent and supplementary prescribing nurses and pharmacists (Medicines Act 1968, s.58 (1)) and, therefore, they require a prescription before they can legally be supplied. Consequently, prescription-only medicines can only be administered by or in accordance with the directions of an appropriate practitioner and any amendments to the initial directions on a prescription must be referred back to the appropriate practitioner.⁽²³⁾ The legal classification of a medicine is determined when a marketing authorisation, previously known as a licence to supply, is obtained.⁽¹⁷²⁾ Whilst the Medicines Act allows independent prescribers to supply and administer medicines with and without licences, other healthcare professionals without prescribing rights may only legally supply medicines within the bounds of their marketing authorisation.

However, it is frequently observed in practice how the instructions from the prescriber are sometimes ignored, i.e. a recent study involving the administration of 1,045 doses to PWD reported that tablets were crushed or capsules opened for 25.5% (266/1,045) of solid oral doses and for 44% of these doses, the tablet crushing had not been authorised by the prescriber (117/266).⁽¹⁷³⁾ If a medicine was used in an unlicensed manner (dose, route or form were outside the licensed terms), it is, in effect, a transgression of the Medicines Act and a criminal offense. Furthermore, if the medicine is found to harm the patient then the Consumer Protection Act may be utilised to demonstrate further transgression of criminal law.

To ensure that criminal legislation is adhered to it is necessary for healthcare professionals to adhere to the policy commonly referred to as the “5Rs” which involves:

- right medicine is given to the,
- right patient at the,
- right time in the,
- right form of the drug at the,
- right dose.

In recent years, nine rights (the five rights plus right response, documentation, action and route) have been proposed in order to decrease the incidence of medication errors.⁽¹⁷⁴⁾

For criminal law to be successfully applied the case has to be demonstrated 'beyond all reasonable doubt' and consequently the burden of proof required is set at a high level. It is, therefore, difficult to demonstrate that the incorrect dose or drug was given and taken without serum blood levels to corroborate it or that the authorised act of crushing a tablet actually caused the adverse event seen.

Two key principles of common law apply to the medicines: the person's right to self-determination (respect must be given to the wishes of the patient)⁽¹⁷⁵⁾ and the practitioner's duty to be careful when prescribing and administering medicines to those in their care.⁽²³⁾

Even though a general practitioner has the right to prescribe a medicine, the medicine can only be given to the person with their consent providing the patient has mental capacity (Mental Capacity Act 2005, section 4).⁽¹⁷⁶⁾

In cases when patients who actively refuse medication but who are judged not to have the capacity to understand the consequences of their refusal, the covert administration of medicines may be necessary or appropriate. Covert medication is the administration of any medical treatment in disguised form. This usually involves disguising medication by administering it in food and drink. As a result, the person is unknowingly taking medication. In the case of lack of capacity, and when there is no designated decision maker appointed under the Mental Capacity Act 2005, the decision to act in the best interests of a patient rests with the general practitioner.

Off-label or off-licence prescribing are terms used to describe the use of licensed medicines in a dose, age group, or by a route not in the product specification outlined within the marketing authorisation.⁽²³⁾ When prescribing off-label, full accountability of any harm that the patient may suffer as a consequence of the off-licence administration goes to the prescriber and administrator if they were aware of the potential for harm and in a position to intervene.⁽¹⁷⁷⁾

An unlicensed medication does not have a marketing authorisation. For example, a doctor may prescribe a medicine for an individual patient in a form that's not readily available, to be made up as a special preparation by a specialist

pharmaceutical company. In some cases, the pharmacist may arrange to obtain an unlicensed medicine from a manufacturer who makes it especially, under a 'Specials' manufacturing licence. PWD are often required to only take liquid medication or to have it administered through the enteral feeding tube. When liquid licensed medications are not available, the use of liquid unlicensed medications, or 'Specials', may be a sensible alternative for the practitioners to prescribe. However, if a patient is harmed by an unlicensed medicine which has been appropriately authorised they or their relatives may actively sue the practitioners involved to obtain compensation.⁽²³⁾

Negligence

A patient can make a claim under civil law for compensation if they are able to demonstrate on the 'balance of probabilities' that the practice they have experienced is negligent. To be successful in court they need to demonstrate that the practitioner had a duty of care⁽¹⁷⁸⁾ to them, the practice was below standards which would normally be expected from a competent practitioner and harm resulted from this.

Duty of care extends to all aspects of the doctor/patient relationship including advice giving, diagnosis, treatment and prescribing practice.^(178, 179) In the case where an older male patient with angina died after his granddaughter had been told to crush his slow-release verapamil tablet by a practice nurse, the family would probably be able to argue that the nurse had a duty of care and that the practice was below that of a competent practitioner; however, they may find it more difficult to demonstrate 'beyond all reasonable doubt' that the harm resulted from the tablet crushing. It may have been possible to demonstrate that this occurred on the 'balance of probabilities', however.⁽¹⁸⁰⁾

In the study by Stubbs et al,⁽¹⁷³⁾ tablet crushing was avoidable by the correct use of more suitable preparations in 57.5% (153/266) of doses. Failing to consider these issues would render GPs liable to negligence if harm is caused or in trespass to the person for unlawful touching if it cannot be objectively demonstrated to be in the person's best interests.

Consequently when prescribing and administering medicines to patients it is always preferable to supply a medicine within its marketing authorisation as the responsibility for any subsequent harm which the patient was not already aware of at the point of receipt goes to the manufacturer. If a medicine is to be supplied outside of the marketing authorisation then this can only be authorised by

prescribers and the safety of the decision requires careful consideration. In such situations, it is preferable to record the decision and rationale as this then provides evidence of practice expected of a competent practitioner. If the patient refuses to receive the medicine then any decision to covertly administer the medicine must be carefully considered taking into account the patient's ability to be involved in the decision, the wishes of relatives and what is in the patient's best interests.⁽¹⁷⁶⁾

This section is highlighting that liability concerns and awareness of dysphagia are factors that may be affecting prescribing practices. Further research on the approaches to these concerns is presented and discussed in chapter 5 of this dissertation.

2.2.3. Administering oral formulations

This section outlines the different oral formulations of a drug and explores the issues surrounding their administration.

Recent literature has highlighted the importance of the formulation of the medicines for PWD.^(155, 181, 182) The different types of oral formulations may represent advantages and disadvantages for PWD and it is, therefore, relevant to explore these differences and how the literature has identified their acceptability within PWD.

2.2.3.1. Tablets and capsules

A tablet comprises of a mixture of active substances and excipients, usually in powder form, pressed or compacted into a solid dose.⁽¹⁸³⁾ The excipients can include diluents, binders or granulating agents, glidants (flow aids) and lubricants to ensure efficient compacting; disintegrants to promote tablet break-up in the digestive tract, sweeteners or flavours to enhance taste and pigments to make the tablets visually attractive. A polymer coating is often applied to make the tablet smoother and easier to swallow, to make it more resistant to the environment (enteric-coated formulations), or to enhance the tablet's appearance. About two-thirds of all prescriptions are dispensed as solid dosage forms.⁽¹⁸⁴⁾

Capsules generally consist of a gelatine shell in two parts with the drug and a filling agent held inside. This is easier for manufacturers to put together and is very often, due to the torpedo shape, easier for patients to swallow.⁽²³⁾

As the ingredients in each tablet or capsule are carefully chosen to not adversely affect the active drug and its absorption, it is never appropriate to crush two different tablets or open two capsules together in the same container.⁽²³⁾ The inactive ingredients from one could theoretically adversely affect the absorption of the active ingredients in another.

In order to control the location in the digestive system where a drug is absorbed, an enteric coating is sometimes applied to tablets and capsules.⁽¹⁸⁵⁾ Most enteric coatings work by presenting a surface that is stable at the highly acidic pH found in the stomach, but breaks down rapidly at a less acidic environment present in the small intestine. Enteric coats are placed on tablets to protect the stomach lining from the drug, e.g. NSAIDs, to protect the drug from the acidic environment, e.g. proton pump inhibitors, or to release the drug where it is required to work, e.g. sulfasalazine in Crohn's disease. Often the abbreviations such as 'EC' or 'Gastro-resistant' are added beside the name of the drug to indicate the additional coating.

Sometimes, capsules and tablets can be prescribed as modified-release formulation. This is a mechanism used in tablets or capsules to release a drug over time in order to be released at a controlled rate into the bloodstream.⁽¹⁸⁵⁾ These formulations are used to prevent peak serum concentrations which arise from immediate release tablets and can cause side-effects in certain medicines, e.g. theophylline, nifedipine and to improve adherence in medicines with short half-lives e.g. felodipine as the patient is required to take the medicine once a day rather than twice daily. The disadvantage of such medicines is that they frequently contain more than the recommended single dose found in an immediate-release formulation. Consequently, any tampering with these formulations increases the chance of side effects and toxicity and as the body metabolism increases to remove the drug more rapidly, it results in a period of time when the drug concentrations are too low to be effective.

Between 15% and 30% of residents in care homes have difficulties in swallowing their medicines,⁽¹⁵⁸⁾ where medicines are most commonly prescribed as tablets and capsules due to cost, availability and convenience. With a professional responsibility to ensure that PWD receive their medicines, it has been found that nurses resort to inappropriate crushing of tablets, dispersing them in water or mixing them with foodstuffs⁽¹⁸⁶⁾ and many of them have not received recent training about enteral feeding in their own homes.⁽¹⁸⁷⁾ The practice of tablet crushing and dispersing prior to administration can be appropriate; however, in

some instances it may be dangerous and, if not authorised by a prescriber, illegal.⁽¹⁸⁸⁾ There is also the problem of a potentially altered response to the drug as changing the formulation through crushing the tablet or opening the capsule can affect its pharmacokinetics, therapeutic efficacy and side-effect profile⁽¹⁸⁹⁾ and result in significant harm. For example, crushing controlled-release formulations such as morphine sulphate tablets (MST), which are designed to release the drug slowly over 8-12 hours, can result in a rapid increase in blood concentration to potentially toxic levels. This can cause the patient to become drowsy and develop respiratory problems and patients do not receive the prolonged pain control expected from the formulation.⁽¹⁹⁰⁾ The clinical sensitisation of PWD and HCPs exposed to contact with the medication or allergy to certain drugs like antibiotics are other problems associated with crushing medication. Exposure to certain drugs also represents a risk of carcinogenesis (tumour formation) from anti-cancer medication.^(189, 191)

In the UK, the administration of medication via enteral feeding tubes was the most common reason to crush tablets and open capsules as reported in a study carried out in 30 hospital wards.⁽¹⁹²⁾ Also, 20.6% of a total of 1,177 participants in an American survey in an acute hospital unit reported routinely crushing and administering enteric-coated medications whilst 14.6% routinely crushed modified-release medications.⁽¹⁹³⁾ Equally, in an Australian survey, 31 hospitals reported that medications were modified at the bedside and most of the tablets or capsules had standard-release characteristics. Eight hospitals crushed modified-release dosage forms and 11 hospitals crushed medications with a narrow therapeutic index. Multiple crushing was a common practice (84% of hospitals).⁽¹⁹⁴⁾ The practice seen in care homes derives from training within secondary care where similar problems are still being identified.⁽¹⁹⁵⁾ In 2002, Wright carried out a survey of 540 nurses attending conferences. The research found that 40% of the nurses that worked in UK care homes admitted to crushing medicines on every drug round; 29% every day and 12% every week.⁽¹⁸⁸⁾ Additionally, nurses reported regularly crushing medicines which were modified-release or had enteric coats and rendering medicines unlicensed prior to administration when licensed alternative formulations were available. There are a large number of surveys carried out internationally on this practice but the difficulty with such surveys is their construct validity, i.e. they are unlikely to provide an accurate estimate of true practice which could only be ascertained via covert observation. While there are a smaller number

of observational studies and these are not covert they are more likely to provide a more accurate reflection of current practice.

In an observational study of medication administration on two long-stay wards for older mentally ill inpatients in the UK, the administration of 1,257 oral doses of medication at 36 medication rounds was observed. Tablets were crushed or capsules opened for 25.5% (266/1,045) of solid oral doses. For 4.5% (12/266) of doses, crushing was specifically contra-indicated by the manufacturer. In 57.5% (153/266) of doses, tablet crushing was avoidable by the correct use of more suitable preparations and caused contamination, spillage and hygiene problems.⁽¹⁷³⁾

An observational study of medicine administration errors in nursing homes in the Netherlands⁽¹⁹⁶⁾ identified a lower crushing rate of 16% (330 observations out of a total of 2,025).⁽¹⁹⁶⁾ Higher prevalence was reported in another observational study carried out in 10 different aged-care facilities in South Australia where tablets were crushed or capsules opened in 34% (n=1,207) of administrations.⁽¹⁹⁷⁾ Very recently, medicines administration to 160 patients across two aged-care facilities in Australia revealed that of the 75 medications crushed prior to administration, 24 (32%) were identified as not suitable for crushing.⁽¹⁹⁸⁾ The results of this study are in agreement with other reports in the literature of a high prevalence of solid dosage form modification in residential aged-care, recording an overall incidence rate of 18% of residents having their tablets crushed prior to administration.^(173, 197, 199) Although some of these studies are carried out outside the UK, their practice and the structures of their health systems are based on UK models and may add important value to the research in PWD. To date, however, there are no UK based studies regarding observed practice in care homes.

The practice of crushing tablets or opening capsules involves altering the formulation of a medication affecting the marketing authorisation granted to a pharmaceutical company. Therefore, if a tablet is crushed, a capsule opened, a medicine tampered with, or if a medication is given via an enteral tube, it is being administered outside the medicine's product licence and the manufacturer ceases to be liable for any harm that occurs from taking the drug under the Consumer Protection Act 1987.^(188, 200-204) There is also the problem of the clinical sensitisation of PWD and HCPs exposed to contact with the medication or allergy to certain drugs like antibiotics and the risk of carcinogenesis.^(189, 191)

When dysphagia is identified in a patient it is appropriate to first ascertain whether suitable alternative formulations are available before resorting to tampering with the medication which may render its administration unlicensed.

2.2.3.2. Dispersible, orodispersible and buccal formulations

Difficulties with and resistance to tablet taking are common and particularly prevalent in geriatric, paediatric, and psychiatric patients.⁽²⁰⁵⁾ Dysphagia can exacerbate adherence problems and undermine treatment efficacy.⁽²⁰⁶⁾ Difficulty in swallowing conventional tablets and capsules has emerged as an additional factor in medication non-adherence and has led to the development of alternative drug delivery strategies such as orodispersible tablets (ODT).⁽²⁰⁷⁾ ODT is a drug dosage form designed to be dissolved on the tongue rather than swallowed whole. The ODT serves as an alternative dosage form for patients who experience difficulty in swallowing or where adherence is a known issue and, therefore, the provision of an easier dosage form ensures that the medication is taken. An additional reason to use ODTs is the convenience of a tablet that can be taken without water. Dispersible tablets are typically dispersed in water or another liquid before they are administered to the patient. This drug product is designed for patients experiencing difficulties in swallowing solid dosage forms like tablets or capsules. While this formulation counts on the advantage of obtaining an increased rate of absorption that can be desirable for example for pain relief, it is highly unlikely that the dose is evenly distributed when adding water to dispersible products. This creates problems when only part of the dispersed formulation is administered.

Buccal tablets are those formulated to dissolve when held between the cheek and the gum, permitting direct absorption of the active ingredient through the oral mucosa. This route is used for anti-nausea drugs and nicotine replacement gums. Anti-nausea medicines are particularly suitable for buccal administration as the nausea itself can cause swallowed tablets to be vomited and, therefore, rendered ineffective.⁽²⁰⁸⁾

ODTs offer some advantageous features over other conventional dosage forms (especially for patients of specific age groups and with disease conditions) such as the removal of the need to swallow a tablet or capsule, thereby reducing the effort and physiological stress associated with tablet swallowing. Thus, ODTs ease oral administration of medication in paediatric and geriatric populations where swallowing may be challenging.⁽²⁰⁹⁾ ODTs also offer easily-measured dosing⁽²¹⁰⁾

thus accuracy of dosage can be obtained.⁽²⁰⁶⁾ The system gives rapid onset of action and increase in bioavailability compared to conventional tablets due to the dispersion in saliva and pregastric absorption. Pregastric absorption avoids first-pass metabolism which can provide a great advantage in drugs that undergo hepatic metabolism.^(211, 212)

A survey of 1,576 Norwegian PWD concluded that in order to achieve good adherence and optimal pharmacotherapy, it is important for medical practitioners and pharmaceutical personnel to be aware of the general problems connected to swallowing tablets, to enable them to select the correctly formulated drug for their patients.⁽²¹³⁾ ODTs may alleviate the problem of swallowing tablets and they offer substantial advantages over ordinary tablets, are more convenient to administer, and enhance the potential for improved adherence in patients who experience difficulty in taking tablets.

2.2.3.3. Liquid medicines and specials

PWD are at risk of adverse drug events caused by the inappropriate modification of the dosage form through the crushing of a tablet or capsule that should not be crushed. In these cases, liquid medicines can be the most appropriate alternative to tablets or capsules for patients who can't swallow solid dose formulations and other routes cannot be considered. A recent study that observed 266 administrations estimated that liquid formulations could be a more suitable alternative in up to 57.5% of those observations.⁽¹⁷³⁾ Liquid medication is designed for PWD; however, they may not always be the best alternative. The switching of solid medications to a liquid form for patients who develop dysphagia can be considered potentially unsafe practice since the patient may have difficulty with both solids and liquids and should only be carried out after receiving specific SALT recommendations.⁽²¹⁴⁾

Liquid medicines are obtained in the form of solutions, syrups, suspensions and mixtures. These are complex formulations that contain not only the active ingredient but a liquid vehicle that provides long term stability, a suspending agent to ensure that the drug is evenly distributed throughout the formulation and often preservatives, flavourings and colourings to make the final mixture longer lasting and more palatable to the patient.⁽²³⁾ These characteristics not only make them easier to swallow than solids but also make them frequently possible to administer via an enteral feeding tube without the need for further manipulation.⁽²¹⁵⁾

However, the advantage gained in the administration of liquid products is often lost because of the inaccuracy of the devices used to measure and administer them.⁽²¹⁶⁾ Such variations may be related to factors such as pouring the liquids from different-sized bottles, the colour of the liquids, and the adequacy of available light. Perhaps the most important factor in measurement is related to the care practiced by the person performing the measuring.⁽²¹⁶⁾ In a study involving 282 carers in American care homes, approximately one in 10 participants measured doses of liquid medication with a volume error greater than 10%, and these dose errors were more common with the etched dosing cup, the dosing spoon, and the printed dosing cup.⁽²¹⁷⁾ This coincides with another similar study by Sobhani et al⁽²¹⁸⁾ in 2008 that showed how droppers and dosing cups were the most commonly used devices in the home for measuring liquid medications. The carers and nurses were more likely to measure an acceptable dose with an oral syringe when compared with a dosing cup. However, a large proportion of study participants were unable to measure an accurate dose with either device.⁽²¹⁸⁾ Lawrence suggested a possible explanation to this fact after a study reviewing notes from SALTs that revealed that while recommendations for swallowing solid oral medications were often present, recommendations regarding the administration of liquid medications were absent in the patients' notes and medication charts.⁽²¹⁴⁾ These challenges were faced when administering liquid medication could potentially be leading to treatment failure according to a survey carried out across 130 participants in primary care clinics in 2000.⁽²¹⁹⁾

Additionally, while the cost of licensed liquid formulations is a significant issue for the NHS,⁽²²⁰⁾ more recently, concerns have been raised regarding cost of unlicensed liquid medicines which nurses request for use in their residents in care homes to ease medicines administration and reduce reliance on tablet crushing and dispersing.⁽¹⁵⁸⁾ As an example, the analysis of specials prescribing in a primary care Trust in 2008 found the average cost to be £102, with prices reaching over £2,000.⁽²²¹⁾

This section highlights the need of exploring the formulation choices made by the prescriber when prescribing to PWD. Identifying ways of optimising the use of medication could be an essential part of a pharmacy intervention and, therefore, the cost of alternative formulations needs to be explored. This is described in chapters 3 and 5 which aim to estimate the financial impact of suggested alternative formulations for PWD.

2.2.4. Challenges to the administration of medication

The next section will describe the three main challenges faced in the administration of medication by nurses to PWD.

As the various studies previously described in this chapter show, the administration of medication to PWD is a complex task that can be challenged by numerous elements. When focusing exclusively in the interaction between the patient and the nurse or carer at the time of the medicines administration, three main problems may challenge this process:

- problems related to the person administering medication,
- problems related to challenging administrations,
- problems in the acceptability by the patient.

This section will explore these problems through the perception of nurses on the administration of medication, the impact on whether medicines are taken as agreed or directed and the impact on the medication administration errors.

2.2.4.1. Nurse views on administering medication

Nurses administer medications every day as part of their practice. Consequently, many studies have explored nurses and the role they play in medication administration. The focus of these studies has often been limited to drug errors, rather than investigating a broader view of the medication administration process from the nurses' point of view.

Several qualitative studies have been identified to reflect some of the likely concerns and perceptions of factors affecting the quality in the administration of medications and altering medication dose forms prior to the administration to patients in their practice setting. These studies outlined categories that were re-classified into broader themes that could provide us with an indication of the perceptions that nurses have on administering medication to PWD. Table 7 summarises the themes reflected in these studies based on the categories identified.

These themes highlight environmental factors, knowledge and skills and time constraints as the main concerns of the nurses. The time concerns coincide with the results of an observational study by Thomson et al⁽²²²⁾ in 2009 where it was concluded that time requirements for the medication administration process are substantial in long-term care facilities, particularly when nurses are unfamiliar with

residents and in the presence of interruptions, potentially affecting the efficiency, quality, and safety of this process.

Numerous concerns highlighted the importance of the interaction between healthcare professionals and between the nurses and the patients^(199, 223-226) and how this communication can be affected by the limited information resources in facilities like care homes.⁽¹⁹⁹⁾ The lack of pharmaceutical knowledge was also highlighted by a survey carried out in 2006 with 34 nurse participants from six different intensive care units in the State of Qatar. The study identified how little was known by the nurses about the different codes used by drug companies in the modified release formulations and about the consequences of crushing these preparations.⁽²²⁷⁾

Theme	Categories
Time	Time constraints. ^(224, 225)
Communication with HCPs	The groups of professionals involved ⁽²²³⁾ Informal communication with other healthcare professionals ⁽¹⁹⁹⁾ Multidisciplinary communication as a contextual barrier ⁽²²⁴⁾ Miscommunications with other Healthcare professionals ⁽²²⁵⁾
Interaction between nurse and patient	Personal attributes of individual staff ⁽²²³⁾ Concerns about implementing appropriate procedures in individual facilities ⁽¹⁹⁹⁾ Patient participation ⁽²²⁴⁾ Interventions for patient care ⁽²²⁶⁾
Nurse's skills	Client implications of the nursing education ⁽²²³⁾ Lack of knowledge ⁽²²⁵⁾ Difficulty of coordinating information and policies about altering medications ⁽¹⁹⁹⁾
Impact of nurse's practice on patient	Client implications of the nursing practice ⁽²²³⁾ Administration of medication with risk ⁽¹⁹⁹⁾ Monitoring medications ⁽²²⁶⁾ Provision of individualised care ⁽²²⁴⁾
Work Environment	Information vacuum ⁽¹⁹⁹⁾ Context of the procedures ⁽²²³⁾ Interruptions and distractions ⁽²²⁵⁾

Table 7: Nurses' perceptions on the factors affecting the administration of medication

No qualitative studies were identified through literature search that were specific to nurses' views on dysphagic patients until 2009 in a study by Kelly et al.⁽²²⁸⁾ Kelly carried out focus groups with a consultant in medicine for older people, a clinical nurse specialist in stroke management, another in enteral nutrition, an endoscopy nurse, hospital and a community pharmacist, a senior lecturer in pharmacy practice, a dietician, and a SALT. Six themes were identified:

- the wide spectrum of dysphagia,
- medicine formulation,
- problems with data flow,
- the primary function of swallowing is nutrition rather than taking medication,
- cost of medicines,
- therapeutic dilemmas.

The fact that only some of the themes identified by Kelly et al⁽²²⁸⁾ have been previously contemplated by the studies presented in Table 7 suggests that administering medication to PWD is a complex process. Although the results from this study by Kelly also include views from other HCPs, the multidisciplinary interaction was also an emerging theme as this study concluded that improvements in inter-professional communication are needed to improve medicine administration to dysphagic patients.

2.2.4.2. Medication adherence

Adherence has been defined as the “active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behaviour to produce a therapeutic result” (Delamater (2006) page 74).⁽²²⁹⁾ Other authors have described it further, exploring how a patient's behaviour in terms of taking medication coincides with medical or health advice.^(230, 231) These definitions imply that the patient has a choice and that both patients and providers mutually establish treatment goals and the medical regimen.⁽²²⁹⁾ Medication adherence usually refers to whether patients take their medications as prescribed (e.g. twice daily), as well as whether they continue to take a prescribed medication.⁽²³²⁾

When exploring adherence it is important to consider demographic, psychological, and social factors, as well as the healthcare provider, the medical system, the

disease, and the treatment related factors.⁽²²⁹⁾ These factors can affect the adherence related to complex dosing or administration requirements, cost, and a lack of understanding of the importance of adherence.⁽²³³⁾

Medication adherence is a complex phenomenon. As individuals assume greater responsibility for decisions about their healthcare, it is essential to support adherence behaviours that reflect a clinician-patient partnership. The term adherence is intended to be non-judgmental, a statement of fact rather than of blame of the prescriber, patient, or treatment⁽²³⁴⁾ and it should not be confused with compliance. Compliance includes taking medication at the desired strength, in the proper dosage form, at the appropriate time of day and night, at the proper interval for the duration of the treatment, with proper regard to food and drink, and consideration of other concomitant medications (both prescribed and non-prescribed) and herbal remedies.⁽²³⁵⁾ However, the notion of compliance is an outdated concept and should be abandoned as a clinical goal in the medical management of patients as it has connotations of dependence and blame and does not move the patient forward on a pathway of better clinical outcomes.⁽²³⁶⁾

As the older population in the UK is increasing,⁽²³⁷⁾ dysphagia is becoming a major problem in medicine adherence.^(213, 238-240) Older people are more susceptible to the adverse effects of medicines and more prone to practical difficulties with medicine-taking such as poor eyesight, trouble opening packaging or difficulty swallowing tablets.⁽²⁴¹⁾ In 2005, a survey of patients attending community pharmacies demonstrated that 68.7% of patients responded to experiencing difficulty with swallowing oral solid dose forms by not taking them.⁽²³⁹⁾ In a study carried out in New Zealand on 316 people over 75 years old, low scores in adherence were related to difficulty swallowing solid dose forms in 14% of the cases.⁽²⁴²⁾ (If a patient is prescribed a painkiller for an injury to be taken as one tablet four times a day for a week but takes only two tablets a day for five days, the adherence would be 36% (10/28)).

As dysphagia may impair a patient's ability to adhere to a prescribed regimen,^(213, 243) HCPs can play a significant role by monitoring patients, identifying potential barriers to adherence, and implementing appropriate intervention strategies. It is recognised that the most frequently reported problem by patients with respect to swallowing is the large size of oral solid dosage forms.⁽²³⁾ If barriers to adherence with solid formulations cannot be overcome, the use of smaller size formulations⁽²³⁾ with equivalent efficacy and acceptable safety can be considered.⁽²³³⁾ Other

alternatives are the replacement with liquid or orodispersible formulations. Difficulty in swallowing conventional tablets and capsules has led to the development of alternative drug delivery strategies such as ODTs.⁽²⁰⁷⁾ Patients with physical swallowing issues have shown a strong preference for ODTs over conventional tablets. A crossover study of 36 adult PWD in the US aimed to evaluate differences in swallowing physiology and safety in PWD between conventional tablets and ODTs.⁽¹⁵⁷⁾ 76% expressed a preference for an ODT compared with a conventional tablet formulation and the authors concluded that the ODT medication delivery technology may provide benefit to adults with dysphagia in convenience, compliance, and accuracy of dosing. Despite the fact that this research was supported by a grant from a pharmaceutical company, there is clear advantage on the use of ODT formulations that may increase the adherence to treatment.

2.2.4.3. Medication Administration Errors (MAEs)

The term 'medication error' has been described as: "A mistake that happens in the stages of either prescribing, dispensing or during the administration of medication where a patient is injured, killed or potential harm could arise" (Wolf (1989) page 8).⁽²⁴⁴⁾ More recently, this term has been redefined as: "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of the healthcare professional or patient" (Jevon (2010) page 146).⁽²⁴⁵⁾

With regards to the administration of medication, MAEs can be defined as: "A deviation from the prescriber's order as written on the patient's drug chart" (Allan (1990) page 555).⁽²⁴⁶⁾ However, it must be noted that a drug prescription does not necessarily contain all the information required to administer a drug safely such as the viscosity required in the administration or the interaction with other drugs.

The Department of Health states that any trained member of staff from health or social care can administer a medicine that has been prescribed by someone who is authorised to do so.⁽²⁴⁷⁾ Although many different healthcare professionals are legally permitted to prescribe and dispense medicines, it is usually nurses and carers who administer the drug to a patient. As a consequence, the responsibility for avoiding potential medication errors is largely held by the nurses.⁽¹⁷⁴⁾ Allan and Baker's definition also does not take into account the responsibility of nurses to use their professional judgement to ensure medicine administration is clinically

appropriate and safe,⁽²⁴⁸⁾ i.e. nurses should not blindly give the medicines prescribed.

Healthcare professionals are often involved in procedures and skills that affect patients, but the administration of medicines is a procedure that will be carried out on a day-to-day basis. Lengthy and repeated drug rounds open up a risk for potential administration errors almost to be made on a regular basis.⁽²⁴⁹⁾ It has been highlighted in the literature that one of the reasons why adverse events are so common is that clinicians are human, and thus prone to error.^(174, 249-252) In a study carried out by Wilson et al⁽²⁵⁰⁾ in 1995 in Australia, the majority (81%) of adverse events associated with errors in the administration of medication were related to one or more human factors, such as lack of knowledge, care or attention. Of the errors that were considered highly preventable, less than 1% were not associated with human error.

Medication errors are one of the main causes of morbidity and mortality of patients who are hospitalised⁽¹⁷⁴⁾ as they carry a high risk of adverse events. In the UK, as many as 10% of hospitalised patients may experience an adverse event, and some may experience multiple events.^(253, 254) Studies from other countries suggest that up to 30% of patients will experience an adverse event, and these come at a very high cost.⁽²⁵⁵⁻²⁵⁷⁾ This clearly shows the need to reduce medication errors so that patients receive safe and efficient care around the medication administered.^(258, 259) Vincent et al (2001)⁽²⁵³⁾ reported that patients experiencing an adverse event in hospitals in the UK remain in hospital for almost nine additional days, incurring an extra annual cost to the value of £290,268 to the Trusts concerned. While these costs are likely to be higher in the present time, in 1999, it was estimated that the total annual cost of preventable adverse events in North America was between £10billion and £17billion.⁽²⁶⁰⁾ However, the most important cost of a medication error is the effect on the patient. Medication administration errors can cause patients to experience adverse events making them 4-7 times more likely to die than those who do not.⁽²⁵⁵⁾

2.2.4.3.1. Types of errors

The best way to understand how medication errors happen and how to prevent them is to consider their classification. The literature recognises that the classification of errors can be contextual, modal, or psychological.⁽²⁶¹⁾ Contextual classification deals with the specific time, place, medicine and people involved.

Modal classification examines the ways in which errors occur (e.g. by omission, repetition, or substitution). Psychological classification explains events (nature of the errors). While contextual classification of errors provides a description of the error within its context, it is hard to explore and classify all the categories described as they can be almost unlimited.

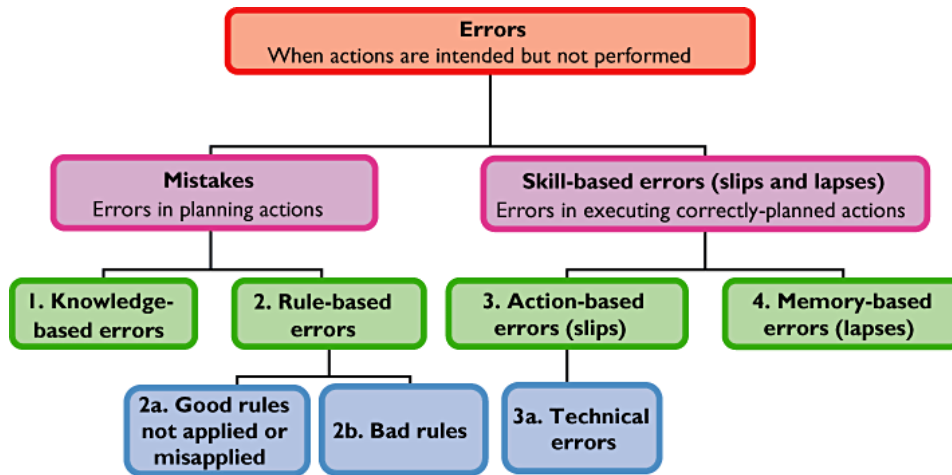
On the contrary, current theories and definitions of psychological and modal classifications are broad but limited to certain categories. For that reason, this literature review will only explore the psychological and modal classification of errors without, however, underrating the importance of contextual categories and their power to contribute to a deeper classification of the type of errors identified. Classification of medication errors is important because the probabilities of errors of different classes are different, as are the potential remedies.⁽²⁶²⁾

Psychological classification

Classification based on psychological theory tends to be preferred⁽²⁶³⁾ as it explains events rather than merely describing them. However, it concentrates only on human behaviours rather than systems-based sources of error. This classification has been discussed in detail and supported by several authors.^(262, 264)

Psychologists consider an error to be a disorder of an intentional act, and they distinguish between errors in planning an act and errors in its execution.⁽²⁶⁵⁾ If a prior intention to reach a specified goal leads to action, and the action leads to the goal, all is well. If the plan of action contains some flaw, that is a 'mistake'. If a plan is a good one but is badly executed, that is a failure of skill.^(262, 266) This theory highlights four types of medication error (numbered 1–4) as indicated in Figure 3. Mistakes can be divided into (i) knowledge-based errors and (ii) rule-based errors. Failures of skill can be divided into (iii) action-based errors ('slips', including technical errors) and (iv) memory-based errors ('lapses').

Knowledge-based errors can be related to any type of knowledge, general, specific, or expert. It is general knowledge that penicillin can cause allergic reactions; knowing that your patient is allergic to penicillin is specific knowledge; knowing that co-fluampicil contains penicillin is expert knowledge. Ignorance of any of these facts could lead to a knowledge-based error.⁽²⁶⁵⁾ Rule-based errors can further be categorised as (a) the misapplication of a good rule or the failure to apply a good rule; and (b) the application of a bad rule.



(Extracted from Ferner & Aronson (2006) page 1013)⁽²⁶²⁾

Figure 3: The classification of medication errors based on a psychological approach⁽²⁶²⁾

Norman, in 1981, defined action-based errors as ‘the performance of an action that was not what was intended,⁽²⁶⁷⁾ e.g. a slip of the pen, when a doctor intends to write penicillin but writes penicillamine’. Technical errors form a subset of action-based errors. They have been defined as occurring when ‘an outcome fails to occur or the wrong outcome is produced because the execution of an action was imperfect’.⁽²⁶⁸⁾ An example is the addition to an infusion bottle of the wrong amount of drug.⁽²⁶¹⁾ Memory-based errors occur when something is forgotten; for example, giving penicillin, knowing the patient to be allergic, but forgetting.⁽²⁶⁵⁾

Modal classification

Attempts are often made by researchers and committees to define or classify the type of medication errors. Many of those definitions are unsatisfactory and have been rejected because of the lack of transferability to other studies.⁽²⁶⁹⁾ Nevertheless, those definitions may be useful in formulating new and better ones, since they may contain helpful ideas. This review aims to examine published definitions of the types of errors to produce a definition that incorporates what is relevant and omits what is not, adding relevant features that may have previously been missed.

In 2002, Barker et al⁽²⁷⁰⁾ carried out a study across 36 healthcare institutions in the US to identify the prevalence of medication errors in patients. This study classified and defined the types of errors found in the administration of drugs in eight different categories. These eight types of MAE were included in a systematic

review in 2006 by McBride-Henry & Foureur⁽²⁷¹⁾ but McBride-Henry & Foureur also included intra venous push rates in their classification.

More recently, a similar study in hospitals in East Anglia, UK⁽²⁷²⁾ combined a classification of errors from the American Society of Hospital Pharmacist⁽²⁷³⁾ with categories reported by Dean.⁽²⁷⁴⁾ This study by Kelly et al included types of MAEs that were not mentioned in McBride-Henry & Foureur⁽²⁷¹⁾ such as “wrong formulation” and “deteriorated medicine”. In the same way, McBride-Henry & Foureur⁽²⁷¹⁾ included “drug compatibility” and “allergy related error” that were not identified within Kelly’s categories. Wolf in 1989 defined MAEs as:

“Mistakes associated with medicines and intravenous (IV) infusions that are made during the prescription, transcription, dispensing and administration phases of medicine distribution” (Wolf (1989) page 8).⁽²⁴⁴⁾

As per Wolf’s definition, we need to include errors derived from inappropriate prescribing in our categories as these are also a contributing factor to the MAE. In conclusion, MAEs can be classified as 14 different types when combining the categories identified by the literature. These categories are outlined and defined in Table 8.

Error Type	Definition
Omission	Patient fails to receive medication by the time of the next scheduled dose
Unordered drug	Administration of a dose that was not prescribed for the patient concerned
Wrong drug	Administration of a dose that was not the medicine prescribed
Extra dose	Administration of a prescribed additional dose of a prescribed medicine
Wrong dose	Incorrect quantity supplied
Wrong formulation	Administration of the correct dose in a formulation different to the recommended/prescribed
Wrong dose preparation and administration	Errors in preparation of a medicine prior to its administration
Wrong route	The administration of the correct drug by a route or site that was not prescribed
Wrong time	The Administration of a medication \pm 60 minutes from its scheduled time
Deteriorated medicine	The physical or chemical integrity of the medicine has been compromised
Drug Compatibility	Administration of two drugs that should not be administered in conjunction
Allergy related error	Administration of a drug that triggered an expected allergic reaction
Inappropriate prescribing	Administration of a drug as a result of an inappropriate drug or formulation prescribed
Others	Any medication error which does not fall into any of the above
Summarised from Wolf (1989), ⁽²⁴⁴⁾ ASHP (1993), ⁽²⁷³⁾ Dean (1999), ⁽²⁷⁴⁾ Barker et al.(2002), ⁽²⁷⁰⁾ McBride-Henry and Foureur (2006), ⁽²⁷¹⁾ and Kelly et al. (2011). ⁽²⁷²⁾	

Table 8: Modal classification of MAEs

2.2.4.3.2. Reporting errors

One of the limitations of retrospective studies is the use of self-reported errors as an outcome measure. Because the identification and reporting of medication administration errors (MAE) is not automated and is a voluntary process, it is important to understand potential barriers to MAE reporting. A range of factors

have been identified as contributing to medication administration errors in these settings and these include: staff being unable to find the patient or the medicine, inadequate protocols, staff knowledge and training, interruptions⁽²²²⁾ and environmental factors.⁽²⁷⁵⁻²⁷⁷⁾ Other individual factors like the fear of disciplinary action, poor communication at the change of shift,^(278, 279) disagreement over error, reporting effort and administrative response⁽²⁷⁹⁾ are contributing factors which decrease the amount of errors reported. The factors that contribute to the identification and reporting of MAEs need to be considered when designing studies that aim to explore or implement interventions where the MAE is used as an outcome measure.

2.2.4.3.3. MAEs in secondary care

The number of medicines administration errors in UK hospitals has been an increasing concern for the Department of Health for the last decade.⁽¹⁷⁷⁾ It was estimated in a UK study that approximately 4% of hospital inpatients experienced an adverse event resulting from a medication error related to prescribing, dispensing or administration.⁽²⁸⁰⁾ In order to reduce the amount of serious errors related to the use of prescribed drugs, the Department of Health set up the National Patient Safety Agency (NPSA). This independent body ran a mandatory reporting system for logging all failures, mistakes, errors and near-misses across the health service. Since it was set up, there had been a significant year-on-year increase in reporting of medication incidents, the majority of which were administration/supply errors.⁽¹⁷⁷⁾

Numerous studies have been carried out to explore the prevalence of MAEs in secondary care. We carried out a literature review of studies that had identified MAE rates as an outcome measure. For the purpose of this dissertation, studies reporting MAEs of intravenous administration were discarded and only observational studies were included. However, the technique used for the observations, the professional background of the observer and the criteria for identifying errors were often different in the studies and, therefore, that data may not always be comparable. These studies are discussed in detail in this section and summarised in Table 9.

Study	Setting	Method	Number of errors observed	MAE rate* (95% CI) §	Including Time errors
Barker et al.(1982) ⁽²⁸¹⁾	10 Hospitals (US)	Observation of nurse-led medicine administration rounds	Not available	11.0	Not available
Bates et al.(1995) ⁽²⁸²⁾	Urban tertiary care hospital (US)	Self-report by pharmacists, nurse review of all patient charts, and review of all medication sheets	530	5.2% (4.7 to 5.6%)	No
Ridge et al.(1995) ⁽²⁸³⁾	6 Hospital wards (UK)	Direct observations of medicine rounds	115	3.5% (2.9 to 4.1%)	Yes
Dean & Barber, (2000) ⁽²⁸⁴⁾	2 Hospital Wards (UK)	Direct observations of medicine rounds	6,067	4.2% (3.7 to 4.7%)	No
Lisby et al. (2005) ⁽²⁸⁵⁾	Hospital (Denmark)	Direct observations, unannounced control visits, and chart reviews	1,065	41% (39.1 to 42.9%)	Yes
Barker et al. (2002) ⁽²⁷⁰⁾	Hospital (US)	Observation, by a research pharmacist	605	18.8% (17.04 to 20.2%)	Yes
Calabrese et al.(2001) ⁽²⁸⁶⁾	Intensive care units (US)	Observational evaluation	187	3.3% (2.8 to 3.7%)	No
Tissot et al. (1999) ⁽²⁸⁷⁾	Medical intensive care unit (US)	Prospective study using the observation technique	132	6.6% (5.5 to 7.7%)	No
Kelly et al. (2011) ⁽²⁷²⁾	Stroke and care-of-older people wards at four acute general hospitals (UK)	Observation of 65 nurse-led medicine administration rounds	817	38.4% (36.3 to 40.5%)	Yes

* There was considerable variability in the criteria used to identify error, so the results of different studies are not necessarily comparable.

§ CI= confidence interval; where it is not quoted in the papers cited, it has been calculated using the equation $P - 1.96\sqrt{\frac{P(1-P)}{N}}$ for the lower CI and $P + 1.96\sqrt{\frac{P(1-P)}{N}}$ for the upper CI where $P = \frac{R}{N}$ and R = number of errors and N = number of observations

Table 9: Summary of studies of MAEs in secondary care

Time errors, where the medicine is over one hour earlier or later than prescribed,⁽²⁷²⁾ are often the most common type of error identified and in many instances, this is not a problem for the patient. However, it can be a significant problem for those patients who require their medicines at specific times, for example, those on anti-Parkinson drugs. For that reason, many studies^(270, 272, 282-287) tend to differentiate between MAE including time errors or excluding them.

In 1982, Barker et al⁽²⁸¹⁾ compared the MAE rate between 10 hospitals and 58 LTCFs using an observational method. Although the MAE rate was found to be higher in hospitals than in LTCFs, not enough accurate data was provided about these rates as the study was evaluating the reliability of the method. The authors concluded that, although the observation method was promising, further evaluation of the observer efficiency with the method was required in order to examine the relationship of medication errors with the process variables.

Bates et al (1995)⁽²⁸²⁾ tried to evaluate the frequency of medication errors using a multidisciplinary approach (self-report by pharmacists, nurse review of all patient charts, and review of all medication sheets) to classify these errors by type, and to determine how often medication errors are associated with adverse drug events (ADEs). Over the study period, 10,070 medication orders were written, and 530 medication errors were reported (5.3 errors/100 orders), for a mean of 0.3 medication errors per patient-day, or 1.4 per admission. Of the medication errors, 53% involved at least one missing dose of a medication; 15% involved other dose errors, 8% frequency errors, and 5% route errors. During the same period, 25 ADEs and 35 potential ADEs were found. Of the 25 ADEs, five (20%) were associated with medication errors; all were judged preventable. Thus, five of 530 medication errors (0.9%) resulted in ADEs. This study highlighted the high prevalence of omission errors in hospital. However, it has to be considered that pharmacists and nurses may not necessarily identify errors equally and the MAEs may not have been accurately or routinely identified.

A study by Ridge et al⁽²⁸³⁾ in the UK carried out a covert observational survey on two general surgical, two medicine-for-older-people and two general medical wards at a district general hospital. The study was explained as a work sampling study, although the authors admit that they were uncomfortable using a covert methodology. Thirty-seven nurses were observed carrying out single-handed medicine rounds. The authors did not provide precise information about how many times each nurse was watched or how many of them refused to be observed but as

the researchers observed 74 medicine rounds, some of the nurses must have been watched at least twice. The observers were pharmacists from another Trust which has the advantage that the nurses did not know them and would probably be less affected by the observation. The researchers intervened discreetly before the nurse left the trolley if the nurse was about to make an error. In the case of omissions, the error was not indicated until after the nurse had signed the drug chart indicating all administrations had been completed. The authors identify three types of error that predominated: non-availability of the drug, omitting to give the drug when available and giving the wrong dose. There was no explanation provided for the likely causes of the errors. The use of a covert technique often raises ethical issues and when compared to studies where direct open observations were carried out, this technique didn't identify significantly different MAE rates.

An observational method was used by Dean & Barber (2000)⁽²⁸⁴⁾ to identify MAEs before and after introducing patients' own drugs (PODs) schemes on one surgical and one medical ward in a teaching hospital in the United Kingdom. A validated severity assessment method was also applied to the MAEs identified. Overall the MAE rate was 4.2% (257 MAEs / 6,067 opportunities for error). There was no significant difference in the overall MAE rate for the traditional system (4.3%) compared to the POD system (4.2%; $P=0.99$). There was also no difference in types of MAE or stage in which they originated. Higher rates of omission of drugs were reported and related to evening times possibly due to unavailability of ward stock medicines. A relationship was also found between error rate and nurse experience, with error rates decreasing with increasing nursing experience ($P=0.004$).

Lisby et al⁽²⁸⁵⁾ detected a total of 1,065 errors in 2,467 opportunities for errors (43%) in a randomly selected medical and surgical department at Aarhus University Hospital, Denmark. It was reported that 20–30% of all evaluated medication errors were assessed as potential adverse drug events. 166 administration errors were observed, omission of drug/dose was the most common of the MAEs. Almost 50% of all errors in doses and prescriptions in the medication process were caused by missing actions. The authors concluded that the number of errors could be reduced by simple changes to existing procedures or by implementing automated technologies in the medication process. However, the study was conducted in one medical and one surgical ward in a single university hospital and therefore results cannot be appropriately extrapolated to other hospitals or cultures.

On a larger scale, Barker et al⁽²⁷⁰⁾ in 2002 carried out an observational study where medication errors were witnessed and verified by a research pharmacist over a stratified random sample of 36 sites in US (several facilities were randomly selected for each of three types of setting in each state: six accredited hospitals, six non-accredited hospitals and six skilled nursing facilities for a total of 36 sites). This study provided data from primarily non-teaching sites, complementing data from large teaching hospitals, and examined the association of accreditation with error rates. In the 36 institutions, 19% of the doses (605/3,216) were in error. The most frequent errors by category were wrong time (43%), omission (30%), wrong dose (17%), and unauthorised drug (4%). Seven per cent of the errors were judged potential adverse drug events and there was no significant difference between error rates in the three settings ($P=0.82$). Accreditation by the relevant regulatory commissions was not associated with significantly lower error rates. Despite the fact that the 36 institutions studied were selected at random (or via random replacement), another 26 institutions declined as they had concerns that they might have poor scores and wanted to improve their performance first. Thus, the error rates presented by this study are likely to be understated due to the large proportion of facilities who declined to participate.

In order to quantify the incidence and specify the types of medication administration errors, Calabrese et al⁽²⁸⁶⁾ carried out an observational evaluation in five intensive care units (ICUs) in the United States. The participants were 851 patients who were at least 18 years of age and admitted to surgical, medical or mixed ICUs during a three-month period. Of 5,744 observations in 851 patients, 187 (3.3%) medication administration errors were detected. Twenty-one errors did not reach the patient and 159 reached the patient but did not result in harm, increased monitoring or intervention. This multicentre evaluation found fewer medication administration errors than the published literature to date, possibly due to the varying observational techniques. As an example of a similar study, Tissot et al⁽²⁸⁷⁾ followed a parallel methodology to assess the type, frequency and potential clinical significance of medication-administration errors. This prospective study also used an observation technique in a medical intensive care unit (ICU) in a university hospital. 132 (6.6 % of 2,009 observed events) errors were detected. The study identified 41 dose errors, 24 wrong preparation technique, 19 physicochemical incompatibility, 10 wrong administration technique and nine wrong time errors. No fatal errors were observed, but 26 of 132 errors were potentially life-threatening and 55 potentially significant. However, the author

concluded that these errors were due to deficiencies in the overall organisation of the hospital medication track, in patient follow-up and in staff training.

In 2011, Kelly et al⁽²⁷²⁾ observed 62 nurses administering oral medication to 625 patients in one stroke and one care-of-older-people ward in each of four hospitals in East Anglia, UK. The wards were selected by staff working in each hospital with the aim of observing as many patients as possible with dysphagia. All the observations were carried out by one researcher using two standard proformas (one for oral administration and one for enteral) to ensure consistency of data collection. Nurses' practice was compared with what had been prescribed and also compared with best practice guidelines. The observer intervened in incidents where there was potential for patient harm but these incidents were still recorded as errors. A total of 65 drug rounds involving 2,129 potential drug administrations were observed in 625 patients. Of the 2,129 potential medicine administrations 817 doses (38.4%) were given incorrectly (95% CI=36.3–40.4). The most common error was either administration of the medicine over an hour early or more usually over an hour late. Excluding time errors there were 228 errors (10.7%; 95% CI=9.4–12.0). 283 patients experienced at least one drug error (45.3%; 95% CI=41.4–49.3), which reduced to 126 (20.2%; 95% CI = 17.0–23.3) when time errors were excluded. 143 different non-time related incidents of which 35 (25%) were purposively selected so as to ensure that all types of error were included as well as an equal number of errors involving dysphagic and non-dysphagic patients. Ten incidents (28.6%) were classified as minor (score < 3.0), 24 (68.6%) as moderate (score 3.0–7.0) and one (2.9%) as severe (score > 7.0). The overall mean harm score of the 35 incidents was 4.1 (range 1.1–8.6, SD 1.8) on a scale of 0–10. The MAE rate and severity scores found in this study were higher, even when time errors are excluded, than similar previous studies. This has implications for MAE research as although it is important to reduce the MAE rate, it is more important for the patient and the health service to reduce the more severe errors to minimise patient harm.⁽²⁷²⁾

This article published by Kelly et al⁽²⁷²⁾ was one of two that described a parent study in which the MAE rate for PWD was explored and compared to the MAE rate of those without. Of the 625 patients, 214 (34.2%) had swallowing difficulties and they accounted for 679 (31.9%) potential drug administrations involving 150 different formulations. A total of 170 patients without dysphagia and 133 PWD experienced at least one drug error. Thirty-six of the 50 patients with enteral tubes experienced at least one error. There were 313 MAEs in PWD and 504 MAEs in patients without (Table 9). After normalising, the frequency of MAEs (excluding

errors) for PWD was 21.1% (95% CI = 18.0 – 24.1%) compared with 5.9% (95% CI = 4.7 – 7.1%) for patients without dysphagia. There was a clear distinction in error-rates between PWD (but without tubes) and patients without dysphagia and a further clear distinction for PWD between those with and those without enteral tubes. MAEs were found to be higher in PWD, and this was largely due to drug formulation or preparation. Although this study is limited to the small sample size, it is the first to concentrate on the MAE rate in relation to PWD and to identify the size of the problem in an acute hospital setting.⁽²⁸⁸⁾

To date, Kelly's was the only study that specifically considered dysphagia as part of the design. However, the study by Haw et al (2007)⁽²⁴⁰⁾ in two older people long-stay wards in an independent UK psychiatric hospital found a strong association between MAE rate and dysphagia (179/480, 37.3% vs. 190/943, 20.1%; $P < 0.0001$). The researchers excluded the doses of medicines where tablets and capsules were tampered with and still found a strong association between PWD and MAE rate (110/377, 29.2% vs 117/780, 15%; $P < 0.0001$). However, the sample size ($n=32$) was composed of only 13 PWD and the authors did not clarify how the results were calculated. Another study by Kelly et al⁽¹⁹⁵⁾ compared the administration of medication by two nurses to the same older patient with dysphagia in a hospital ward. Using root cause analysis, the administrations were compared and contrasted in order to gain an understanding of how nurses interpret and administer multiple medicines to a PWD. While the administrations of medicines by both nurses were not considered optimal, the authors concluded that the fundamental root cause of the problem was insufficiently skilled staff. Although the results of this analysis are limited by the fact that only two nurses were observed, this study is highly relevant to the research topic of this thesis as it not only identifies flaws in the practice of the nurses, but also highlights the lack of standardised practice observed in the hospital wards when administering medication to PWD.

There is a large variation between the type of observations and observers in the studies presented. However, there seems to be concordance in the literature about the most likely types of errors, being time errors, omissions and dose errors the most frequently found. Although there are many studies exploring the MAE rates to patients in secondary care, no other studies have been found to relate MAE rates to PWD. The old age of patients with this condition and the complexity of the administration of oral medication in dysphagia are likely to show more MAEs in line with those found by Kelly.

2.2.4.3.4. MAEs in long-term care facilities

Medication administration errors in care homes and other LTCFs are common despite regulations and national minimum standards introduced to protect residents' safety. The governments in Wales and England have introduced minimum standards which must be met by care home providers but still, medicines management in care homes remains problematic. According to a recent report by the Care Quality Commission, 30% of care homes for older people in England are failing to meet the minimum standards required for the management of medicines.⁽²⁸⁹⁾ However, the evidence for interventions to reduce medication administration errors in care homes is limited. In this section, we will examine some of the literature available. In parallel with the literature search carried out for MAEs in secondary care, most of the studies included are observational. Those where intravenous administration is examined were excluded. A summary of the studies reviewed is outlined in Table 10.

Study	Setting	Method	Number of errors observed	MAE rate* (95% CI) §	Including Time errors
Haw et al., (2007) ⁽²⁴⁰⁾	2 older people long-stay psychiatric units (UK)	Direct observation, medication chart review and incident reports	1,423	25.9% (23.7 to 28.2%)	Yes
Barker et al. (1982) ⁽²⁷⁰⁾	58 LTCFs (US)	Observation of nurse-led medicine administration rounds	Not available	12.2%	Not available
Pierson et al. (2007) ⁽²⁹⁰⁾	Nursing Homes (US)	Evaluation of recorded detailed information about medication errors	631	Not applicable	Not applicable
Van den Bemt, et al. (2009) ⁽¹⁹⁶⁾	Nursing Homes (Netherlands)	Observation technique	2,025	21.2% (19.4 to 23.0%)	Yes
Allred et al. (2009) ⁽²⁷⁵⁾	Residential homes and care homes(UK)	patient interview, note review, observation of practice and examination of dispensed items	116	8.4% (7.0 to 10.0%)	No

* There was considerable variability in the criteria used to identify error, so the results of different studies are not necessarily comparable. § CI= confidence interval; where it is not quoted in the papers cited, it has been calculated using the equation $P + or - 1.96\sqrt{\frac{P(1-P)}{N}}$ where $P = \frac{R}{N}$ and R = number of errors and N = number of observations

Table 10: Summary of studies of MAEs in LTCFs

Haw et al⁽²⁴⁰⁾ investigated the frequency and nature of medication administration errors by nurses on two older people long-stay wards in an independent UK psychiatric hospital. Errors occurred in 25.9% drug administration opportunities (369/1,423) and the most common errors were: unauthorised tablet crushing or capsule opening (111/369, 30.1%), omission without a valid reason (100/369, 27.1%) and failure to record administration (87/369, 23.6%). One of most relevant findings of this study was that more errors were associated with PWD, even after crushed doses of medication were excluded from the analysis. Although this study was carried out in hospitals, it was included as part of the LTCFs literature review as the patients studied were not atypical of those found in nursing homes and it may have applicability to the care home setting, particularly homes with older people mentally infirm (OMI) beds. However, it took place on two wards of an independent sector hospital, and thus the findings may not apply to National Health Service hospitals or community settings.

Van den Bemt et al⁽¹⁹⁶⁾ used a disguised observation technique to measure administration errors at three nursing homes in the Netherlands, over a two-week period (Monday, Wednesday, Thursday, Friday only). 137 residents were included in the study. Medication was supplied to each home in a plastic bag filled with the tablets that needed to be administered to each patient, at each medicines round. Errors in picking the right medication from a central supply were therefore reduced. Errors were observed in 428/2,025 (21.2%) administrations and of these 312 errors related to wrong administration technique. Incorrect crushing of tablets was identified as a common problem, with crushing occurring even with enteric coating or modified release formulations. Another frequently occurring problem was the failure to supervise the intake of medication when instructions to do so had been given. Supervision was considered important for patients with dementia to ensure medication was actually taken and to prevent dementia patients from taking the wrong medication. Incorrect time errors accounted for 18% (77/428) of administration errors and were defined as medication not given within 60 minutes of the prescribed time. Patients that were prescribed antibiotics were significantly more likely to experience an administration error odds ratio (OR) 11.11 (95% CI, 2.66-46.50), and it was postulated that this might be due to the short-term nature of antibiotics and staff being less familiar with the medication. Errors were also more likely to occur between 7am-10am, OR 2.28 (95% CI, 1.50-3.47) and 10am-2pm, OR 1.96 (95% CI, 1.18-3.27) compared with later in the day. The authors did not measure workload but hypothesised that this increase could be linked to increased

staff workload in the mornings when residents needed help getting out of bed, getting dressed, having breakfast, etc. They also suggested that pharmacists could help reduce this workload by considering which medication could be administered in the afternoon or evening instead of in the morning.

Allred et al⁽²⁷⁵⁾ observed administration of medication in 55 UK care homes. Two drug rounds were observed for each of the 256 residents included in the study. Administration errors by opportunities for error were 8.4% (116/1380) [95%CI 7.0-10.0] and 22% of residents were exposed to an administration error in one or other of the drug rounds. The mean harm score from administration error was 2.1 (range 0.1- 5.8) on a scale of 0 to 10 where 0= no harm and 10=death. Nearly half (49.1%) of the 116 administration errors observed were omissions and a further 21.6% errors were due to the wrong dose of medication being administered. This study had a high recruitment rate (72% (79/108) of homes, 67% (269/399) of residents and 61% (54/89) of general practices) and the results were supported by a strong mixed methodology of qualitative and quantitative methods. The qualitative work was ethnographically informed and involved field notes, observation and semi-structured interviews with the home staff, GP or pharmacist based on Reason and Vincent's frameworks^(263, 291) to help understand the causes of specific errors. The results identified:

- patient factors included patients' lack of awareness of their medicines, fears about medicines,
- task factors included inability to find the medicine, failure to order the right quantity of "as required medicines",
- individual factors related to the staff included lack of knowledge about inhalers and the timing of medicines with respect to food,
- team factors included the medication administration record chart, which should be the documentary line of communication among GP, home and pharmacist; these records were often inaccurate,
- work environment factors included homes being hot, airless, having unpleasant smells, being poorly lit, noisy and short of space. There were often staffing problems in the morning round. The members of staff were frequently interrupted and did not have dedicated time to order medicines.

Although the author considered the sample size as a limitation, the high recruitment rate, the transparency of the results and the methodology design made this study one of the most relevant studies in care home settings in the UK. Despite

the fact that the MAE rates in PWD was not explored as part of the design, this methodology and the results could help in identifying the factors to consider for future research on PWD.

The results from a web-based error reporting system introduced into nursing homes in North Carolina, US, were reported by Pierson et al.⁽²⁹⁰⁾ This study was an evaluation of recorded information, in contrast to the rest of the studies presented in this section of the literature review which used observational techniques. However, the results helped in identifying the type of MAEs and a likely estimation of the MAE rates that could be found in other observational studies. Of the 25 homes that volunteered to take part in the study, 23 successfully entered error reports into the system during the one-year study period. 631 error reports were made covering 2,731 discrete error instances when weighted by the number of times the errors were repeated before being addressed. The most common errors were:

- dose omission (203, [32%]),
- overdose (91, [14%]),
- under dose (43,[7%]),
- wrong patient (38, [6%]),
- wrong product (38, [6%]),
- wrong strength (38, [6%]).

Most errors occurred during medication administration (296, [47%]) and, of the errors with the most serious patient impact, 67% (34) first occurred in the administering phase. Nearly half of all errors were attributed to basic human error (402, 48%). The author concluded that the web-based medication error reporting system had strong indications that it would be a valuable tool for preventing future errors. Although this study outlines the most common errors reported, the author did not contemplate the factors that stop errors from being reported and, therefore, the accuracy of the results is questionable.

Studies investigating medicine administration errors in LTCFs consistently identify dose omission as a significant problem with wrong dose and incorrect administration errors also being a concern. Equally to the studies in secondary care it seems sensible to estimate that the MAE rate in future studies in LTCFs with PWD will show higher figures than those identified in general patients.

In summary, the practice of nurses may affect the care received by PWD. The factors which affect that practice need to be identified in order to design a pharmacy intervention that overcomes likely difficulties in the nurses' practice. While the subjective views of the nurses are essential to identify barriers in the administration of medication - and therefore explored in chapter 4 - the observation of MAEs can provide an objective description of the practice of the nurses in care homes. It is important to also highlight how direct observations are rated as better practice over those covert techniques. The descriptions of the types of errors observed during drug rounds are presented in chapter 5 of this dissertation.

2.2.5. Alternatives to medicine administration

After exploring the challenges that are faced by nurses during the administration of medication to PWD, it seems sensible to explore the alternatives available to avoid some of the problems introduced in the previous section and the rationale for them. Tablets and capsules are often the preferred method by practitioners for the administration of drugs to patients due to the numerous advantages in cost, accuracy and drug stability of these formulations. When difficulties in the swallowing function appear, HCPs play an important role in identifying the ability of the patient when taking oral medication and also in identifying ways on how to overcome that problem. National guidelines are available which outline how to approach prescribing for PWD.⁽²⁹²⁾ These guidelines identify several strategies.

Alternative formulation

When dysphagia is likely to be long-term or when treatment cannot be stopped suddenly at the onset of dysphagia, a liquid or a dispersible/orodispersible product could be considered providing that the patients can still swallow these formulations. Wright⁽²³⁾ in 2011 describes in his book what needs to be considered when changing to liquid or dispersible formulation (Table 11).

- Viscosity – patients may have problems controlling liquids when swallowing them and so the correct consistency needs to be prescribed, or a thickener such as Thick and Easy[®] or Nutalis[®] added to provide the correct consistency. NB: There are no tests undertaken to demonstrate how the addition of such thickeners may affect the bioavailability of a drug.
- Consider if the patient can pour and measure the dose accurately.
- Check dose equivalence – bioavailability can be greater with liquids.
- Adjust dose frequency if necessary.
- Evaluate efficacy and side-effects.
- Recognise that some liquid medicines are unlicensed (Specials) (consult a pharmacist to identify what is obtainable).

Table 11: Considerations when changing to liquid or dispersible formulations (Wright 2011, page 14)⁽²³⁾

Alternative medication

When products are not available in an alternative dosage form, another drug with similar pharmacological effects could be considered, e.g. sachets of Macrogol can replace the intake of senna tablets.

Alternative route

If the patient is unable to take medication by the oral route and a suitable preparation is not available, the prescriber may request the medication to be given by an alternative route, e.g. transdermal, rectal or parenteral,⁽²⁹³⁾ e.g. transdermal glyceryl trinitrate patches could be used instead of modified release isosorbide trinitrate.^(23, 215) Often, the availability of these medications for use via the transdermal route is limited. Also it needs to be considered that rectal administration may be undesirable or unpleasant for the patient, and parenteral routes are usually more expensive, inconvenient, painful and require trained staff to prepare and administer them.⁽²⁹⁴⁾

Altering solid-dose formulations

The majority of patients need their drugs and often there are not suitable alternative medicines or dosage forms. A frequent response to this is to crush tablets or open capsules and to mix the residue with food or to administer via the patient's enteral tube.^(173, 188, 192, 193, 287, 294, 295) Tablet crushing or capsule opening should only be recommended as a last resort and only carried out after discussion with a

pharmacist or local Medicines Information Centre.⁽²³⁾ Although limited, there are evidence-based reference sources available which provide recommendations for the administration of medicines for PWD and via enteral feed tubes.⁽²¹⁵⁾ If used appropriately, then reliance on potentially expensive unlicensed medicines can be minimised whilst still optimising patient care.⁽²³⁾ The reference sources are designed for use by pharmacists and rely on a good understanding of pharmaceutical formulations and availability of medicines.

Medication discontinuation

Occasionally it may be possible to stop the medication either temporarily if the dysphagia is believed to be transient or permanently if the risks of the medication outweigh the benefits.

A pharmacy intervention for PWD needs to consider alternative strategies as the condition develops. It is, therefore, important to explore the factors that are relevant to the administration of medication from the point of view of the HCPs. The perceptions and feedback from nurses on the implementation of a pharmacy intervention are essential for a suitable development of the intervention. These feedback and perceptions are therefore explored in chapters and 3 and 4, respectively.

2.2.6. Medicines management in dysphagia: the role of the pharmacist

Medicines management could be defined as the practice that seeks to maximise health through the optimal use of medicines and it includes all aspects of medicine use from the prescribing of medicines through to the ways in which medicines are taken or not taken by patients.⁽²⁹⁶⁾ Medicines management also involves the systematic provision of medicines therapy through a partnership of effort between patients and professionals to deliver best patient outcomes at minimal cost.^(297, 298)

The management of dysphagia is a complex process. Dysphagia can appear suddenly after stroke or it may emerge gradually as it happens with ageing or Parkinson's disease. It is, therefore, important that HCPs are able to early identify, assess and when possible treat the condition. As previously mentioned, older patients are prone to polypharmacy specially those in care homes who are prescribed eight medicines on average.⁽²⁹⁹⁾ Also in this setting, 50% of residents are believed to have some form of dysphagia⁽²⁸⁾ with anything between 15 and 30% of them reported as finding it difficult to take medicines.⁽¹⁸⁸⁾

The likelihood of the presence of pharmacological treatments in older PWD requires the pharmacist to be involved in the medicines management of dysphagia, this including identification, assessment, treatment, communication with other professionals and further individualised interventions required by a patient.

Identification of dysphagia

Due to easy accessibility, pharmacists are the first point of contact for patients in the healthcare system in countries like the UK, America or Australia.⁽³⁰⁰⁾ This provides an ideal location for pharmacist to identify early signs of dysphagia from their patients.

In 2005, a survey conducted by Strachan & Greener⁽²³⁹⁾ aimed to determine whether community pharmacists could identify patients with difficulties in swallowing solid medicines in the community. The survey involved 17 pharmacies from England and Northern Ireland which distributed a questionnaire to customers who were suspected (by the pharmacist) to experience difficulties swallowing solid medicines, based upon their clinical judgement and knowledge of the customer. The 792 returned questionnaires were completed by patients (85%) and carers (15%). From all the patients, 90% were aged between 60 and 89 years. The results showed that almost 60% (n=477) of respondents stated that they experienced difficulties in swallowing tablets or capsules. Furthermore, 68% (n=333) of those who answered that question needed to open a capsule or crush a tablet to swallow the medication. A similar proportion (69%; n=305) admitted to not taking a tablet or capsule because it proved hard to swallow. Thus, about two thirds of customers that pharmacists suspected might have problems, did have dysphagia. What was more revealing from this study was that 72% (n=218) of patients and carers reported that their doctor or nurse never asked if they have difficulties taking tablets or capsules before writing prescriptions. In the same year, a survey carried out by Morris⁽¹⁵⁹⁾ in a health centre found 80% of patients said that they did not inform their doctor or pharmacist if they could not take their medication. Only 22% of patients said that their doctor or nurse asked them if they had problems swallowing before issuing a prescription.

These surveys suggest that enquiries about dysphagia are not made regularly enough and highlight how the community pharmacist is in an ideal position to identify PWD through medication review or consultation with the patient. Dysphagia is a well-established warning sign for some cancers and other gastrointestinal diseases⁽³⁰¹⁾ and such enquiries could be especially important in the

middle-aged and older people. As compared to younger subjects, people aged more than 55 years are 9.5 times more likely to develop gastrointestinal cancers than younger subjects.⁽²³⁹⁾

Assessment of dysphagia

Solid dose medication has become the mainstay of medical treatment for many reasons, including safety with dosing, convenience, and efficiency. However, the task of swallowing a solid dose medicine is quite complex. From infancy we are taught to chew food well. The gag reflex is designed to eject foodstuffs that are not adequately chewed as a safety mechanism for choking. Particles as small as 2mm will trigger a chewing reflex.⁽⁴⁸⁾

There are numerous screening and assessment tools available for dysphagia^(101, 302-304) of which the TOR-BSST is the most thoroughly evaluated, based upon best available evidence. The measurement properties of the TOR-BSST have been established in a well-controlled study and it has a prepared education module. However, to date, none of the screening and assessment tools have contemplated the assessment of swallowing medication and in consequence, the role of the pharmacist has been excluded from the group of HCPs that these tools have targeted.

Swallowing a solid dose medicine requires a deliberate learning to override both the need to chew and the response to gag. Some medications have the same length as a coin or a cashew nut. Both nuts and coins are recognised choking risks but little thought is given to the dimensions of some solid dose oral medicines. However, for people with dysphagia, risk of aspirating solid dose medications is very real. They have lost the oral control and in some cases the sensation within their mouth to identify where the bolus is

Pharmacists, from their knowledge of medications, have an important role in assessing the medication regimen of PWD for potential problems that might impact patient safety, adherence, and therapeutic outcome. An assessment may be requested by the patient's primary care or other health provider (such as a speech and language pathologist). Ideally, an assessment should take place soon after the patient is diagnosed with dysphagia. For example, a patient who is hospitalised following a new stroke that resulted in dysphagia should have their medications reviewed so that any changes or instructions for proper medication use can be provided prior to discharge. Often the availability of the SALT outside of standard

working hours or in aged-care facilities means that it is difficult to obtain a timely swallow evaluation. However, the need for the medication is immediate.

Advice to the prescriber

Drugs are increasingly being marketed in an assortment of sophisticated formulations that are intended to improve the efficacy of the active ingredient.

A study carried out by Lesar et al⁽³⁰⁵⁾ identified that the most common error (in 70% of cases) in hospital wards was the failure to specify the extended-release formulation when it was intended (e.g., prescribing nifedipine 60mg orally once daily instead of nifedipine XL 60mg). Although these errors were identified and intercepted by pharmacists, they had the potential for serious consequences if the short-acting formulation had been given in the dose intended for the long-acting drug.⁽¹⁶⁵⁾ These results agree with those highlighted by Kelly et al⁽²²⁸⁾ who also identified that prescribers are not always aware of the availability and cost of the prescribed formulations.

Pharmacists are the only HCPs trained in formulation science and are aware of the formulations available. Therefore, they are the most suitable professionals to provide advice to the prescriber on the best available formulation for PWD. Before prescribers recommend unlicensed medication, alternative routes of administration (buccal, intravenous, transdermal, rectal, intramuscular, subcutaneous or liquid medicines) could be recommended to the prescriber. When specials are prescribed for PWD, pharmacists have a responsibility to help ensure that prescribers are aware they are prescribing an unlicensed medicine.⁽³⁰⁶⁾ Also, the pharmacist is advised to periodically reconfirm with the prescriber that the ongoing use of an unlicensed product is appropriate, having regard to any circumstance that might suggest that a licensed product may become more suitable. It is also recommended that any discussions between the prescriber and pharmacist in relation to the unlicensed nature of the product and its suitability should be documented. The urgency of the patient's need for the medicine should also be noted and reasonable steps taken to ensure timely supply.⁽³⁰⁶⁾

Guidance to the patient and provision of medication

Pharmacists should become familiar with the causes of a higher risk for medication-induced oesophageal injury in older people and recognise those agents considered to raise the risk in this vulnerable population. Older people do not always drink enough water when they take medication.⁽³⁰⁷⁾ If a patient in a recumbent position ingests a tablet or capsule with less than 15mL of water, the

medication's passage through the oesophagus is hampered⁽³⁰⁸⁾ and, therefore, patients should be discouraged from taking medications at bedtime with small sips of water.

Pharmacists sometimes suggest that patients can split capsules or crush tablets, which are dispersed in a small amount of water and drunk immediately. Wright (page 34)⁽¹⁵⁸⁾ suggests considering crushing of medication or opening of capsules only 'in the rare instance of no alternative administration route or liquid formulation being available'.

Several authors have highlighted that specific educational interventions could help patients.^(217, 227, 239) Often, patients use the wrong technique when swallowing tablets.⁽¹⁵⁶⁾ Whilst most patients tip their head back to allow the tablet to drop towards the back of the mouth, this narrows the oesophagus and makes swallowing more difficult. A pharmacist can inform PWD in using better techniques such as dropping their head and looking down as this widens the oesophagus.⁽²³⁹⁾

In other cases where other symptoms are involved, the pharmacist has the expertise to review the patient's medication and identify underlying concerns. In a study of 600 older Americans, 33% took at least one medication that could cause or exacerbate xerostomia.⁽³⁰⁹⁾ Xerostomia can present as a cause or a consequence of the medication management of dysphagia. If patients report xerostomia and /or difficulties swallowing their medication, pharmacists could review the medication for drugs associated with dry mouth. According to Parsons et al,⁽³¹⁰⁾ medication review has the potential to address several of the issues identified that contribute to sub-optimal use of medicines but also can be used to promote appropriate polypharmacy and is also an opportunity to promote medication adherence. In addition, medication review can identify and resolve problematic medication issues for patients such as alternative medicine formulations, i.e. non-oral products, can also be recommended for PWD.

Training and supporting other HCPs

Multidisciplinary management of dysphagia ensures that the dysphagic patient receives careful, in-depth assessment and treatment/rehabilitation of their swallowing disorders, and its underlying aetiology.⁽³¹¹⁾ Members of this team usually often include the SALT, gastroenterologist, radiologist, ENT doctor, neurologist, respiratory specialist, pharmacist, dietician, occupational therapist, physical therapist and nurse.

When considering that the nurses and carers are often in charge of the administration of medication to PWD, it is sensible to assume that this nursing team should receive enough support to develop their skills and knowledge in their role on the medicine management of dysphagia. However, available literature^(270, 272, 282-287) repeatedly highlights deficiencies in the practice of the nurses when administering medication possibly due to the lack of support from other professionals.

While the awareness and the correct use of measuring devices remains a challenge for the nurses,⁽²¹⁷⁻²¹⁹⁾ other more complex gaps in their knowledge can represent a bigger concern. The resulting availability of multiple products with similar names and a lack of carers' understanding of the properties of the various preparations create a significant risk of adverse drug events.⁽¹⁶⁵⁾ For example, a study carried out in the state of Qatar⁽²²⁷⁾ assessed the nurses' knowledge of the purpose of modified-release (MR) preparations, codes used for such medication, the consequences of crushing these preparations, and their interactions with enteral feeds and feeding tubes. All the nurse participants (n=34) were recruited from six different intensive care units and invited to complete a questionnaire. The study revealed a complete lack of awareness on MR codes and poor knowledge on correct crushing of solid preparations, 35% to 90%, and interactions with the enteral feed or feeding tubes from (35% and 51%, respectively). This offered an opportunity for pharmacy staff to develop a two-day training programme that consisted of a presentation of the results of the questionnaire, leading to a statement of the objectives of the training. This was followed by a series of presentations that included an overview of incidents reported in the literature, formulation and absorption of drugs, technology of MR and other modified-release preparations, alternative routes and methods of drug administration, managing drug therapy in patients receiving enteral nutrition, drugs and the EFTs, and chronic use of phenytoin in patients with feeding tubes. Twelve (32%) nurses who completed the questionnaire at baseline took part in the training course and, therefore, completed the same questionnaire at the end of the training programme. Overall, the scores on the knowledge questions were increased by 40% for CR codes and to almost 90% for the other knowledge-related questions. This study highlights the need for support from the pharmacy team and its impact on the nurses' practice.

Other studies in care homes have also supported this data. In 2002, an exploratory study of issues concerning the nursing practice of altering medication dose forms prior to administration of medicines to residents in homes for older people was

carried in South Australia by Barnes et al.⁽¹⁹⁹⁾ The study used semi-structured interviews with 11 registered nurses working in a purposive sample of 10 residential homes for older people. The results highlighted that nurses felt constrained to ensure that prescribed medication was administered to residents and they were concerned that they were working in an information vacuum, due to limited information resources and informal communication with other healthcare professionals such as speech pathologists, pharmacists and general practitioners. There was also concern about the difficulty of coordinating information and policies about altering medications and of implementing appropriate procedures in individual facilities. The authors concluded that clinical guidelines for the processes surrounding the alteration of medication dose forms and relevant pharmaceutical information are needed in all residential homes for older people as well as ongoing education for nurses in this area.⁽¹⁹⁹⁾

Several authors and organisations have issued guidelines and educational charts emphasising the correct practice and providing plenty of rationale for doing so.^(215, 292, 312, 313) However, this information may not be readily available, and nurses may not be adequately trained in the selection of the correct formulation and how to prepare it for administration. Without updated knowledge on drug formulations and the possible consequences of cutting and crushing these formulations, patients can be exposed to serious unwanted effects or sub-therapeutic doses.⁽²³⁾ This is also in addition of other issues commonly found in practice like incomplete drug administration charts, lack of records of pre-existing drug allergy, topical application and self-medication in care homes with nursing.⁽³¹⁴⁾

Following appropriate swallowing assessment training, members of the medical or allied health team could screen for swallow safety for solid and liquid dose medicines, ensuring that the patient's medications continue uninterrupted, but provided in the safest form possible. With appropriate medication training, medical or allied health team members administering medication could also ensure that only medications that can be modified safely are modified.

However, the results of the discussed studies contrast with a recent systematic review which found little research on the efficacy of nursing educational interventions in reducing medication administration errors.⁽³¹⁵⁾ Also, in a recent RCT, the use of dedicated medication nurses who had undergone brief review training in safe medication use did not result in a reduction in medication administration errors compared with the control group.^(277, 316)

To overcome these educational challenges other authors have suggested the creation of lists of commonly used medications or drugs on the formulary that should not be crushed, with suggestions for alternative products, the inclusion of instructions on the medication administration record that can provide the nurse with guidance regarding appropriate administration of specific drugs (e.g. “mix liquid medication in pureed food”)⁽¹⁶⁵⁾ and the implementation of a dedicated service from a specialised HCP to reduce the problems of medicine administration to PWD.⁽³¹⁷⁾ The literature could, therefore, be suggesting an opportunity for the pharmacist in developing training for other HCPs in the administration of medication to PWD as part of medicines management of dysphagia.

In summary, this section is indicating that the management of dysphagia offers an opportunity for the involvement of the pharmacist. Pharmacists could potentially identify and assess dysphagia as well as provide training and support for HCPs. The perceptions and experiences from other HCPs on this extended role need to be explored in order to identify its acceptability as part of an intervention for PWD. These factors are explored and discussed in chapters 3 and 4 of this dissertation.

2.3. Summary

Dysphagia is more commonly observed in older patients and is found to be more prevalent in institutionalised patients compared to those in their own homes. Whilst it is often related to the ageing process, it also appears as a consequence of structural and neuromuscular disorders⁽⁴⁸⁾ in conditions such a stroke which is one of the most commonly recognised causes of this condition. One of the main complications of dysphagia is the presence of respiratory conditions such as aspiration pneumonia which is known to be a major cause of morbidity and mortality and may result from patients receiving food, liquid and medicines of the wrong consistency, i.e. thin runny fluids may be more likely to be aspirated than thicker gloopy ones. Due to patients concerns regarding choking or aspiration, administration of medication becomes a complex challenge for HCPs involved in their care.

The administration of medication to PWD requires more creative prescribing methods to ensure that patients receive their medication appropriately. Difficulties identifying suitable formulations may result sometimes in under-prescribing medication or choosing the wrong formulation for that patient. It is recognised that liquid formulations are, in the majority of cases, the best formulation for PWD as

they avoid the tampering of solid dose formulations and provide a safer administration for the patient and the administrator.⁽²³⁾ However, the cost of licensed and unlicensed liquid formulations is a significant issue for the prescriber and the NHS.

Research within the hospital environment has demonstrated that due to the complexity of administering medicines to PWD they are three times more likely to be at risk of medication error. It has been found that environmental factors, knowledge and skills and the time constraints are the main concerns of the nurses when administering medication to patients. In order to ensure that PWD receive their medicines, nurses resort to inappropriate crushing of tablets, dispersing them in water or mixing them with foodstuffs and many of them have received limited relevant training.⁽¹⁸⁸⁾

Due to the high likelihood of errors and evidence that practice in hospital varies dependent on the practitioner, an intervention to improve medicines administration in this environment is warranted. Individualised guides to medicine administration for each patient with dysphagia should increase and standardise the quality of practice in the secondary care setting. In line with MRC guidance for complex interventions⁽²⁾ all new ideas require testing for feasibility before being piloted and tested definitively.

If the intervention to improve medicines administration in dysphagia in the secondary care setting was found to be effective then the natural next location for implementation is within the care home. The differences in the settings with respect to inter-professional communication, constraints on prescribing and the less frequent medication changes warrant some understanding before any intervention is transferred across.

The development of a theoretical model to describe medication administration processes in the care home setting would help to refine any hospital-based intervention to improve medicines administration for the care home setting. To test the validity of the theoretical model which would underpin the design of the final intervention and refine it further, observation of practice with respect to medicines administration in care homes is appropriate.

3. Implementing and evaluating a novel service in dysphagia in secondary care

Problems of acceptability, compliance, delivery of the intervention, recruitment and retention, and smaller than expected effect sizes can challenge the evaluation of services,⁽³¹⁸⁾ which is why it is important to understand the context in which interventions take place. Also, researchers need to decide which outcomes are most important and represent the best use of the data or provide an adequate assessment of the intervention. Service evaluations can help in understanding processes when they explore the way in which the intervention under study is implemented. They can also provide valuable insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised.

The following study adds components of feasibility and evaluation to the process of defining a complex intervention in medicines management (highlighted in Figure 4).

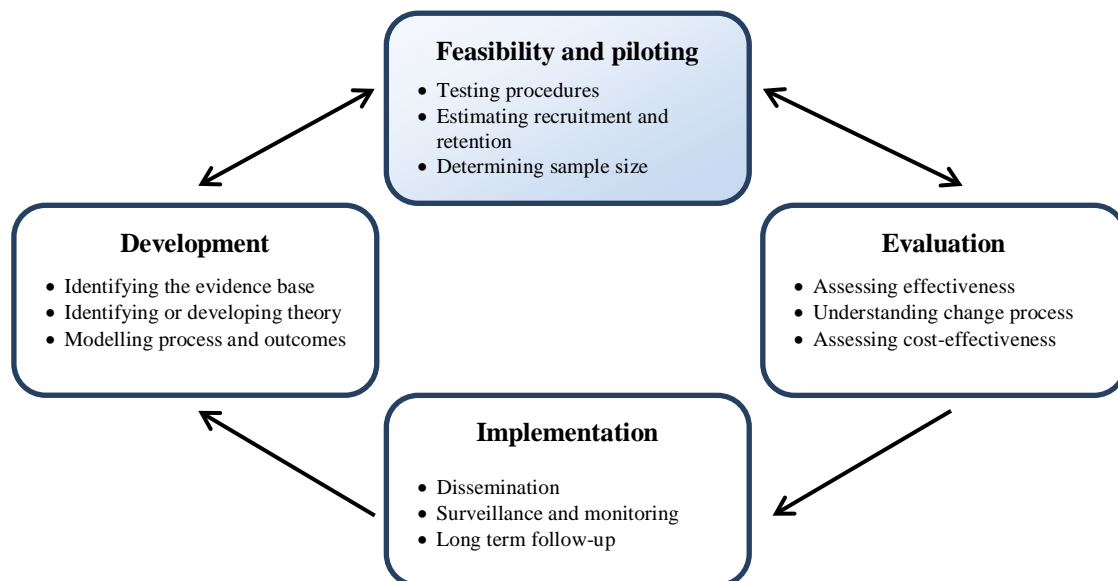


Figure 4: Initial components of feasibility and evaluation (Craig et al 2008, page 980)⁽¹⁾

3.1. Introduction

Before the commencement of the research described in this thesis, a pilot study had been designed by Jennifer Kelly (former PhD student and chief investigator), her supervisors at the university of East Anglia, healthcare professionals in the Norfolk and Norwich University hospital and lay members of Patient and Public Involvement in Research. Her pilot study aimed to determine the design of a randomised controlled trial in which a dedicated pharmacist trained in the management of dysphagia and enteral nutrition (via naso-gastric and percutaneous endoscopic gastrostomy tubes) promoted best practice in relation to medicine administration to PWD on care of older people and stroke wards through the use of Individualised Medication Administration Guides (I-MAGs) (Appendix 1) which are described in this chapter.

The study received ethical and governance approval from the appropriate Research and Ethics Committees and relevant Clinical Governance Committees (08/H0302/153).

The addition of the pharmacist in charge of delivering the dysphagia service as part of the steering committee provided an opportunity for more in-depth research of the administration of medication to PWD. This opportunity developed into a PhD project reflected in this thesis.

The dysphagia service pharmacist (DP) was responsible for:

- training the nurses in the use I-MAGs in the intervention wards,
- the development of software to help in the generation of I-MAGs,
- the delivery of the service in the intervention wards,
- obtaining consent from the patients to be approached by an independent researcher,
- collecting the data from the patients recruited during the six months follow-up.

The DP also performed a service evaluation aiming:

- to better understand how to implement I-MAGs,
- to identify the workload issues associated with the guides,
- to describe the acceptability of I-MAGs,
- to determine whether it would be feasible to recruit patients to a future trial based on the service,
- to determine the quality of data collection,
- to determine what outcomes, if any, may be appropriate for such a trial.

Figure 5 shows the structure and the timeframe of the study.

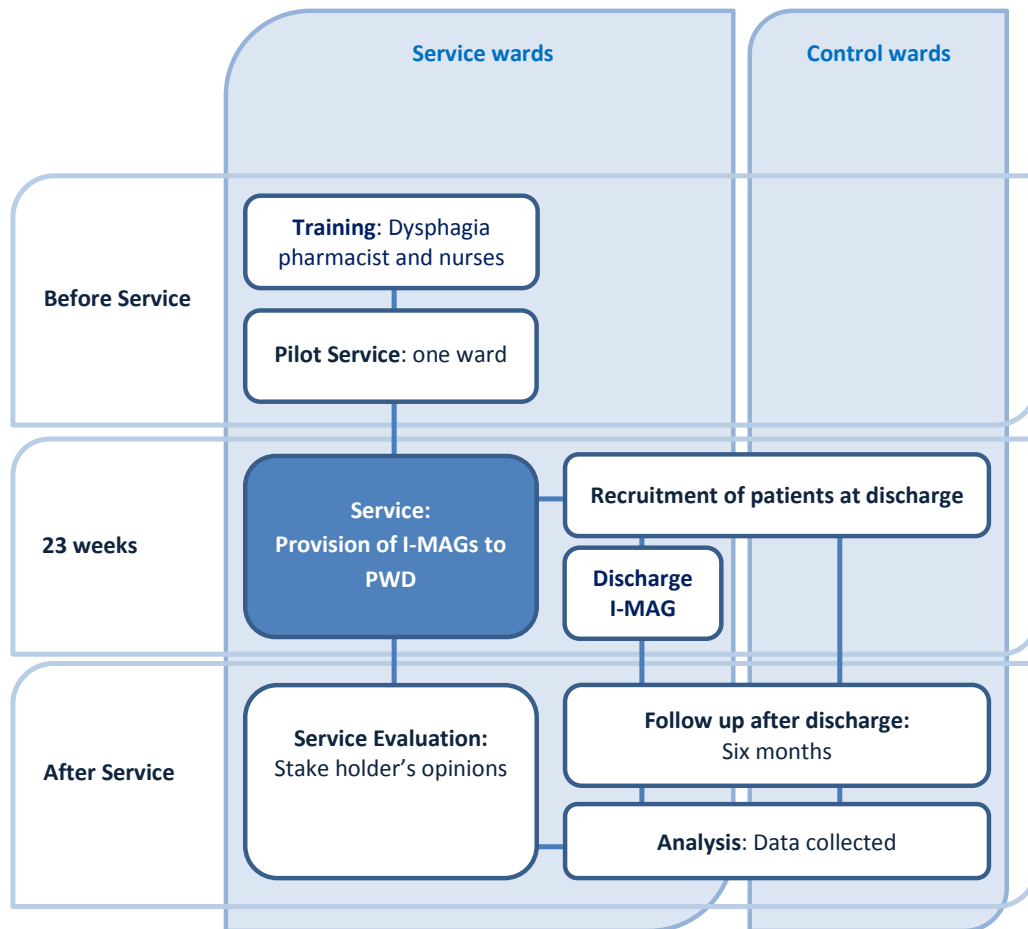


Figure 5: Structure of the responsibilities of the DP in the pilot study

3.2. Aim and objectives of this section

This chapter aims to evaluate the feasibility of the I-MAG service and to explore the consent and recruitment rates obtained during the service. The data obtained will contribute to the development of our complex intervention for PWD.

The main objectives of the service evaluation were:

- to describe and define the elements of an I-MAG service,
- to determine the acceptability by HCPs in the wards, the suitability of the training provided by the pharmacist to the nurses and the potential workload implications,
- to estimate the proportion of patients for whom I-MAGs are suitable,

Implementing and evaluating a novel service in dysphagia in secondary care

- to determine the recruitment of participants and the patient outcomes of the service,
- to identify the potential costs that would need to be explored in future research,
- to estimate the cost of prescribing alternative formulations that are more suitable for PWD,
- to explore the acceptability of the I-MAGs service by the HCPs and their opinions on the provision of the guides (main focus of this chapter).

3.3. Methods

This section will explain the methods that composed:

- the main pilot study,
- the clinical interventions made by the DP,
- costing estimates of recommendations,
- service evaluation.

Although the main focus of this dissertation is the service evaluation, this will be explored last to follow the chronological sequence of the study.

3.3.1. Development of the service and main pilot study

The aim of the pilot study designed by Jennifer Kelly was to determine the design of a randomised controlled trial in which a dedicated pharmacist (DP) trained in the management of dysphagia and enteral nutrition via NG and PEG tubes promoted best practice in relation to medicine administration to PWD on care-of-the-elderly and stroke wards through the use of I-MAGs. In her original design, the primary objective was to estimate the effect of I-MAGs on nurses' clinical practice using observations of MAE rates and nurse questionnaires to evaluate nurse-stated practice. The secondary objectives of Jennifer Kelly's study were to estimate:

- a. whether randomisation for a full trial should occur at ward or hospital level,
- b. the most efficient method of patient recruitment, the likely 'drop out' rate, the best outcome measures, and the feasibility of a full cost-effectiveness analysis,
- c. the effect of the introduction of I-MAGs on patients' health-related quality-of-life, satisfaction with medicine information, post discharge adherence and hospitalisation.

Jennifer Kelly's dissertation addressed the primary outcome and the first secondary objective (a). It didn't address objectives (b) and (c) as these objectives related to

recruitment of patients on discharge to a six month questionnaire based study to evaluate the usefulness of I-MAGs to patients themselves and those objectives (b and c) were explored in the dissertation presented in this document. Although the data formed part of this PhD thesis, Jennifer Kelly co-supervised this secondary part of the study. This section of this chapter will present the methods employed to prepare and develop the I-MAGs service and the components of the pilot study based on that service.

3.3.1.1. Development of the service

This section will explain how the service was prepared and developed. It is important to highlight that the I-MAG service was provided only in wards restricted by the main pilot study and, in order to enhance the clarity of this document, references to the sections relevant to the study are made as part of this section.

3.3.1.1.1. I-MAG and software development

I-MAGs were developed by the Steering Committee of the study. The guides consisted of individualised instructions on the administration of medication to be used by the nurses and the carers of PWD with or without enteral feeding tubes (EFTs). I-MAGs (Figure 6 and complete version of example in Appendix 1) contained:

- patient details,
- information regarding the diet texture as recommended by the SALT,
- a list of the patient's medication with frequency and instructions on the administration adapted to the patient's needs,
- contact details for the pharmacist generating the guides.

The information provided in the I-MAGs was developed to be used in the hospital wards in conjunction with the standard medication charts and was based on the BAPEN Guidelines on administering drugs via enteral feeding tubes,⁽³¹⁹⁾ the algorithm for medication management of adults with dysphagia⁽³²⁰⁾ and specific information about each drug extracted from current literature such as "Handbook of drug administration via enteral feeding tubes"⁽²¹⁵⁾ and "The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or dysphagia".⁽³²¹⁾ The guides were designed to provide clear guidance on which formulation should be used, how tablets and capsules should be modified (if

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required) and how the medicine should be measured (in the case of liquids) or administered.


Patient's Name:	xxxxxx xxxxxxxx	Hospital Number:	1234567	
Signature		Date of IMAG:	05/08/2011	
Individualised Medicine Administration Guide (I-MAG) for Patients with Swallowing Difficulties				
I-MAGs work alongside the patient's drug charts. Ensure that you administer medicines from the patients Medicine Chart and do not rely solely on the I-MAG.				
Other details about Dysphagia:				
Patient chews tablets				
Consistency able to swallow	Solids: Soft Mashable Diet	Liquids: Level A (2 scoops T&E/200mL)	Vol. of Fluids used with medication 1.5L Max per day	
Medicine prescribed:	Frequency	Advice on Administering		
Concentrated Thick and Easy Mix for level A (prepare before administering medication)		Use two scoops of T&E in 100mls of Water and use this as Concentrated mix for administering drugs. (when mixed with the same amount of water carrying the tablets, it will form a Level A consistency suspension)		
ASPIRIN 75mg dispersible tablet (Regular Medication)	in the morning	Disperse the tablet in 10mls of water in a medicine cup. Add 10mls of the concentrated Mix of T&E prepared before in the pot with the drug, mix it and administer to the patient immediately. Add another 5mls of the concentrated T&E Master mix and 5 ml of water to the cup, mix with any possible trace left in the cup and administer to the patient		
DIPYRIDAMOLE (Persantin) 200mg MR Capsules (Regular Medication)	twice a day	If patient cannot swallow the capsule whole, recommend prescriber to prescribe liquid formulation. When giving liquid formulation, use 5mls spoon and administer to the patient immediately		
Patient's Name:	xxxx xxxxx	Hospital Number:	1234567	
IMAG Number: 24	If you have any queries call the Dysphagia Pharmacist: Manuel Serrano (Switchboard / 01603 000000) Pager 0700000000 (outside call)		Page 1 of 2	

Figure 6: Example of an I-MAG

The I-MAG was introduced to assist nurses to give medications safely to PWD. It was envisaged that the nurse would refer to the I-MAG every time they administered medicines orally or via enteral tube to the patient. The I-MAG was intended to ensure consistency in medicines administration and, therefore, reduce errors.

In order to ease the generation of I-MAGs in the hospital wards, the DP created a database of over 450 drugs with information based on current literature on how to administer those drugs to PWD with or without EFTs and possible alternatives that could improve the administration. The database was then incorporated into a Microsoft Access tool that allowed the addition of patient details and their medication and combined them with the information in the drug's database. The tool also permitted the editing of the information about medicines by the DP in order to produce individualised guidance for the nurses, carers, and relatives of patients or PWD on how to administer the medication.

3.3.1.1.2. Dysphagia pharmacist training

The main researcher and DP was a pharmacist with expertise in care for older people who received some training in the issues surrounding the administration of medication to PWD.

The DP was trained to the level of Foundation Dysphagia Practitioner⁽¹⁴⁹⁾ of the Inter-Professional Dysphagia Framework between July and November of 2010. It was implicitly required that the DP:

- demonstrated acceptable performance undertaking protocol-guided assessment of swallowing,
- identified presenting signs and symptoms, and undertook a protocol-guided assessment of dysphagia,
- initiated and implemented the actions dictated by the protocol and disseminated this information to the patient, the carer and the team.

The training for the DP also consisted of different sessions with some of the healthcare professionals involved in the care of PWD. These sessions included:

- shadowing a senior SALT during the assessment of PWD admitted to the wards,
- informative session with a Nutrition Nurse Specialist followed by theatre observations of the insertion of EFTs to PWD,
- communication partners: this course consists of training sessions for healthcare professionals within the NHS that aims to optimise the communication with patients with speech impediments secondary to another condition such as stroke, which is one of the main conditions associated to dysphagia,
- hospital training for a wider understanding of the wards' management on the provision of medication and medicines reconciliation.

3.3.1.1.3. Service introductory sessions

The healthcare professionals in the participating wards (see section 3.3.1.2) were invited to attend introductory information sessions about the content and the rationale of the study. These sessions were part of the original study designed by J. Kelly. Flyers (Appendix 2) were placed during July 2010 in the common areas of the study participating wards and in the pharmacy, SALT and dietetics departments in order to obtain participation of different professionals involved in the care of PWD. The comments collected from these introductory sessions provided the main researcher with an opportunity to identify the training needs of the nurses in the

training sessions that were carried out prior to the implementation of I-MAGs. These sessions also offered an opportunity to liaise with other professionals involved in the care of PWD and to explore the views of the attendants with regards to the study design. The attendants were given a short feedback form (Appendix 3) to provide their optional evaluation feedback on the sessions and to suggest other areas of practice to be covered in the subsequent training sessions.

Two introductory sessions per day (on 27th July and 3rd August) were held in order to facilitate attendance. Nineteen healthcare professionals attended the sessions (three pharmacists, eight SALTs, one dietician, one assistant practitioner and six staff nurses).

3.3.1.1.4. Training sessions on the use of I-MAGs

On 21st of September 2010 and 30th September 2010, one-hour training events were held on the two service (intervention) wards by the dysphagia pharmacist. The event was repeated four times each day to enable at least 85% of relevant staff to attend. Flyers (Appendix 4) were placed in the service wards and feedback forms (Appendixes 5) were collected from the attendants. The training sessions were aimed at the nurses but were open to all staff on the two intervention wards if they were involved with prescribing, dispensing and/or administering medicines. The feedback from the introductory sessions helped to identify the issues that the researcher needed to cover during these sessions. The content of the training was discussed with two sister nurses on the service wards one week before the events in order to confirm that the content would be suitable for the understanding of the nurses. The sessions served to introduce the I-MAG and rationalise and maximise its use, in relation to crushing tablets and opening capsules, using liquid formulations, and administering medicines through enteral tubes. Handouts of the material covered in the training session were made available to those staff attending and those unable to attend the sessions. These handouts included:

- recent publications highlighting the issues in the administration of medication to PWD,
- general guidance on the administration of medication to patients with dysphagia. This guidance contained information gathered by the DP related to the types of formulations and their uses and applications to PWD and/or EFTs,
- printouts and descriptions of available devices for the correct administration of medicines,

- A copy of an I-MAG.

A total of 19 staff nurses (60% of the employed nurses) and six healthcare assistants from the intervention wards attended one of the three sessions.

3.3.1.1.5. Piloting the service

The implementation of I-MAGs was tested in one of the intervention wards for six weeks (1st December 2010 until 9th January 2011) before the complete service delivery. The aim of this preliminary part of the study was to estimate the time, facilities and equipment required for a regular provision of I-MAGs and to prepare the environment for delivering the intervention. A diary was used to record any problems identified. Implementing a new service may encounter unexpected challenges especially as some components of the pilot study such as the software used to generate I-MAGs or the inclusion of DP in the wards had not yet been tested.

3.3.1.1.6. Implementation of the service

For 23 weeks (from 10th January until 17th June 2011) the DP generated an I-MAG for all the patients diagnosed with dysphagia by the SALT on the two service wards.

The provision of I-MAGs allowed the DP to collect data regarding:

- the number of PWD admitted to the intervention wards,
- the number of patients suitable to receive I-MAGs,
- the number of new and updated I-MAGs generated,
- the number of drugs contained in the guides,
- the estimated cost of the drugs prescribed,
- the time involved in producing the guides,
- the length of stay of patients with I-MAGs in the intervention wards.

The number of PWD admitted to the intervention wards was identified from the daily referral report received by the SALT department, to which the DP was granted access by the head of the department for the purpose of the service. The number of those patients that were suitable for receiving I-MAGs was then identified by medication assessment (explained in Section 3.3.2.) and recorded in a Microsoft Excel database created by the DP for analysis. The number of new and updated I-MAGs generated, the number of drugs contained in the guides and the length of stay of patients with I-MAGs in the intervention wards were obtained

from the software used to generate the I-MAGs. The estimated cost of the drugs prescribed was obtained from Drug Tariff⁽³²²⁾ as indicated in Section 3.3.3.

Although the complete dataset was analysed to present the characteristics mentioned above, the time involved in producing the guides was extracted from the provision of I-MAGs to 10 patients selected randomly (the first patient of the day during 10 consecutive days) towards the end of the study. A sample of 10 was taken as the variation in time was limited and consequently a greater sample size would provide no greater precision. The time involved in producing the guides included not only the electronic data generation but also a review of the patient's notes and availability of the medication prescribed in the medicines cabinet next to the patient's bed.

3.3.1.2. Main pilot study

The pilot study was conducted on four wards at the Norfolk and Norwich University Hospital, a large teaching hospital with over 800 beds providing acute secondary and some tertiary hospital services to the population of central Norfolk including Norwich, much of South Norfolk, Breckland, North Norfolk and Broadland.

Inclusion criteria for these wards were that they:

- routinely care for adult medical patients,
- routinely care for patients who have neurological conditions that can affect swallowing, e.g. strokes.

Exclusion criteria for these wards were:

- senior nurse unwilling for his / her staff to participate in the study,
- expected closure of the ward during the study period, e.g. for decorating.

The two control wards for the study were formed by two care-of-older people (COO) wards while the intervention wards were formed by a COO and a neurological-stroke unit. Further discussion about the choice of these wards can be found in the chief investigator's dissertation.⁽³²³⁾ The participating wards will be referred to as indicated in Table 12 for the rest of this dissertation.

	Intervention		Control	
Type of ward	Neurological-stroke unit	Care-of- older people	Care-of- older people	Care-of- older people
Nomenclature	I1	I2	C1	C2

Table 12: Nomenclature of the wards

During the preparation for the pilot study it was identified that the neurological-stroke unit often transferred patients that require specialised care post-stroke to a recovery unit off-site that provided longer-term care. Unless otherwise specified, the recovery unit is considered an “extension” of the neurological-stroke unit during this thesis and, therefore, combined data from the two units will be referred to as data from the neurological-stroke unit.

3.3.1.2.1. Patient recruitment

It was estimated, based on previous work in the type of wards being used for this study, that approximately 15 patients would be recruited per ward per month,⁽³²⁴⁾ making a total of 360 patients, 180 each on the intervention and control wards during the six months of recruitment. However, allowing for 33% not consenting or consenting and dropping out, we expected that data would be available from 240 patients.

For the 23 weeks (from 10th January until 17th June 2011) whilst the research was in progress, it was standard practice for all PWD on the two intervention wards to have I-MAGs prepared for them by the dysphagia pharmacist. Patients were recruited for the purposes of the study to provide feedback on the use of the I-MAG and to provide data on its effectiveness. Figure 7 shows the recruitment flow after the implementation of I-MAGs and the collection of data for the patient outcomes.

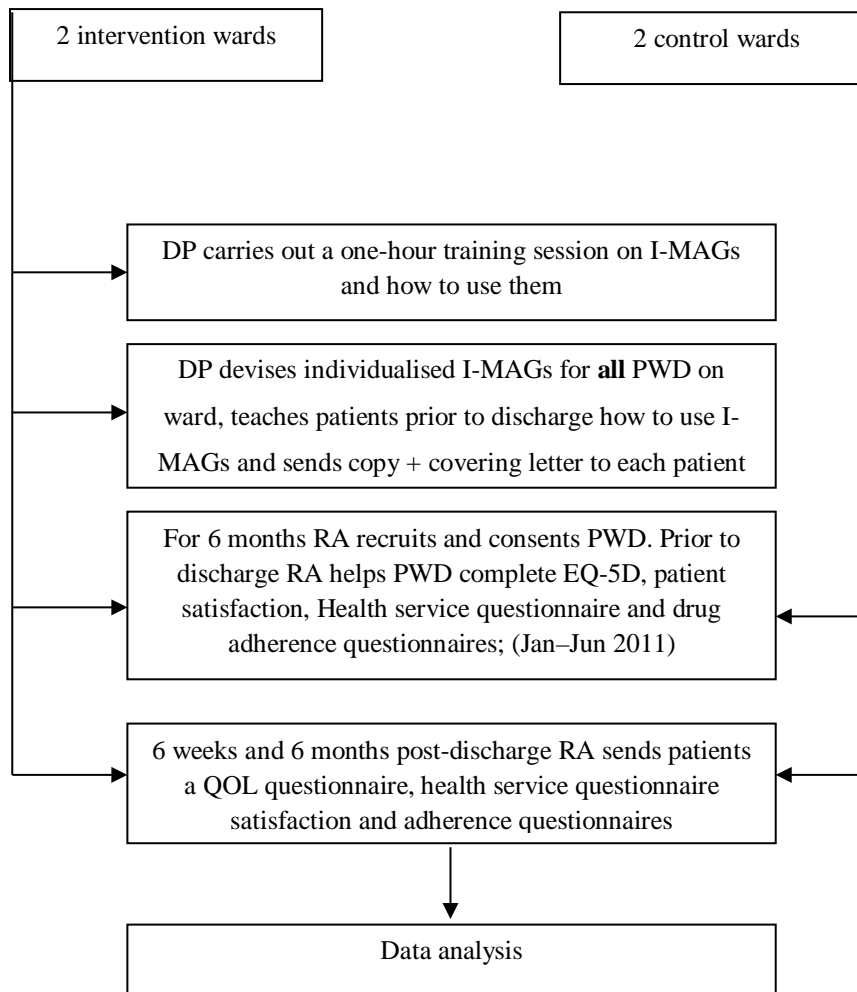


Figure 7: Recruitment and data collection flow chart

In order to comply with good clinical practice, a clinician in the ward was to ask the patients if they were happy to be approached by a researcher to receive information about the study before any involvement by the research team. This was achieved and recorded using CTA forms (Appendix 6). SALTs, nurses, ward pharmacists and the DP were able to ask the patients or their carers for Consent To Approach (CTA) in the intervention wards but this role was exclusively done by the DP. The DP then annotated the outcome in order not to ask the same patient again. In the control wards, where the DP was not carrying out any intervention, only the clinicians in the wards were able to ask for CTA from the patients and when a negative answer was given, the clinicians in the control wards preferred not to release this information in order to protect the confidentiality of the patient, therefore, only data from the patients that provided CTA to the research team were recorded.

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PWD were approached from all four intervention and control wards by the research assistant, who visited the wards daily. The research assistant liaised with the ward staff to ensure that patients or their relatives were willing to be approached by a researcher. The research assistant selected patients who meet the following criteria:

Inclusion criteria:

- current problems with swallowing as diagnosed by the SALTs,
- problems taking medicines as identified by the nurses, e.g. patient chews tablets as unable to swallow whole.

Exclusion criteria:

- patient unwilling to give informed consent,
- patient lacked mental capacity and their dysphagia is completely unrelated to the reason for their mental incapacity, as judged by the clinical team caring for the patient and personal consultee was unavailable,
- the consultee advised that the person would not have wanted to take part in the project.

The research assistant, when seeking patient consent, was guided by the clinical staff and used the Mental Capacity Act 2005⁽³²⁵⁾ definition to identify whether the patient was lacking capacity and thus was unable to consent to taking part in the study, i.e. if they were unable:

- to understand information relevant to the decision,
- to retain that information,
- to use or weigh that information,
- to communicate a decision.

If the patient was found to be lacking capacity, the research assistant discussed the criteria with the patient's carer and explained why he did not believe the patient could consent to taking part in the research, and hence why he was asking for the carer to act as personal consultee. Personal consultees were offered a copy of the Department of Health's booklet 'Making decisions: A guide for family, friends and other unpaid carers',⁽³²⁶⁾ which includes a section on research to help clarify the situation for them.

The research assistant gave each patient a copy of the patient invitation letter and the patient information sheet (Appendix 7). Where patients were unable to consent, but the personal consultee had indicated that, in their opinion, the potential participant would have wanted to take part in the project had they retained capacity,

the research assistant gave them a copy of the personal consultee invitation letter and information sheet (Appendix 8). The research assistant returned the next day to answer any questions the patient or personal consultee might have and obtain their written consent or assent (Appendix 9 and Appendix 10).

Patients who had given written consent to be involved in the study, and identified as ready for discharge, received a pre-discharge information session from the DP to ensure that they could use the medicine administration guidelines at home and that these were easy to read and understand. This session was also used to address any concerns the PWD had regarding the administration of their medication.

For all patients who were recruited to the study, the researcher included a copy of the I-MAG and a covering letter with the discharge information normally sent to the patient's general practitioner. The patient was also given a copy of the I-MAG and a covering letter to give to his community pharmacist. In the cases where the patient was discharged to a care home, the DP also visited the home and the nurse in charge of the care of that patient to inform her/him about how to use the I-MAG, the purpose of it and the nature of the study. The discharge I-MAGs had the dysphagia pharmacist's contact details at the bottom and the number and nature of queries made were recorded as part of data collection.

3.3.1.2.2. Patient outcomes

Secondary outcome measures were recorded at the time of recruitment to the trial, i.e. at discharge, at six weeks and again six months later. Patients who provided written consent were requested to complete the following:

- health-related Quality of Life measure: the EQ-5D^(327, 328) was be given to patients to identify its acceptability and validity, in terms of convergent validity, for the main study,
- a patient satisfaction questionnaire about information and pharmaceutical care (SIMS),^(329, 330)
- a medicine adherence questionnaire – patient or carer (Morisky),⁽³³¹⁾
- a health services use questionnaire (Appendix 11).

The EQ-5D and the SIMS are both validated tools. The medicine adherence questionnaire is based on questions developed by Morisky et al (1986) to measure compliance with antihypertensive medication. They have been demonstrated to show predictive validity (alpha reliability = 0.61)⁽³³¹⁾ and they have been used to assess adherence with medication for a variety of disease states, including asthma

and HIV. The questions are phrased in such a way that the answers demonstrating compliance require the patient to answer 'no', thus overcoming patient's yes-saying bias.⁽³³²⁾

The research assistant explained these to the patients after gaining their written consent and assisted the patients, if necessary, to complete the forms prior to discharge. At the time of discharge the research assistant collected the questionnaires.

Six weeks and six months after being recruited to the study and after discharge from hospital the research assistant posted the following evaluation forms for self-completion by the patient:

- health-related Quality of Life measure – the EQ-5D,
- Morisky's adherence questionnaire,
- patient satisfaction with information and pharmaceutical care questionnaire (SIMS),
- health services use questionnaire.

Two weeks after posting, the research assistant followed-up with a telephone call to non-responders and those who needed help filling in the forms (as identified at the time of discharge by the research assistant). The research assistant also reviewed the hospital electronic data (PAS system) to identify the number of emergency hospital admissions each patient had had.

3.3.2. Clinical interventions made by the DP

Previous to the generation of the I-MAG, a medication assessment based on current guidance⁽³³³⁾ was carried out on the patients identified. This assessment consisted of:

- reviewing the patient's dysphagia treatment plan, specifically for food and fluid consistencies recommended for the patient,
- reviewing the patient's medication profile for medications that may be difficult to swallow, are potentially dangerous if crushed or chewed, or can cause harm to others if crushed or handled incorrectly (e.g., finasteride),
- identifying dosage forms that should not be crushed include the following:
 - enteric-coated (EC),
 - extended-release (ER, XR),

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- long-acting (LA, XL),
 - controlled-release/delivery (CR, CD),
 - sustained-release/action (SR, SA),
- asking the patient or carer the following:
 - how they intend to administer each medication,
 - if any medication is difficult to swallow, or causes choking or gagging, have they been chewing or holding medications in the oral cavity,
 - being prepared to suggest alternative methods of administration, dosage forms, or therapeutic agents that are in a more suitable formulation if necessary or recommending a liquid dosage form may not always be appropriate as the liquid may be too thin or the suspension too thick. There is no data on the stability or bioavailability of liquid medications mixed with thickening agents,
 - communicating findings and recommendations in the medical record to the SALT and other allied healthcare professionals.

The outcome of the assessment was reflected on the generation of individualised recommendations on I-MAGs and stored in a database as part of the I-MAG software (see screenshot of database in Appendix 12). The DP also recorded those cases where good prescribing practice was not achieved (i.e. unsuitable formulation choices made by the prescriber, recommendations not based on scientific evidence or prescriptions containing non-existent formulations) and those where the DP's suggestions were disregarded. A printed red-paper form was used to record these events, which included date, nature of the event and, when possible, the outcome.

I-MAGs were updated during the admission in response to feedback, medication changes, and changes in the patient's condition.

The researcher visited the wards daily to identify new patients that were suitable to receive I-MAGs and also to update the current I-MAGs placed in the wards. When new I-MAGs were generated, the DP liaised with the ward pharmacist to confirm compliance with internal policies of the hospital (formulary, etc.) and once agreed the I-MAG was printed and placed with the patient's medicines chart. Subsequent ward rounds identified whether any changes were made by the prescriber to the patient's medication and, when necessary, the I-MAG would be updated and confirmed again with the ward pharmacist.

At the time of discharge, the DP issued I-MAGs for the patients to take with them. Before leaving the hospital, the DP explained to these patients or their carers how to use the I-MAGs and confirmed that the guides were understandable and legible by the patient or the carer. The outcomes of these conversations were not formally recorded as the outcomes were not part of the original pilot study design.

3.3.3. Costing estimates of recommendations

The recommendations presented in the I-MAGs represented the safest option to the drugs prescribed taking into consideration availability of the drug in the hospital formulary and the likely increase on the cost of alternative drugs or formulations.

The I-MAG software recorded all the recommendations made by the DP. These records helped to identify where safer alternatives for the patient were not recommended due to formulary restrictions. The likely cost of the safest alternatives not recommended was compared to the estimated cost of the available recommended formulations based on pricing obtained from Drug Tariff,⁽³²²⁾ which reflected what would be paid to pharmacy contractors for NHS services provided for reimbursement (the cost of the drugs, appliances etc. supplied against an NHS prescription form).

3.3.4. Evaluation study of stakeholders' opinions

A mixed methods evaluation was developed as a follow-up of that trial to assess the delivery of the guides. I-MAGs had not been provided before and their design may not be optimal. Opinions and experience on the relevance and acceptability of the I-MAGs from the HCPs involved in the delivery of the service were explored in this evaluation. Ethical review for the service evaluation was sought for this study and approval was granted by the Faculty of Health of the University of East Anglia on 22nd September, 2011. Due to the low risk of the research based on the evaluation character of the study, the school provided a fast-track pathway for ethical approval where full ethics committee review was not needed and an email confirmation of approval for the study as a service evaluation was received without further referential registration.

The aim of this evaluation section was to explore the acceptability of the I-MAGs service by the HCPs and their opinions on the provision of the guides.

The objectives of this evaluation were to:

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- obtain opinions on the advantages and disadvantages of the guides and the suitability of the service provided by the pharmacist,
- describe the acceptability of the I-MAGs service,
- compare the views of the HCPs on the use of these guides compared with normal practice,
- describe how I-MAGs could be improved,
- identify what support could help the care staff to use these guides.

In order to achieve the aim of this part of the study, a questionnaire was designed to be workable in practice, acceptable to participants and to effectively and efficiently gather valid and reliable data.⁽³³⁴⁾

Various methods to maximise recruitment rates were used in the design of the questionnaire such as university sponsorship, use of stamped return envelopes, and including a statement that others had responded.⁽³³⁵⁾ It was also recognised that a covering letter was likely to increase response when it includes the aim and sponsorship of the survey and emphasises the importance of the response and how the results will be used.⁽³³⁶⁾

The strength of using questionnaires for this purpose is that they are useable to collect unambiguous and easy to count answers, leading to quantitative data for analysis.⁽³³⁶⁾ However, pre-coded choices may not be sufficiently comprehensive and not all answers may be easily accommodated and respondents may, therefore, be “forced” to choose inappropriate pre-coded answers that did not represent their views.⁽³³⁶⁾ To compensate for this disadvantage of the questionnaires, there was a space for further comments at the end of every question and at the end of the questionnaire so the respondent could express any other opinions not fully represented by the pre-coded answers.

The style of the closed questions consisted of a combination of Likert scale and dichotomous in order to get an opinion from the audience in limited words, assess how the participants felt towards a certain issue or to avoid ambivalent answers, respectively depending on the issue approached.

Face validity checks were carried through peer review discussions of the questionnaire with the academic supervisors. However, in order to avoid the risk of sharing similar perspectives,⁽³³⁷⁾ a preliminary version of the questionnaire was piloted with a hospital pharmacist which also served to explore the content validity of the questionnaire in relation to the extent to which the design could gather data

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relevant to the topic. The questionnaire was piloted with the ward pharmacist from the intervention wards at the end of September 2011. This pharmacist didn't identify any concerns when completing the questionnaire and highlighted that it took no more than 20 minutes to complete the open and closed questions.

All participants received the same questionnaire (Appendix 13 and Appendix 14) but two additional questions relevant only to nurse practice were included in the nurses' questionnaires to enhance content validity: one related to the nurse training sessions and the other referred to the practicality of the I-MAGs when nurses were following the recommendations on the guide.

This service evaluation was carried out in one of the wards where almost all I-MAGs (94.5%) were implemented. The participants were all nurses, pharmacists and SALTs who were practising in the ward during the term of delivery of the I-MAGs. The chosen wards relied on the regular support from 20 members in the nursing team, three pharmacists and three SALTs during the delivery of this service.

The questionnaire covered the six main aspects of the delivery of the service across 26 questions. These aspects were:

- preparation and training sessions before I-MAG introduction,
- the presentation of I-MAGs,
- the practicality of I-MAGs,
- delivery of the service by the Dysphagia Pharmacist (DP),
- content of the I-MAG,
- personal opinions of participants.

The DP that had been fully involved in the delivery of the I-MAGs approached in person the potential participants during September and beginning of October 2011, two months after the removal of the I-MAGs in the intervention ward. The participants were encouraged to take the questionnaire away for completion. All the questionnaires were pseudo-anonymised (anonymised within the group of HCP) and then presented to the staff members involved during the delivery of the service, with the cover letter explaining the purpose of the study with the questionnaire (Appendix 15) and a pre-stamped envelope addressed to the DP. Due to the limited size of the group of participants, only their role in the ward was asked for as part of the demographic data in order to safeguard the confidentiality of the

responses. The participants were then coded with a letter that represented their role (S for SALT, P for pharmacist and N for nurse) followed by a randomised number.

3.3.5. Data analysis

The analysis of the data obtained was a combination of qualitative and quantitative elements gained from the delivery of the service, the recruitment and follow-up of the participants of the pilot study and from the stakeholders' opinions (service evaluation).

The data obtained from the delivery of service was used to identify the prevalence of dysphagia in the hospital wards. Additional data was collected about the number of patients receiving I-MAGs, time spent on the generation of the guides, number and formulation of the drugs included in them and the length of stay of the patients receiving I-MAGs with the aim of exploring elements of feasibility of the service. The analysis of optimising the administration of medication to PWD receiving I-MAGs was carried out through an estimation of the percentage increase in the cost of providing suitable alternative formulations in order to estimate potential costs in a larger trial.

The comments and answers to the open questions were analysed using a simple qualitative thematic analysis. Thematic analysis is one of the most commonly used methods of qualitative analysis and the task of the researcher was to identify a limited number of themes which adequately reflect their textual data. As with all qualitative analysis, it was vitally important that the researcher was extremely familiar with the data as the analysis was dynamic (prompting emerging themes) and insightful (inductive).⁽³³⁸⁾ For this reason, the researcher carried out the data collection himself and then coded the data. On the basis of the codings, the researcher then identified themes which integrated substantial sets of these codings. The researcher tried to define each theme sufficiently so that it was clear to others exactly what the theme was. The recruitment rates were also identified and analysed. It was intended that the analyses of the follow-up questionnaires were carried out by fitting generalised linear models to the data, with the aim of estimating the sizes of any differences between the groups and their standard errors. Models fitted⁽³³⁹⁾ would respect the structure of the data (before and after pairing for example), and baseline measures would have been included as covariates where appropriate. A sub-group analysis would have been performed when a patient representative had completed the questionnaire as they would provide a third-party estimate of Quality of Life.

3.4. Results

In line with the structure followed in the presentation of the methods, the results are presented in four different sections:

- the main pilot study (including service),
- the clinical interventions made by the DP,
- costing estimates of recommendations,
- service evaluation.

3.4.1. Development of the service and main pilot study

This section explains the results of the delivery of the service and explores the outcomes of the pilot study.

3.4.1.1. Development of the Service

3.4.1.1.1. Piloting the I-MAGs

The implementation of I-MAGs was piloted for six weeks in one of the intervention COO wards and three patients received I-MAGs during this period.

The delivery of the service during this period identified:

- further required development of the software: the tool used to generate I-MAGs had not been tested in the field before and it required additional features such as record keeping of enquiries and interventions made by HCPs,
- the need for Standard Operation Procedures (SOPs): although all the HCPs involved in the care of PWD were invited to participate in the introductory sessions, the implementation of I-MAGs required written SOPs to help the delivery of the service,
- technical support: the electronic collection of any patient's details required certified devices capable of encrypting content and assure data protection. Several days were spent on setting up the technical support for the service.

3.4.1.1.2. Implementation of I-MAGs

During the provision of the service, 755 patients were admitted in the service wards (I1 and I2). A total of 244 (32.3%) suffered from dysphagia of which 75 (9.9%) patients received I-MAGs. Table 13 compares the proportion of PWD that received I-MAGs within the different service wards.

	I1	I2	Female (% from total)
Admissions	479	276	Not available
PWD (%)	203 (42.4%)	41 (14.9%)	108 (44.5%)
Patient with I-MAG (% from PWD)	61 (30.0%)	8 (19.5%)	31 (41.3%)

Table 13: Proportion of patients that received I-MAGs in the service wards

The patients that received I-MAGs were female in 31 cases (41.3%). The Median (Quartiles) of the age of these patients was 81.6 (74.7, 87.1) in females and 80.1 (72.7, 88.4) in males.

The remaining 169 patients did not receive the administration guides due to:

- patient had been discharged or transferred to other wards of the hospital before DP's assessment of the patient (n=99),
- limited access to the wards during Norovirus outbreak (n=18),
- dysphagia was no longer present (n=19),
- patient was on IV medication or palliative care (n=29),
- patient deceased before DP's visit (n=4).

3.4.1.1.3. Number of medicines

A total of 523 items were prescribed during the stay of the 75 patients that received the I-MAGs, with each patient receiving a mean (SD) of 6.9 (3.2) medicines during their stay.

3.4.1.1.4. I-MAGs generated and number of recommendations

When the medication was reviewed, the patient's condition changed or the patient was discharged the I-MAGs were updated or removed, as appropriate. Almost half of the 75 patients received only one copy of their I-MAG while 51% received at least one further update/revision (Figure 8). A total of 164 I-MAGs were issued containing a total of 1,002 different recommendations on how to administer the medicines showing a Median (Quartiles) of 6 (5, 8) per I-MAG.

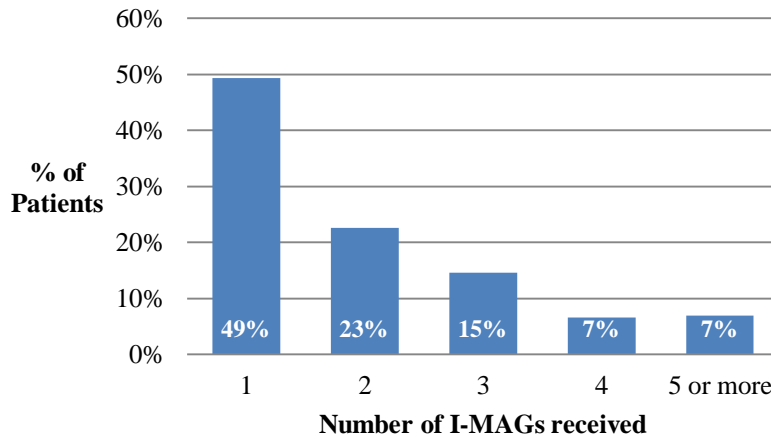


Figure 8: I-MAGs received per patient

3.4.1.1.5. Length of stay in the intervention wards

PWD stayed in hospital 24 days (Median 24.5, Quartiles 9.7, 34.2) between admission and discharge. Differences in the length of stay were observed within our sample as indicated in Figure 9. The length of stay was increased to an average of 55 days if patients were transferred to the recovery unit from the neurological-stroke unit where the average length of stay was 31 days.

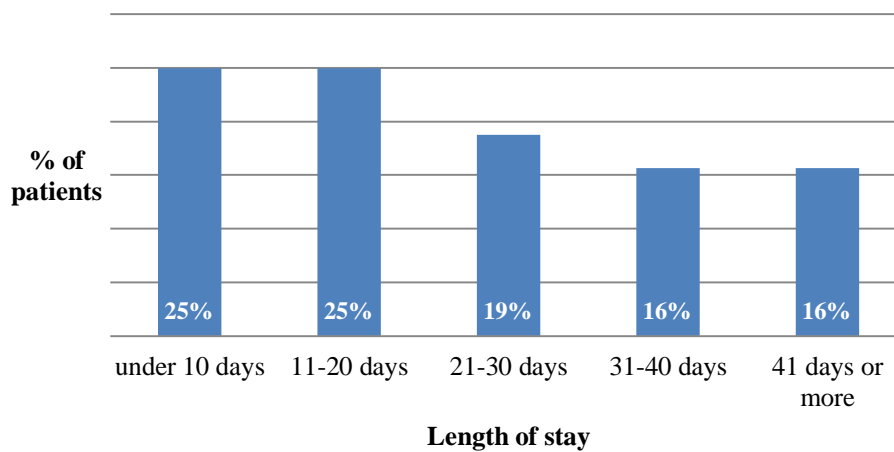


Figure 9: PWD's length of stay in the Stroke Unit (I2)

3.4.1.1.6. Time to produce I-MAGs

The mean (SD) time dedicated to issuing the I-MAGs from a randomly selected sample of 10 patients indicated that the DP required 30.4 (6.2) minutes per I-MAG plus an average of seven minutes on the initial assessment of the patient. This

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assessment included review of the patient's notes and availability of the medication prescribed in the medicines cabinet next to patient's bed.

3.4.1.2. Pilot study

3.4.1.2.1. Recruitment of Patients

During the 23 weeks of the intervention in the hospital wards, 755 patients were admitted the intervention wards and 621 were admitted in the control wards (Table 14). In the intervention wards, a total of 244 PWD (32.3%) were referred to the SALTs after an early assessment by the nursing team. Figure 10 (page 122) shows a summary of the recruitment flow throughout the study. Data on the number of patients admitted to the wards was provided by the ward clerk; however, no further details such as gender, age or condition for the admission were made available.

I1	I2	C1	C2
479	276	278	333
Total: 755		Total: 621	

Table 14: Number of admissions to hospital during research period

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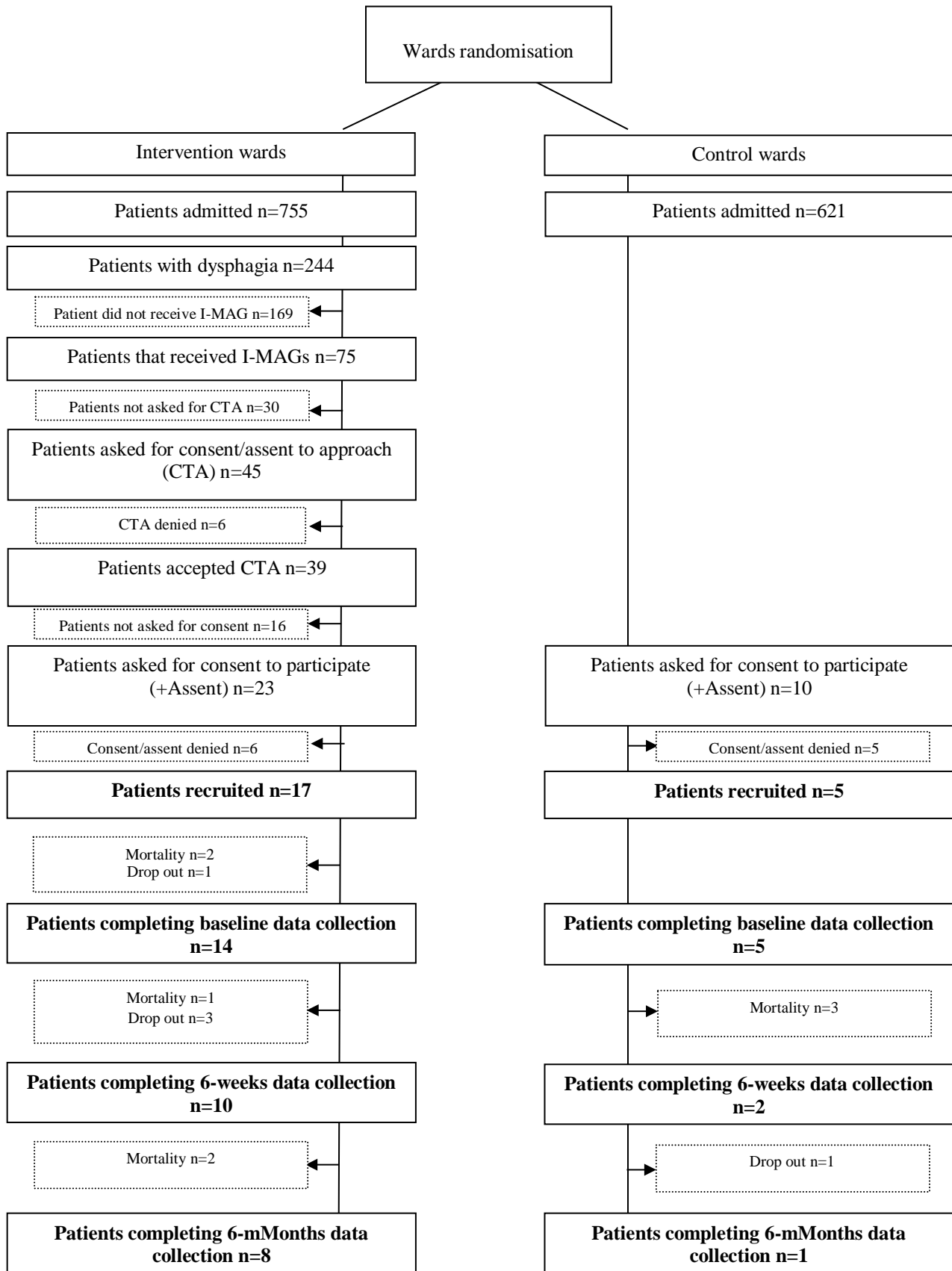


Figure 10: Recruitment flow chart

3.4.1.2.1.1. Consent to approach

In the intervention wards, a total of 75 patients were eligible to take part in the study and 45 of them were asked for CTA. The remaining 30 patients were unexpectedly discharged before the estimated discharge date (EDD) (n=29) or the patient did not have capacity to respond to the question and no relatives were available (n=1) (Table 15). CTA was accepted by 10 patients in the control wards but no data about the number of patients that did not want to be approached by the RA were provided to the research team by the clinicians in the ward.

	I1	I2	Total intervention
CTA accepted	37	2	39
CTA denied	6	0	6
CTA not asked	25	5	30

Table 15: Obtaining CTA from eligible patients

3.4.1.2.1.2. Consent to participate

From the 39 patients that consented to be approached by the RA in the intervention wards, 23 were interested in receiving more information about the study. 16 were not asked for consent to participate as, between getting CTA and the RA having the opportunity to approach the patient, they were discharged (n=14), transferred to another ward (n=1) or the patient did not have capacity to respond to the question and no relatives were available (n=1). The total of 23 patients in the intervention wards interested in receiving more information about the study were asked to participate and 17 patients were recruited for the study.

All the patients that consented to be approached by the RA in the control wards were visited by the RA and offered the opportunity to participate. Consent was obtained from five of the 10 patients in the control wards (Table 16).

	I1	I2	Total intervention	C1	C2	Total Control
Consent obtained	16	1	17	3	2	5
Consent denied	6	0	6	0	5	5
Consent not asked	15	1	16	0	0	0

Table 16: Summary of consent obtained

If found lacking capacity, a ‘consultee’ who was willing to be consulted about the person’s participation was identified. During the recruitment period the decision of taking part in the study was made by the consultee in 17 cases (51%). This proportion was higher in the intervention wards where in 15 cases (65.2%) the consultee made the decision compared to two cases (20.0%) in the control wards as seen in Table 17.

	I1	I2	Total intervention	C1	C2	Total Control
Consent given by patient	6	0	6 (26.1%)	3	2	5 (50.0%)
Consent denied by patient	2	0	2 (8.7%)	0	3	3 (30.0%)
Assent given by NOK	10	1	11 (47.8%)	0	0	0
Assent denied by NOK	4	0	4 (17.4%)	0	2	2 (20.0%)

Table 17: Comparison of consent and assent rates

After giving consent to be approached by the RA, 73.9% and 50.0% of the patients in the intervention and control wards, respectively, were interested in taking part in the study and were, therefore, recruited. Table 18 provides a summary of the recruitment rates in the control and intervention wards and a comparison of these rates when considering the total number of patients eligible for the study and also the total number of patients approached.

	Total intervention	Total Control
Total Eligible Patients (TEP)	75	Not known
CTA obtained from TEP	39 (52.0%)	Not known
CTA obtained from approached patients	39 (86.7%)	Not known
Consent obtained from TEP	17 (22.6%)	Not known
Consent obtained from approached patients	17 (73.9%)	5 (50.0%)

Table 18: Recruitment rates

3.4.1.2.2. Patient outcomes

As mentioned during the methodology of this study, the recruited patients were followed-up six weeks and six months after discharge and after completion of the baseline data collection.

From the total of 22 recruited patients across the intervention and control wards, nine patients (eight intervention and one control) completed the study. Eight patients passed away during the follow-up period and another five dropped out (Table 19).

	I1	I2	Total intervention	C1	C2	Total Control	Total
Consent obtained	16	1	17	3	2	5	22
Dropped out	3	1	4 (23.5%)	1	0	1 (20.0%)	5 (22.7%)
Mortality	5	0	5 (29.4%)	2	1	3 (60.0%)	8 (36.3%)

Table 19: Drop out and mortality rates

Due to the small number of participants completing the questionnaires during the period of follow-up to measure secondary outcomes, no statistical analysis was

carried out. However, the questionnaires were returned fully completed in the majority of cases and they offered an opportunity to identify whether the patients were being discharged to care homes or to their own homes.

It was expected that the differences between the conditions suffered by the patients would probably not allow the observation of any side-effects directly related to the implementation of the service. However, a clinical audit was carried out by the research and development coordinator at the same hospital. This audit reviewed the medical history of the patients receiving I-MAGs and of those recruited for the study. The report generated on 23rd May of 2012, didn't identify any side-effects or negative outcomes as a consequence of the implementation of the service.

3.4.2. Cost of medication prescribed

During the provision of I-MAGs, 116 different medicines were prescribed to PWD receiving the guides in the intervention wards. These 116 medicines were recommended in the I-MAGs as a safe option within alternatives offered by the hospital's formulary and restricted by price. Table 20 provides information about medicines and their formulations for the 20 most frequently prescribed. These medicines represent 66.3% of the oral medications prescribed for PWD. This table also shows the differences in cost between the formulations and the likely rates of increase of the cost when all the oral solid formulations are replaced by a safer liquid or dispersible alternative.

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Drug	Formulation used	Times prescribed	Cost per dose (dose)	Liquid formulation or dispersible tablet available	Cost of alternative formulation per dose	Percentage increase of cost when using alternatives on all administrations*
Paracetamol	Efferves. tablet	108	11p (500mg)	Paracetamol 250mg/5ml suspension	13p	18.2%
Aspirin	Dispersible tablet	75	3p (75mg)	N/A	N/A	N/A
Lansoprazole	Capsules	17	4.6p (15mg)	Lansoprazole 15mg Orodispersible tablets	10.6p	21.2%
	Orodispers. tablets	38	10.6p (15mg)	N/A	N/A	
Simvastatin	Tablets	48	4.2p (40mg)	Simvastatin 20mg/5ml suspension	148p	3,423.8%
Amlodipine	Tablets	44	3.5p (10mg)	Special Amlodipine 10mg/5ml solution	452.3p	12,822.9%
Digoxin	Tablets	41	3.8p (125mcg)	Digoxin 50mcg/ml elixir	22.3p	425.9%
	Elixir	1	22.3p	N/A	N/A	
Bisoprolol	Tablets	39	4.1p (5mg)	Special Bisoprolol 2.5mg/5ml solution	441.7p	10,673.2%
Thick And Easy	Used as carrier for medication	33	N/A	N/A	N/A	N/A
Senna	Syrup	27	5.38p (15mg)	N/A	N/A	N/A
Citalopram	Tablets	25	3.4p (20mg)	Citalopram 40mg/ml drops	28.5p	552.9%
	drops	1	28.5p (20mg)	N/A	N/A	
Clopidogrel	Tablets	25	6.7p (75mg)	Special Clopidogrel 75mg/5ml solution	270.6p	3,938.8%
Levothyroxine	Tablets	17	9.9p (25mg)	Levothyroxine 50mg/5ml solution	137p	373.0%
	Suspension	3	137p	N/A	N/A	
Prednisolone	Soluble Tablets	16	68.1p (5mg)	N/A	N/A	23.3%
	Regular Tablets	4	3.7p (5mg)	Prednisolone 5mg Soluble tablets	68.1p (5mg)	

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Drug	Formulation used	Times prescribed	Cost per dose (dose)	Liquid formulation or dispersible tablet available	Cost of alternative formulation per dose	Percentage Increase of cost when using alternatives on all administrations*
Metoclopramide	Suspension	19	95p (10mg)	N/A	N/A	N/A
Morphine	Suspension	12	8.25p (10mg)	N/A	N/A	-3.6%
	Tablets	4	9.48p (10mg)	Morphine 10mg/5ml oral solution	8.2p	
Ramipril	Capsules	15	4p (2.5mg)	Special Ramipril 2.5mg/5ml solution	266.7p	6,567.5%
Thiamine	Tablets	15	4.8p (100mg)	X	N/A	N/A
Gabapentin	Capsules	13	2.5p (100mg)	Gabapentin 50mg/ml solution	76.7p	2,968.0%
Lisinopril	Tablets	12	3.5p (10mg)	Special Lisinopril 5mg/5ml solution	416.5p	11,800.0%
Perindopril	Tablets	12	6.7p	X	N/A	N/A

Prices obtained from Drug Tariff 2013⁽³²²⁾

*This figure indicates the percentage increase of the total amount of administrations =

$$\frac{(\text{cost of alternative formulations} + \text{cost of the ones without alternative}) - \text{Cost of the current practice}}{\text{Cost of current practice}} \times 100$$

Table 20: 20 most common drugs prescribed on patients with I-MAGs

Table 20 shows that the cost of the alternatives is usually much greater and the largest differences are seen when the alternative is an unlicensed ‘special’. Further analysis of this cost is reflected in Table 21 in which a general approximation of the cost of alternative formulations with and without the use of specials is shown. While the use of available liquid or dispersible formulations would be 2.4 times larger than the original cost, the use of special formulations in all the administrations where no other alternative is available would be almost ten times greater.

	Cost	Increment
Current administration	6,926.38p (£69.26)	N/A
Current administration when adding only available alternatives	16,735.5p (£167.35)	141.62%
Current administration when adding available alternatives and special formulations	69,043.1p (£690.31)	896.69%

Table 21: Comparison of cost increment (percentage increase) between alternative available formulations and special formulations

3.4.3. Clinical interventions made by the DP

A total of 1,002 different recommendations were reflected in the I-MAGs during the delivery of the service as indicated in section 3.4.1.1.4. (see example extracted from database in Appendix 12).

During the period of the study, several cases were observed where the DP intervened in changes to the current medication prescribed before the administration was carried out. While the role of the DP was often limited by the hospital formulary to suggest correct ways of administering the medication prescribed, in certain instances further suggestions had to be highlighted to the prescriber or to other HCPs to safeguard patients' wellbeing. These suggestions were grounded on:

- corrections of human errors or inadequate practice identified,
- drugs that were not part of the hospital formulary,
- lack of evidence based practice on the prescribing.

While these interventions could be considered part of the normal practice of a ward pharmacist or a pharmacist trained on dysphagia, they have been selected as they may help in gaining more understanding about the context in which the nurses routinely practice. The cases presented are all related to challenges due to the formulation.

Morphine sulphate MR case

A patient received a prescription for Zomorph 5mg. Zomorph is a 12-hours modified-release formulation in capsules, where the lowest strength manufactured

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is 10mg. As the dose prescribed was lower than the lowest strength formulation, the nurses administered MST continus 5mg tablets (also a 12-hours modified-release formulation). This tablet was previously crushed as patient was recommended by the SALT team to have liquid medication. On observation, the DP stopped the administration and alerted the ward pharmacist who endorsed the prescription as “morphine sulphate/MST” with the intention of safeguarding the practice of the nurse. The DP highlighted the issue to the prescriber and the prescription was then changed to Zomorph 10mg capsules twice a day which can be dispersed in water and administered to the patient safely.

Amisulpride case

A patient was prescribed amisulpride 25mg tablets twice a day for negative symptoms of schizophrenia and was under the recommendations of the SALT team of only taking liquid medication. The lowest dose manufactured in tablet form is 50mg. During observation, it was identified that the nurse had been halving the tablets and crushing them before dispersing them in water. These tablets are not licenced for crushing and there is no evidence of their efficacy when being crushed. The DP identified amisulpride liquid as an alternative and suggested it to the pharmacy department as a replacement. Despite not being part of the formulary, and after justifying its use, the liquid formulation replaced the original prescription of tablets. This intervention involved a total increase of £11 in the treatment of the patient across four months of treatment (£2.75 per month) but it made the administration of this medication safer than crushing tablets.

Co-amoxiclav case

Co-amoxiclav is an antibiotic that was often prescribed in the intervention wards. In three cases, this antibiotic was prescribed in tablet form for the administration via enteral feeding tubes. Although the suspension form is manufactured, it is very resistant to flushing and, therefore, the use of dispersible tablets is recommended for its use via enteral feeding tubes.⁽²¹⁵⁾ The DP highlighted these recommendations with evidence-based references and dispersible tablets replaced the regular tablets.

Felodipine MR case

Similar to the morphine case mentioned above, felodipine is a modified-release formulation that is not licensed for crushing. The prescription had been endorsed by the ward pharmacist with “crush” next to it as the patient was recommended only liquid medication. The DP suggested liquid alternatives of drugs with similar

effects. In the process of changing the prescription, the patient passed away as he was terminally ill.

Lisinopril and digoxin cases

Throughout the 23 weeks of the implementation of I-MAGs, it was observed that the patients that had been prescribed lisinopril (treatment of high blood pressure) and digoxin (treatment of atrial fibrillation) were administered these tablets sublingually when the patients had problems swallowing. The use of these medicines sublingually is not licensed and there is no evidence to support this way of administration. However, the prescribing team refused to change it or justify it as they considered that the effect of the medication was the same as that of the licensed administrations.

3.4.4. Service evaluation

3.4.4.1. Recruitment

All of the pharmacists (n=3, 100%) and all of the SALTs (n=3, 100%) but only 13 out of 20 (65%) members of the nursing team completed the questionnaire. Reasons for not completing included some of them having moved from their job on the ward, not being in charge of administration of medication or working on occasional night shifts and so could not be approached during the period for completion.

3.4.4.2. Closed responses to the questionnaire

Eighteen out of the 19 respondents affirmed that they would like this service to continue being provided with most adding substantial comments to the open questions. Due to the small size of the groups of SALTs and pharmacists, the answers to the closed questions presented are those from the nurses. However, Appendix 16 offers a summary of the answers from all the participants.

Preparation and training sessions

Six of the 13 participating nurses remembered attending the training sessions organised in September and October 2010. Figure 11 summarises the opinions of the respondents about the training sessions offered.

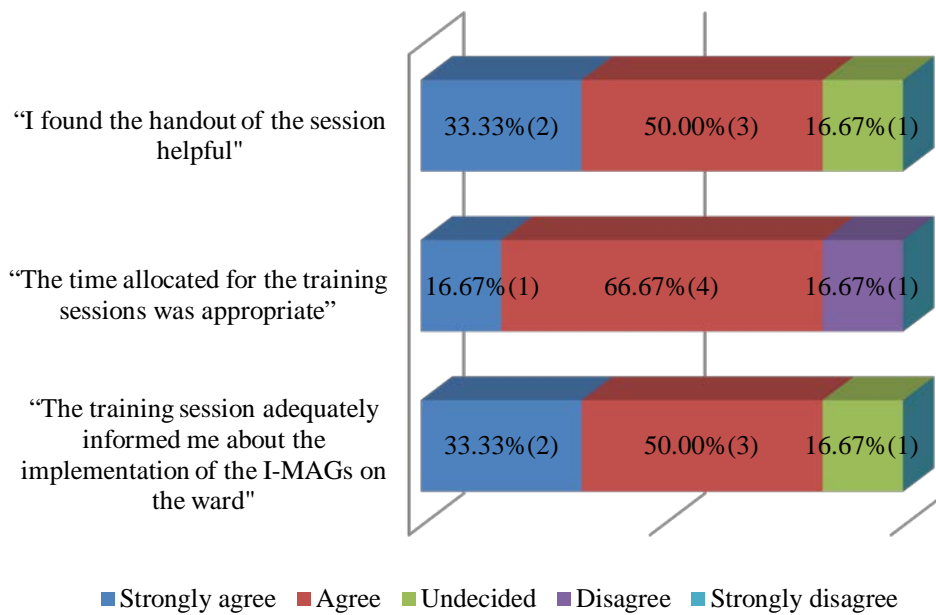


Figure 11: Nurses' evaluation rates of the training sessions [%,(n)]

Presentation of I-MAGs

All participants said they had seen I-MAGs in the ward and agreed that the medication chart was the best place to locate the guide as it had been done during the delivery of the service. Nine nurses stated that they would have preferred the I-MAG in portrait layout compared to four who preferred the landscape format in which it was provided. Eleven of the respondents considered that the format and the font size of the I-MAGs were easy or very easy to read, while the rest were undecided.

Practicality of I-MAGs

The answers from the nurse participants identified very positive results to the incorporation of the I-MAGs in their practice on the ward as illustrated in Figure 12. Additionally, eight out of the 13 nurses felt more confident in their practice when the I-MAGs were in place. The remaining five answered that they did not feel more confident because very often or every time they would have done the same as indicated in the guide.

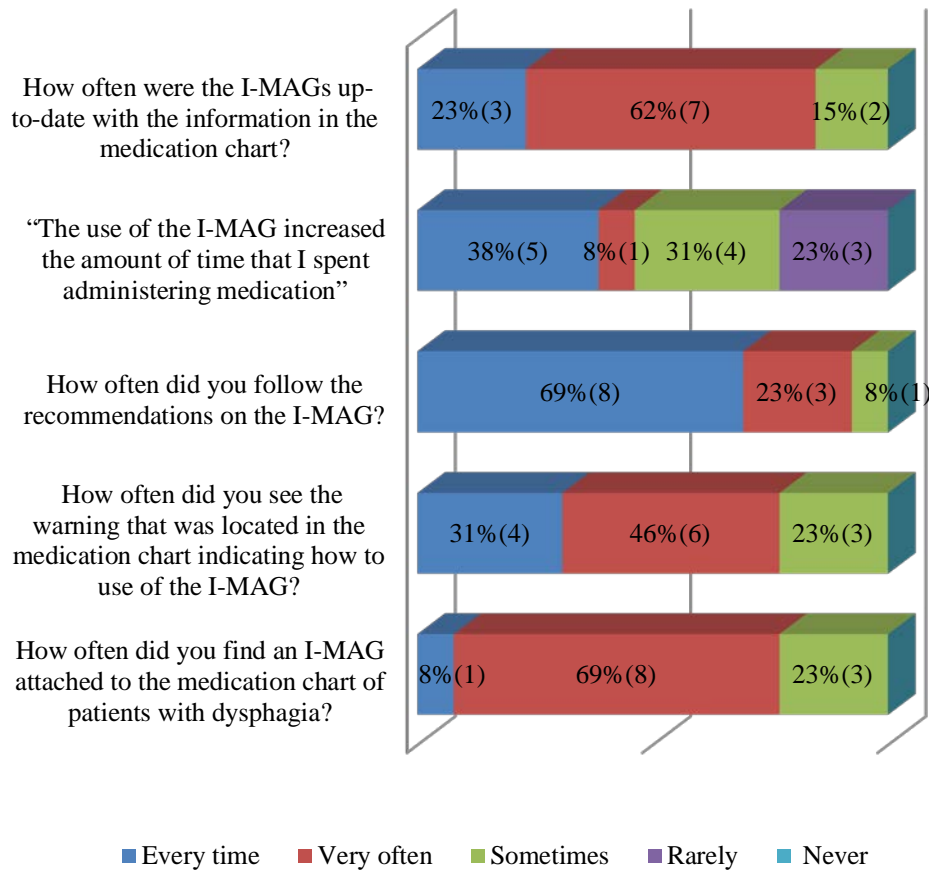


Figure 12: I-MAGs practicality evaluation [%,(n)]

Delivery of the service by the dysphagia pharmacist (DP)

A total of nine of all the nurse respondents considered that the availability of the DP was adequate, but this was in marked contrast to the four nurses who wanted more DP availability such as during evenings and weekends.

Content

While all the respondents confirmed that they found the instructions in the I-MAGs easy to understand, eight of the nurses accepted that without the guide, mostly or every time, they would have administered medication differently.

In the final section of the questionnaire, 12 out of the 13 nurse participants concluded that they wanted the I-MAGs to carry on being implemented as a regular service.

3.4.4.3. Open responses

Seventeen out of the 19 respondents provided further comments where space was made available at the end of each section of the questionnaire. The qualitative analysis of all additional comments from respondents highlighted several themes related to the use of I-MAGs for administration for PWD. The most common themes were:

- time,
- safety,
- usability,
- presentation,
- practicality,
- training.

Time

I-MAGs had the potential of having an impact on the routines of the HCPs involved. Time was the most concerning issue for the participants. Most of the answers made a clear distinction between the time it takes to administer medication, the time pressure that nurses feel in their routines and the time needed by ward pharmacist to improve the recommendations on how to administer medication. The comments highlighted how the I-MAGs can increase the time of directly administering medications, but responses also noted that the guides reduce the time needed by the nurses in checking with the pharmacists on how to proceed with medicines administration when instructions have not been provided. One of the nurse participants mentioned:

“Medication given more timely (no need of checking with pharmacy about crushing, etc. first.” (N23)

Other professionals’ responses highlighted other types of issues. The time of the ward pharmacist adding elaborated endorsements to the medication chart is reduced as the presence of the DP avoids having to initiate enquiries to the medicines information centre or having to check literature on the administration of drugs. One of the pharmacists commented the following about this issue:

“Presence of I-MAG avoided need for pharmacy endorsement and drug chart re-administration of medication.”(P6)

The time of the drug rounds is strongly related to other issues in the ward (staffing, paperwork, etc.) and some participants highlighted the need for more members of

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staff in the ward. They considered that this would allow them to concentrate more on the I-MAGs especially when they are first implemented. Some of the nurse participants identified that the I-MAGs were taking some extra time to start with but once they got used to them the time spent on the drug round was actually reduced.

"If we followed IMAGs, it took a lot of time to finish the meds round, but later it was easy." (N18)

One of the issues more closely related to the time spent on the drug rounds is how the time is affecting their confidence. I-MAGs seem to be accepted as a very time-efficient tool as the nurses receive precise instructions and that makes them feel confident about the time spent in the administration and the quality of care that they have provided. Not only medication is given more 'timely', but also the nurses feel more confident in their practice. Comments from these respondents also highlighted specific ways in which safety was prioritised and improved during the administration of medicines:

"More confident in my practice, knowing right way of administering each drug." (N27)

Safety

The respondents highlighted emphatically how the use of I-MAGs could improve the safety from two different perspectives:

- safety of the patient when receiving the right formulation adequately as the participants consider that the I-MAGs are an improvement to the patient care:

"Patients receive medication in the correct format/administered the correct way. Safer for patients and staff." (S1),

- safety of the nurses administering the medication as correctly administering medication may avoid harm to nurses from exposure to certain drugs such as steroids or cytotoxic drugs, but also legal liability concerns when manipulating incorrectly the original formulation of the drug. The safety of the healthcare professional had not been considered before, but these comments identify other concerns in the practice carried out in the wards:

"Increases staff safety (e.g. avoid exposure to medication that should not be crushed)." (P7)

Usability

Some comments added by the respondents pointed out wider potential uses of the I-MAGs to other patients without dysphagia, implementation of I-MAGs from time of admission, and its uses for carers or relatives of PWD at home. Some of the participants highlighted that the safety that the presence of I-MAGs offered, should be expanded not only during the patient's stay in the ward but also at the time of discharge to secure appropriate care of PWD.

“Very useful to obtain provision of I-MAG to patients being discharged before, or having not recovered their swallow to assist them with medicines administration on discharge.” (P6)

The I-MAGs were originally being considered by the researchers for use in the hospital environment. However, the respondents identified numerous further uses for the guides. For example: implementation at the time of admission linked to the information provided to the nurses when a patient commences their stay in hospital:

“A chart in the department with all information of commonly used drugs in dysphagia patients will improve basic understanding and is useful in newly-admitted patients as well as newly commencing medicines whilst waiting for I-MAGs.” (N27)

In primary care, the implementation of the guides could support relatives and carers in the administration of medication and also other nurses and professionals in care homes when the patients are discharged to these settings:

“Use by the patients themselves or, e.g.: carers/family as appropriate either at home or if discharge to a rehab unit, residential/nursing home, etc.” (P6)

Presentation

Comments provided confirming that only minor changes in the format would be needed reiterated:

“They are quite wordy. Maybe drug and dose in larger font.” (P8)

Practicality

Participants found I-MAGs to be a very convenient tool for their practice, as already confirmed it in the closed questions. I-MAGs were found to promote a safer and more time-efficient administration of medication. Some of the

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participants also identified that the I-MAG could help highlighting areas of improvement in their practice:

“Useful. Made me realise of how I can improve.” (N16)

Training

The respondents considered that more detailed training would be needed before implementation of an I-MAG service to get a full understanding of the purpose of the guides. Although the training sessions were aiming for increasing the awareness of dysphagia, it is clearly needed to facilitate the access of resources to the nurses on the ward to help them increase their knowledge in the subject. The participants also reflected in their comments the positive approach towards learning and training:

“More detail training sessions could improve understanding and effective use of the I-MAGs.” (N27)

Other themes

The open responses also identified other concerns of the participants such as individualised treatment of PWD, disadvantages of new services, clinical confidence and availability of the I-MAGs. One of the pharmacist participants described this novel service as:

“Provision of individualised uniform information for nurses regarding medication administration.” (P6)

Further comments showed that the participants received the service very positively and the general acceptability of the guides was exceptional:

“I would like to see them continue and expand.” (N23)

3.5. Discussion

The main aim of this study was to explore the provision of I-MAGs by a specialised pharmacist to PWD and in liaison with other healthcare professionals as part of a pilot study. The discussion of the results will help us to understand how to enhance the design, delivery and evaluation of future research with similar interventions in older PWD. It is, therefore, important to consider that the main, but not only, focus of this discussion is on how to improve the implementation and evaluations of novel and complex interventions that may not necessarily show a

significant change in the health of patients but in the practice of the healthcare professionals involved in the care of those patients.

3.5.1. Provision of the service

Based on the results presented (Section 3.4.1.1.5), it could be estimated that a patient with dysphagia with average stay in hospital of 20 days would require around 105 minutes of the DP's time in order to receive I-MAGs. On average, this would mean spending just over five minutes per day with each PWD admitted to hospital.

It was also highlighted by the stakeholders that full time availability of the DP was required to deliver the service. It was important that the I-MAGs were generated at a particular time after the medicine reconciliation was carried out in order to apply any changes to the medication chart before any medication was dispensed. However, this process does not mean that the DP is required to constantly stay on the same ward but that he would need to be fully contactable to enable revision and update of I-MAGs when needed. The prevalence of dysphagia tends to be much higher in the stroke unit as dysphagia is a common condition post-stroke. The diversity of the wards and the patients admitted to them makes it hard to precisely estimate the scope of the workload for a potential DP, but based on the novel implementation of I-MAGs where the DP was able to manage two wards in half a working day, it seems sensible to admit that the regular provision of such a service could be managed by one single person assisting PWD from no less than four and no more than seven wards of the size and characteristics mentioned above. This, however, raises the question as to whether the additional costs are justified by the improvement in patients' safety and whether the role of the DP could be incorporated into the care-for-older-person pharmacist role.

3.5.2. Professional and personal views of the DP's training and development

The DP was an innovative role that combined the experience and knowledge of the pharmacist with specialised knowledge in the administration of medication to PWD and the issues surrounding dysphagia such as assessment, management and implementation of guidance.

The IDF, however, only provides competences for the different levels and the required training for this innovative role could only be estimated. As DP and author of this thesis, I judged that the training received had fulfilled the requirements of

the framework appropriately based on confident assessments of the patients' medication. Nevertheless, the experience and knowledge of other pharmacists may differ and the suitability of this training should be explored when applied to other environments and received by other individuals.

It is important to highlight the essential role of the DP as the link between other professionals such as ward pharmacists, SALTs, nurses and prescribers. It was identified in the pilot study that the DP would liaise with all these professionals during the delivery of the service. However, this role became an essential part during the research period and it could set an example of good practice for the HCPs in the ward. The DP role could also offer an opportunity to use the unique expertise in formulation science and to extend the role of the pharmacist in the management of chronic conditions as it has been supported in literature by increasing the involvement in admission assessment,⁽³⁴⁰⁾ optimisation of inpatient therapy, discharge education, implementation of self-management plans, enhanced medication liaison and post-discharge follow-up.⁽³⁴⁰⁻³⁴²⁾

3.5.3. Training needs for nurses and carers

The training provided was positively received within the majority of the respondents (page 131). However, the lack of general agreement about the competences required by nurses in the management of dysphagia makes the assessment of the training and the identification of measures of effectiveness a complicated task. Previous publications by nurses⁽³⁴³⁻³⁴⁵⁾ indicated the need of the nurses to acquire more knowledge of the physiology of swallowing disorders and in the management of dysphagia.

It is, therefore, reasonable to consider that the training received helped some of the nurses to obtain a wider understanding of issues around administering medication and at least increased the awareness of issues surrounding medication in dysphagia. Measures and records of competency should be included in future training when similar services are permanently implemented in order to identify the effect of this training in the changes of practice and in order to be able to observe the changes in the patient's health which solely derive from this training.

3.5.4. Acceptability of the service by HCPs

The results of this study indicated that the delivery of I-MAGS was generally well received by the nurses, pharmacists and SALTs as most of them stated that they would like to see the service continued. The one-hour training before the service

was implemented was well-received by the participants and the answers to the questionnaire suggested that only minor amendments to the presentation of the I-MAGs were needed.

The nurses' perceptions on improvements in safety for the patients and for the nurses were some of the remarkable findings of the study. It is possible that the nurses were not aware of the risk of being exposed to certain medication like steroids or antibiotics and having the I-MAGs present in the ward was a reminder of what medications require special caution.

Often time constraints are the main concerns in the practices of the nurses as highlighted in chapter 1. The implementation of I-MAGs was seen as a positive feature by the participants as the time spent reading the instructions was outweighed by reducing the time spent by the ward pharmacist endorsing general comments on the administration, as well as by reducing the need for the nurses to check with other HCPs on the correct ways of administering medication.

Some of the participants recognised that the I-MAGs could not only be used in the hospital ward, but they could also help carers and nurses in LTCFs. As observed by personal experiences (nurses previously known by the DP from community work , conversation with nurses during drug rounds, comments from ward sisters, or comparisons made by the nurses during training sessions), nurses in the hospital wards often had worked before in community settings like care homes. Identifying the potential of I-MAGs in other LTCFs could be indicating that they are aware of the high prevalence of challenges in the administration of medication to PWD in care homes. It is also important to consider the positive perceptions of the nurses on their clinical confidence when the I-MAGS were in place. Although this study is limited to the opinions of a small group of participants, this finding could be indicating that the support offered by this intervention may have the potential of reducing the gaps in knowledge and skills identified in the literature in similar settings.^(195, 288)

The results discussed also offer an opportunity to incorporate outcomes that had not been identified before such as confidence and safety when implementing I-MAGs as part of a larger trial.

3.5.5. Participation of healthcare professionals

The recruitment of HCPs for participating in research can sometimes be seen as a methodological challenge. However, the majority of the stakeholders (20 out of 26)

were recruited when completing the questionnaire that explored their opinions about the practicality and delivery of the service. It takes time to develop a collaborative relationship between researchers and ward staff but this relationship may be vital for the recruitment of participants.⁽³⁴⁶⁾ A study carried out by Nuttank and colleagues⁽³⁴⁷⁾ attempted to determine the potential contribution of a new healthcare practice model based on a specialist menopause pharmacist (SMP) role. Similar to the DP, the SMP also had the role of researcher and a questionnaire combining qualitative and quantitative methods was introduced to explore the acceptability of HCPs and patients of this innovative role. This pharmacist practice model was positively accepted both by patients and health professional colleagues.

Although similar reactions to the study by Nuttank were observed in our questionnaire, it seems appropriate to mention that the questionnaire responses may be affected by a tendency of the respondents to answer questions in a manner that will be viewed favourably by the researcher as the individuals on the ward knew that the DP would be analysing the results and may want to please rather than being perfectly honest (i.e. social desirability bias).⁽³⁴⁸⁾

3.5.6. Optimised prescribing

During the study, it was noticed how most of the PWD receiving I-MAGs were prescribed medication as solid dosage formulations. While the majority of solid dosage formulations have an alternative treatment in the form of liquid preparation or dispersible tablet, prescribing tablets or capsules was usual recommended practice within the hospital in PWD as indicated previously in Table 20. Consequently, the nurses had no choice other than to crush, disperse or encourage the patient to take their tablet whole.

Although there is no national guidance that recommends the exclusive use of liquids when prescribing to PWD, recent consensus in the administration of medication⁽²⁹²⁾ to PWD agreed that when the oral route is appropriate and a liquid or dispersible product is available, these types of formulations should be prescribed. Liquid medication may not be, in some cases, the best alternative but it is a much safer option for PWD when the right consistency of the formulation is achieved.

Based on the cases presented previously (page 129), it could be estimated that prescribers are not always aware of the appropriateness of the formulations recommended and the importance of evidence-based practice within a product

licence. The factors that lead prescribers to recommend oral solid medications may not always prioritise safety and, therefore, these factors should be explored.

It is undeniable that enhancing the administration of medicines to PWD is a complex task and it may involve an increase in the cost. As it was indicated in Table 21, the use of liquid formulations as an alternative could significantly raise the cost of the medicines supply. However, this increase in the price may be outweighed by a reduction in health complications such as aspiration when administering solid dosage forms which is one of the main reasons for chest infections and pulmonary diseases in older people that could lead to hospital admissions. Although the link between the use of liquid formulations on PWD and the decrease of hospital admissions has not been researched, it would be sensible at the time of making decisions on the cost of treatment, to model the costs involved against the complications appearing as a result of sub-optimal formulation choices.

3.5.7. Elements affecting the recruitment of patients

The original design of the pilot study estimated that during the length of the intervention a total of 360 patients (180 in the intervention wards and 180 in the control wards) could be recruited after considering that in similar studies 33% of the patients may drop out for different reasons. Although these calculations represent a difference to the 22 patients recruited (17 in the intervention group and five in the control), we need to consider that 244 patients were eligible for receiving I-MAGs and were, therefore, potential candidates for recruitment. This section will discuss the barriers that affected the recruitment and will suggest how to enhance these rates in future research.

The first barrier found in the intervention group was the prompt transfer of patients to other wards. The identification of eligible patients required the correct diagnosis of dysphagia after a written referral to the SALT team by clinicians in the ward after the admission into hospital. Between the time that the patient was admitted and the first chance for the DP to identify the referral to the SALT team, 58% of the 244 PWD admitted in the intervention wards had already been transferred to other wards excluded from the study. Another 11% no longer had the condition and a further 19% had deceased or were administered medication intravenously under palliative care pathways. These rates indicate that only 75 patients (30.7%) out of the 244 originally identified with dysphagia at the time of admission suffered from this condition and stayed in the intervention wards for long enough as to be considered an eligible patient for the study.

Another explanation for the low recruitment rate is the need to obtain consent from the patient or a representative by a clinician in the ward before being approached by the researcher (CTA). Despite the value of this safeguarding policy, the 39 opportunities in which eligible patients were approached and asked for CTA after showing interest in receiving more information about the study (Table 15) were reduced to 23 opportunities to ask for consent to participate. When considering that 17 patients were recruited out of the 23 that were offered to take part in the study, this requirement could mean that another 12 patients from the 16 missed after receiving CTA could have also become potential participants. The presence of this policy should, therefore, be considered when estimating the recruitment of future studies as it could potentially reduce the amount of participants by 40%.

The unstable health of the recruited patients may represent another barrier when trying to maintain the number of participants. Over 50% of the patients recruited were not able to complete the survey due to death or to having lost capacity to respond to the questionnaires. Many of the patients are at the end of their lives and a period of six months of follow-up may become too ambitious when considering their life expectancy.

One of the main methodological elements affecting the recruitment was the fact that patients were being recruited at the time of discharge instead of at the time of the admission or when dysphagia was first identified which stopped the researchers from recruiting patients that recovered from dysphagia. However, this still would not have eliminated the problems with transfers to other wards or access to the patients during viral outbreaks on the wards and higher drop out rates would have been reported instead of low recruitment rates. This is, therefore, suggesting that in order to increase recruitment while keeping drop out rates low in a future larger study, it would be necessary to either involve in the research study, all the hospital wards where patients are likely to be transferred or to develop a multi-site study that would also overcome the problems with viral outbreaks. Additionally, the recruitment rate should be based on calculations of not only prevalence of dysphagia in the stroke units and care-for-older-person wards, but also on the estimations of periods of lower risk of outbreaks, number of patients with the mental capacity to take part in the research and mortality rates of patients admitted to wards where the study is developed.

3.5.8. Outcomes of the follow-up of recruited patients

The small number of patients completing the survey did not allow a statistical analysis that could justify the variance around the difference in the primary outcome measures between the control and the intervention groups after the implementation of the I-MAGs and recruitment.

However, the questionnaires were returned completed in the majority of cases which should allow for a robust quantitative analysis of the data obtained from the outcome measures selected and it is possibly highlighting the appropriateness of the questionnaires chosen. Equally to recruitment, it would have been of interest to obtain baseline data at the time that dysphagia was diagnosed, as well as at the time of discharge as it would allow us to explore the changes in the patients' health that are due to the effect of the I-MAGs when comparing it to patients on the control wards.

It should also be contemplated that all the patients recruited and those that just received I-MAGs had their medication reviewed by the pharmacist. Medication review has shown reductions in the hospital admission in older patients. A RCT carried by Krska and colleagues⁽³⁴⁸⁾ on 332 older patients with chronic disease studied the effect of medication review led by pharmacists using medicine costs, use of health and social services and health-related quality of life as outcome measures. The large sample size allowed them to observe a small non-significant increase in contacts with healthcare professionals and fewer hospital admissions among the intervention group than the control group. However, 70% of the care issues that had been resolved in the intervention group (vs. the 14% that had been resolved in the control group) did not lead to changes in health-related quality of life in either group. Although the patients were not identified as dysphagic, it could be assumed that the large scale implementation of our service could show similar outcomes based on the similarities between the outcome measures in our study and those presented by Krska and colleagues.⁽³⁴⁸⁾ Conversely, it needs to be considered that a systematic review and meta-analysis carried out by Holland et al⁽³⁵⁰⁾ concluded that pharmacist-led medication review does not reduce hospital admission in older people and puts in question its potential clinical benefit as the only studies that suggested positive effects on the quality of life were not statistically significant.

The majority of the healthcare professionals involved in the administration of medication to PWD in the settings where the I-MAGs were present felt that

patients' safety and care were improved by the implementation of the guides which represents a clear benefit. These outcomes were not contemplated in the patients' health indicators, but if similar intervention is carried out in future research, the outcome measures should specifically focus on observing changes in factors such as patients' safety and clinical confidence of the nurses.

In order to determine the effect of the service on patients' health, pharmacy practice researchers should continue incorporating quality of life outcome measures, complemented by clinical, economic, and other humanistic outcome indicators.

3.6. Limitations and strengths of the research presented

One of the main limitations of the pilot study was the low availability of eligible patients for recruitment at the time of discharge, as discussed before. During the 23 weeks when the I-MAGs were implemented, the hospital experienced an outbreak of Norovirus which peaked in the months of our study (Figure 13). The Norovirus outbreak prevented full access to the wards for recruitment for seven weeks and partial access for another nine weeks, significantly affecting the production and updating of I-MAGs in the intervention wards and decreasing the chance of asking for consent to participate from the patients.

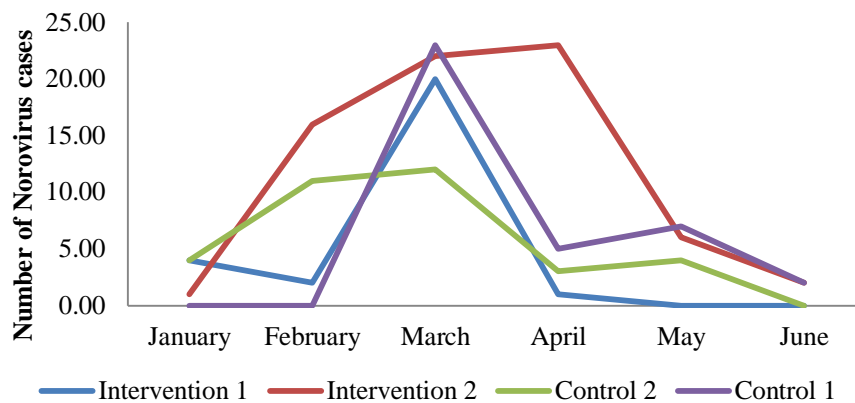


Figure 13: The number of confirmed cases of Norovirus from January to July 2011

When considering safer alternatives to the administration of the prescribed drugs in the intervention wards, the DP was limited to the list of drugs in the hospital formulary. This list didn't contain many liquid formulations, and the request of a non-formulary item (like the amisulpride case described in section 3.4.3.) required the completion of several authorisation forms and the waiting time for obtaining

the product from the supplier. As a consequence, there was a delay in the generation of I-MAGs and, what it was more important, a delay in the patient getting the suitable formulation.

The importance of having local policies adapted to the needs of the hospital should not be ignored. However, in some cases like the use of lisinopril and digoxin sublingually, these policies have no evidence and are decisions based solely on directly incurred costs and not costs which may derive from this policy.

The fact that this evaluation was only carried out on one ward, and the length of time which elapsed between the training sessions and the evaluation, may have limited the results of this study. Transfers of members of staff to other wards or hospitals made them no longer approachable and the views of members of staff on non-rotational night shifts were not sought as in the same way they were not able to attend the training sessions. The nurses on night shifts were exposed to the use of I-MAGs in the ward but they could not rely on the immediate support from the DP during their shifts and, therefore, the answers in questionnaires completed by these nurses could have highlighted different issues that the daytime members of staff did not necessarily identify.

Despite many of the issues identified in the study being able to likely enhance the implementation of a similar service on a larger scale through a strong analytical point of view, the limitations presented are seen as weaknesses of the research even if they were part of a pilot study.

3.7. Conclusions

This study has shown how a pharmacist-led service for PWD is potentially acceptable to healthcare professionals. There are, however, significant costs associated with the delivery of the service both in terms of training and ongoing provision and these would require justification before NHS resources could be allocated to this role.

During the delivery of the service, patients receiving I-MAGs benefited from an optimised practice in the administration of medication and were able to use those recommendations in their own home or in the care home where they were discharged to. This created awareness in the patient of the importance of the correct administration of medication that could potentially change behaviours towards

medications. These potential changes and the acceptance of the guides may form the base of a future study.

The need to explore any changes in the health of PWD that received I-MAGs was not identified while the I-MAGs were implemented. However, this may have a large impact in the post-hospitalisation care of patients and could potentially lead to changes in factors like readmission to hospital or prevalence of respiratory conditions. These factors could impact on NHS costs and research should be carried out to explore this.

This study failed to identify significant changes in the patient's health due to the small number of participants. It is, however, important to highlight the cases identified above where the intervention of the DP:

- avoided substantial administration errors,
- encouraged a safer practice for the nurses and the patient,
- provided evidence based guidelines for the prescribers.

This study identified several cases in which prescribing could be optimised in order to minimise the risk of errors during the administration of medication to PWD. The lack of knowledge in formulations available, the use of medication in unlicensed ways and the lack of evidence in some recommendations could be identifying a potential need of training for the prescribers and administrators. Further research is, therefore, needed to identify the suitable educational support for prescribers and administrators.

Nurse participants identified a gap in knowledge in the administration of medication to PWD. Although in the hospital environment this issue can be partially resolved by the presence of other professionals on the ward, it stills places significant pressure on the time and workload of nurses who may be forced to crush tablets or open capsules and consequently act inappropriately. A specific training in the administration of medication to PWD that is followed with measures and records of competency should be included as part of nurses' continuous professional development. However, further research may be required in identifying appropriate outcome measures and competency framework.

The role of the DP was strongly guided by the presence of a dysphagia competency framework. This framework could be extrapolated to primary care but the approach to the competencies in primary care may be different to secondary care. The training needs of the pharmacist in primary care may require further development

Implementing and evaluating a novel service in dysphagia in secondary care

than in secondary care due to the different interactions between professionals and the different environments.^(347a) The limited level of interventions on the patient's treatment for these professionals also needs to be considered and extended research on pharmacist training required for this intervention should also be contemplated.

The delivery of I-MAGs provided an organised service that required a small use of the resources available. Had the recruitment provided a significant sample size capable of proving differences on patient's health, the DP would be providing a specialised service throughout a hospital for the small addition of a Band 7/8 pharmacist to the pharmacy team. The role of the DP as a link between HCPs was also essential for the delivery of this service and hence this study suggests that further research is required on identifying the impact in the patient treatment of this liaison between professionals and the DP's input.

The approach of recruiting patients at discharge to determine the long-term benefits of I-MAGs demonstrated that the size of the population suitable for such a study is too small, i.e. too many hospitals would need to be involved to provide the study with a sufficient sample size and the results may not warrant the cost of such a research project. It may be preferable to test the I-MAG in an environment where there is sufficient numbers of PWD from the outset, such as care homes. The recruitment of patients at the point of admission rather than at discharge could significantly increase the sample size, but it would only allow to implement the intervention to a large number of patients for a very short period of time, which could limit the observation of any likely impact on health outcomes. It could also be beneficial to incorporate research nurses to help with the recruitment of patients at the different stages of admission.

The success of the I-MAG is based on its ability to enable implementation of the most appropriate formulation for the patient. In an environment where the opportunity to provide an alternative formulation is not present and the primary recommendation is formulation tampering, then the impact is also likely to be limited. The I-MAG may, therefore, be more effective in care homes where patients are likely to experience their effect for sustained periods of time and where practitioners may have more autonomy in the selection of the best formulation for residents. Therefore, the acceptance of the guides by the patients, relatives of the patient and/or the nurses in the care home, and the impact of the awareness generated by the pharmacist of the patient after being discharged from hospital needs to be explored.

Implementing and evaluating a novel service in dysphagia in secondary care

The following points summarise the learning points from this section:

- a pharmacist-led service for PWD is feasible, but it may require the identification of adequate outcome measures that recognise changes related to the intervention in the patient's health,
- a future randomised controlled trial should contain a very precise recruitment strategy with specific and defined inclusion criteria over a long period of time or in multiple locations,
- all the clinicians in the intervention wards should be made fully aware of the research and consent to be approached should be sought at the time of admission,
- the recruitment of participants should be carried out from the time of implementation of the I-MAGs by researchers with thorough knowledge in the field and the ability to communicate to the patient the importance of taking part in the research,
- the consideration of barriers, such as Norovirus outbreaks and the transfer of patients from intervention wards to other wards of the hospital, can be crucial to maximise the recruitment,
- the implementation of I-MAGs increased the nurses' confidence in their practice and contributed to acceptance on the intervention wards.

4. Exploring the current model of administration of medication to PWD and the acceptability of changes

Before testing an intervention, it must be developed to the point where it can reasonably be expected to have a worthwhile effect. As researchers, we need to identify what is already known about similar interventions. These comments extracted from the MRC guidelines describe optimally the next steps required for the development of our intervention:

“The rationale for a complex intervention, the changes that are expected, and how change is to be achieved may not be clear at the outset. A key early task is to develop a theoretical understanding of the likely process of change by drawing on existing evidence and theory, supplemented if necessary by new primary research.”

Page 981, Craig et al (2008)⁽¹⁾

The study presented in this section will describe components related to the development of interventions such as identification of theory and the development of new theories in order to explore the impact of our likely intervention as highlighted in Figure 14.

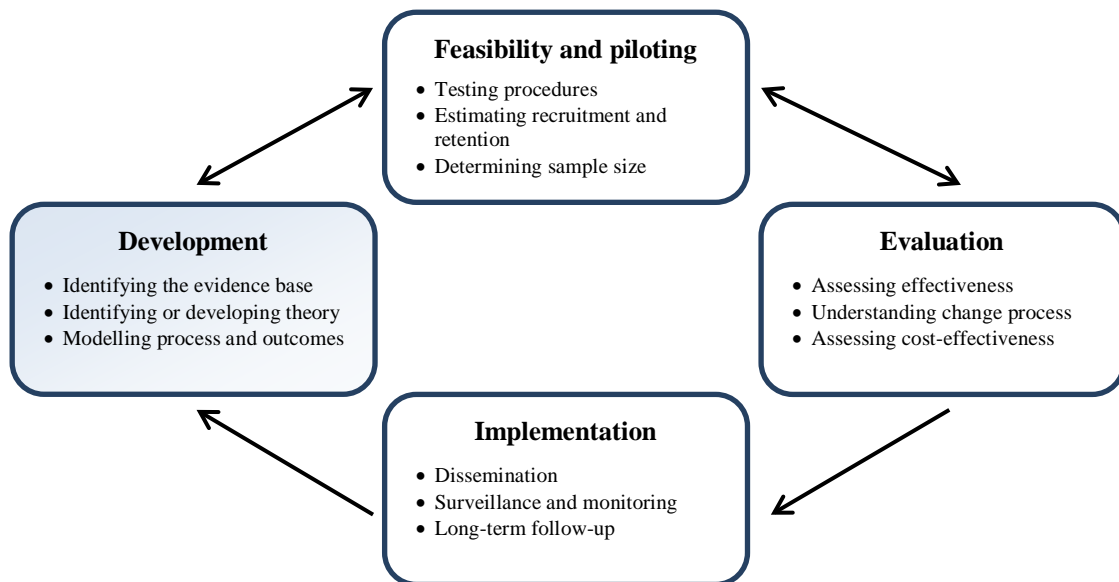


Figure 14: Developmental components of an intervention (Craig et al 2008, page 980)⁽¹⁾

4.1. Introduction

To address the difficulties associated with administering medicines to residents who cannot swallow on the ward and to standardise care, I-MAGs were introduced on COO wards in the Norwich and Norfolk University Hospital as part of a previous research project and a proportion of patients with I-MAG were discharged to care homes where the I-MAG might have been equally useful.

Whilst I-MAGs were well-received in the hospital environment, where there are a wide range of healthcare professionals to provide support, they may not be appropriate within the care home environment. The communication between healthcare professionals in the hospital tends to be seen as more frequent than in the care homes where the visits from these professionals are scheduled less often than in secondary care.^(326, 351) Additionally, the increase in the time that drug rounds take may make the I-MAGs unacceptable and to successfully introduce them, they may require more specific training in the administration of drugs for the care home staff.

The views of members of the nursing team in the care home on the relevance and acceptability of the concept of individualised medication administration guides for PWD had not been ascertained and, therefore, needed to be explored. Patients being discharged from hospital with an I-MAG to the care home facilities provided an opportunity to interview carers and explore their views in the use of the guides in the care home and identify issues surrounding the implementation of these guides previous to or after receiving the I-MAGs. The data obtained from the nurses could obtain information of sufficient quality to enable the production and implementation of I-MAGs more suitable for use within the care home environment.

4.2. Aims and objectives

The aims of this study were to explore:

- the current model of administration of medication to PWD from the perspective of nurses in care homes,
- how I-MAGs might be received and, where applicable used, in care homes for administering medication to PWD.

The objectives of this study were to:

- identify elements that affect the administration of drugs to PWD in the normal practice of care home staff,
- identify whether care home staff require any specific training in the administration of drugs to dysphagic residents,
- introduce the concept of I-MAGs to care home staff,
- obtain the views of care staff on the perceived usefulness of the I-MAG compared with normal practice,
- explore the opinions of the members of the nursing team about whether, and what, professional support could help care staff use these guides in the care home,
- identify any likely education support needed for the use of I-MAGs or for the general administration of medication to PWD.

4.3. Methods

This study collected data on the views of the members of the nursing teams in care homes about using the I-MAGs for administering medication to PWD. A qualitative interview design was chosen as it is often the most adequate and efficient way to obtain information related to the insights, experiences and opinions of the carers required to contend with the difficulties of an empirical situation.⁽³⁵²⁾ Exploring the understanding of the nurses on the I-MAGs will help identify the type of educational support needed and the improvements needed in these guides in order to enhance its usability.

Semi-structured interviews allowed the respondent to reply in his or her own words where the range of responses was unknown and could not be readily categorised and also helped the researcher to clarify any ambiguities in the perceptions and experiences in the use of I-MAGs.⁽³³⁶⁾ Many issues important to the interviewee were probably hard to anticipate, therefore, a semi-structured interview was used. This comprised core interview topics provided in a question guide and also allowed flexibility in the order they were asked in pursuing topics of importance to interviewees. The main guide included research questions to explore knowledge, insights, experiences and opinions of the carers about the use of I-MAGs in the care home environment. Optional sub-questions were used to help adapt the interview to the specific situations and points of view of the interviewee, while ensuring the interview focused on the purpose of the study. The interviews were

Exploring the current model of administration of medication to PWD and the acceptability of changes

carried out by the main researcher, drawing on his previous experience as a dysphagia pharmacist.

The main researcher (also the author of this thesis) had been trained in general research methods at the University of East Anglia during September 2010 and February 2011. To enhance his qualitative research skills, the main researcher attended the following courses:

- further qualitative research methods at the University of East Anglia (Master's level) during March and June 2011. This course was aimed to gain further knowledge on qualitative study design, practical skills needed in the planning and design, the data collection, analysis, and interpretation,
- introduction to qualitative interviewing, University of Surrey, in June 2011 (postgraduate level). This one-day intensive course included sessions exploring the characteristics of qualitative research, interview preparation and advice on how to conduct interviews effectively and developing interview discussion guides,
- introduction to qualitative data analysis, University of Surrey, in September 2011 (postgraduate level). This one-day course covered different approaches to analysing qualitative data, 'grounded theory' principles, the process of coding data, the development of more conceptual ideas through analysis and issues such as validity and generalisability.

The University of East Anglia's Faculty of Health Ethics Committee granted ethical approval on 30th September, 2011 (Appendix 17). Only 63 (0.5%) of the 12,955 care homes with nursing in England⁽³⁵³⁾ belong to the NHS, these were very likely to have completely different systems and management processes, as well as residents. Consequently, it was more appropriate to focus on private care homes. The exclusion of these care homes meant NHS ethical approval was not needed. Only healthcare professionals (and not patients) were involved in this part of the study, but they were discussing their experiences when administering medication to patients in their care. One of the major ethical issues for the qualitative interviews research was maintaining confidentiality of the issues discussed. The need for confidentiality was identified in the documents sent to the potential participants and was also identified as one of the ground rules before the interview. As both the interviewer and the interviewee were healthcare professionals and maintenance of confidence was part of their ethical code, maintaining confidentiality would not be seen as likely to become a problem. However, if the interviewee had revealed activities that could have caused or were likely to lead to harm to an individual in

the care home, the main researcher had a duty of care and would have needed to report it to the relevant authorities. The ethics committee's extensive comments on revising this study contributed to the coherence of this study and reinforced good clinical practice during its conduct.

4.3.1. Participant recruitment

It was required to find participants with the particular characteristic of administering medication to PWD in care homes in order to identify the perceptions of the nurses. Purposive sampling was, therefore, used to select these possible participants. We aimed to construct a sample or study group which was meaningful theoretically to build certain characteristics to develop this suggested theory. The processes of sampling, data generation and data analysis are viewed dynamically and interactively as suggested by Mason (2002)⁽³³⁸⁾ in relation to the need to seek setting-relevant dimensions of participant experience of administering medications in care homes. Some details of sample decision-making emerged during the process and deciding sample size depended on the adequate generation of a theory so that not all volunteers went on to be interviewed. Volunteers were made aware in a participant information sheet that they might not be selected. After consenting, the participants were given a questionnaire to gather preliminary information about different categories (including their qualifications, age group and location of the home) to assure that the purposively selected sample was as diverse as possible. As suggested by Marshall (1996),⁽³²⁵⁾ the researcher actively selected what he considered the most conceptually-productive sample frame to answer the research question. This involved developing a framework of the variables that might influence an individual's contribution. These were the professional experience of the participant, cultural and educational background, location of the workplace and role. Their identification and selection was based on the researcher's practical knowledge of the research area, the available literature and evidence from the study itself. These variables were utilised during the analysis in order to "build" a grounded theory.

The participants were nurses or carers in charge of administering medication in care homes where one or more residents had dysphagia or used enteral feeding tubes (EFT) for the administration of drugs. The sample was purposefully drawn from male and female participants, with and without English as first language, with and without degrees in nursing, with education from a UK university/organisation and from abroad. All the categories that helped building the sample were reflected

Exploring the current model of administration of medication to PWD and the acceptability of changes

in the preliminary questionnaire (Appendix 18) handed out to the participants to complete after giving consent.

During October 2011, 72 care homes in Norfolk and neighbouring counties were sent a letter addressed to the registered manager containing:

- a covering letter to explain the nature, aims and implications of the study (Appendix 19),
- an information sheet explaining the topic and organisation of study, its aims and the implications of the study for those potential participants wishing to take part (Appendix 20),
- an example of the consent form that the potential participants were offered before the interview (Appendix 21),
- an initial contact acceptance letter addressed to the main researcher (Appendix 22).

The covering letter asked the registered managers to let care home staff know that there was the opportunity to be interviewed and to participate in the study. This would avoid coercion as the registered managers would only be informing participants of this opportunity while explaining that they were free to decide whether to take part. After receipt of the initial contact acceptance letter from the care home manager, the main researcher then provided further information on the study to the potential participants, and arranged the consent and the time for the interview with those interested in participating. A pre-stamped envelope was enclosed to help maximise the response rate.⁽³³⁵⁾

When no reply was received within two weeks after sending the invitation, a copy reminder letter was again sent to the home. If there was still no response, no further letters were sent. The flow of the recruitment, purposive sampling and study analysis are represented in Figure 15.

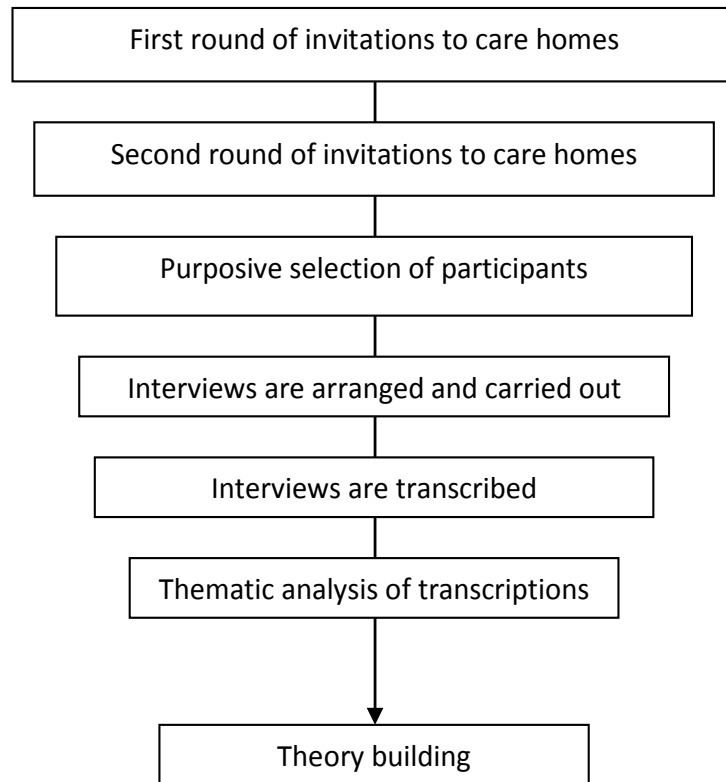


Figure 15: Study flow chart

When the care home manager had identified interested carers or nurses in their care home and sent their acceptance letter, the main researcher contacted him/her to agree a convenient time to provide further information to the potential participants and to proceed with consenting and interviews. When consent was not provided immediately before the interview, participants were still asked to confirm that he/she still wanted to take part. A £10 voucher was offered to participants completing the interview.

Considering the narrow scope of the study, the obvious nature of the topic and that the design of the study only required one interview per participant, it was anticipated that a small number of interviews ($n=10$) would be needed to reach saturation.⁽³⁵⁴⁾ However, taking into account that the quality of data may be poor in some interviews, and to allow for emergent issues to be taken into account as the data was analysed, the maximum number was increased to 15 interviews to allow scope to provide enough relevant information to achieve the aim of the research.

Inclusion criteria:

Members of the nursing team were considered eligible if they were:

- any nurse or carer in charge of administering medication to:

Exploring the current model of administration of medication to PWD and the acceptability of changes

- residents with dysphagia,
- residents that require the use of EFT,
- in a nursing home or care home with nursing in Norfolk and surrounding areas of neighbouring counties.

Exclusion criteria:

Potential participants were excluded when:

- the premises of the care home were located outside the coverage area of the NNUH (Norfolk and adjacent areas of neighbouring counties),
- the registered manager⁽³⁵⁵⁾ of the eligible care home was unwilling to take part,
- participants identified did not provide informed consent.

Individuals who consented to participate were then selectively invited to take part in the research depending on whether their characteristics met the range of pre-defined purposive sampling criteria. The purposive selection was shaped by the analysis of the interviews to follow the principles of a grounded theory approach.

4.3.2. The interview process

4.3.2.1. Rationale

In this study, we tried to explore the social reality of the care homes' environment through carers' knowledge, views, opinions, perceptions and reactions about administering medication to PWD. These properties are commonly recognised as meaningful information provided in qualitative interviews.⁽³³⁸⁾ Semi-structured interviews can yield highly accurate data about the perceptions on the use of the guides and this method is more appropriate for complex and unknown issues.⁽³³⁶⁾ The setting of a face-to-face interview allowed the researcher to probe more complex issues and to clarify answers, especially when the questions referred to issues in the practice of the interviewees and when the information could be more sensitive (asking about the care home setting when the interview is carried out within these premises, conditions of employment, social conditions of the interviewee, etc.).⁽³³⁶⁾

The design of the interview questions was presented and discussed with two academic supervisors in order to assess the appropriateness of the design to the aim and objectives of this study. These discussions provided additional points of view to that of the main researchers and helped in the generation of more refined questions and sub-questions. Following those discussions, a first draft was piloted

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with a hospital nurse who had previous experience in care homes. This nurse was a staff member in the hospital where I-MAGs had been implemented (previous study) and she volunteered to be interviewed simulating the care home environment as remembered by her experience. The purpose of this pilot was to identify any challenges faced by the researcher and the interviewee related to the technique and the design of the interview questions. This pilot interview was “audio-recorded” with a similar recorder to the one planned for the research and a small part of the interview was transcribed and analysed by the main researcher and one of his academic supervisors. The transcription was utilised by the main researcher to practice the analysis technique and the code generation, but the dataset obtained from those codes was not used for the analysis of the study. As a learning outcome of the piloting, the terminology used in the interview highlighted the need to explain the concept of “administration of medication” to the interviewees within the context of the “physical provision of drugs to patients” rather than the administrative organisation of documents related to medication. This explanation was included in the introduction received by the actual participants previous to the research interviews which were carried out during the months of November and December 2012.

4.3.2.2. Structure

The interview normally took place in a private room in the care home at a time when it was least likely to be interrupted. It consisted of a meeting of no longer than one hour that covered a list of semi-structured questions to identify the opinions of participants based on their professional views and experience in relation to whether, and how far, they thought that they might find the I-MAG useful and what reasons they gave for their reply.

Introduction

The interview began by offering information about who the interviewer was and about the project. The interviewer checked whether participants had any further questions about the study, whether they were still happy to take part, and for the interview to be recorded.

Preparation for interview

The interviewer explained the structure of the interview and emphasised the importance and value of the interviewee’s own views in their own words, stated

that there were no right answers and the interviewer would encourage them to express their views in their own way.

Questions

The core of the interview consisted of five topics developed from the different objectives which reflected the aim of the study. The participant was given a card with the question to help remain focused on the topics of the interview. However, the researcher had other sub-questions that may or may not be asked depending on the flow of the interview and to help to raise relevant issues during the conversation.

The questions and sub-questions (Appendix 23) were developed to explore any factors already known to the research team that can affect administering medication to PWD (like the care home environment, the workload, responsibilities within the care home, qualifications, etc.). However, more factors that may not have been so obvious to the researcher, but may have been relevant to the participant were expected to come up during the interview so that some sub-questions in the guide were not asked and other improvised questions were.

All these indicative questions were refined as the interviews proceeded based on the principles of the grounded theory approach. The schedule of the interviews can be seen in Appendix 23.

The first main question, “What is it like working in this care home?”, and sub-question topics were used to gain an idea of the interviewee’s view of the care home, what issues were relevant to them, and how far they saw themselves as interacting with the residents. This was needed because the research approach sought to understand the personal perception of the participant’s role in the care home and, therefore, the main question and sub-questions sought to explore the experience of what the carer/nurse in that particular nursing home was to provide contextual information for their other responses. The interviewer also supported interviewees to provide more specific details by asking them to discuss specific examples.

The second main question, “What is your role within the care home?”, and sub-question topics were used to gain an idea of the interviewee’s background and how she/he saw her/himself in the environment of the care home. This was needed because when administering medication in nursing homes, carers and nurses are often asked to practice jobs or to take on roles that are not part of the role of a carer

or nurse. It was important to identify the lived routines and expectations of the nursing home and its team to determine how the IMAGs could be designed to fit better within that routine. It was also needed because in developing the implications of findings, this information could also help to identify any further education that the interviewee would like to receive in relation to administration of medications in this setting.

The third main question “When you give medication to residents with dysphagia here what does this usually mean you need to do?”, aimed at finding their level of knowledge about administering drugs to PWD, how resources might be used and their access to resources, their view on the implications of using drugs, and their awareness of their own liability. In developing the implications of findings this information also helped identify ways to improve this administration, who or where they might have wanted to get help from and what kind of help or support they would have liked.

The fourth main question was “What would you expect if you were asked to use an individualised medication administration guide to help your work with people you look after?” At this stage the interviewee had not yet seen an I-MAG so they could give their view on what that might mean before them actually knowing what an I-MAG looked like. This research was seeking the participant’s view of a general concept of a guide with individualised information about medication, based on their existing experience of often trying to administer medications without individualised information and perhaps having heard about I-MAGs rather than using them in practice. At this stage we needed to explore what preconceptions and expectations a nurse or carer had about individualised information on medication. However, some interviewees had been exposed to I-MAGs via a resident having been admitted to the hospital and the sub-question aimed to clarify these cases.

The fifth main question was asked after showing the I-MAG to the interviewee. “Now you have looked at this example of an I-MAG, how do you think I-MAGs could be used in this care home?” This question sought to explore what ways they thought this could be used in administering medication, what kind of support they saw themselves as needing, and whether they could identify any ways of amending the I-MAG to make it more suitable for their care home environment, whether they had at this stage ideas about training in administering medication which were relevant for their work, and what kind of support they would have liked and from whom in using I-MAGs. This topic also provided insights into interviewee views

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on the impact that a change in the way of administering drugs could have on the resident.

Queries and acknowledgements

The final part of the interview provided an opportunity to thank the interviewee for their time and to provide another chance for them to ask questions or to make further comments. The participant was also informed of what would happen next with the outcomes of the information, and then, the interview ended.

4.3.3. Data

4.3.3.1. Data Collection

The interviews were audio-recorded and lasted up to one hour. A MP3-type recorder was used for all the interviews and the recordings were transferred to a digital storage device (pen drive) which was password protected. In cases where the researcher considered that extending the time of the interview was especially useful, consent from the participant would be obtained before carrying on.

4.3.3.2. Data storage

The interview recordings were kept in a locked filing cabinet in the University of East Anglia under restricted access to the researcher. These recordings were listened to by a research assistant and the supervisor of the study so that they could be transcribed. The verbatim transcription was then anonymised and stored as hard copy in the researcher's filing cabinet and as an electronic file on a password-protected pen drive. The recordings will be destroyed three years after the completion of the study.

4.3.3.3. Data analysis

The strategy for the analysis drew on grounded theory principles. Grounded theory can be seen as the creative activity of theory building founded on observational work.⁽³⁵⁶⁾ We needed to generate theory based on the previously unexplored perceptions of individuals involved in administering medications that could provide means of identifying relevant issues, including problematic issues (and reasons for them and in relation to a variety of contexts) involved in the administration of medication to PWD. The theory generated was then applied to improve content and procedures relating to I-MAGs.

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This involved generating categories from the data as presented, positioning them within a theoretical model and then explicating a story from the interconnection of these categories.⁽³⁵⁷⁾ These categories derived data from the interviews in an interpretive manner⁽³³⁸⁾ to help to understand what those interpretations were in this particular context. The main researcher indexed these categories cross-sectionally in order to delineate the scope and coverage of the data systematically and consistently.⁽³³⁸⁾ Another member of the research team (FP) reviewed the transcripts and the index to confirm range and type of categories identified. Data-gathering continued until the research team considered that no new themes emerged, that was until theme saturation was reached. When the participant did not have the specific information required, secondary selection for sampling was used.⁽³⁵⁴⁾ Secondary selection is a method that involves carrying out the interview then, instead of immediately analysing or transcribing it, the interview is set to be drawn on only if further analytic development of the study identifies the interview as specifically “pertinent to the research goals” as Morse and Field mentioned in 1995.⁽³⁵⁴⁾

The qualities of the interviewee and the interview were only fully assessed once the interview had been carried out following the inclusion criteria. As the main researcher was not formally defining the qualities of a good interviewee, the usefulness of the interview was ultimately defined by those points which emerged as relevant to the study.

Any information which enabled identification of individuals was anonymised and no quotes were used in a way which can link them so as to identify any of the participants in any of the reports or publications related to the study.

4.3.4. Quality assurance in the study

The rigorous methods of gathering good quality data, including the involvement of other experienced researchers in the supervisory team during the analysis and interpretation of data and the purposive selection of the sample⁽³⁵⁸⁾ increased credibility in the study, making it a source of reliable information. A thorough description of the environment of the nursing home, time and participant and detailed transcription of the interview was used to maximise transparency as a way of showing the process by which the data were collected and analysed.⁽³⁵⁹⁾

The audio recordings and the researcher triangulation were used to confirm the accuracy of transcriptions and appropriate interpretation of the information,

respectively. Internal validity was increased by individual participant validation. When considering the aims of the study, we needed to reflect our research approach, which meant that only the participants could confirm the truthfulness of the types of data we collected from them. It was, therefore, needed to check this with the respondents. The normal practice of nurses/carers, their ideas on the usability of the IMAGs, the effect of the IMAGs on the practice of the nursing home, and so on, are concepts that can only be understood by the nurses or carers and, therefore, it is the participants who had epistemological privilege by their standpoint.⁽³³⁸⁾ The validation process enabled the participant to validate the interpretations and themes emerging just from his/her own interview but they were not asked to validate the theory grounded on the whole group of interviews. Theory was developed from a synthesis of the perspectives of a number of participants, and, therefore, it was inappropriate to expect that individual participants would have the ability to 'validate' the findings of the research study as a whole.⁽³⁶⁰⁾

The confidentiality of the interview transcriptions and the results of the validation of the participants were continuously reassured during the process.

4.4. Results

4.4.1. Recruitment of participants

During the first round of communications, 30 homes were invited to take part in the study. Five of them responded and agreed to receive more information leading to nine interviews being arranged. After two weeks, a second round of invitations was sent to 67 homes, including the non-respondent from previous round. Nine care homes responded, four of them rejected the invitation and another five accepted it, and six more interviews were arranged. Figure 16 shows the flow and results of the recruitment of participants.

When contacting the participants, one of them pointed out that an I-MAG had been in place in the care home as part of the hospital study explained in this thesis. It was expected that care homes previously exposed to I-MAGs in the past would be more willing to participate in this study. However, identifying these homes for the purpose of this study would require identifying the details of the hospital patients linked to them. This could raise ethical concerns around confidentiality and data use without actually contributing significantly to the aims of this study and it was, therefore, left to the participants to identify whether they had been in contact with the previous IMAG study or not.

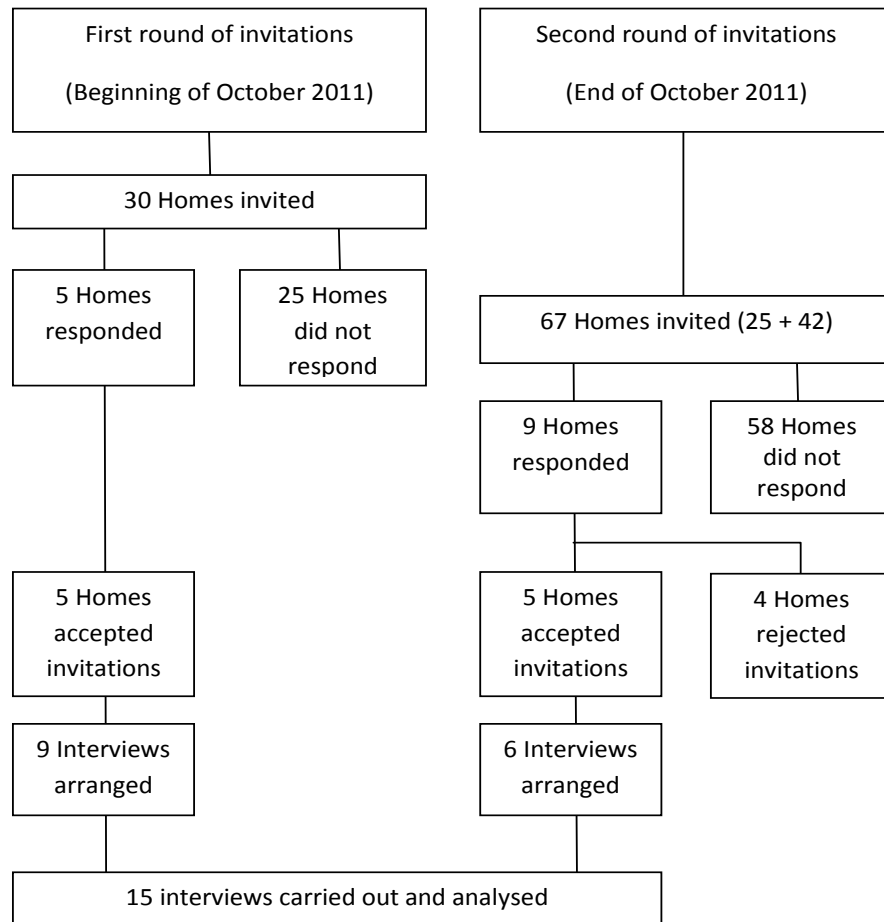


Figure 16: Participants recruitment chart

Participants were given a preliminary demographic questionnaire and were assigned a participants code. Table 22 shows the data collected from the questionnaires.

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Participant code	Role	Age group	Gender	Location of care home	Nursing qualification	Employment	Nursing experience	Nationality
N1	Care home manager/nurse	36-50	Male	Rural	UK qualified	Full time	23 years	UK National
N2	Senior nurse	51-65	Female	Rural	UK qualified	Full time	34 years	UK National
N3	Nurse	20-35	Female	Suburban	Non-UK qualified	Full time	6 years	Non-UK National
N4	Nursing student	20-35	Female	Rural	UK student	Part time	3 years	UK National
N5	Carer	20-35	Male	Rural	None	Full time	2 years	UK National
N6	Nurse	36-50	Female	Suburban	UK qualified	Full time	25 years	UK National
N7	Nurse	20-35	Female	Suburban	UK qualified	Full time	18 years	UK National
N8	Nurse	51-65	Male	Rural	UK qualified	Full time	30 years	UK National
N9	Nurse	51-65	Female	Rural	UK qualified	Full time	33 years	UK National
N10	Care home manager/nurse	51-65	Female	Rural	UK qualified	Full time	35 years	UK National
N11	Nurse	36-50	Female	Rural	UK qualified	Full time	3 years	UK National
N12	Nurse	36-50	Female	Town centre	Non-UK qualified	Full time	28 years	Non-UK National
N13	Senior nurse	36-50	Female	Suburban	Non-UK qualified	Full time	4 years	Non-UK National
N14	Nurse	51-65	Female	Suburban	UK qualified	Full time	30 years	UK National
N15	Nurse	20-35	Female	Suburban	Non-UK qualified	Full time	8 years	Non-UK National

Table 22: Participants' demographics (N=15)

4.4.2. Analysis of the interviews

All the interviews were transcribed and analysed one by one. The transcriptions were then coded as represented in Appendix 24. All the codes generated were then manually grouped in categories (see images in Appendix 25) as they were emerging. A basic thematic diagram was built after the analysis of the first

interview. The codes and themes obtained from the next interviews were reorganised within the original diagram and new themes and sub-themes were represented in different colours that were assigned to the interview where those sub-themes emerged from. Drafts of these diagrams can be found in Appendix 26. While this explains the techniques used for coding and grouping the codes into sub-themes and themes, the next section (4.4.2.1.) will explain the approach taken for the thematic analysis drawing on grounded theory principles. The themes obtained were reorganised into detailed diagrams that represented and related the main themes identified. These diagrams are presented in Appendix 27.

4.4.2.1. Identifying components and themes

This section presents the components that enabled the suggested theory to be constructed by exploring the perceptions and experiences of our participants from perspectives that emerged as a thematic analysis was developed.

The first four interviews (N1, N2, N4 and N5) were carried out in the same care home. The different roles of the participants in the home helped to identify the role in the care home as a variable in the construction of any emergent theory as well as the rural location of the care home as another variable. Therefore, the analysis of following interviews looked at the variability in these views depending on the location of the care home as the interviewees indicated. The next step was to focus on care homes located closer to bigger towns or a city or inside a residential area of them.

The analysis carried on with the exploration of another three interviews (N3, N6 and N7) from participants that worked in care homes located in suburban areas. These interviews revealed the importance of contemplating the use of temporary members of staff (commonly denominated “agency nurses”) and the impact of receiving new residents in the care home. Therefore, it was worth exploring the reality of homes where there are constant new members of staff and new residents.

This phenomenon was not very frequent in care homes but it was very common in respite homes where residents spent only hours or a few days and new members of staff were required with short notice to look after these temporary residents. This location was not expected to resemble the reality of a care home but the effect and the concerns of the interactions between new members of staff and new residents with regards to administration of medication.

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The main limitation on the attempt to observe the effect of frequent changes on staff and residents was that only one respite home consented to take part and interviewed (N8). So as to examine a home with a high turnover of residents and members of staff, a large care home was visited to interview participants (N9, N10 and N11). The observation of larger care homes revealed many more categories than those with fewer residents and a smaller turnover.

Looking back to the interviews already analysed, numerous new categories emerged during an interview with a non-UK trained nurse. The experience of having worked in different countries and seeing different practices could give the participants different points of view about the administration of medication which should also be considered.

The interviews with N12 and N15 identified a relatively low number of new categories but none of the previous participants had experienced implementation of administration guides in their care homes, therefore, the following interviews (N13 and N14) were carried out with participants that had experiences in the implementation of services that provided guidance in the administration of medication. Although saturation was unlikely to be reached, the interviews did not reveal new emerging themes.

The thematic analysis carried out revealed that within the framework of the administration of medication to PWD in care homes and within the components explored (location of the care home, role of the participant, employment status and experience of the nurses), the following themes were identified:

- the issues that affect the administration of medication to PWD. Five main themes were identified in the interviews. These are:
 - the care home environment,
 - interaction between healthcare professionals,
 - nurses' heavy workload,
 - professional development of the nurses,
 - residents' health conditions,
- the issues that affect the implementation of a new service providing I-MAGs in care homes with nursing. The thematic analysis identified the following themes:
 - preparation in the care home,
 - generation of I-MAGs,
 - the content of I-MAGs,

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- the location of I-MAGs,
- the usability of I-MAGs,
- the impact of I-MAGs.

4.4.2.2. Factors that affect the administration of medication to PWD

4.4.2.2.1. Care home environment

The care home was for many nurses the only environment of work and their experience of work may have been limited to such settings. What it looks like, where it is, what I do and how I do it, were important perceptions in the daily routines of the nurses of the home and in the way that residents received care. Some of these different aspects about the care home were identified by the researcher as relevant in the way that they affected the care of the residents and the way that residents received medication.

Roles in the care home

As participants highlighted, the ultimate role of the nurses and carers was the provision of care. Participants' understanding of care greatly diverged across different roles in the care home. Managers and senior nurses considered care to be a more organisational concern that involves much time away from direct contact with the residents, completing reports and making sure that the staff and premises complied with regulations. Care home structure, training, reputation and paperwork were some of the concepts that were repeated by participants in senior or managerial roles while their clinical roles were a secondary priority for them. For example, this is how participant N2 described her role in the home:

“My role is care. [...] putting the structure, putting training into place, building up a good reputation and things like that putting a lot of hard work into it, putting the paperwork in place and making carers understand about accountability that at the end of the day this is a client's home.” (N2)

In contrast, nurses in non-managerial roles focused their caring role on the direct contact with the residents. For these participants, their role in caring involved personal care of the residents, such as dressing and hygiene, the general well-being of the residents and the physical administration and organisation of their

medication. Most of our participants in general nursing roles highlighted the importance of their regular tasks in their routines:

“I’ll be in charge of the units, so that would involve having a handover from the last shift, handing over to the care staff that are coming on, giving medication, um, doing dressings, taking bloods...”(N6)

These members of staff were in close contact with residents that suffered from dysphagia and were able to identify health concerns as the resident’s conditions evolved. Participants often commented on the frustration experienced when facing difficult administrations during the drug rounds, as commonly they had to accept that the resident was not taking the medication the way that the nurses considered optimal and, therefore, they were not confident on the effect of the drug. In response to the question *“When you give medication to residents with dysphagia here what does this usually mean you need to do?”* participant N5 responded:

“You just have to sit with them really to be honest (resident’s name] will suck it which is not great but what can you do.” (N5)

Participant N5 pointed out in this comment how the closeness to the resident is important. However, his comment clearly identified a lack of knowledge from the participant in the pharmacological effect of sucking a tablet and the lack of participant’s clinical skills to identify action that could improve that issue. In summary, these comments highlighted that the care received by the PWD may depend on the understanding of the condition by the care providers and the role of those professionals in the care home. Even when all these healthcare professionals had a nursing background, they had different perspectives which were reflected in the care they gave to residents.

Location and appearance of the care home

Some participants identified how the appearance and location of the home could raise concerns that could affect the residents’ care and well-being. It seems to be hard for care homes remotely located to fulfil the staffing needs in the home. Two issues were often highlighted by the participants. One was that new staff in the nursing team were harder to recruit when their access to the ruraly-located home was not as convenient for them as in urban areas. The second issue was the greater likelihood of losing their members of staff to other homes that offered both further professional opportunities and a location in more largely populated areas with

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easier access. When one of the participants was asked whether she thought that she counted on enough staff to look after the residents in the care home, she answered:

“Not at the moment, We have had four staff leave in the last few months for various reasons one girl went home, two girls left because the travelling was too much and this is a problem you know we are very tucked away in a little village and a lot of the staff have to come in on the train so it’s quite expensive for them [...] so sometimes it takes a little while to get good new staff.” (N2)

This comment highlighted how the difficulty of recruiting trained members of staff had an impact on the way that medication is administered as not only the same tasks were shared by less people but also the training standards may not have been as high.

Some care homes visited were located in old buildings which some participants described as “tatty”. Others described it as “homely”, as some of the participants considered that the residents were often used to living in similar looking properties in their own homes. Although many of the participants pointed out the appearance and the structure of the care home as a negative highlight, for some of the interviewees, it was not considered a reason to compromise the quality of care offered or the potential of the home, but an opportunity to adapt to a more particular type of residents and care. For example:

“We cannot change building but we can change standard of care um and I thought that because of no big huge space for people to have really open space to walk around I thought this home couldn’t really meet clients’ needs but can give really good really high standards for clients with end of the life care palliative care so we um started to change the type of the client we care for.”(N12)

It was worth highlighting the perception of some participants on the appearance of the home. Some pointed out how the old-fashioned look of the building could reflect the presence of very traditional approaches to care and the lack of evolution to reflect new recommendations:

“The home that I came from was very clinical, it’s purpose built, it was very structured this is it’s a nice home. My biggest concern with this home is (manager’s name) and I have often discussed is some people have been here a very long time and there is a touch of the set in stone mentality (referring to and quoting the nursing team) this is the way we’ve always done it.” (N2)

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Although the location of the home seemed to be a clear factor in success in recruiting healthcare professionals, the appearance of the home provided different points of view. It seemed that in some cases not enough consideration was taken by the interviewees on how the appearance of the building could compromise the care received by the residents and also how the residents perceived their care. On the contrary, other participants able to identify these issues, were capable of optimising the care by targeting a group of residents for which the care home would not be a limiting factor in the care provided. This was highly relevant to the care received by the residents with dysphagia as it highlighted how the care team needed to adapt and prepare for the needs of the residents rather than them expecting the residents to adapt to the nursing team. In summary, the comments from the participants showed that the administration of medication to dysphagic residents may require specialised care and knowledge and it was important that the resources were made available to the nursing and caring team regardless of the location of the care home.

Care home policies

Internal policies in the care home affected the way that residents received their medication according to the comments of the participants. Nurses and carers identified having policies as something positive for their practice that gave them confidence in what they do. When guidance was implemented in the care home, some of the participants highlighted a positive sense of confidence inspired by the support provided by specific instructions on how to practice at the time of making clinical decisions about the care of the residents. For example:

“Well, we’re lucky with the fact that (care home’s name) has a policy to follow. [...] It’s written on the risk assessment what medication you’re giving and in what form it is and why you’re giving it and so everybody is happy.” (N6)

Having to implement excessive guidance also carried risks. None of our participants commented on the quality or purpose of the policies, and instead, they followed them without question. This often resulted in very passive practices where the nurses did what they were told which, according to the comments of one participant, could de-skill their professional clinical practice. As mentioned before, nurses felt frustrated when difficult medication administrations challenged recommended practices:

“I’ve never thought about it. I was just doing what I was told to do.” (N7)

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More importantly, having these policies in place did not always mean that they reflected usual nursing practice when administering medication, showing a lack of standardised practice in the care home. Despite participants' awareness of the differences in practice between nurses in the administration of medication to residents, they generally seemed to accept this issue without any concerns for their potential consequences for the residents and for their profession. Several participants highlighted how different ways of practising may cause confusion during the training of staff members.

"I've seen staff doing it in different ways in terms of whether they mix the medication all together with water and give it all at once or flush out the tube first and then give the medication and then some more water...[...] it seems to be done differently by different people, so ah, I'm not sure." (N4)

The comment by this participant showed that current practice was being transferred to newly-trained members of staff. Due to this lack of standardised practice, the criteria when handling the formulation for medicines prescribed for residents also varied greatly. The nurses and carers resorted to manipulating original formulations without doctors' consent for different reasons such as thinking that it was better for the resident, not challenging the information received or just because the formulation was easier for them to administer without considering the consequences for the resident:

"[...] and I have seen when working in other care homes how we were told to crush the tablets if the patients couldn't take them and then we would sort it out with the doctor, but that could take days and sometimes the GP came and told us that he had not authorised that." (N2)

When talking about a resident with dysphagia recently discharged to the care home, one of the participants commented with frustration:

"We recently had somebody who did have a swallowing difficulty come from hospital with virtually all of their tablets being crushed um we weren't happy with some of them particularly being crushed. [...]doesn't nobody seems to identify those before people get here and people like (name of other nurse) and myself are saying I'm sure we shouldn't be crushing this we need to check it out." (N10)

This quote recognised shared confusion and uneasiness with this practice for members of staff that were capable of identifying issues with the administration of

medication. When talking about it, as here, some participants sometimes identified the alteration of drug formulations as an issue of potential concern but they did not usually follow these up. For example:

“We have a lady at the moment who is epileptic very, very difficult because of her dementia to get her sodium valproate into her. She’s a spitter and bless her she actually had two very nasty fits yesterday and I feel it as a result of the sodium valproate not being swallowed. [...] I think in a situation like this there is an issue.”
(N2)

In summary, the interviewees revealed that there was, in general, a lack of initiative to challenge current instructions given to the care home by other external healthcare professionals which was leading to a practice in which nurses were not always applying their clinical knowledge in their routines when administering medication to residents with dysphagia.

4.4.2.2.2. Interaction between healthcare professionals

There were numerous HCPs from different disciplines involved in the care of PWD and residents in the care homes often received treatment from other clinicians in secondary care and acute care in hospital, as well as a large input from the GPs and other healthcare professionals in primary care due to the complexity of the conditions that residents of care homes may suffer from. Communication between HCPs and the level of involvement in the care of residents with dysphagia played an important role in the way that the residents received their medication. The analysis of these interviews helped in identifying the nature of that interaction with HCPs within and outside of the care home.

Secondary care environment

Care home residents often need treatment for a short period of time for a brief but serious illness, injury or other health condition in a hospital or by secondary care providers that did not work in hospitals, such as occupational therapists or physiotherapists. The majority of participants commented that the hospital environment was often very different to the care home and the information received from secondary care was not always suitable within the care home environment. This was widely recognised by the participants, which also described the care home as a place where much more general care was provided, with higher involvement from the family and where more time was dedicated to the resident in comparison to the hospital where, from the points of view of the participants, often

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set practices in primary care that were not suitable for the care home. The following quotes are an example of the differences identified by the participants in relation to the administration of medication:

“Oh quite busy um obviously different from hospital because here you probably have more general needs to take care of as well as the drugs and dressing and things like that and family involvement is quite a lot as well.”(N8)

On the contrary, one of the main differences that the participants highlighted is the access to other healthcare professionals such as doctors and pharmacists. There was a feeling of isolation in the care home where the interaction with other professionals - the majority of times - only occurs by phone, compared to hospital where consultants, SALTs, pharmacists, nurses, etc. are working much more closely. One of the participants commented on this:

“I guess in hospital it’s different because you have more professionals in one area to get together whereas when we call a doctor in or we can phone the pharmacist or a SALT or the dietician, they visit when they visit whereas in hospital you have more there don’t you.” (N9)

Many participants explained the difficulties that they needed to overcome when contacting professionals in secondary care. In consequence, the interviewees often referred to the hospital as some kind of unreachable source of information from which they just accepted the instructions received as they arrived. A feeling of frustration for the lack of recognition from the hospital for the work done in the care home was identified. This relationship with secondary care professionals could often bring friction between clinicians within primary care too, especially when changes had to follow approval from both the GP and the consultants in the hospital and sometimes no agreement was achieved between all parties. It was observed during the interviews how this affected the confidence of other professionals’ expertise. An example of one of the several cases indicated is the experience of participant N11 when one of the residents received instructions from the hospital on crushing a film-coated tablet. Our participant complained about the fact that the GP would not question the hospital instructions and, therefore, the nurses in the care home were not confident on whether they were doing something appropriate or not:

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“It would be nice to have a guideline to refer back to and got the correct answers so when we’re referred back to the doctors and they say it’s how it happened in the hospital and they don’t like to interfere.” (N11)

The members of the nursing team in the care home tended to liaise primarily with the GP even when the information about the resident’s condition came directly from the hospital. The participants identified this as a consequence of the lack of quality in the communication (for instance, access and approachability) between the nursing team in the care home and the professionals in secondary care. The GP was seen as the main key contact for the care home when the nurses needed to know or queried any information about the resident’s medication:

“Sometimes they come (from hospital) with tablet forms. In that case we liaise with the GP with regard to whether we can crush medication and then swallow or prescribe a liquid form or form which will be more suitable for someone with dysphagia to swallow their medication and we tend to do like to liaise with GP.” (N13)

Interactions within the primary care environment

Primary care includes the healthcare services which play a role in the local community involving HCPs who act as a first point of consultation for all residents within the healthcare system or, in our subject, residents in care homes. The main source of interaction in the care homes with healthcare professionals derives from primary care and includes mainly the GP, the pharmacist and the SALTs when considering PWD. The geographical and organisational closeness of these professionals was not seen by the participants as a factor that improved a fluid communication and interaction between them and the care home:

“One of the GPs that look after our patients is only around the corner, but sometimes it is just easier to speak to the emergency doctors to organise a visit and then they ask why we didn’t call the GP instead!” (N2)

The nurses expected to receive some specific consent from the GP to enable them to alter original formulations consequently rendering the administration unlicensed. It was frequently the nurse’s role in the care home to request this consent or to request liquid medication. This situation was one of the main sources of conflict with the doctor as mentioned by the interviewees. The following quote identified legal liability as one of the main concerns for all the professionals involved in the care of residents from the point of view of a nurse in managerial role and another

one with clinical roles. Sometimes the nurses perceived this interaction as a lack of commitment from the GP afraid of accepting liability as indicated by participant N1, originating friction between the care home and the GP:

“If you have a GP and I have seen them, who say right, just give these, but crush them, can you put that on the prescription please? No. Because they know that they will then be liable. In which case, we’re not administering it. [...] My nurses I know will come to me if they have an issue and I will go fight that battle for them.”
(N1)

The comments from this participant highlighted uneasiness when trying to discuss issues with the GP at the same time as an imposing attitude from the manager of the care home to obtain the outcome that he expected from the GP without considering the views of the doctor. In the second instance, nurses felt coerced to administer medication without the resident being aware. Following the recommendations from the GP was not always an easy task for the nurses who feel that the whole liability of the administration falls on them after crushing a tablet:

“We had a gentleman here who has sadly died and the doctor was not prepared to write this gentleman up for liquids. We did ask repeatedly but we were told we had to crush them and it wasn’t actually written on the MAR chart. We were not prepared to crush and again both (care home manager’s name) and I am very stringent on that I don’t give covert medication. If a client refuses medication we don’t give it.” (N2)

The participant N2 showed an impression of the doctor as someone whose principals were not based on caring for the resident, or not with the same strong drive as the participant.

The same challenges could also occur when the HCPs involved were temporary clinicians such as locums or emergency doctors. Participant N3 explained that often they needed to contact the doctors in an emergency and when the prescriber was a locum doctor who did not know the resident and her/his needs, the locum doctor tended not to sign their consent and, therefore, the nurse had to contact who she called “the proper registered GP” and get the medication changed or the consent signed.

It is important to mention that the participants focused their attention mainly on negative experiences when obtaining consent. Although this reality can be a very

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regular experience for many nurses, some other participants mentioned that often they would contact the regular GP and consents would be received without the need of much discussion.

Another common concern for most participants was the communication with occasional nursing staff referred to as “agency nurses” by the regular nurses in the care home. Having to update occasional members of staff with a lot of information was considered “*difficult*” (N14) and “*time consuming*” (N13):

“We have to give them (agency nurses) lots of details and usually write a list of everybody and what their diagnoses are and if they got any special medication like if they’re say like on antibiotics twice a day the timings of that we’d highlight anything like that or insulin’s yes that would be highlighted on hand-over and written so that they could refer to it as opposed to just giving them the keys and letting them get on with it.” (N9)

When this communication did not provide the right information, it could often result in serious incidents in the administration of medication. However, the participants were not made aware by the care home managers of the outcome of the action taken about the incident. One participant explained their experiences in relation to an incident involving the administration of crushed medication without consent from the doctor:

“One agency nurse crushed the tablets before having consulted and we informed the manager and the manager contacted another particular person who came for shift and they informed the agency as well that did the mistake and I don’t know actually what they did but we just follow the rule here.”(N3)

The interviewee was able to identify good practice by knowing what to do on the administration of medication and what action to take when an error has been identified.

The relation with the pharmacist was perceived as very positive in the majority of cases. It was often explained by the participants that when they had any queries about whether they could crush tablets or open capsules, the GP would be contacted as a first source of information and then sometimes, and as a second choice, they would contact the pharmacist:

“We tend to rely on the doctors to know what can and can’t be crushed but if we’re in any doubt we would ask the pharmacist as well.”(N6)

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To the contrary, other participants recognised the role and expertise of the pharmacist. However, it was highlighted by the participants' comments how the lack of agreement between the advice given by the pharmacist and by the GP could present a challenge to the relationship between the nursing team and the GPs. The following comment from one of the participants highlighted how the concerns of the interaction between primary and secondary care could also be reflected in the general practitioners and the impact that it might have on the interaction between the care providers in primary care settings:

“It’s quite difficult um... we recently had somebody who did have a swallowing difficulty came from hospital with virtually all of their tablets being crushed um... we weren’t happy with some of them particularly being crushed and checked that out with the pharmacist who said no you shouldn’t be crushing those tablets. The GP was then very reluctant to give us alternative preparations because he said the hospital weren’t doing it so why should he, which to some extent you have to agree with and when the person was assessed by the SALT in the hospital they had recommended that they had all liquid medicines but that hadn’t happened so it does make things difficult sometimes.” (N10)

The interaction between the GP, the pharmacist and the SALT in the example described by participant N10, occurred only with the care home staff as a mediator. There was no discussion between the pharmacist and the GP or the SALT directly, and the nurses found themselves dealing with issues related to prescribing or the assessment of dysphagia which was in this case beyond their expertise and responsibility. Participant N3 indicated how these conflicts were avoided by making better use of the professional’s expertise and liaison between GP and pharmacist. The participants’ comments identified that a good network of healthcare professionals eased the flow of problem solving in the care home. When the professionals making recommendations or suggestions on the administration of medication (GP, pharmacist and SALT) communicated between them, it was described as much smoother process than the ones described previously:

“The best person if you work here is like the pharmacist yes even if you call the GP sometimes they don’t tend to give the answers so we’ll go through pharmacist and they’ll speak to GP and finally they’ll come to the conclusion and let us know what exactly so it’s more like you know the pharmacy people pharmacist is the one you know telling all the information.”(N3)

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The SALTs were valued very positively by the majority of the nurse participants as “*very supportive and accessible*” (N1). Their expertise in speech impediments and their availability were their most appreciated qualities. These characteristics seem to have an enormous positive impact on the relationship with the care home as it was described in this example:

“She (referring to SALT) will give you an off-the-record opinion as to well I should think you should get a swallowing assessment done or you know she’s useful we can always get her advice even if it isn’t her in her official capacity.” (N14)

In summary, the comments presented identified that the relationship between healthcare professionals in primary care was affected by the inadequate use of the resources and expertise available as well as by the legal concerns about liability that the complexity of some drugs administrations may bring.

Within the care home

It was important to explore the professional relationship between members of staff within the care home. It was, in general, observed that the members of the team were working in a very structured pattern where the roles of the managers, senior nurses, nurses and carers were clearly defined, but they counted on support from each other when this was needed. The majority of the participants acknowledged strong support from the carers, managers and senior nurses within the care home that could be perceived as effective team work. Often managers had to leave their managerial role to help with the clinical role of the nurses. Also, nurses and carers would support each other when possible. Availability and expertise were again important qualities that were highlighted by most of the team members at any level:

“You know there’s always one (nurse) on this side if you need help but you know and I’m quite lucky because you can just pop over and ask them.” (N5)

4.4.2.2.3. Nurses' heavy workload

Despite having certain routines in place, the members of staff in the care home needed to be prepared for unexpected health episodes with the residents that can increase the nurses' heavy workload. Most participants described their regular days as “*stressful*” (N3) or “*running back and forward*” (N7). Participant N1 described his work as “*new challenges every day and a lot of the clinical care issues*” (N1).

In this section, the perceptions of the nurses on workload elements that could relate to the care received by the residents with dysphagia were identified.

Physical workload

The work of the nurses involved drug rounds, monitoring of some conditions and behaviours of residents, stock control and completion of reports as the main daily tasks. As part of their current role, the nurses were in charge of the hand-over from the last shift, giving medication, dressings, taking bloods, but also sorting out operational organisation like covering off-duties, rotas, appraisals and supervision for the staff.

Most of these tasks had to be completed on a daily basis within each shift. However, the time involved in achieving them often seemed to be underestimated as unexpected events regularly interrupted the planned schedules causing the nurses to work extra time in order not to compromise the care of residents. This often meant that administrative jobs were sacrificed in the care home for other tasks of higher priority:

“Normally I can work up to 60 hours a week nursing especially for sickness. It’s not very often I’ve actually got an office day. This is quite rare. I was actually promised an office day when I came but we’ve had all sorts of issues with nurses coming and going and things so that never really materialised.” (N2)

While this comment highlighted that the direct care of the residents was prioritised above other jobs, it also pointed out that the care was being provided under pressured circumstances for the nurses and by over-worked members of staff that had to fulfil other tasks within a care home lacking in professional resources. Nurses tended to identify the amount of paperwork to be completed as one of the most excessive chores of the day. They saw this task as something a bit detached from their clinical role and it seems to drastically increase their workload and keep them apart from the direct contact with the residents:

“Sometimes in the morning it take us at least an hour to attend one client with personal care and then we have the medication and the form filling and appointments and all those and I do find sometimes like this is we go from thinking have I sent that, have I done that, which of the six clients?” (N15)

Participant N15 made obvious once again that the nurses in care homes often had to work under high-pressure conditions. Participants, however, did not consider the administrative tasks as part of the care of the residents and those tasks were often not prioritised.

Emotional workload

The daily tasks of the nurses and carers were undoubtedly laborious and may have represented a heavy physical workload for them. However, some of the interviews also highlighted the importance of the emotional workload that care in nursing carried and differentiated the view of residents as subjects from the view of them as human beings. The participants felt responsible for the care provided at the last stage of the life of the residents. There was a sense of humane responsibility in the comments from the participants, but also a sense of frustration for not being able to achieve what they wanted for the resident due to the excessive workload. Participant N4 comments on this emotional pressure:

“When you’re working with people who are extremely vulnerable and obviously, I suppose for a lot of these people, um, sort of this is their last point at which they’ll be cared for, so there’s a real, I personally feel and I’ve spoken to others about this and they feel that um, you know, you really have a responsibility to get it right, because you are that last point of care.” (N4)

Emotional pressure was, however, not reflected in any regulation or policy mentioned by the participants but just mentioned as a personal concern. One of the nurses in a managerial role highlighted this issue for how he tried to encourage that closer view of residents, not only as human beings but as relatives:

“All I ask of my staff is that they treat everybody as they like to be treated themselves and the simple rule is if this is your mum or your dad, what would you like? Very simple.” (N1)

4.4.2.2.4. Professional development of the nurses

It has been mentioned, on page 168, how the care provided by the nurses can vary in its qualities depending on the standpoint of the person offering it. The analysis of these interviews helped the researcher categorising several components that are involved in the quality of care provided by the nurses. These components are presented in this section.

Professional experience

The participants’ understanding of experience differed greatly between their descriptions in the interview. Some participants would say that it is defined as the number of years practising the same job, but others identified professional experience as the number of places where a nurse had practiced, the number of

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roles, the type of residents who they offered care to, the countries where a nurse had practiced or even a combination of all of these.

Some interviewees could not explain their ways of providing care without looking back at their personal experience, but it was also these experiences that allowed them to see the threshold of care that they could currently provide. Participant N1 explained how his experience in dysphagia had influenced his current practice and how certain roles had been more de-limited in order to specialise the care of PWD:

“Certainly on the acute medical wards we were taught and certificated in actually doing simple dysphagia assessment. Now I would not use it as an assessment tool. A) Because the license for it is long expired and B) I am not certain on the suitability of it, C) if I had those kinds of doubts there are healthcare professionals that are far more capable than I am. I can make a simple decision, is this person capable of swallowing? That’s enough. Then after that it has to go to another remit.” (N1)

This comment also highlighted the acceptance of change in practice and the way that nursing roles have evolved throughout time partly due to the specialised practice of other HCPs. Based on previous experience in other care homes and in past years, some of the participants considered that there was a greater involvement of the nurses in the residents’ care that had led to a much more personalised care which was often seen by the participants as an improvement compared to practice in the past:

“There’s a big difference and they’re more involved. There’s more one-to-ones going on here, There’s people that need it more than what there was in other places[...] It’s better.”(N7)

But in most cases, practice experience in different roles was what helped participants to improve the care provided to residents. Participant N12 explained how her experience was being reflected in the well-being of residents. In her case, her experiences came from being in a variety of roles, in different countries. Observing mistakes made in the past and working on many different roles provided, according to some participants, could help to identify how to improve current practice and relationships with the team members. These improvements based on experience would be likely to be reflected in better care for the residents. As participant N12 explained, communication and understanding of the impact of decisions on the team and the residents were key for the good functioning of a team:

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“When I was a position of carer or even cleaner I realised, actually because everybody does mistakes, how many mistakes management have done.[...] I never made any decision without talking with my staff and I know how much any decision which is made by head office by manager can affect staff. [...]” (N12)

The participants emphasised how their experience was what made a difference in the quality of care provided to the residents, but it was also important to transmit that feeling of care to the residents:

“I think we come to that point when we reach really high standards you know with care and improved quality of life for our clients and that is the most important thing even if they are very poor condition physical medical conditions they still have that sense of well-being.” (N12)

The professional experience of the nurses was one of the most valued elements that affected the care of PWD. Any intervention that could enhance their experience was perceived by the participants as a positive approach towards the well-being of the residents:

“I always think that when I have learnt new ways of doing things, like small things, you know, like wounds or stitches, different to when I went to the nursing school, I feel better in what I do, more confident, you know, and my clients are receiving better care.” (N8)

Training and qualifications

There was not substantial inconsistency between the participants on their qualifications and previous training. However, their approach towards the need for training and qualifications, and the routes to implement change, varied greatly between participants. Often, negative approaches towards new ways of practicing were observed in the interviews. This was more common within teams that have not been up-to-date with newer recommendations, triggering conflicts in the delivery and implementation of new guidelines between the members of the team. The subjective evaluation of new policies by members of staff, and the addition of workload as a consequence, could bring challenging situations that could create differences in the quality of care provided. The implementation of changes in the care home was challenged by these approaches from the members of staff and traditional practices. The managers often had the role of talking their staff through the rationale for changes and sometimes followed the new processes closely to

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ensure the implementation of new practices by the members of staff. Participant N2 explains the difficulty of implementing changes in practices in her care home:

“They don’t understand why they have to do that. [...] Sometimes it’s very difficult you’ve got some staff that will accept change very well, very readily and as I say some staff who prove difficult and then we need to start off and go down the supervision route and things like that, but most of them you know once you explain to them why we have to do things and sometimes you might have to explain it two or three times but they usually get the general idea. [...] Then they think well yes ok don’t always like it, but yes, they can see the thinking behind it the principle behind it.” (N2)

This comment, once again, describes how the practices seen in care homes could vary greatly between different members of the nursing team and how this could be related to different approaches to practice.

In some cases the perception of changing practice was identified as a correction of “wrong practice” rather than as an enhancement of a current one. Some participants tended to see the appropriateness of their practice on a ‘black or white’ scale rather than a scale with small improvements to enhance the care of the residents. Participant N14, when asked about including additional guidance to help with the administration of medication to residents with dysphagia, responded:

“If we were doing them wrong but I’d like to think that we weren’t so you know if we’re doing them correctly anyway, it’s not going to make any difference, is it? so and I’d like to think we are doing what the guidelines would be but not that something like this would be to change our practice completely because that would mean we’d be doing it horribly wrong wouldn’t it?” (N14)

Participant N14 clearly highlighted the confrontation between what personally was correct and what was correct according to professional guidelines. There were certainly negative approaches towards the implementation of change, but the majority of the participants admitted that they would happily accept changes to their normal practice especially if those changes improved the well-being of the residents. In her role of nurse, N2 commented:

“I’ve never believed in being stale in old practice and I would be prepared to try anything that certainly improves practice and keeps clients safe and keeps nurses

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safe, my seniors safe, yes particularly for the seniors. I think nurses are always aware of their pain. They're aware of their responsibility, their duty of care.“(N2)

Participant N2 was clearly highlighting the importance of a strong rationale in the implementation of change and a description of how it could benefit the resident. In summary, the comments from the participants highlighted that the implementation of training for nurses was a challenging task for the managers in the care homes where very traditional approaches towards change remain embedded and it may require strong supervision and follow-up of the new practice to ensure the compliance of the members of the nursing team.

Decision making process

Previous knowledge and experience were characteristics that may have affected the administration of medication by the nurses. However, nurses had to face unexpected situations and challenges during drug rounds and they cannot always count on enough guidance on how to act on challenging administrations of medication. This section identified some of the elements that affected their process of clinical decision-making in these situations.

The rapid development of a resident's conditions and problems with swallowing could force nurses to question what Participant N1 refers to as “deciding if this drug is appropriate at this time” (N1). There was recognition that altering the original formulation of a drug carries liability issues which are sometimes the basis of the decision made. Participant N1 commented:

“The doctor is not responsible for my registration as a nurse. I am. Part of my code of conduct, if something I think is wrong, I cannot do it. If I do do it, I have broken my code of conduct. I have knowingly put somebody at risk. It is also my duty and duty of care and bearing in mind the recent changes within safeguarding legislation, by not challenging it, I could be guilty of neglect by omission if I have not challenged it which I believe now carries a five year jail term.” (N1)

The comments made by participant N1 showed how nurses were under pressure not only as a team in the care home, but also as individuals, and they had to individually assess the correctness of every administration of medication. Again, the fear of the consequences of misconduct was one of the reasons for a constant self-assessment in their practice.

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It was often mentioned by the participants that the nurses knew the residents well enough to believe that they could make decisions on what is the preference of the resident. Based on that, participants often tried to ‘direct’ other professionals in getting what the nurses thought to be best for the resident. Participant N3 commented:

“We change the dose you know like if they start some medication even though they want to do it during that shift and we come next morning and we know what the resident likes and we will approach the GP, you know, the proper registered GP and we will try and change the dose of different antibiotic different form of antibiotic.” (N3)

Participant N12 talked through the changes and decisions they made regularly based on what they thought was best for the residents at the time and using their internal assessment tools and clinical knowledge:

“We sometimes have to, after two hours, we have to change advice for the staff who care for that client because condition you know change and that is the best way [...] Also we have self-management review techniques for our clients so actually we use that tool to assess the client before if we are start to be concerned for them.” (N12)

In other cases the decisions were made based on instructions and nothing was questioned. Participant N9 responded with the following when talking about following instruction at the time of administration:

“I don’t know why but that’s what they tell us we must do so it would be interesting to know why but I don’t know why but that’s what they say we must do so that’s what we must do.” (N9)

These findings highlighted that liability, closeness to the resident, current practice in the care home and the guidance implemented in the care home were some of the elements likely to influence the clinical decisions made by the nurses when facing challenging administrations of medicines to residents with dysphagia.

Clinical confidence of the nurses

Clinical confidence was an essential part of the practice of any healthcare professional as often clinical decisions had to be made to adapt to the individual needs of the residents or in this case the residents of the care home. During the study, this subject was often highlighted by participants implicitly when talking

about the causes and results of a lack of confidence. It was, therefore, relevant to explore the elements that affected their clinical confidence from their own perspectives.

The lack of confidence can add to the pressure that nurses face in the administration of medication. Previous elements, like the knowledge, experience or their main focus at the time of making a decision, can affect their confidence. For example, one participant stated the following when talking about altering formulations:

“No I don’t really like doing that. I don’t know what’s in them if you know what I mean what’s in the capsule so I don’t know you know I might end up doing more harm than good [...] If I’m worried, I won’t do it.” (N5)

Some participants highlighted the importance of getting the right sources of information in order to help with their confidence in their practice. External professional guidance could provide enough evidence to back-up their queries in the communication with healthcare professionals in different settings and it would avoid the use of unreliable sources of information, as indicated in some of the comments from one of the participants:

“It (guidance on administration) would certainly help us to be more confident about what we give and how we are giving it because sometimes it is a bit awkward. You get something and it might have to be given in a particular way but we’re relying sometimes on residents for that information.” (N8)

The lack of input from other professionals and the lack of complete understanding of the prescribing rationale had a significant impact on the nurses’ confidence as indicated by participant N10. Specific instructions and expert guidance seemed to be essential during the administration of residents with dysphagia:

“We’re crushing this. Should we be crushing this? Has anybody checked it? What are we going to do about it? Why won’t the doctor prescribe something else? So I think that helps from that point of view that we’re working from more specialist advice than just from ourselves.” (N10)

Participant N10’s comment highlighted that nurses may require individual confirmation of how to administer every drug for them to feel confident in their practice. However, being able to identify weaknesses in confidence may be an advantageous standpoint. Being over-confident can lead to bad habits of practice

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by over-riding concerns that can be significant in the care of residents as explained by some of the participants. The comments of some participants suggested that the provision of any changes in practice should never over-ride the professional decision-making process of the subjects in order to avoid the habit of stopping questioning everyday practice. Participant N2 also highlighted how very structured routines, regardless of being based on good or bad recommendations, could lead to bad practice:

“You can get into bad practice and very easily and sometimes you’re not questioning and sometimes I think they (the nurses) are not checking because they’ve always done it like that and they (the residents) have always been on this medication and they’re not actually looking.” (N2)

However, views on confidence varied throughout our group. Participant N3 mentioned how training helped them with their confidence and they are able to identify who to refer to when needed:

“Definitely we’re confident because we do know what we are doing and we have a proper training to do that and if anything, something wrong with the machine but still we have the numbers to ask them what is wrong with them, but still we all fine.” (N3)

4.4.2.2.5. Residents’ health conditions

Participants identified how different conditions triggered different views from the carers as well as from the residents. As one participant said about this interaction:

“[...] just by a different approach you have to whichever way you’re going to connect with that person with dementia and obviously different people are going to connect with that person maybe differently as well.” (N9)

This comment highlighted that the individual ideas of each resident, nurse and carer could condition the kind of interaction between them and this could be reflected in the care received in relation to the administration of medications.

Perceptions of the residents’ choice and approach to medication

Many residents in the care home had none or almost no capacity to express their choices or approaches towards medication. In certain cases, residents were seen to take a very passive approach towards their medicines and consider the management of their drugs, including the administration, to be somebody else’s responsibility as

they classified that as part of the care they paid for. Participant N1 explains this as adopting ‘the sick role’:

“[...] also there are some people who take on the sick role. I have come to a care home, why should I worry about my tablets, I want them to come and give me them.”
(N1)

It was frequently observed by the interviewed nurses that numerous residents “*don’t like*” (N5) their tablets. Our participants generally assumed that flavour was the main cause of dislike and often alternative formulations were attempted in order to over-ride that rejection. However, this approach ignores other elements conditioning the approach when liking or disliking a drug, such as the texture of the medication and the difficulty swallowing it. An experience described by participant N13 demonstrates this difficulty:

“We tend to liaise with GP and ask for to prescribe liquid medication and sometimes they (the residents) don’t like it so we go back to the tablet. We have a lady; she doesn’t like the soluble paracetamol. She doesn’t like the baby paracetamol (liquid formulation for babies) um all that’s it, isn’t it? And we went back to tablets but they seem to be more difficult and she struggles with them.”
(N13)

Participant N13 was also highlighting how every resident had individual needs and how that could affect the adherence to the medication prescribed and the management of dysphagia. The approaches of residents towards medication may vary drastically depending on the residents’ conditions. The nurses in the care home were in a good position to identify the preferences of the residents but this identification required an open-minded approach from the nurses in order to adequately observe those variables:

“I have heard how some nurses just say that the patient is funny about swallowing and carry on, but we are the ones that should take notice those problems because we spend our days with them, is that right?” (N11)

Dysphagia awareness

Dysphagia assessment in the UK is currently a role beyond general nurses, tending to be allocated to SALTs. As dysphagia appears or worsens, the nurses are the first professionals identifying signs of dysphagia. Whilst several participants reported referrals to SALTs or GP when the signs appeared, none of the nurse participants

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were able to comment on the level of difficulties or to carry out any small assessment on the resident's condition and instead they would limit their practice to following instructions from the resident's care plan. When asked about undertaking dysphagia assessment, one participant responded:

"I can make a simple decision, is this person capable of swallowing? That's enough. Then after that it has to go to another remit." (N1)

Information in the resident's care plan

On occasions when dysphagia appeared before or during a hospital admission, the information in the care plan was not suitably adapted to the needs of the care home and created confusion in the practice of the nurses. It had already been identified how the communication with secondary care and other health care professionals was not always optimal, and this was reflected further in the information contained in the care plan:

"I think for people coming out of hospital the SALT advice needs to be followed and if they should be having liquid preparations then that's what they should come out of hospital with and I think if they came out of hospital with them then the GP would happily continue to prescribe them. I think it's they're coming out of hospital with tablets saying they're all fine to be crushed and then us saying something different." (N10)

Participant N10 was commenting on the challenges found when her regular practice contradicted new guidance from other professionals. Contradictory or incomplete information in care plans affected nurses' trust on the grounds of their own clinical practice. When the instructions given to the nurses did not match the information in the care plans, it created a sense of frustration as the rationale for this practice was not explained:

"So what do I do when the doctor says something about the medication but he doesn't write it anywhere? I can't just go and wait another day for him to come and add it to the care plan, but I can't do different to what the plan says either. Yes, sometimes it is very frustrating." (N14)

This highlighted that any guidance containing the rationale of any discrepancies with the information contained in the care plan could help the nurses to understand the reasons behind those recommendations and hence feel more confident about applying their clinical judgement during the administration of medication.

Access to care plans

As the administration of medication was very conditioned by the information contained in the care plans, the access to them also affected the level of dysphagia awareness within the nursing team. It was mentioned how the care plans are accessible to carers and nurses for them to read and to input any significant events about a resident's health.

When some of our participants were asked about how often the nursing team refers to the care plan to find out information about a resident's health, there seemed to be no regularity in the access of the care plans and recent or significant changes in a resident's health were not always known by the members of staff looking after a resident. There was a general assumption within the nursing teams in the different care homes about the lack of need to read the care plans as they "know" the resident. Participant N1, in a senior role, commented the following about the frequency of access to the care plans by the nursing team:

"They should do and they should read it. Whether or not they do, well a lot of the things because we have our residents for quite a long of the time we know them very well. It is documented, but we might not know it's documented, it's just that's what we do. We know it. But it certainly is ah... Whenever a new resident comes here we take time getting to know them and make sure that we get things right for them. [...] so we don't always have the time to check the plans everyday but we know the patients well anyway." (N1)

Participant N1 was justifying not accessing the care plans on every drug administration as it may become too time consuming.

4.4.2.3. Factors affecting the implementation of I-MAGs in care homes

The interviews with members of the nursing team in care homes offered an opportunity to investigate the acceptability of a new service provided by a community pharmacist providing individualised guidance in the administration of medication to residents with dysphagia. These section presents the themes which emerged as previously outlined.

4.4.2.3.1. Preparation required for I-MAGs in the care home

The majority of the participants were interested in the concept of the I-MAGs but also explained that they would expect a certain level of training on how to implement the changes and how to use the guides. According to them, the

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pharmacist would be the most suitable professional to provide this kind of training as the participant acknowledged the expertise of the pharmacist on the administration of medication:

“I think possible if we could have a pharmacist when we start this one just to talk a little bit, I mean it is very clear there and there but sometimes you know, yes I don’t think a doctor, probably a pharmacist.” (N15)

In the minority of cases, the participants mentioned nurses in senior roles, maybe due to traditional practice where senior specialist nurses from secondary care often offer training sessions in care homes. However, the participants would expect that the person offering the training would also be someone who had experience in how to use the guides and that can provide the rationale for the implementation of this service and answers any questions that could potentially emerge during the training and implementation of the guides:

“I guess it would help to have a chat with somebody and understand why it’s implemented I think sometime if they’ve got a rationale or any recommendation it helps I’d just be happy using it.” (N11)

The preference for training by the care home should consist of short sessions where all the members could be made aware of the implementation of the new service and how to use it, as well as who to refer to for potential enquiries:

“I think the only thing that we’d need, would be somebody who’s used to the tool and actually having maybe an hour or two question and answer session with my trained and senior carers and just to thrash out things and then tell people this is what we are going to do and this is how we are going to do it and sort out the logistics as in to stay with the MAR charts, medication administration record or would it stay with the care plan or would it stay with the client.” (N1)

Participant N1 was suggesting that a short intervention by someone experienced would be enough support. The participant’s approach to this intervention was rather imposed on the members of staff and did not contemplate the nursing team’s opinion on the individual suitability of the service in the care home or any explanation on the rationale of the service.

The consensus view seemed to be that the implementation of I-MAGs could be enhanced by preparing brief training sessions that are supported by a professional

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that provides experience and expertise and that liaises with the members of staff in the home to adapt the implementation of those changes.

4.4.2.3.2. Generation of I-MAGs

Participants identified two particular areas of concern when exploring the provision of I-MAGs by a community pharmacist after training provided within the care home. These were:

- the communication between healthcare professionals which would include the pharmacist, GP, SALTs and the nurses in the care home and in the health centres,
- how regular updates of the guides would be managed.

Issues with communication between professionals were identified by the researcher earlier in the analysis (page 173). However, our participants highlighted how essential the involvement of certain healthcare professionals over others in the implementation of I-MAGs was. Often, they expected the expertise of more than one healthcare professional to be combined, but in most cases the pharmacist was expected to be present:

“I think it would need to be a combination of SALT and pharmacist and the nurses really. I don’t expect the GP would want too much input but I would think it would be very helpful to have the pharmacy input and the SALT information you might have separately anyway which we could then input into it, but I think the pharmacist input would be quite significant and would make a difference to what we were actually doing.” (N10)

The collaboration between a SALT, as a dysphagia specialist, and the pharmacist’s expertise in medications were considered the main components to integrate into the nursing team according to this participant. Concerns about the regularity of the updates for I-MAGs arose from the infrequent visits of the community pharmacist to the care home. Many of the participants highlighted how they thought that the care home could benefit a lot from more pharmacy advice and more regular visits and support from their community pharmacist:

“We would need to have good two-way relationship with them (the members of staff in the pharmacy) to keep those as up-to-date as possible.”(N6)

The nurse participants would expect I-MAGs to be updated regularly, at least once a month, and as medications change. In contrast to this, the interviewees pointed

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out on several occasions how the pharmacist's visits to the care home were limited to only once a year in several cases. Participant N8 commented about this:

"A monthly update would be the most valuable and contact with the pharmacist would generally would be very useful if we had that, so they understood how we work I think sometimes, it's just people having an idea of you in their heads sort of thing."(N8)

It was hence identified how the collaboration between the SALT and the pharmacist is essential for the implementation of the guides. This collaboration would be enhanced by a close relationship with the members of staff in the care home, and regular follow-ups from the pharmacist.

4.4.2.3.3. Content of I-MAGs

The majority of the participants commented on the need for certain sections contained in I-MAGs. While essential parts such as resident's details and a core section containing clinical information about the drugs and their administration were anticipated by the research team, the interviewees highlighted the importance of the following sections.

Signatures of the healthcare team members producing and/or utilising I-MAGs

This would provide an opportunity for the nurses to sign the I-MAG as proof that they have read it and also it would be an opportunity for the pharmacist, GP and SALT to sign the recommendations offering reassurance and consent on the instructions given:

"I think that it's something that everybody certainly understands. I think that maybe there should be something in the back where staff could all sign to say that they agreed that they at least read it and agreed with what was on it and that they then sign to indicate that they would then carry it out you know and to adhere to it yes I like it you know it's safe practice."(N2)

Comments box

Although regular updates would be made to I-MAGs, a comments box would offer the chance to add any events or suggestions about the medication or about the resident that may emerge on the daily practice. These comments could then be reflected in the following updated version and it would help with the communication between the healthcare team:

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“Here it’s really clear advice and actually, if doctor come and review during the month or during the week, we can put some comments. Each nurse can put some comments and when GP come to review client it’s clear information because it can be about preference also monitoring.” (N12)

Information about times for the medication

This would not refer to all the times to give the medication, only those medicines that require special attention about when to administer them. This would help in identifying which drugs are more or less flexible to be administered within a time threshold. Participant N9 commented on this when she was given a chance to suggest any further additions to the I-MAG:

“Timing, as if there was any problem with timings, you know. Some drugs have to be given at special times whatever for Parkinson’s drugs, etc. um maybe then if the timings were wrong...” (N9)

Information about compatibility with food and other drugs

This would consist of additional information about how the tablets would interact with food or with certain foods and whether drugs needs to be taken with or without food. The lack of comments would offer reassurance to the nurses that there is no compatibility issues with the drug as only significant interactions would be highlighted:

“Maybe things like the best thing to give it with obviously we do have things like with food without food but that’s not always but if somebody’s got 10 tablets to take I can’t go back 10 times (...) some things are more basic side-effects basic problems to look for not mixing that sort of thing yes.” (N2)

Detailed information about the devices required for the administration

A few participants highlighted how they were not sure about the accuracy of the measuring devices that should be used when administering medication and the effects of inaccurate measurements. It seemed that the nurses could benefit from having this information reflected in the I-MAG:

“The carers were saying to me do we use a syringe or do we use a spoon and I couldn’t tell them and I said whichever you use just use one all the time if you’re going to use a spoon use it all the time if you use a syringe use it all the time don’t deviate but I didn’t really know just how accurate a 5ml spoon is.” (N2)

4.4.2.3.4. Location of I-MAGs

It seemed relevant to our research topic to identify the best location of I-MAGs based on previous experience in the hospital. If I-MAGs were placed in an accessible location, the users could easily refer to the guides without being distracted from their duties and facilitating the identification of any necessary information as well as easing entries of new significant events. Participants all identified that the I-MAG should be attached to the MAR chart of the resident:

“Um, I think this should be with their MAR chart because as we give the medication, we sign up that it’s given and if that is there or we have any doubts how to give it, so we can always refer back to the information there. I think that should be with the MAR chart.” (N13)

4.4.2.3.5. Usability of I-MAGs

I-MAGs were originally designed to be used by the permanent nurses in the care homes. The interviews revealed that, from the nurses’ point of view, the implementation of I-MAGs would be beneficial especially when new residents were admitted in the care home and the regular members of staff were not familiar with the behaviour and conditions of the resident. It seemed, based on the comments from participant N9, that I-MAGs could enhance the resident’s records with enough information to improve the administration of medication to new residents:

“If it’s a new resident who’s come in and we need to (administer medication) and it’s not clearly stated in their records, then maybe that could be an improvement.”(N9)

Participants expressed a very positive attitude towards the use of I-MAGs in the care home while also highlighting the specific benefit of implementing I-MAGs for times when the care home has to use “agency nurses”. The agency nurses were not always familiar with the care home or with the resident and the administration of medication was a bigger challenge for them as they did not often know all the details about the resident. Participant N3 commented the following when asked about this subject:

“So even this will help when new staff come and does the medication first time isn’t it, because if it’s from agency or bank staff still it’s really helpful how to give medication for them you know, to have a brief idea. This is a brilliant idea really,

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yes I think, more than this because it covers everything here what diet you know how to mix the liquid and everything yes (N3)

According to participant N3's comments, I-MAGs are a useful tool to communicate the information required about the administration of medication in hand-overs of shifts to nurses not familiar with the home or its residents.

4.4.2.3.6. Impact of I-MAGs

In order to explore the likely impact of an I-MAG service on the nurses' practice, it was also necessary to recognise the effect of I-MAGs on care homes' routines. The interviews revealed five areas of concern for the implementations of I-MAGs:

- time of the administration during drug rounds,
- standardisation of practice,
- nurse's clinical confidence,
- skills of nurses,
- residents' health.

Time of the administration during drug rounds

In the care home environment, nurses did not count on immediate support of other professionals. It was highlighted by the interviewees that the guides could actually help reducing the time of administration as I-MAGs would provide a quick reference on how to administer medication correctly to each particular resident. When asked about the impact on the drug rounds time, participant N10 commented:

"I think it might actually make that easier because you would know from the start what your plan was for that person and everyone else would know and so you wouldn't be thinking each time how am I crushing this? What am I dispersing in it? How thick am I making the liquid to give them? So I don't think it would make a medicines round take any longer and hopefully it would help a little bit not make the problem shorter but run more smoothly maybe." (N10)

The comments of participant N10 indicated that, on some occasions, the decrease in time in the drug rounds maybe due to the absence of need to double-check the way of administering medication with other colleagues in the care home. In this way, the nurse or carer giving medication can concentrate in administering medication without distractions:

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“Probably save time because if it’s written down on here I wouldn’t need to pop over and double-check with them (nurses in other wings of the care home).” (N5)

It was also believed that I-MAGs could save time when the nurses have to do the hand-over from different shifts as the guides would contain any information needed for the administration and new comments about recent events in the resident’s health. Participant N13 commented on how laborious the handover was and how having I-MAGs in place would provide accurate and accessible information for the nurses on duty:

“It takes longer to explain everything and even then you cannot explain everything. [...] It probably will be very useful for them to um, at least it (the I-MAG) will give them information at the time they need it say in the middle of the night, I don’t know they have to deal with certain medication or resident so if they don’t know if it’s there they always can refer to that and continue so I think it will help them.” (N13)

In other cases, time was not always a concern for our participants, but the efficacy of the drug round. This however, would be reflected in a reduction of the time involved in completing reports and possibly in a more effective and accurate administration of medication as mentioned by one of the participants:

“It’s not about reducing time, it’s about increasing efficacy and accuracy like I say sometimes when you’ve got complex regimes or complex ways of dispersing medication or whatever then to have accurate information about how to do that would reduce the likelihood of errors from a nursing point of view so it should reduce our incident reporting which is time consuming so yes it would definitely support our practice I think.” (N8)

In summary, the participants’ comments in this section highlighted that I-MAGs had the potential to optimise the time involved in drug rounds while also enhancing that practice. The efficacy and accuracy of the information provided are factors that may determine the usability of the guides.

Standardisation of practice

It had already been noted that the lack of standardised guidance affected the administration of medication depending on the different practices of the nurses giving the medicines to the resident. Participants suggested that I-MAGs could set standards of practice within the care home so everyone would be administering

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medication the same way. Our participants identified this as beneficial when challenging administrations appear as the guide would ensure that all members of staff carry out the same processes in the administration of medication to residents with particular needs as mentioned by participant N4:

“It would be useful to know, to what extent they struggle and what works best for them because I find myself, you know, having to ask again and again and ah, if I could have that information to hand for individuals, that would be helpful.” (N4)

Nurses’ clinical confidence

Many interviewees identified ways in which the presence of I-MAGs could enhance their practice and increase their clinical confidence when administering medication to PWD. Participant N8 commented:

“If it comes direct from the pharmacist then you know, if it were signed, it would certainly help us to be more confident about what we give and how we are giving it because sometimes it is a bit awkward, you get something and it might have to be given in a particular way, but we’re relying sometimes on relatives for that information.” (N8)

This comment also identified the importance of obtaining confirmation from the HCPs involved on the guidance provided in order to support the good practice of the nurses.

Skills of Nurses

There could be a point where excessive support could be detrimental for the nursing team by causing the alienation of individual capacity to make clinical decisions about their practice. Participant N4 commented:

“I think it’s definitely useful. The only thing I can think of, the only downside is perhaps it, if this were used, sort of as standard perhaps it might, I don’t know, de-skill nursing staff if they became reliant on a system like this. And, you know, reading the instructions, reading the instructions and not, hmm. That would be my only concern, but I think the benefits far outweigh that.” (N4)

This comment is indicating that any guidance or support should always be implemented allowing certain flexibility to apply the clinical knowledge of the nurse if necessary, transforming that support on an educational tool rather than dictation.

Residents' health

When exploring the views of the participants on how I-MAGs could have any likely effect on residents' health, several participants mentioned the difficulty in identifying any changes on residents' health. Some participants suggested considering the medication administration error rates as a possible indication of improvement in care:

"I think obviously it would maximise our efficiency or help to maximise our efficiency which it's more from our point of view of reducing the likelihood of incidents and accidents of not giving people exactly the correct dose or not doing it in the correct way so obviously there would be a knock on effect and improvement in health." (N8)

In this quote, participant N8 is pointing out how current practice not only may not be very efficient, but also how that lack of efficiency may have affected the care received by the residents. This was identified as a direct link between efficiency and residents' safety by our participant.

Other participants considered that I-MAGs could have an impact on residents' health related to medication adherence. According to participant N6, if adherence to the treatment was increased and aspiration of drugs was avoided, the chances of chest infections would be reduced. Participant N6 mentioned the following when asked about her opinions on the likely effect of I-MAGs on residents' health:

"Definitely. They're getting medication they should be and properly, so yeah. And also, obviously, it's telling you to use (brand of dietary thickener) and so, that's also going to help um, preventing chest infections and things like that." (N6)

This comment still highlighted that the nursing team may not be necessarily able to identify the challenges of the administration of medication without guidance. When trying to explore ways of measuring the impact of our intervention on the residents' health.

4.4.3. Building the theory: DIAMMOND

It was essential after obtaining the main codes, categories and themes, to identify a way to relate them in order to build our theory. The categories and themes that emerged during the previous part of the analysis took on different roles when constructing a model that could represent the reality of the administration of medication to PWD within the framework of our study. While many of the codes

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were identified as substantive codes in indicating the substance of the experience in this research, it was the theoretical codes that integrated the way that the substantial codes may relate to each other and formed the framework for an emergent theory:

“Theoretical coding, in establishing new connections that make ideas relevant is so often the new and original about theory.”

Page 145, Glaser B.G.⁽³⁶¹⁾

Theoretical codes gave integrative scope, broad pictures and a new perspective that helped the researcher - as the analyst - to maintain the conceptual level in writing about concepts and their inter-relations.

While the approach originally adopted navigated along the different components in a lineal structure to identify the emerging themes (Figure 17), the principles of grounded theory also informed a component approach that explores the relations between themes and sub-themes. For instance, one of the sub-themes linked to the professional development of the nurses was “confidence”. However, “confidence” could also be linked to “workload” and appeared to relate to and affect other themes like “interaction with healthcare professionals”. It was, therefore, more authentic and useful to change from a lineal thematic structure to an inter-related structure which can be visually represented by a Venn diagram in Figure 18.

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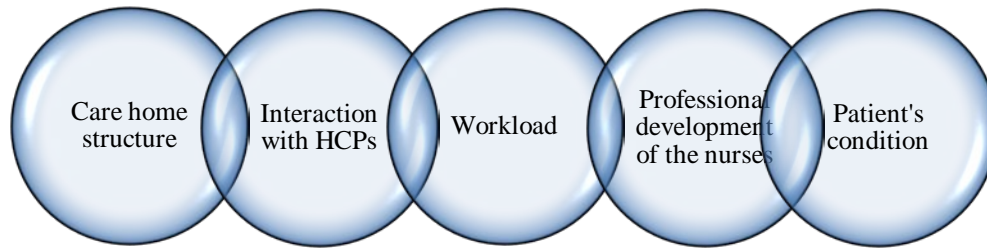


Figure 17: Representation of the first analysis approach

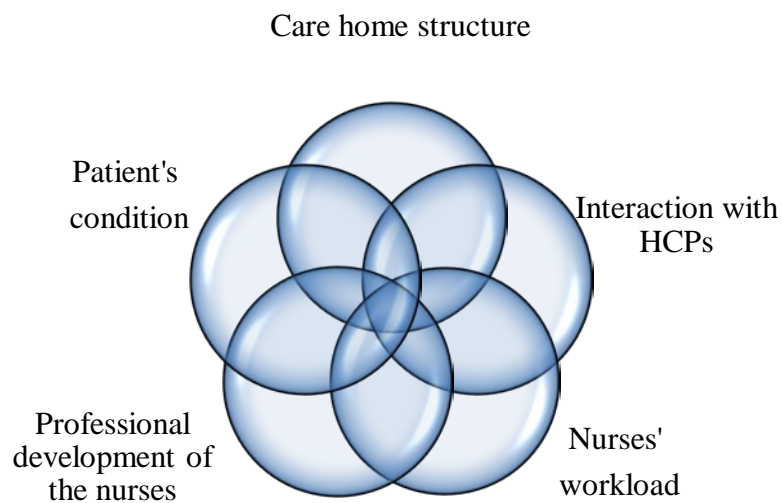


Figure 18: Representation of the second analysis approach

Further examination of these relationships between themes and sub-themes in the interviews helped the main researcher to identify four categories which the participants had recognised to have a direct impact on the administration of medicines to PWD. These were:

- dysphagia awareness,
- the formulation choices,
- patients' choice,
- time spent with the patient.

The reorganisation of the themes identified and the focus on categories with direct and indirect impact on the administration of medicines to PWD, provided an opportunity to represent a theory based model that had potential to explain the

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interactions between all the themes that emerged from the analysis. This model is explained in the next part of this section (DIAMMOND).

DIAMMOND: Designing and Improved Administration of Medication MOdel iN Dysphagia

The analogy of our theory with a diamond follows the principle of a very complex structure in which our theoretical themes are highly dependent on each other. As in any crystalline diamond, not all vertices outlining the theory may be visible but this study tried to relate those that can shape the structure.

The model is not a theory of direct cause-consequence, but a network of direct and indirect theoretical components that can shape the way that PWD receive their medication. DIAMMOND (Figure 19) aims to reflect how those components inter-relate and which of them would be likely to be positively and/or negatively affected when changes in the current model of administration are implemented.

The vertices of the DIAMMOND model are represented in Figure 19, in three “traffic light” code colours:

- red vertices: to be avoided or decreased,
- yellow vertices: likely to have both positive and negative implications for the relationship with other codes, not indicating changes without caution,
- green vertices: generally found to have a positive effect on the administration of medication to PWD and, therefore, related changes in practice likely to enhance these vertices, could be encouraged.

The arrowed links between the vertices indicate whether the interaction occurs in one direction (single arrow) or in both directions (double arrow). Dysphagia awareness, formulation choices, residents’ choices and time spent by the nursing team with PWD represent the four main components that compose the administration of medication to PWD.

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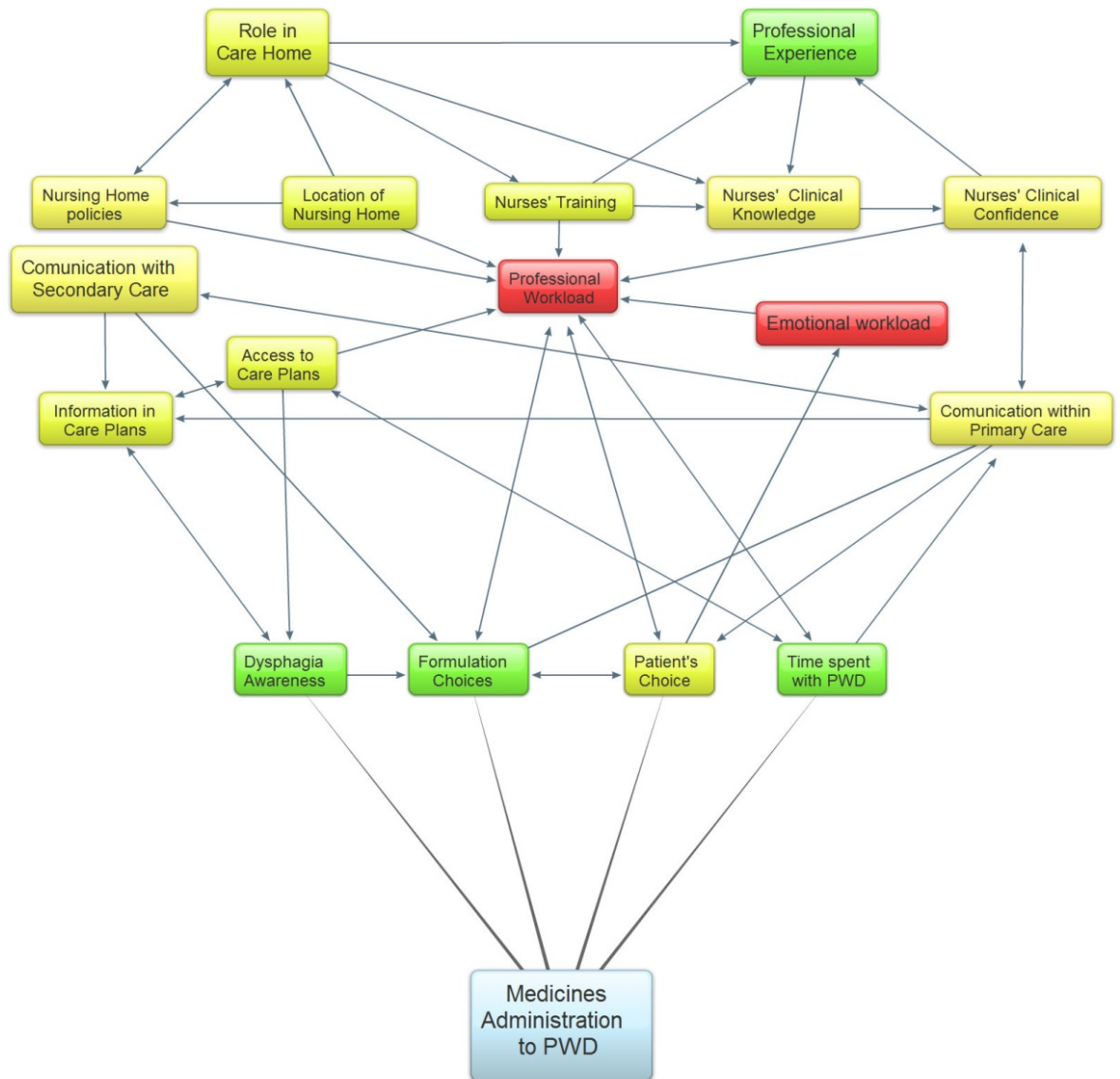


Figure 19: DIAMMOND Model ^{1 2}

¹ The DIAMMOND model contains the four categories identified as directly related to the medicines administration to PWD (dysphagia awareness, formulation choices, patient's choice and time spent with PWD). All the direct and indirect categories are colour coded: green represents positive outcomes; yellow represents caution when affecting that category and red when changes affecting that category should be avoided.

² The model suggests practice-based direct and indirect conceptual links between theoretical components that can shape the way that PWD receive their medication but it does not imply a theory of direct cause-consequence.

The following examples are presented to gain some understanding about the practicality of this model. In continuation with the previous chapter of this thesis:

- example 1 illustrates the effect of one of the main differences from the hospital which is the isolated location of the care home,
- example 2 will illustrate how the implementation of an intervention similar to the one introduced in the hospital in chapter 3, could fit within the care home.

Example 1: The scope of the role of the nurse in the care home may be affected by the location of the care home. That role will required specific training that will enhance the professional experience of the nurse, their knowledge and their confidence in practice. However, the implementation of that training may increase the workload of the nurse. This is in addition to the heavy workload that may be conditioned by the location of the home. Heavier workload may divert the attention of the nurse from accessing care plans and identifying dysphagia, as well as affecting the time spent with the residents. These interactions can ultimately be reflected in the administration of medication to PWD.

Example 2: If we wanted to implement an intervention to improve the communication between primary care and secondary care through more accurate information in care plans for PWD, it is likely that it would increase the awareness of dysphagia in the care home and would enhance the formulation choices for the residents and their administration. However, it would also be likely that such intervention had an impact on the nurses' workload (i.e. challenging formulations, more frequent access to care plans required, etc.). That impact (positive or negative) on the nurses' workload and other interactions could be identified prior to implementing the intervention when following the DIAMMOND model.

4.5. Discussion

4.5.1. Making professional resources more accessible to nurses

From the interviews with the participants, it seems that the care home environment may lack professional resources (workforce) and that this could be compromising the care to PWD by not including enough nurses in the team, causing the important responsibility of administering medication to often fall on a single person in the unit or even on the care home. Additionally, the reliance on temporary and locum

staff and high turnover means that institutional memory and good practices are quickly lost.

The results of this study point out that recruitment and retention of staff, and education and training were priority issues believed by nurses to influence the quality of care they could deliver. These results bear out previous literature that also identified financial constraint as the main cause for the lack of resources.⁽³⁶²⁾ Besides the financial constraints, the interviews outlined other limiting elements not previously identified by the literature, such as the location of the premises and the professional isolation of the care home environment that make the provision of enough qualified members of staff in the home less accessible.

This study also identified that the lack of training for staff adds to the extreme pressure on the workforce often leading to poor staff morale. This has also been recognised by a recent report published by the Royal College of Nursing that outlined how nurses working in care homes are facing huge challenges in providing care for people⁽³⁶³⁾ as there are not enough full time registered nurses employed and they did not have adequate training, equipment and medical supplies to meet residents' needs.

While the main role of nurses clearly remained the care for residents, the study participants highlighted how this role had evolved into a role where reports and feedback about the residents' care are drastically increasing nurses' workload and could potentially affect the quality of care provided by reducing their time with the residents. In particular, PWD need more specialised care. They often require compensatory strategies such as dietary modification, postural manoeuvres and postural adjustments therapy^(17, 104, 105) and this can add extra pressure to the administration of medication on the nurses in charge. The care of PWD requires much individualised guidance based on a standardised practice from the nursing team, but multiple elements such as background, training and approach towards changes challenge the implementation of standardisation of care.

This research suggests that the care of PWD could be enhanced by:

- implementing methods that improve and encourage the access of nurses to care homes remotely located,
- incorporating changes that standardised practice in the administration of medicines,

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- optimising the time spent on completion of reports and the time involved in direct care of the resident.

4.5.2. Communication between healthcare professionals

Many efforts are being made to improve the transfer of residents between secondary care and primary care as well as to assess the care received in the care homes.^(363,364) The NHS provides general guidelines on the design of a care plan at the time of discharge and also provides advice for the carers.⁽³⁶⁵⁾ However, these instructions are only informative and its execution, according to our participants, is not always standardised or what is more important, adapted to be received by the care home.

The involvement of multiple professionals in the care of PWD tends to reveal communication problems in the care home environment due to the lack of synchronised interaction between these healthcare professionals. This is as well as the challenges faced on the communication between primary and secondary care when residents are transferred from hospital or acute units to the care home and vice versa. The participants identified issues such as not questioning current practice or over-riding practices implemented by other professionals, as described by participant N5 in section 4.4.2.2.1. These issues (as mentioned by the interviewees) revealed frictions between primary and secondary care that were eventually reflected in a lack of standardisation of the care of PWD between primary and secondary care settings. In addition, it is important to explore decisions made in secondary care as GPs tend to follow these without question. These challenges were already highlighted in studies by Kelly & Wright⁽³¹⁷⁾ and Cornish,⁽¹⁶⁵⁾ mentioned in chapter 2, and suggesting that systems for close communication between doctors, SALTs, nurses, and pharmacists need to be developed in order to minimise adverse events related to inappropriate administration of medicines to PWD. The implementation of a pharmacy service providing guidance - like the one presented in I-MAGs - was identified by the participants as a beneficial tool to improve the communication between HCPs. This matches the suggestions by Kelly & Wright⁽³¹⁷⁾ for the need to employ a HCP with an interest in dysphagia to liaise with all the professional groups involved. This HCP could develop and evaluate policies and procedures, before cascading them throughout the hospital and local community Trusts so as to improve care for this client group.

It could be added to the argument, however, that some of the communication problems are due to wrong expectations of the communication between HCPs as a result of the lack of awareness of who is the best person to refer to when challenges arise. A study carried out by Dean et al⁽³⁶⁶⁾ where prescribers were interviewed after making a prescribing error, revealed that many doctors considered the task of prescribing was unimportant, and they expected that pharmacists would check and correct the doctors' prescriptions. This is in contrast with what our participants highlighted about how often they needed to contact the GP in order to get permission to tamper with medication. When we consider that the pharmacist is the professional with the highest level of expertise in drugs and their administration, the pharmacist should be the first line of advice to be sought. On the contrary, the participants revealed that the pharmacist is often excluded from the nurses' enquiries about medication and the doctors' recommendations on their administration.

The fact that medicine management in PWD lies on the inter-professional boundaries means that it risks being marginalised.⁽³⁶⁷⁾ When responsibilities are not clearly designated or seen as central to one's role and professional identity⁽³⁶⁷⁾ they may be missed as each professional assumes the other is taking responsibility. In consequence, the workload of the healthcare professionals is sub-optimally increased, their expected roles are not developed and what is more important, the resident is not receiving the most appropriate care. Some comments indicated a total transfer of the liability of recommendations on the care of patients from the SALT to doctors or other HCPs. The SALT was sometimes perceived by the nurses as someone perhaps with less authority in their recommendations, but bringing a much more personal (rather than professional) approach with 'off-record' opinions.

The results of the study, therefore, suggest that, while standardised systems in the transfers between primary and secondary care could be beneficial for enhancing a continuous high quality of care of PWD, it is also very important to delineate the basic end roles of all the professionals involved in the care of residents in order to optimise the interaction between these professionals.

4.5.3. Setting standards of practice

Nurses in care homes are the professionals who spend more time in direct contact with the residents and they play an important and continuous role in observing any changes in the health of the residents. With such an important task as the direct

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care of residents, it is important that the nurses count on the appropriate training, knowledge and experience to deliver the expected level of care in the home.

Some participants identified as a problem the lack of standardised practices in the care home. This problem was further compounded by the fact that in order to give many PWD any medications at all, unlicensed medicines need to be used, without full knowledge of the effects of their actions. This issue was also identified by the literature.⁽¹⁸⁹⁾

The Care Quality Commission (CQC)⁽¹²⁶⁾ set national standards of care that are classified as essential when receiving care services. When referring to safety, the CQC requires that residents receive the medicines they need, when they need them and in a safe way and it will be performed by members of staff that have the knowledge, skills and experience needed to meet the residents' health and welfare needs. However, it could be argued that the provision of care always complies with these standards based on comments from our participants who did not always have the knowledge, the skills or the confidence to carry out a complex task like the administration of medication to PWD. This lack of confidence could also be a reason for the participants not being able to challenge other professionals that they may consider 'above' them such as doctors, pharmacists or even nurses in secondary care at the time of making basic clinical decisions on the administration of medication. Enhancing the clinical confidence of nurses is a hard task that may require achieving a balance between receiving expert guidance and applying their own clinical judgements. Conversely, there is a tendency from the nurses to assume that they know better because they are in closer contact with the resident.

The participants also identified that the drive for good practice was not always the clinical knowledge, but the fear of legal action when a clinical error is made. In this case, the fear could result in under-reporting of errors and the subsequent loss of the ability to learn from it.

In connection with previous discussion, it has been highlighted by the interview participants how the lack of standardised practice between nurses due to different training, experience or approaches can inefficiently increase the workload of the nurses and have negative consequences for the quality of care received during the administration of medication to PWD.

The participants also commented about the view that regulatory bodies recommend high standards of care, but these standards do not necessarily articulate values like

sympathy, patience or closeness to the resident. Those regulations may be overriding an area of personal conflict for the nursing team where these values are essential to the care of the residents. Introducing these human values as stated policy, then to be enacted in practice may however lead to an increase in the workload of the nurses and their professional pressures. Conversely, these perceptions of human values open another component of caring and it calls into question whether nursing as a profession may be becoming detached from the human side of care (from which it originated) and moving into a more technical job focused on complying with regulations and policies.

This piece of research highlights the importance of setting standards of practice in the administration of medication to residents with dysphagia, but beyond that it identifies that the implementation of changes, training or other processes that are designed to enhanced the skills of the nurses or the clinical confidence in their practice, could potentially have a negative effect on their workload that would also be reflected in the care received by the residents. It is, therefore, important to analyse the effects that new services have on nurses' workload in order to ensure that the likely benefit for the residents outweighs the negative impact on nurse practice.

4.5.4. Individualised resident care

The care of PWD requires a highly individualised approach in the various aspects of their care such as the administration of medication.⁽¹⁵⁵⁾ Our participants identified the importance of recognising the residents' conditions and their personal choices and approaches towards medication in order to communicate it to other members of the nursing team and other healthcare professionals. This individualised care was anticipated in chapter 1 where studies identified the perception of nurses on having to closely monitor medications⁽²²⁶⁾ and the relevance of providing individualised resident care by the nurses.^(224, 228)

Participants recognised that not all residents will necessarily fit into clear models of care and considered that it is essential to obtain a detailed history of the presenting problem and how it is managed to ensure that the most appropriate course of action is taken. This information should come from family members, professional caregivers from residential or care homes with nursing, and ward or community health teams.⁽³⁶⁷⁾ A structured approach to information gathering, assessment and management was outlined in the literature review with practical application in recently published guidelines and research evidence, which ensures appropriate

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individualised care.^(215, 313) As described by our participants and the literature reviewed in chapter 1, an approach which considers ethical, legal and cultural issues surrounding the individual, and not solely the diagnosis, is needed.⁽³⁶⁷⁾ The interviews revealed concerns about establishing the preferences of the residents with regards to medication (section 4.4.2.2.5.), and, therefore, as part of the individualised care of PWD, it should be established whether the resident has capacity to make advanced decisions on the management of the medication or has appointed someone to make healthcare decisions on their behalf, should they lose capacity.

It was believed by the interviewees that this increase in the awareness of dysphagia has a likely beneficial effect for the resident but it is important to highlight that this information should be reflected upon and made accessible to all of the professionals involved in the care of the resident with dysphagia. When considering the workload of nurses and the other members of the healthcare team, the participants identified that information about the residents' medical conditions should be held in a very accessible location. The suitability of the care plans to ease the access to the information about the resident could be argued as these plans are not reviewed by the nurses daily. When taking into account that the medication chart is accessed at least once a day, this location could be optimal for identifying significant events related to the administration of medication that need to be communicated to the rest of the team.

4.5.5. Awareness of the available formulation

As described in chapter 2, the formulation of the medicine is as important for PWD as the active ingredients⁽¹⁵⁵⁾ and, therefore, it is vital to ensure that each resident has an individualised medication regimen.

Participants recurrently described how obtaining alternative formulations prescribed for the residents was a challenging task and how, most of the time, this also excluded the pharmacist from that interaction. In agreement with the research presented in chapter 1 that identified that prescribers are not always aware of the availability and cost of the prescribed formulations,⁽²²⁸⁾ the participants also identified that, in their opinion, the pharmacist was the HCP that would hold the most expert knowledge regarding the availability of different formulations. Although the interviews revealed that the pharmacist was frequently not the first

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line of help, they agreed that it should be the pharmacists' role to introduce the available formulations to the prescriber when dysphagia is identified.

The participants also showed a preference for the administration of liquid medication for PWD based on the easiness of administering such formulation. Although liquid medicines have their advantages and are often recommended as the solution to putting drugs through feeding tubes,^(321, 370) their viscosity can also be a problem and dispersible and orodispersible tablets may be more suitable. These issues were not considered by the nurses possibly due to the lack of pharmaceutical knowledge.

4.5.6. Expanding the role of HCPs

The provision of care to PWD is complex in its own nature. It requires the input of different healthcare professionals in order to provide adequate individualised care. While in the hospital environment, the communication and interaction between all these professionals is close and immediate, the participants highlighted during the interviews that the care of residents in care homes is a very different situation. In the community, these professionals come from the private and the public sector; they are conditioned by different budgets and guidelines and often from locations of difficult access to the care home. Synchronising the work of these professionals is seen as a very hard task.

Several participants explained that some residents spat or chewed their medication. While this could be indicating that dysphagia is not being identified, healthcare professionals need to find out if residents have problems swallowing their medication and, if so, exactly what they are.⁽³⁷⁰⁻³⁷³⁾ The pharmacist has the potential to play an important role in the identification of dysphagia recognising those issues, especially as residents are not always forthcoming about their problems. Wilkins et al⁽³⁷⁴⁾ found that 46% of PWD do not tell their doctor about the problem and hypothesised that the data reflects the continuous process of problem definition that occurs as residents translate symptoms to problems in need of medical help. Therefore, the challenge for professionals is to identify resident problems in partnership with them and then fit the service to their needs.⁽³⁷⁵⁾

As models of dysphagia assessment and management are often derived from the stroke population,^(101, 302-304) the participants identified how they gradually have become more detached from the basic assessment role of dysphagia. An early pharmaceutical assessment of the medication taken by the resident as part of the

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guidance provided to care homes was seen by some of the nurses interviewed as a beneficial intervention that could improve the understanding of the properties of the various preparations. The literature has previously identified that this intervention could reduce the risk of adverse drug events.⁽¹⁶⁵⁾

The comments from some participants indicated their lack of understanding of dysphagia and suggested that PWD were less likely to receive an assessment from a SALT when suffering from mild difficulties with swallowing. This finding may point to the need of implementing basic assessment tools for nurses to enable them to accurately identify when to refer, which professional to refer to and what actions to take whilst awaiting support and guidance.

The preference for liquids and the concerns discussed previously in this section may be highlighting that the pharmacist could develop a role in training nurses and other HCPs in the best use of medication, expanding not only the role of pharmacists and their expertise, but also developing specialised nursing roles within the care homes based on frameworks like the IDF mentioned in chapter 1. Also, it offers an opportunity to encourage the advising role to the prescriber as identified in the literature review.

4.5.7. Relating the DIAMMOND model to literature

The saturation represented by the numerous instances in the data and the selective coding provided the empirical evidence to identify theoretical codes and relationships to ground this more comprehensive theory. However, in order to indicate how this theory contradicts, confirms or extends existing theories, any emerging theory needs to be integrated with the existing ones in the field.

The scope of our theory is difficult to specify as no literature has been found which identifies a nurse's view of the factors affecting the administration of medication to PWD. Nevertheless, it is important to consider that the description and interpretation of our theoretical codes and relationships contain a substantive focus that may be enhanced by reviewing other theories on the same substantive level.

Several studies and theories identified various concepts of this suggested theory in the literature, some indicated in Table 23. The high level of specificity to the topic of the model did not allow the main researcher to identify or compare current theories and concepts integrated in DIAMMOND such as how the administration of medication to PWD is affected by the emotional workload of the nurses, or how the location of the care home can indirectly affect the care provided to its residents.

Relationship	Examples of Relevant Literature
Communication between primary and secondary care	<p>Kripalani et al⁽³⁵¹⁾ highlights the need of standardised summaries and how the deficits in communication and information transfer at hospital discharge are common and may adversely affect resident care.</p> <hr/> <p>Paterson⁽⁴⁵⁾ indicated the importance of how primary care physicians must be aware of the role of non-specific treatments offered by other health professionals to improve residents' care.</p>
Dysphagia awareness	<p>Young & Durant-Jones⁽¹³¹⁾ identified how the improved communication between professionals in primary care increases the awareness of dysphagia and enhances residents' care.</p>
Time spent with PWD and resident care	<p>Bates-Jensen et al⁽³⁷⁶⁾ observed how the time spent with residents in care homes was mainly conditioned by the workload of the members of staff and conditioned the quality of care of the residents.</p>
Nurses' training and workload	<p>Werner⁽³⁷⁷⁾ identified the benefits of specialised training for nurses. However, there are no remarks about the impact of the training in the workload of the nurses.</p>
Formulation choices and residents' choices	<p>Kelly et al⁽¹⁵⁵⁾ highlighted how PWD required better communication with healthcare professionals and how PWD could benefit from being aware of other formulation choices.</p>

Table 23: Relating the new theory to literature

4.5.8. DIAMMOND and I-MAG: implications for our research question

It was implied in our research questions that the implementation of any changes in current methods of practice requires the prior identification of the theory on the administration of medication to PWD, before implementing any changes aimed to enhance its delivery.

The development of the DIAMMOND model in the administration of medication to PWD in care homes provided an opportunity to highlight elements that had not been identified before, as well as to theoretically predict the potential impact of the implementation of services and changes to the current model of practice before the

actual empirical implementation. Therefore, it seems appropriate to discuss how implementing I-MAGs could theoretically affect current practice within the framework of our model.

The comments from the participants revealed that the design of the guides should be optimised in order to be an accessible document, not only to the nurses, but to other healthcare professionals whose input could be reflected in I-MAGs. When located within the MAR charts of the resident, it should contain significant information that may already be reflected in the care plan regarding the dysphagia directly or indirectly related to medication, but it will also be an opportunity to add any additional events related to the swallowing function of the resident. The nurse participants identified themselves as first-line professionals when recognising any changes in the residents' ability to swallow and, therefore, the reflection of those changes in the I-MAG could increase the awareness of other healthcare professionals on the presence and development of dysphagia.

The guides would also serve as a tool to identify appropriate formulation at all times. When any changes in the resident's condition are reflected in the I-MAG, the nurses, pharmacist, SALT or GP could apply changes to the formulation or refer the case to another professional for immediate action.

Residents' approach towards medication, and how nurses perceive it, are some of the main limiting elements affecting the administration of medication to PWD as mentioned by the participants. The lack of capacity from the resident, reluctances to change and the impact of the residents' behaviour on the emotional and physical workload of the nurses should be considered in the decisions of the prescriber at the time of choosing a particular formulation. However, the presence of I-MAGs could potentially reduce the effect of this limiting element by providing a clear set of information relevant to the resident which could potentially increase the awareness of the level of the current swallowing problem.

This research identified serious concerns from the nurses about the liability of manipulating medication. The difficulty of coordinating information and policies about altering medications⁽¹⁹⁹⁾ had already been recognised in the literature, but our participants also remarked that those concerns were reflected in lower confidence in their practice. The clinical and legal liability of drugs administration may have become a concern for practice when nurses were not confident on what was the best way of administering medication, according to their comments. Nurses might often have to query this and some participants even resorted to obtaining

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information from the residents' relatives. I-MAGs would not only contain precise and individualised instructions on the administration but also would include signatures of other healthcare professionals agreeing with that practice to provide reassurance to the nurse administering the medicines.

Although it was highlighted by our participants how the presence of I-MAGs could reduce the time of the drug rounds by not having to contact other members of the team, searching information on how to administer medication, etc., this is not the primary aim of the guides. The nurse participants highlighted how important it is to get to know the resident and hence I-MAGs would provide enough information to help them understand their residents' preferences and how to safely and efficiently administer medication so they could focus on spending more time actually with the resident.

The implementation of any changes in current practice may require some training sessions for the nurses and, possibly, to other professionals involved. In the case of I-MAGs, nurses would expect short sessions explaining the rationale behind the use of I-MAGs and the implications of the use of the guides. Although some clinical or administrative issues may have to be covered by the training, the participants found I-MAGs very understandable in concept, as the guides are in their nature a training tool and an intervention simultaneously.

The implementation of I-MAGs was perceived by our interviewees as a learning and practical tool that could increase the clinical confidence when administering medication and could also help coordinating the care of residents when they are moved between services. Although at this stage the value of the implementation of I-MAGs in care homes is virtually theoretical, it is, in essence, an intervention very closely related and focused on meeting the essential national standards set by the CQC and by requests of recent reports from the RCN⁽³⁶³⁾ that recommended:

- re-evaluation of how funding is allocated to cover the needs of residents in care homes,
- national guidance on staffing levels and ratios for care homes,
- a government review of care home workforce planning and to ensure that this workforce is appropriately supported, trained, qualified and valued.

This discussion is, therefore, suggesting that the implementation of I-MAGs could be positively received within the care home as, theoretically, the components of such an intervention take into consideration similar interactions to the ones in the

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design of DIAMMOND where the ultimate aim is the care of PWD. However, the model only represents theoretical interactions and, therefore, a practical observation of the problems that challenge the medication management of PWD in care homes should be considered as a method of triangulation.

4.6. Limitations and strengths of the research

The volume of data obtained, and the structured methodological process followed in analysing it, are strengths of this work. Credibility was enhanced by the interview techniques which encouraged the participants' openness and provided sufficient information to identify the current model of practice in the administration of medication to PWD from the perceptions of nurses in care homes. The structural coherence of the grounded theory method (generation of codes, construction of categories, statements of relationships and scoping of the theory) helped to identify the true values. Data triangulation with current theories and the density of the sampling also increased the credibility of the research and the valid interpretation of the data.

The sample was selected purposively to represent relevant characteristics of the general group such as experience, background, nationality and location. The description of the settings, approaches and contextualised findings increase the transferability of this suggested theory. While the generalisability of this suggested theory could be strong within the UK, and possibly countries with similar health systems, it is questionable whether it could be generalised to locations where the variables of the sample reach different components or new variables need to be included.

It would be difficult with these study data and findings to further extrapolate the relationships between our theoretical codes to apply these categories to different fields or populations, i.e. nurses working in hospitals have a very different interaction with the other HCPs than those in our sample, or older residents in their own homes where they are usually also cared for by a relative instead of by only a nurse.

The generation of codes and categories was carried out manually without the aid of any computer software. While the strength of this laborious process enhanced the immersion of the main researcher in the data, it could be argued how this affected the level of abstraction from the data at the time of generating the theory. For example, "formulation choices" is a theoretical code closely related to our research

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question and present in the model despite other codes that appeared more often could not necessarily be represented in this suggested theory. The (manual) process of analysis is long and slow which may also trigger omission of significant information during the generation of codes.⁽³³⁶⁾ To minimise these limitations and secure the rigour of the analysis, blind generation of codes by one academic supervisor was carried out and compared with a small number of interviews analysed by the main researcher.

4.7. Conclusions

The administration of medication to PWD is a complex process defined by numerous elements such as the care home environment, the interaction between healthcare professionals, the nurses' heavy workload, the professional development of the nurses and the residents' health conditions.

The interaction between these components may have an impact on the awareness of dysphagia, the formulations chosen for the administration, the choices made by the resident regarding their medication and the time spent by the nurses with the resident during the administration.

The current health system could benefit from extending the role of the professionals involved in the care of PWD in order to maximise the use of the expertise of multidisciplinary teams through novel interventions like I-MAGs. A greater involvement of the pharmacist in the care of PWD may improve the knowledge of nurses in care homes and enhance the interaction with other HCPs like GPs and SALTs.

I-MAGs are identified as a tool that is likely to reduce the workload of nurses in care homes by optimising the time spent in communicating with other healthcare professionals and increasing the clinical confidence of nurses in the administration of medicines to PWD. These guides can be used as a tool to enhance the clinical confidence and experience of the nurses and to increase the awareness of dysphagia.

I-MAGs have not yet been proven to have an effect on resident's health, but they could offer a step toward providing standardised practice and individualised care. The guides may also improve prescribers' awareness of available formulations in the residents' medication which enhances the assessment of personal needs suggested by the CQC⁽¹²⁶⁾ as essential for the promotion of good resident care.

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While reducing the heavy workload of nurses and its impact on PWD remain a challenge in care homes, the DIAMMOND model may help to identify the theoretical effect of implementing interventions that can improve the administration of medication to PWD.

The theory highlighted by the DIAMMOND model identified several implications for PWD that had not been explored in the current model of practice. Despite the fact that the communication between different settings and professionals had historically been identified as a concern with potential consequences in the resident care, other elements more indirectly related like the location of the care homes and the enforcement of updated policies, can also have implications to the services and the care received by the residents.

The DIAMMOND model could be enhanced by the observation of drug rounds to residents with dysphagia in care homes in order to test the applicability of the model as well as to identify other elements that may affect the administration of medication to PWD that a qualitative approach may not have recognised.

5. Observation of drug administrations in care homes

While exploring the perceptions of HCPs can provide a strong theoretical component for the development of a complex intervention, researchers should be aware of their limitations and interpret and present the findings with due caution when non-experimental methods are used.⁽¹⁾ As identified by Rutter (2007)⁽³⁷⁸⁾ wherever possible, evidence should be combined from different sources that do not share the same weaknesses.

The relevancy of combining quantitative and qualitative methods during the development and evaluation of a complex intervention has been strongly recognised in the last few years.^(1, 2, 7, 9, 14) Campbell et al⁽²⁾ described the strengths of this approach:

“Although these trials pose substantial challenges to investigators, the use of an iterative phased approach that harnesses qualitative and quantitative methods should lead to improved study design, execution, and generalisability of results.”

Page 696, Campbell, Fitzpatrick et al. 2000⁽²⁾

The following study will contribute to the development of a pharmacist-led intervention, by identifying a range of measures that may be needed for our intervention and specifying a required degree of adaptation to local settings, see Figure 20.

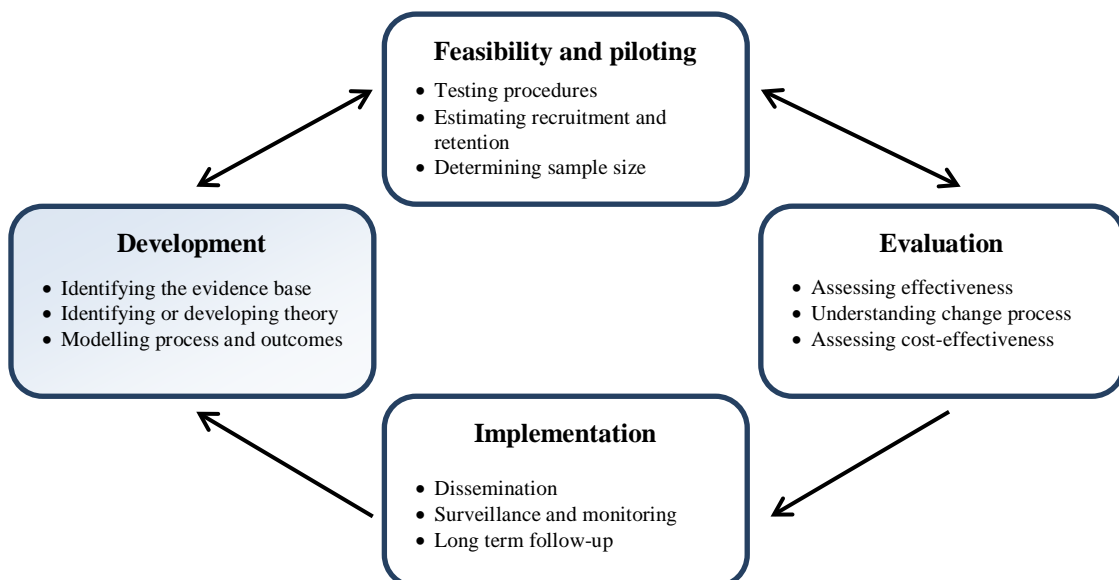


Figure 20: Developmental components of an intervention (Craig et al. 2008, page 980)⁽¹⁾

5.1. Introduction

The problems identified in hospital wards when administering medicines to PWD were related to errors such as giving medicines unlicensed when licensed alternatives were available. Other errors involved processes associated with the preparation of medicines which could be optimised. A qualitative analysis of the perceptions and experience of nurses in care homes outlined common challenges to those found in hospital as well as other elements more specific to the care home environment. However, the empirical identification of the difficulties experienced on the administration of medication to PWD by nurses in care homes and the extent of such problems has not been explored. It would also be helpful for the researcher to identify if there are situations in which administering medication becomes more challenging and results in medication administration errors as a consequence of sub-optimal prescribing. Identifying these issues and the nature of the errors could help to enhance the administration process, to estimate the effect of nurses' decision-making and poor formulation choices, and to recognise any other constraints of the environment. Such information could contribute to the development of training packages for HCPs.

The approaches to these human errors applied in healthcare organisations have been thoroughly discussed in the literature. Reason (2000)⁽²⁶³⁾ described how the human error problem could be viewed in two ways: the person approach and the system approach. Each has its model of error causation and each model gives rise to quite different philosophies of error management.⁽²⁶³⁾ While it would appear that nurses are more susceptible to blame than other professional groups, especially from their colleagues,^(379, 380) several approaches to error theory recognise that the contribution from those involved at the sharp end in a given error is likely to be just one component of causation.⁽³⁸¹⁾ Reason (2000)⁽²⁶³⁾ addressed some of the key principles in a summary overview and concluded that the differences between two approaches have important practical implications for coping with the risk of mishaps in clinical practice. This theory was followed by other more comprehensive papers from medical practitioners such as Pani et al (2004)⁽³⁸²⁾ and psychologists such as Parker & Lawton (2003)⁽³⁸³⁾ which supported the system approach by recognising that errors are a consequence of the systems in which humans work. Other authors focused on the theories in identifying mechanisms that avoid errors. Leape et al (1994)⁽³⁸⁴⁾ identified five specific mechanisms that should be used to avoid errors: reduced reliance on memory, improved information access,

error proofing, standardisation, and training. A more recent publication by Amalberti et al⁽³⁸⁴⁾ described five systemic barriers that can lead to a safer healthcare system:

- acceptance of limitations on maximum performance,
- abandonment of professional autonomy,
- shift from a hierarchical mind-set to professional equivalence,
- system leadership,
- simplification of professional rules and regulations.

Human error theories have traditionally been associated to a cause analysis of errors. However, as outlined by Armitage et al,⁽³⁸¹⁾ error theory can also have applications in the management of errors in the nursing profession. This paper explained how error theory can:

- provide a framework for incident analysis and even feedback that considers the individual's behaviours in conjunction with the other factors discussed above,
- systematise the resultant action taken,
- review any changes to reduce the likelihood of similar errors recurring ,
- identifying priorities in education and training or, if more appropriate, personal supervision.

These applications of error theory are related to the development of interventions in health organisations and, therefore, the following study presented will focus on describing the type of errors observed and will discuss the applicability of error theory to the development of pharmacy interventions for PWD.

5.2. Aims and objectives

The aim of this study is to describe the quality, type of errors and frequency of errors in the administration of medication to elderly residents with dysphagia in care homes.

The objectives of this study are to identify:

- the methods used by nurses and carers in the administration of medication to residents in care homes that suffer from dysphagia or receive medication via enteral feeding tubes (EFTs),
- the medicines administration error rate in PWD and without dysphagia,
- the approaches when prescribing to PWD where medication choices could potentially be improved to enhance the administration process.

5.3. Methods

5.3.1. Declaration of funding and liaison with collaborators

The study presented was designed by the author of this dissertation with the intention of exploring the practice of administering medication in care homes. Due to the cost of this research, external financial support was sought. A pharmaceutical company (Rosemont Pharmaceuticals), who had previously expressed interest to UEA for research in swallowing difficulties, was approached. The main supervisor connected the main researcher with GPs in North Yorkshire who had contacted him through a joint meeting arranged by Rosemont Pharmaceuticals. As a result, a meeting was arranged in North Yorkshire in November 2011 where the main researcher, the two GPs and a representative from Rosemont Pharmaceuticals attended and agreed to support the processes required to carry out the research. The study was fully funded by Rosemont Pharmaceuticals as agreed in December 2011 (see page one of agreement of funding in Appendix 28). The grant was an unrestricted education grant and, therefore, the company had no input in the design of the project or in the data analysis.

5.3.2. Collaboration of care homes and recruitment of participating nurses

Registered managers of care homes within the North Yorkshire Primary Care Research Network and receiving services from two medical centres in York (UK) interested in research on PWD, were contacted to describe the nature of the study. The project was also communicated to other GPs via the local Primary Care Research Network (PCRN) in PCRN meetings to give them the opportunity of engaging with this research in their practices and the care homes that they provide care to. Medical practices that demonstrated an interest in the study contacted the registered managers from care homes that received care from any of those medical practices. Any other GP practices that were willing to collaborate in this study were also invited to participate in the research to allow the main researcher to follow the nurses or carers while administering medication to PWD in drug rounds. Figure 21 shows the study development and recruitment flow.

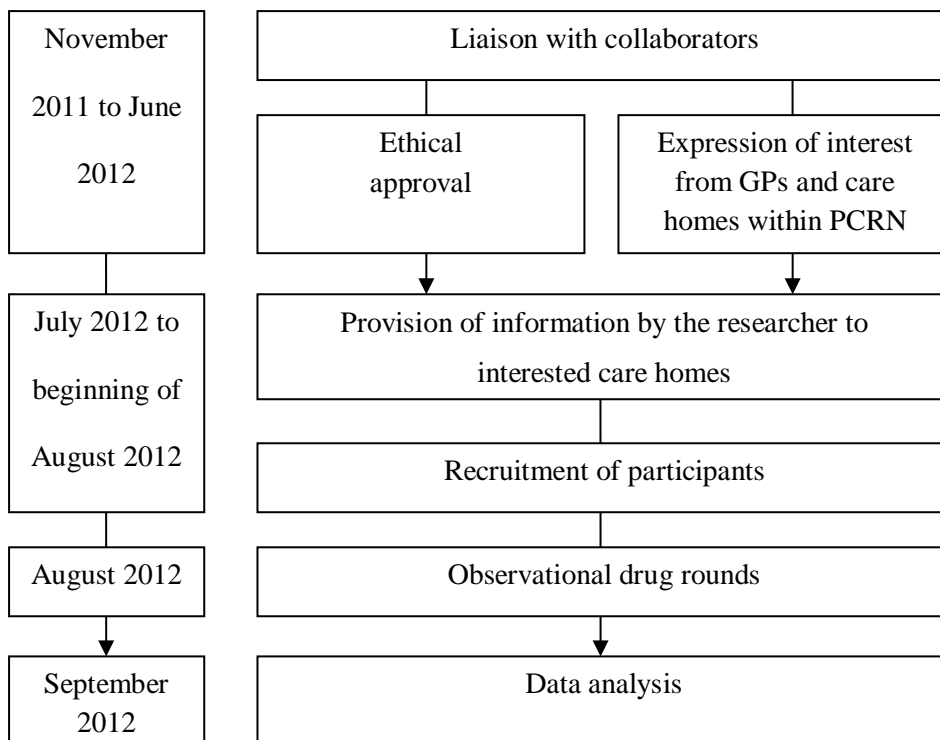


Figure 21: Study development and recruitment flow chart

The GP practices sent to the registered managers of the care home:

- a letter to explain the nature, aims and implications of the study,
- an information sheet,
- an example of the consent form for the potential participants,
- an initial contact acceptance letter addressed to the main researcher,
- a pre-paid envelope to help maximise the rate of response addressed to the main researcher.

In the letter describing the study (Appendix 29), the registered manager was asked to inform the nurses and carers in the care homes that there was the opportunity to participate in the study. Coercion from the researcher to the participants was avoided this way as the registered managers were only informing the participants about this opportunity and making it clear that they were free to decide whether to take part or not.

The information sheet explained the topic and organisation of the study, its aims and the implications of the study for the potential participants who wished to take part (Appendix 30). The registered managers also received an example of the

consent form that the potential participant was also offered previous to the drug round (Appendix 31).

The initial contact acceptance letter was sent back to the main researcher from the registered manager as a confirmation that the registered manager agreed to be contacted by the main researcher. The main researcher then provided further information on the study to the registered manager and potential nurse participants and arranged the consent and the time for the drug rounds with the nurses and/or carers if the care home had shown interest in participating.

If no reply from the registered manager was received within two weeks after sending the invitation, a reminder letter with the same content was again sent to the home. If again no response was received, no further letters were sent.

At the time agreed with the registered manager and before the observational drug round and after the registered manager of the homes had accepted to participate, the nurse or carer was given:

- an invitation letter (Appendix 32),
- an information sheet about the study (Appendix 30),
- a consent form for being observed whilst administering drugs (Appendix 31) that would only be collected at the time of the observation.

The researcher allowed one week between sending the participant information sheet to the nurses and the time of the observation. It was planned that two observational drug rounds would take place in each care home on different days and where possible, with different members of staff.

The care homes were then selected based on the following inclusion and exclusion criteria:

Inclusion criteria:

Care homes were eligible if they received services from any GP practice within the North Yorkshire Primary Care Trust and:

- the responsible nurses or carers were in charge of administering medication to:
 - PWD,
 - residents that required the use of enteral feeding tubes,
- the care home was located in the area of coverage of the North Yorkshire Primary Care Research Network,
- private care home.

Equally to the previous study in care homes mentioned in this thesis (Section 4.3), NHS care homes were excluded as only 63 (0.5%) out of the 12,955 care homes with nursing in England⁽³⁵²⁾ are NHS homes and these were very likely to have completely different systems and management processes as well as residents. Consequently, it was more appropriate to focus on private care homes.

Nurses in the participating care homes were eligible when they administered medication to PWD or residents with enteral feeding tubes.

Exclusion criteria:

Potential participants were excluded when the care homes or all the staff nurses in the home did not wish to participate in this research or if it was a NHS care home.

5.3.3. Sample size

In a study carried out on residents in care homes,⁽²⁹⁹⁾ it was found that 22.3% (95% CI 17.3 to 27.9%) were exposed to at least one situation where administration of medication could be enhanced. A more recent study in four hospitals of East Anglia identified that 32.6% (95% CI 26.2-39.8%) of residents with dysphagia suffered from at least one medication error.⁽²⁷²⁾ Based on these proportions, it was estimated that a sample size of 150 residents would provide 95% CI of $\pm 6\%$ and 100 residents would provide 95% CI of $\pm 8\%$ around an identified proportion of 30%.

The hospital study by Kelly⁽²⁷²⁾ identified MAE rates of 13.8% (95% CI = 10.5–17.2%) for residents without dysphagia in comparison to the 32.6% (95% CI= 26.2–38.9%) of PWD. The frequency of MAEs, excluding time errors, was 5.9% (95% CI = 4.7–7.1%) for those without compared with PWD which was 21.1% (95% CI = 18.0–24.1%).

Adjusting for time errors, Kelly et al⁽²⁷²⁾ reported an approximate error rate difference between the two groups of 15% and an error rate of 5.9% in the control group (residents without dysphagia). At 80% power of study, at least 76 administrations in each group (total sample size of 152) would be appropriate to be observed in order to detect a significant difference on a level < 0.05 .

As the average size of a care home has been recently increased to 32 residents,⁽³⁸⁶⁾ and considering that dysphagia affecting medicines are present in up to 30% of residents in care homes,⁽¹⁸⁸⁾ it was estimated that eight care homes would provide our required sample size.

5.3.4. Outcomes

The primary outcome is the type of medication administrations that could be improved. The classification of the observed administrations allowed us to highlight the main points where future interventions should focus to improve current practice in the administration of medication to PWD. Examples of these administrations are:

- medicines mixed inappropriately,
- crushing tablets or opening capsules when authorisation would be appropriate,
- use of unlicensed medication when licensed formulations are available.

Where the selection of formulation could minimise the risk for errors and simplify the administration process, comparison was made with national guidelines⁽²¹⁵⁾ as nurses were not deviating from the instructions from the prescriber. Where practice was not following national guidance,⁽²¹⁵⁾ the researcher identified whether this was due to formulation selection of the drug or to the practice in the care home. The observer was the main researcher of this thesis and had extensive background in applying national guidelines⁽²¹⁵⁾ in administration of medication to PWD and able to independently compare observations with recommended practice. The observer was also able to classify the type of errors^(244, 262, 270-272, 274) according to the literature presented in chapter 2 (page 71).

The researcher also aimed to identify, as a secondary outcome measure, available alternative formulations of medicines which could make the administration easier. This required describing the prescribing practice to PWD in order to explore the likely reasons for the selection of those formulations by the prescriber. When considering that inappropriate food or medication texture is the main risk factor for aspiration pneumonia,⁽³⁸⁷⁾ it seemed appropriate to explore any possible association between the formulation choices at the time of prescribing and aspiration in PWD.

In order to identify when a formulation was not suitable due to the elevated risk of aspiration, the researcher recorded those cases in which aspiration had already been acknowledged by other HCPs or when two or more signs of aspiration were observed at the time of the drug rounds. As recognised in the literature,⁽⁷⁹⁻⁸³⁾ these signs included:

- absent swallow,
- coughing when lying flat or sitting up quickly from a reclined position,
- choking,
- hoarsened voice during or after taking medication, eating or drinking,

- difficulty handling secretions,
- reflexive cough after water bolus.

5.3.5. Data collection

5.3.5.1. Observations of drugs administrations

A week previous to the day of the observational drug round, the main researcher in liaison with the nurses, handed out a letter of information to the residents observed (or to their relatives when the resident didn't have capacity to respond) explaining to them the nature of the study and giving them the opportunity to choose not to be observed (Appendix 33). The methodology for this part of the study had already been used and tested in a hospital environment as part of a larger study observing nurses administering medicines at four hospitals in East Anglia. The methodology and documentation received scientific peer review and research management approval from East Norfolk and Waveney Research Governance Committee (Administration of medicines to older persons with dysphagia – is it optimal? Ref No. 2007MFE03S (93-06-07)) and ethical approval from West Kent Research Ethics Committee (REC Ref No. 07/H1101/65). The methodology followed that within another study (“Will an individualised service improve medicine administration to adults with dysphagia – a pilot study? REC 08/H0302/153) approved by NRES Committee East of England – Essex.

The researcher had previously obtained experience observing the administration of drugs by nurses in the hospital study. He observed nurses' drug rounds at the same time as the chief researcher of the hospital study mentioned in this thesis (J. Kelly). They both used the same data collection form and the results were compared between them to assure that similar data had been collected.

Before the drug round, the nurse requested verbal consent from the resident on behalf of the researcher on the day of the observation, before the researcher joined the nurse and the resident to observe the administration. During each drug round, the researcher observed the nurse participants administering medication to residents with and without dysphagia as diagnosed by the SALT. At the time of the observation, the researcher collected data reflected in the patients' notes about identification and diagnosis of dysphagia (i.e. the HCP that made the diagnosis, any symptoms identified, any signs of aspiration reflected in the notes, etc.) as well as information about food intake (time, allergies, texture) Notes were taken during

the observation on standardised data collection forms (Appendix 34 and Appendix 35) for the administration of medication. These forms collected information regarding the time of the administration, medication, dose, time of administration, route, etc. and allowed the researcher to record details of the observation using the same codes from the previous study where the forms were obtained. These codes described the preparation, texture, time, missed dose, etc. The forms only contained encrypted data of the participants to preserve confidentiality.

5.3.5.2. Care home environment notes

The observation of the administrations and the visit to the care homes provided an opportunity to explore the interaction between the nurse participants and the residents, as well as what care values might be highlighted in the care home environment.

Although field notes are traditionally associated to qualitative ethnographic studies, Emerson⁽³⁸⁸⁾ highlighted the power of field notes when :

- transforming direct observations into vivid descriptive results,
- identifying and following processes in witnessed events,
- conveying participants' explanations for when, why or how particular things happen,
- identifying the practical concerns, conditions and constraints that people confront and deal with in their routines.

It was recognised by the main researcher that collecting field notes during the observations as originally planned, could be a challenge as they would have required ongoing recording to provide very thorough descriptions which could compromise the data collection at the time of observing the administration of drug rounds. However, a description of the environment based on the principles of field notes could potentially help understand the nature of suboptimal practice in the administration of medication and therefore notes describing the care home were annotated during the observations (referred to henceforward as environment notes in the remainder of this document).

5.3.6. Data storage

Both the care homes and the nurses recruited were coded and encrypted with numbers when the data was recorded. The coding sheets listing the care homes/nurse names and their corresponding study numbers, together with the

completed consent forms were kept separately in a locked filing cabinet in the School of Pharmacy at the University of East Anglia, Norwich. No information recorded about the administration of medication identified any resident or participant. Only the encrypted data was analysed by the main researcher and this was stored on a password-protected laptop computer, used solely for the purpose of research, and kept at the main researcher's office. The access to any confidential data and the use of it complied with the NHS code of practice⁽³⁸⁹⁾ and the guidance provided by the Research Council of the United Kingdom.⁽³⁹⁰⁾ All confidential documentation will be destroyed in five years' time. During this time, the data will be stored in the University of East Anglia in designated areas for that purpose and only accessible to the main researcher and his academic supervisors.

5.3.7. Data analysis

The number of medicines administrations to PWD was recorded along with the number of times that the administration process could be improved to better meet national guidelines. As for the purpose of this study, these deviations were classified as medication administration error (MAE).

The main aim of this study was to describe the type of administration that could be optimised. Therefore, the analysis of the administrations observed identified the focus points of future training packages that will aim to improve current practice in the administration of medication to PWD. This analysis will also test the theoretical model of administration of medication to PWD in care homes identified in a previous chapter (DIAMMOND).

The analysis of the data obtained from the observations aimed to test the following null hypotheses:

- there is no difference in the MAE rate between residents with and without dysphagia,
- there is no difference in the number of drugs prescribed for PWD compared to those without,
- there is no difference in the appropriateness of prescribing to PWD compared to those without.

Data analysis focussed on the MAE rate which was calculated from the number of administrations with one or more errors divided by the sum of the number of observed drug administrations plus the number of omitted drug administrations

(opportunities for error), calculated as a percentage. This MAE rate formula was also used in the study by Kelly (2011):⁽²⁸⁸⁾

$$MAEr = \frac{\text{Observed errors}}{\text{Total number of opportunities for error}} \times 100$$

Equation 1: MAE rate formula as per Kelly (2011)⁽²⁸⁸⁾

The general MAE rate should be calculated considering that each administration may carry more than one error (i.e. a drug can be administered late and also prepared differently to what was prescribed). However, that carries the risk of obtaining a figure not representative of the reality due to the variation that could be when, for example, one administration carries four different errors and others carry one. For that reason, for the purposes of this study, the MAE rate was calculated based on administrations that carry at least one error. This way, our MAE rate represents the probability of having at least one medication error per administration.

With regards to the analysis of the type of errors, it could be argued that a late administration could count as an omission, so in order to avoid duplication of errors, time-related omissions were classified only as time errors. Those cases where the resident refused to take medication were not included under omissions and, therefore, for the purposes of this study, only omissions related to the practice of the nurses were explored.

The analysis of the 25 medications most prescribed helped the researcher to estimate how often the formulations which may be more suitable for PWD were chosen, what the estimated cost of current administrations was and the likely impact of improving the formulation choices on the financial cost of the prescribing.

5.3.8. Ethical approval

Ethical approval was sought and obtained from the Faculty of Medicine and Health Sciences Research Ethics Committee on 28th June 2012 (Appendix 36).

The main ethical concern was that the researcher was witnessing potential errors and had to face deciding whether to intervene or not. The researcher also had to consider that those administrations would occur in his absence and that by interfering, the researcher might have affected the MAE rate reported. This could have had an educational effect and, therefore, could affect the subsequent similar

administrations during the research. Besides, the participants might have felt under pressure by being observed and corrected and that could also have affected the real MAE rate. However, the researcher was a registered pharmacist with the General Pharmaceutical Council and must abide by the Standards of Conduct, Ethics and Performance, especially the first one in which, as a pharmacist, he must make the residents' health his main concern.⁽³⁰⁶⁾ With these issues in mind, the researcher therefore only intervened when the error represented a significant risk to the resident (e.g. wrong dose or wrong drug given, medication given to the wrong resident) that could result in a sudden negative change in the health of the resident (extreme drop or raise of blood pressure, sedation, undesired effects, etc.). However, the majority of errors were thought to have minimal propensity for harm.^(274, 391, 392)

The other ethical concern was that the researcher was aware of the medicines being prescribed to a resident which is information that they would not normally have access to.

The focus of the research was on the practice of the nurses and, therefore, by default, the researcher observed residents' medication details. However, residents' personal details were not recorded as part of the process. Information on medicines was recorded but completely anonymously. Residents and relatives were informed of the study and were given the opportunity to opt out. However, there was no risk associated with the study, which was designed to ultimately enhance nursing and prescribing practices and, therefore, it was not deemed necessary to obtain individual resident consent to participate.

5.4. Results

5.4.1. Recruitment of participants

A total of five health centres showed interest in taking part in the research. The GPs from those health centres invited the managers of care homes to which they provide services to participate in the research. Eight care homes received information from the researcher but only six of them accepted the invitation. The six participating care homes received services from only three of the medical practices.

These homes provided an opportunity to observe a total of 13 drug rounds with 11 different nurses during morning, lunchtime, teatime and bedtime drug rounds. A

total of 166 residents, with and without dysphagia, were observed while receiving medication totalling of 738 administrations. Table 24 reflects how the observations were divided.

Medical practice	Care home code	Nurse code	No. residents	No. of administrations				Total
				Morning (7-9am)	Lunchtime (12-2pm)	Teatime (6-8pm)	Bedtime (10-11pm)	
1	1	7	20	88	0	9	0	97
	2	1	6	33	0	0	0	33
	3	2	28	136	1	0	0	137
2	4	3	19	88	0	0	0	88
		4	18	0	0	0	36	36
	6	9	15	67	0	0	0	67
		10	12	44	0	0	0	44
	3	5	16	79	0	0	0	79
		6	14	74	0	0	0	74
3	5	8	6	36	0	0	0	36
		Total	166	691	2	9	36	738

Table 24: Sequence of observations

5.4.2. Environment of the observations

Recording data on observations of the administration of drugs rounds provided an opportunity to collect a modest amount of environment notes. The star ranking that the CQC used to rate the observed care homes was identified from online reports (www.cqc.org.uk) in September 2012 following these observations so as to avoid environment notes being biased by any researcher’s preconceptions about the home. The CQC rates the care homes based on the care provided being:

- safe,
- effective,
- caring,
- responsive to people’s needs,
- well-led.

Care home 1 (CQC rated 5*)

The care home is in a rural location, looks clean, tidy and well organised. During the first visit, one nurse was unable to attend work due to sickness so the other

nurse had to do the drug rounds for all the residential and nursing residents in the home which made the drug round very slow and often residents had for their medication beyond the regular time recommended (after 11am). Measuring cups and disposable spoons were normally washed and reused, but as in the previous drug round, the nurse misplaced them, the participant nurse had to spend 30 minutes looking for them and started the drug round later than expected. Two residents refused to be observed. In a second visit, only three residents that were not observed in the morning were seen.

Care home 2 (CQC rated 5*)

The care home has a homely feeling and plenty of memorabilia. The bedrooms are big with classic decoration and have numerous family pictures. Most of the residents are still in bed at 9am and they get served breakfast in their own room. The members of the nursing team were very laid-back (as described by themselves) and the drug round started late as the hand-over took longer than expected. The drug round was done with the sister who was not distracted by carers, phones or other tasks. The nurse assured that residents take the medications most times due to their friendly and familiar approach to residents.

Care home 3 (CQC rated 3*)

All rooms are spacious, modern and comfortable and residents have en-suite bathrooms. The care home was described by the nurse as a building that retains the clinical look of a hotel from the 1990s. Despite its large size and the 32 residents accommodated there, there is only one nurse to do the entire drug round which in consequence requires an early start and late end.

The nurse remarked that due to the visit of the researcher, she warned the rest of the carers not to interrupt her whilst doing the drug round which actually meant that she finished earlier than usual. The participant highlighted that residents' attitude toward swallowing in most residents with capacity seemed different due to being observed. By the end of the morning drug round, the nurse participant had a short break and then carried on with the lunchtime drug round and so on with the evening drug round. According to the participant, the medication rounds often takes all or most of her 12- hours shift at work. The nurse participant would not leave the resident's room until making sure that the residents had taken their medication (except when the resident explicitly refused to take it).

Care home 4 (CQC rated 5*)

The morning drug round started after 9am. The participant nurse seemed quite indifferent about residents taking the medication. She left the pot of tablets next to the residents and asked the resident to take them. Some residents seemed a bit surprised when she actually tried to help them take the medication by putting it their mouths. She seemed rushed and concerned mainly about getting the drug round done and showed a very indifferent attitude towards the residents. The round took two hours and ten minutes with 18 residents and 88 observations.

During the evening drug round (8:30pm) in dementia units, it was common during the observations to find residents in the wrong rooms. Members of staff did not take any remedial action. The participant nurse was very relaxed about the residents' behaviour and relied constantly on carers to come and move residents around. The drug round was perceived as time inefficient by unnecessarily taking too much time for the organisation of medicines causing residents to receive medication such as sleeping tablets far later than recommended. For every single resident, the nurses' office would be opened, dispensing trolley unlocked, blister packs taken out, pop out tablets, put blisters away, lock the trolley, lock the office and walk to the resident's room or wherever the resident was located. Hardly any resident has more than one or two tablets to take at this time of day, and it took two hours to administer medication to 14 residents and 35 observations.

In a third visit that occurred in the morning, most of residents were still in bed at 9am and waiting for breakfast. The participant nurse had to prepare breakfast for the residents as well as administer the medication as part of her daily routine. The nurse seemed very confident but often forgot to give some medication.

Care home 5 (CQC rated 2*)

During the first drug round, the nurse seemed to know well most of the residents' relatives. The nurse participant ensured that residents were aware that they were being observed and that they took their medication. Time seemed to be a big concern for the nurse. Although the drug round started late due to problems locking the dispensing trolley, most residents received their medications in an appropriate time. The members of staff were very friendly to the residents.

In a second visit, the nurse participant seemed very friendly with the residents and knew most of them. However she was asked to cover the drug round on that floor because of the researcher's visit. She was confident on the needs of the residents but she almost constantly forgot to ask residents about pain and constipation relief.

Hardly any residents required pain relief, but most of them required laxatives when offered. The drug round ended late and the nurse blamed it on not being familiar with that floor. Two residents refused to be observed.

A third visit revealed a nurse participant with a very indifferent approach to the residents; she forgot their names and on several occasions she approached the residents referring to medications as “I bring you that disgusting stuff”. The nurse often did not offer constipation and pain relief expecting residents to ask for it if they need it.

Care home 6 (CQC rated 5*)

The care home looked very new, clean, tidy and homely. Not much memorabilia was present. Only two nurses agreed to be observed and the other two refused on the grounds that they were new and had concerns about being observed. The first visit was a dementia unit with 13 residents. The nurse was a bank nurse. She was very confident in her decisions; however, she was not very constant in her practice and often did not administer pain relief or constipation relief if she did not consider it necessary.

In the second visit, the nurse was the manager of the dementia unit. She went through all 16 residents very quickly as most of the time they didn't demonstrate any problems taking medication. Only one resident had dysphagia but he was fine taking liquid medication. Not having to face challenging administration of medication allowed the nurse to finish the round in 45 minutes and proceed with other jobs.

5.4.3. Prevalence of dysphagia

From the total of 166 residents observed, 38 (22.9%) had been diagnosed with dysphagia. The diagnosis was made by the GP, SALT, or in some cases by HCPs in the hospital and this diagnosis was identified in the patient's care plan or in the patient's notes. These residents were accountable for 143 observations (19.4%) out of the total 738. PWD received a mean (SD) of 3.76 (1.8) different drugs compared to those without who received 4.65 (2.4), which is 23.67% lower for PWD when compared to those without. Table 25 shows how the observation of dysphagia varied across the different care homes and medical practices.

Medical practice	Care home code	No. residents			Administrations		
		Total	PWD	%	Total	PWD	%
1	1	20	12	60.0%	97	46	47.4%
	2	6	1	16.7%	33	6	18.2%
	3	28	3	10.7%	137	11	8.0%
2	4	52	8	15.4%	191	30	15.7%
	6	24	6	25.0%	91	20	22.0%
3	5	36	8	22.2%	189	30	15.9%
Total		166	38	22.9%	738	143	19.4%

Table 25: Prevalence of dysphagia

5.4.4. Frequency of administration errors

A total of 300 administration errors were identified during the drug rounds across 100 residents. Thirty (78.95%) PWD and 70 (54.7%) of the residents without dysphagia suffered at least one administration error. Table 26 shows the frequency of errors in residents with and without dysphagia from the total amount of administrations observed, i.e. the combination of dysphagia and time errors was present in 5.4 % (9) of the total 166 residents.

Observation of drug administrations in care homes

Type of error	No. residents (N=166)					Administrations (N=738)				
	Total	PWD N=38		No dysphagia N=128		Total	PWD N=143		No dysphagia N=595	
		N	%	N	%		N	%	N	%
Wrong time	30	9	5.4%	21	12.7%	126	21	2.8%	105	14.2%
Omission	19	5	3.0%	14	8.4%	31	14	1.9%	17	2.3%
Wrong drug	2	0	0.0%	2	1.2%	2	0	0.0%	2	0.3%
Extra dose	0	0	0.0%	0	0.0%	0	0	0.0%	0	0.0%
Wrong dose	5	4	2.4%	1	0.6%	8	5	0.7%	3	0.4%
Wrong technique	9	4	2.4%	5	3.0%	22	9	1.2%	13	1.8%
Unordered drug	0	0	0.0%	0	0.0%	0	0	0.0%	0	0.0%
Wrong adm. prep	5	4	2.4%	1	0.6%	7	6	0.8%	1	0.1%
Wrong route	0	0	0.0%	0	0.0%	0	0	0.0%	0	0.0%
Deteriorated medicine	3	1	0.6%	2	1.2%	3	1	0.1%	2	0.3%
Drug compatibility	5	2	1.2%	3	1.8%	7	3	0.4%	4	0.5%
Allergy	0	0	0.0%	0	0.0%	0	0	0.0%	0	0.0%
Inappropriate prescribing	19	14	8.4%	5	3.0%	44	35	4.7%	9	1.2%
Others	45	5	3.0%	40	24.1%	50	5	0.7%	45	6.1%

Table 26: Frequency of errors from the total number of administrations

5.4.5. Description of errors and analysis

5.4.5.1. Wrong Time Administrations

Table 27 shows how PWD were commonly less exposed to late administrations compared to those without.

Observation of drug administrations in care homes

	Administrations	
	To PWD N=99	To residents without dysphagia N=201
Type of error	N (%)	N (%)
Inappropriate prescribing	35 (35.4%)	9 (4.5%)
Wrong time	21 (21.2%)	105 (52.2%)
Omission	14 (14.1%)	17 (8.5%)
Wrong technique	9 (9.1%)	13 (6.5%)
Wrong adm. prep	6 (6.1%)	1 (0.5%)
Wrong dose	5 (5.1%)	3 (1.5%)
Others	5 (5.1%)	45 (22.4%)
Drug compatibility	3 (3.0%)	4 (2.0%)
Deteriorated medicine	1 (1.0%)	2 (1.0%)
Wrong drug	0 (0.0%)	2 (1.0%)
Extra dose	0 (0.0%)	0 (0.0%)
Unordered drug	0 (0.0%)	0 (0.0%)
Wrong route	0 (0.0%)	0 (0.0%)
Allergy	0 (0.0%)	0 (0.0%)

Table 27: Comparison of frequencies of errors by type between the two groups of residents

On a total of 126 (17.1%) occasions the residents' drugs were administered at least one hour late affecting 30 (18.1%) of the residents. Table 28 shows the drug groups most commonly administered at the wrong time.

Observation of drug administrations in care homes

Drug group	Total	%	PWD		No dysphagia	
			N	%	N	%
Antiplatelet	16	12.7%	1	6%	15	94%
Supplements	14	11.1%	2	14%	12	86%
Gastrointestinal disorders	11	8.7%	2	18%	9	82%
Laxatives	11	8.7%	2	18%	9	82%
Antidepressant	10	7.9%	3	30%	7	70%
Pain killers	9	7.1%	1	11%	8	89%
Antidiabetic drugs	6	4.8%	0	0%	6	100%
Cardiac glycosides	6	4.8%	1	17%	5	83%
Diuretics	6	4.8%	0	0%	6	100%
Thyroid regulators	6	4.8%	1	17%	5	83%
Antiepileptic	5	4.0%	2	40%	3	60%
Anti-hypertensives	5	4.0%	0	0%	5	100%
Anti-parkinsonism	3	2.4%	2	67%	1	33%
Anti-angina	2	1.6%	0	0%	2	100%
Lipid-regulating	2	1.6%	0	0%	2	100%
Calcium salts	2	1.6%	2	100%	0	0%
Dementia	2	1.6%	1	50%	1	50%
Steroids	2	1.6%	0	0%	2	100%
Gout control	2	1.6%	0	0%	2	100%
Antibiotics	1	0.8%	0	0%	1	100%
Antihistamines	1	0.8%	0	0%	1	100%
Antineoplastic	1	0.8%	0	0%	1	100%
Antipsychotic	1	0.8%	0	0%	1	100%
Anxiolytics	1	0.8%	1	100%	0	0%
Nausea and vertigo	1	0.8%	0	0%	1	100%
	126	100%				

Table 28: Frequency of wrong time errors by drug group

5.4.5.2. Omission

One of the most common errors observed was the omission of medication by the nurse and in consequence residents failed to receive medications by the time of the next scheduled dose. Omissions were found to be the third most frequent type of error in PWD and higher in this group than in the group of residents without dysphagia (Table 27).

While the majority of omission cases (18) were due to the nurses not considering it necessary or suitable to give that medication for various reasons (having to wake

up the resident, resident often refused the medication, etc.), in seven cases nurses forgot to administer that medication to the resident. The remaining six incidents were due to not having organised the provision of the right medication. On the seven occasions when the nurse forgot to administer the medication, and in one case when the omitted drugs could affect the resident's well-being (vertigo medication), the researcher, in his duty of care, felt the need to intervene and discretely reminded the nurse of the missing administration. Table 29 compares the drugs that were omitted and the reason between PWD and those without.

Observation of drug administrations in care homes

Reason	PWD	No dysphagia
Resident had refused medication previously	Alendronic acid 70mg tablets	
	Amlodipine 10mg tablets	
	Folic acid 5mg tablets	
	Isosorbide mono. 20mg tablets,	Macrogol sachets
	Levothyroxine 100mcg tablets	Paracetamol 500mg
	Levothyroxine 25mcg tablets (x2),	tablets
	Paracetamol 250mg/5ml liquid	
	Sotalol 40mg tablets	
Resident asleep	N/A	Calcium salts tablets
		Clopidogrel 75mg tablets
		Lactulose solution
Nurse identified the need to check with pharmacy as dose was confusing	Erythromycin 250mg tablets	Calcium salts tablets
		Macrogol sachets Nitrofurantoin 50mg tablets
Tablets have not been reordered with the monthly prescription	Furosemide 40mg tablets	N/A
Capsules dispensed instead of orodispersible tablets so not administered	Lansoprazole 30mg OD tablets	N/A
Nurse didn't consider that the drug was needed	N/A	Macrogol sachets
		Paracetamol 250mg/5ml liquid (x2)
Nurse run out of tablets	N/A	Paracetamol 500mg tablets
Nurse forgot to administer it	Cetirizine 10mg/1ml liquid	Calcium salts tablets (x2)
		Macrogol sachets (x2)
		Alendronic acid 70mg tablets

Table 29: Drugs omitted and nurse's reason for omission

5.4.5.3. Wrong drug

On one occasion, the medication for two of the residents (lorazepam and simvastatin) was prepared remotely during an evening drug round and each resident's tablet was put in a pot. At the time of administering to the resident, the nurse could not differentiate which tablet was which and the wrong medication ended up being given to the wrong resident. The researcher identified the case and intervened before residents actually took the tablet. No other cases were identified.

5.4.5.4. Wrong dose (under dose)

In eight cases, a reduced dose than the one prescribed was administered to the resident. These erroneous doses were as a consequence of using extra utensils that retain residues of the medication and are not rinsed after use, or as a result of mixing medication with food that was only partly taken by the resident. While the preparation for the administration was correct, the resident did not receive the whole dose. The researcher highlighted this issue to the participant at the end of the administration.

The tampering of medication resulting in smaller doses being administered was more likely to occur in PWD. This was observed in PWD three times more often than in those without (Table 27).

5.4.5.5. Wrong technique recommended

This type of error applied to 22 administrations that had been prescribed correctly for the resident but they were given to the resident for her/him to chew them despite the inappropriateness of the formulation for being chewed. Although this classification of error had not been originally described as a type of its own, the high frequency observed of this type of error, made the researcher consider it as a type in its own right based on the description by Barker in 2002.⁽³⁹³⁾ This error was defined as an incorrect performance in the administration of each dose of medication.⁽²⁷⁰⁾

Drugs administered	
PWD	No dysphagia
Aspirin 75 mg tablets (x2)	Aspirin 75 mg tablets (x2)
Bisoprolol 10mg tablets	Codeine 30mg tablets
Digoxin 250mcg tablets	Ferrous fumarate 210mg tablets
Lansoprazole 30mg capsules (x2)	Lansoprazole 30mg capsules
Lisinopril 5mg tablets	Levothyroxine 100mcg tablets
Paracetamol 500mg tablets (x2)	Paracetamol 500mg tablets
	Mebeverine 135mg tablets
	Quetiapine 25mg tablets
	Simvastatin 20mg tablets
	Trazodone 50mg tablets

Table 30: Drugs administered for chewing as per nurse advice

Four PWD counted for nine of those administrations while the remaining 13 administrations belonged to five residents not diagnosed with dysphagia, making PWD more commonly exposed to medications wrongly administered for chewing (Table 27).

5.4.5.6. Wrong dose preparation and administration

These administrations refer to cases where wrong preparation had led to unsuitable administration. Seven cases were identified where the method of preparation by the nurse compromised the administration. These are some examples:

- orodispersible tablets were dispersed following instructions for capsule formulation of the same drug,
- nurse didn't thicken the solution containing the dispersed drugs despite clear instructions from the SALT recommending only thickened fluids,
- part of the content of the sachet was left behind accidentally.

Four PWD accounted for six of these administrations and the single resident without dysphagia accounted for one.

5.4.5.7. Wrong route

The observations of these drug rounds did not identify any cases where the administration of drugs could have been compromised by having used the wrong route for the administration of drugs to the residents.

5.4.5.8. Deteriorated medicine

Only three cases occurred where a deteriorated medicine was administered. These were:

- a sachet prepared with water is not administered until 3.5 hours later against manufacturer instructions,
- tablets were dispersed in water without doctor's consent and against manufacturer instructions,
- drug was administered with food despite recommendations explicitly requiring the opposite.

No significant difference was found between groups in the frequency of this error (Table 27).

5.4.5.9. Drug compatibility

Ten drug incompatibilities were found during the observations of a total of seven residents that were exposed to these erroneous administrations. The main reasons for these incompatibilities were:

- calcium salts and proton pump inhibitors were administered together compromising the absorption of calcium,
- alendronic acid was going to be administered with the rest of the morning medication to a PWD despite the risk of oesophageal damage caused by reflux.
The researcher intervened but the resident refused to take the medication.

5.4.5.10. Unordered drug, extra dose and allergy related error

No cases of extra dose or allergy-related errors were identified during the observations in any resident with or without dysphagia. Nor did the observations of these drug rounds identify any cases where the administration of drugs could have been compromised by not having ordered any particular drug for the residents.

5.4.5.11. Inappropriate prescribing

Several cases were observed where the risk of an adverse drug event outweighed the clinical benefit, particularly when safer or more effective alternatives were available⁽¹⁶⁴⁾ and, therefore, classified as inappropriate prescribing (IP). Based on that definition, IP was identified in the administrations where:

- doses were prescribed incorrectly (i.e. antibiotics like nitrofurantoin prescribed as required),
- there was incompatibility between the drugs prescribed (i.e. lansoprazole and calcium salts prescribed to be taken together),
- inappropriate formulation choice by the prescriber (i.e. prednisolone EC tablets prescribed for PWD when soluble tablets are available and were suitable for that patient).

This classification took into consideration specific instructions made by the prescriber. For example, when lansoprazole and calcium were both recommended to be taken daily with breakfast, it was classified as IP. It was not considered IP in those cases where incompatible drugs were not specifically prescribed to be taken together.

Table 31 shows the percentages of administrations affected by inappropriate prescribing comparing the group of PWD and the one without.

	Total	Inappropriate prescribing administrations to PWD N (%)	Inappropriate prescribing no dysphagia N (%)	Fisher's exact test P
Medical practice 1	267	20 (7.5%)	2 (0.7%)	p<0.01 (0.000)*
Medical practice 2	282	9 (3.2%)	6 (2.1%)	p<0.01 (0.000)*
Medical practice 3	189	6 (3.2%)	1 (0.5%)	p<0.01 (0.000)*
Total	738	35 (4.7%)	9 (1.2%)	

*As represented by SPSS

Table 31: Comparison of inappropriate prescribing between medical practices

The analysis of the data revealed that signs of aspiration were present in 20.3% of the administrations of medication to PWD and this was significantly higher in PWD than in those without (Fisher's Exact, $p < 0.01$). Inappropriate formulation choices increased the rates of aspiration in both groups but these rates were higher in the group of PWD (Table 32).

	PWD		No dysphagia		Fisher's exact test p
	Signs of aspiration N (%)	Number of admins.	Signs of aspiration N (%)	Number of admins.	
Appropriate formulation choices	2 (1.9%)	108	1 (0.2%)	586	$p < 0.01$ (0.000)*
Inappropriate formulation choices	27 (77.1%)	35	3 (33.3%)	9	$p < 0.01$ (0.000)*
Total	29 (20.3%)	143	4 (0.7%)	595	$p < 0.01$ (0.000)*

*As represented by SPSS

Table 32: Association between aspiration and formulation choices in PWD

5.4.5.12. Others

On 50 occasions the administration of medication was considered erroneous for reasons not specifically contemplated in the classification of errors used. These errors consisted in administrations that differed from the instructions recommended by the prescriber or the pharmacist and were always associated with the administration of the drug with or without food or on empty stomach:

- in 11 cases, aspirin was administered on an empty stomach contrary to prescriber's instructions,
- iron salts were given on an empty stomach against the recommendations from the doctor to avoid gastrointestinal disturbances in 15 administration,
- proton pump inhibitors and oral antibiotics accounted for another 24 cases.

5.4.6. Medication administration error rates

A total of 99 administration errors were observed across the 38 PWD in comparison to the 201 errors observed in the group of 128 residents without dysphagia.

Observation of drug administrations in care homes

The classification of medication errors per individual type showed significant variability within types and groups. Table 33 indicates MAE rates of each type of error when considering the opportunities of error as 143 and 595 in the group of residents with and without dysphagia, respectively.

Type of MAE	Administrations			P value (Fisher's Exact)
	Total	PWD N (MAE rate %)	No dysphagia N (MAE rate %)	
Time	126	21 (14.7%)	105 (17.6%)	0.458
Omission	31	14 (9.8%)	17 (2.9%)	0.001
Wrong drug	2	0 (0.0%)	2 (0.3%)	1
Wrong dose	8	5 (3.5%)	3 (0.5%)	0.009
Wrong technique	22	9 (6.3%)	13 (2.2%)	0.023
Wrong adm. prep	7	6 (4.2%)	1 (0.2%)	<0.001
Deteriorated medicine	3	1 (0.7%)	2 (0.3%)	0.476
Drug compatibility	7	3 (2.1%)	4 (0.7%)	0.137
Inappropriate prescribing	44	35 (24.5%)	9 (1.5%)	<0.001
Others	50	5 (3.5%)	45 (7.6%)	0.095

Table 33: MAE rates per type of error

As represented in Table 34, a total of 82 administrations to PWD contained at least one error, compared to the 183 in the group of residents without dysphagia.

	Dysphagia		P value (Fisher's Exact Test)
	Yes (N=143)	No (N=595)	
Administrations with at least one error (MAE rate)	82 (57.3%)	183 (30.8%)	<0.001

Table 34: Comparison of MAE rates for residents with and without dysphagia

Table 34 shows a MAE rate in PWD almost double (1.86 times higher) than in those without. However, time errors appeared far more common in the group without dysphagia (Table 33) due to the fact that the other errors occur less frequently in that group. Besides, the wrong time administrations are probably due to the large amount of drugs involved on each drug round and the complexity of its administration.

While the rest of the administration errors could potentially be avoided by improving practice, time errors are virtually inevitable and, therefore, a second analysis of MAE rates was carried out for this study based on the same mathematical principles, but not including time errors.

In consequence, the amount of administrations that carry at least one error not including time was reduced to 65 for PWD and 89 for those without as reflected in Table 35. The statistical analysis showed association between PWD and MAE rates (excluding time errors), making PWD three times more likely to be exposed to an administration error not related to time compared to those without dysphagia.

	Dysphagia		P value (Fisher's Exact Test)
	Yes (N=143)	No (N=595)	
Administrations with at least one error (MAE rate)	65 (45.5%)	89 (15.0%)	<0.001

Table 35: MAE rates excluding time errors

5.4.7. Medication most frequently prescribed to PWD

A total of 54 different drugs were prescribed in the 143 administrations to PWD in comparison to the 125 drugs observed in the 595 administrations to residents without dysphagia. From those 54, 25 drugs represent the most prescribed (twice or more) of the sample. The 25 medications most commonly prescribed to PWD accounted for a total of 114 (79.7%) of the administrations.

The majority of alternatives suggested an increase in the price of the administration (Table 36). However, the consideration of this percentage increase in cost per formulation would assume that all the administrations are sub-optimal. It is, therefore, important to reflect the percentage increase of replacing sub-optimal formulations but also considering that some of those formulations are already appropriate. For example, the percentage increase of optimising the administration of paracetamol considers optimising nine administrations of tablets and effervescent tablets plus the cost of six administrations of liquid formulations. Hence, the percentage increase of optimising paracetamol in our sample is 74% rather than the percentage increase from 2.9p to 13p (348.3%). Table 36 summarises the individual cost of the top 25 drugs prescribed to PWD and the potential price increments when optimal formulation choices are available and prescribed.

It was estimated that the cost of a hypothetical drug round containing these drugs in the same frequencies would be £15.48 but only 53% of those formulations would be considered alternative which removes the need for formulation tampering for PWD. If alternative licensed formulations were prescribed, the cost would be affected by a 77.4% increase going up to £27.47 and by 361% when special unlicensed formulations were recommended with a total cost of £71.34.

Further comparison of the 25 medications most frequently prescribed in PWD and residents without dysphagia highlighted the main differences between these groups. In the group of residents without dysphagia, the top 25 medications accounted for 419 administrations (70.4%).

Observation of drug administrations in care homes

Drug	Formulation used	Times prescribed (N)	Cost per dose (dose)*	Liquid formulation or dispersible tablet available	Cost of alternative formulation per dose*	Percentage increase of alternative administration
Paracetamol	Tablets	8	2.9p (500mg)	Paracetamol 250mg/5ml suspension	13p	74%
	Effervescent tablet	1	11p (500mg)	Paracetamol 250mg/5ml suspension	13p	
	Suspension	6	13p			
Macrogol	Oral Powder	12	22p			
Aspirin	Gastro-resistant tablets	2	3.2p (75mg)	Dispersible tablets	3p	-1%
	Dispersible tablets	8	3p (75mg)			
Citalopram	Tablets	5	3.4p (20mg)	Citalopram 40mg/ml drops	28.5p	79%
	Liquid	5	28.5p (20mg)			
Calcium salts	Effervescent tablet	1	15.5p (1.5g)	Chewable tablets 1.5g	8.25p	-10%
	Chewable tablets	7	8.2p (1.5g)			
Lansoprazole	Orodispersible tablets	2	10.6p (15mg)			61%
	Capsules	4	4.6p (15mg)	Lansoprazole 15mg orodispersible tablets	10.6p	
Sodium valproate	Solution	5	9.4p (200mg)			-3%
	Crushable tablets	1	11.2p (200mg)	Sodium valproate 200mg/5ml oral solution sugar free	9.43	
Levothyroxine	Tablets	5	9.9p (25mg)	Levothyroxine 50mg/5ml solution	137p	1,284%
Co-beneldopa	Capsules	2	11.8p (25/100mg)	Dispersible tablets (25mg/100mg)	10.45p	-6%
	Modified release tablets	1	12.77p (25/100mg)			
	Dispersible tablets	1	10.45p (25/100mg)			
Co-codamol	Effervescent tablet	3	8.2p (8/500mg)			16%
	Tablets	1	3.7p (8/500mg)	Effervescent tablet 8mg/500mg	8.2p	
Folic acid	Tablets	3	4p (5mg)	Folic acid 2.5mg/5ml oral solution sugar free	61.1p	1428%
Omeprazole	Dispersible tablets	2	41.4p (20mg)			42%
	Capsules	1	4.78p (20mg)	Dispersible tablets 20mg	41.4p	

Observation of drug administrations in care homes

Drug	Formulation used	Times prescribed (N)	Cost per dose (dose)*	Liquid formulation or dispersible tablet available	Cost of alternative formulation per dose*	Percentage increase of alternative administration
Sertraline	Tablets	3	27.53 (100mg)	Unlicensed Sertraline 50mg/5ml oral suspension	657.5p	2,288%
Co-careldopa	Tablets	3	6.9p (12.5/50mg)	Unlicensed co-careldopa 25mg/100mg/5ml oral suspension	371.3p	5,281%
Atenolol	Liquid	2	9.31p (25mg)			
Bisoprolol	Tablets	2	4.1p (5mg)	Unlicensed bisoprolol 2.5mg/5ml solution	441.7p	10,673%
Cetirizine	Tablets	1	3.7p (10mg)	Cetirizine 1mg/ml oral solution sugar free	9.6p	44%
	Liquid	1	9.6 (10mg)			
Digoxin	Tablets	2	3.8p (125mcg)	Digoxin 50mcg/ml elixir	22.3p	487%
Fludrocortisone	Tablets	2	5.1p (100mg)			0%
Fluoxetine	Capsules	2	3.5p (20mg)	Fluoxetine 20mg/5ml oral solution	30.5p	771%
Furosemide	Tablets	2	3.1p (20mg)	Unlicensed furosemide 50mg/5ml oral solution sugar free	267.1p	8,516%
Lactulose	Solution	2	6.64p (10ml)			
Memantine	Liquid	2	123.2p (10mg)			
Co-careldopa with entecapone	Tablets	2	72.4p (50/12.5/200mg)			
Trimethoprim	Tablets	2	4.3p (100mg)	Trimethoprim 50mg/5ml oral suspension sugar free	21.3p	395%

*Price obtained from Drug Tariff 2013⁽³²²⁾

Table 36: Comparison of the cost of medicines when optimising formulation choices

The table in Appendix 37 shows how 16 of the drugs were repeated in both groups and how the main differences fell on the higher proportion of antiepileptic, anti-Alzheimer's disease and anti-parkinsonism drugs prescribed to PWD. These medications accounted for 12.9% of the total administrations to PWD and 14.9% of the top 25 drugs. Table 37 reflects a comparison of the prescribing rates for those drugs in both groups.

Drug	Prescribing rate to PWD	Prescribing rate to other residents
Sodium Valproate	4.2% *	0.3%
Co-Beneldopa	2.8% *	0.3%
Co-Careldopa	2.1% *	0.2%
Memantine	1.4% *	0.7%
Co-Careldopa with Entecapone	1.4% *	0.2%

* Drug is part of the top 25 drugs prescribed

Table 37: Comparison of the use of antimentia and antiepileptic drugs

5.5. Discussion

5.5.1. Time of the drug rounds

One of the objectives of this study was to identify the factors that affect the administration of medicines to PWD. The comments from the participating nurses made it obvious to the researcher before and during the drug rounds that time was one of the factors with a large impact on the nurses' practice. This is in agreement with studies highlighted in the literature review, where time constraints remained one of the main concerns for nurses.^(224, 225)

Some of the environment notes taken during the observations revealed how very often drug rounds not only did not start on time but they took over most of the nursing time in care homes. It was possibly the time constraints that triggered the different approaches of the nurses observed when administering medication. While some nurses achieved drug rounds within the scheduled time, this was often achieved at a certain level of indifference towards the residents, rushing them to take their medication or just leaving the medication for them to take.

Time constraints and, as a consequence, wrong time administrations were not only a problem of PWD but a problem for residents in care homes in general, as one late administration was often just the cause and the consequence of another late administration regardless of the nature of the conditions suffered by the resident. While the severity of taking certain medication at a later time than prescribed could be argued to be small, some of the late administrations consisted of antiepileptic drugs like phenytoin, which is recommended to be taken at the same time every

day, with breakfast, to avoid gastrointestinal side-effects such as nausea, vomiting, diarrhoea and constipation.

Although it could be said that time errors are hard to avoid due to lengthy drug rounds and the complexity of administrations, this study suggests that further research should explore interventions that enhance the time-efficiency of the drug rounds without compromising the direct care of nurses for their residents.

5.5.2. Errors not related to time

The omission of medication was a common error observed during the drug rounds but the nature of those omissions varied greatly. Following the error classification by Ferner & Aronson (2006),⁽²⁶²⁾ the causes for most of the omissions observed were the lack of pharmaceutical knowledge about the importance of administering medication and the inappropriate assessment of the need for medication. These are called genuine mistakes. Often these mistakes were the result of the nurses' assumptions of the resident's willingness to take the medication. On other occasions the nurse decided to prioritise the immediate comfort of the resident without considering the potential health consequence of omitting medication. In addition to these genuine mistakes, lapses in memory and slips in the processes (action-based errors) were the cause of the other omissions. However, these errors bring up the argument that the genuine reason for the omissions could be the time pressure of having to administer medication to residents that often reject their medicines. The time pressure could also be the cause of the omissions related to the forgetfulness of the participant that could find it hard to focus on appropriately administering medication. This may be suggesting that not only can time constraints be the trigger of other types of errors, but also that the nurses could benefit from simple interventions that enhance their knowledge and act as a reminder of good practice during the drug rounds.

The lack of knowledge on the legal liability issues and the pharmacokinetics of the medicines could be the cause for practices that trigger deterioration of drugs and tampered administrations without formal consent from the doctor. These were therefore described as knowledge-based errors.⁽²⁶²⁾

For those cases where residents received the wrong medication, action-based slips were the most likely reason. The identification of tablets is not a task that is related to the knowledge of nurses; however, the processes involved in the prevention of errors in the administration of drugs, as well as the storage and the delivery of the

medicines to the residents rely completely on the skills of the nurses. In these cases the nurse did not see the need for taking the medicines trolley out of its storage room and, instead, the tablets were placed in pots and delivered to the residents on the other side of the building without any notes accompanying the medication. At the time of administering it to the residents, the nurse wrongly guessed which drug was which and had it not been for the intervention of the researcher, two residents would have received the wrong medication (lorazepam instead of simvastatin and vice versa). This error could have easily been prevented by keeping the residents' medication and any information about how to administer it in the residents' rooms. In certain homes, this is not always possible as the medication is stored in lockable rooms where the care plans for the residents are also kept. However, keeping just the relevant information about the administration of medication would promote a safer practice and would highlight any issues relevant to the way that the resident has his/her medication administered, like in the case of PWD.

Skills-based issues were also the cause of the wrong dose administrations as nurses failed to identify the use of food and utensils as potential factors that affect the amount of drug that the resident received. During the observations, the same measuring devices (which are designed for single use) were used for several residents in one of the care homes and certain medications were mixed with food. Although it was not always necessarily incorrect to do this, nurses should only carry out this practice with certainty that the full dose will be taken and otherwise it should be avoided. Time constraints might have encouraged nurses to rely on mixing medication with food in the hope that the carers would administer the mix of food and medication, allowing the nurse to carry on with other tasks. The joint administration of incompatible drugs was also considered a skills-based error due to the fact that nurses are provided with information regarding the compatibility of the medicine with food from the pharmacy and that information is labelled on the medicine container.

This study identified the lack of skills on the administration of medication, inappropriate assessment (rule-based) and lack of knowledge as primary causes for administration errors to happen in care homes. These results are in accordance with those identified by numerous qualitative studies where the nurses expressed their concerns about their skills,^(199, 223) knowledge⁽²²⁵⁾ and the influence of their environment on those elements.^(199, 223, 225) However, time pressure when carrying out drug rounds remains a concern for the nurses and it is reflected in their practice.

One of the main concerns was the numerous times that the researcher had to intervene. While in several cases, the interventions were due to human errors like forgetting the administrations of drugs, in many others, the researcher intervened according to his judgement on the severity of the errors. This judgement, however, was undertaken from a pharmacist's point of view and it may indicate that optimising the administration of medicines is highly dependent on different professional views and, therefore, could be benefited from a multidisciplinary approach.

This study brings to the discussion the two approaches of errors theory identified by Reason⁽³⁹⁴⁾ as, while it could be said that the nurses are to blame as the ultimate cause for the error, the context of the administrations observed exposed a system in which time pressure and lack of professional development (skills and knowledge) are very often part of the nurses' practice. Therefore, the implementation of interventions to improve the care received by PWD should consider both a general and an individual approach, i.e. this study suggests that pharmacist-led interventions in the care home could enhance the knowledge and the skills of the nurses when administering medication to PWD while reducing the prevalence of knowledge-based and rule-based errors.

5.5.3. MAE rates in hospital compared to care homes

Although other studies have contemplated the rates of medication errors in PWD, our study used the same methodology of data collection and analysis as used by Kelly,⁽²⁸⁸⁾ carried out in hospital wards. The same issues were described by Kelly with regards to the time of the administrations, leading to calculation of the MAE rates based on the exclusion of time errors. Kelly concluded in her study that the proportion of MAE rate was over three times (3.6) greater in PWD compared with those without. These results are in agreement to those in our study where PWD were also three times (3.03) higher than those without.

MAE related to IP were the most frequent in our study. Although in Kelly's study those classified as 'others' were the most frequent errors, her classification didn't consider IP. This may explain the high rates of 'others' in our study. Nevertheless, after excluding time errors and IP as part of others, the frequency of errors by type are similar in both studies.

It is concerning, however, that the MAE rates for PWD and those without are more than double (45.5% vs. 21.1% and 15.0% vs. 5.9%, respectively) in the care home

compared to hospital. It is hard to identify the actual reasons for this increase in the MAE rate but one of the reasons that was identified by the nurses in qualitative studies is the isolation of the care home environment described as an information vacuum by Barnes.⁽¹⁹⁹⁾

Despite the current efforts of the CQC on improving the safety of the residents in care homes, the reports generated by this commission may not be specific enough to identify the raised risks that PWD are exposed to. Care homes highly rated as five stars by the CQC were identified in this study to have some of the highest MAE rates where 70% to 100% of PWD observed were exposed to at least one administration error not related to time. While more effective changes should be encouraged to reduce the amount of MAEs in care homes, PWD should be a priority target when implementing interventions to improve the practice of HCPs.

5.5.4. Inappropriate prescribing in PWD

It was the inappropriate formulation choices made by the doctor at the time of prescribing to PWD which revealed the highest MAE rates. Despite the fact that the signs of aspiration in PWD were strongly associated to the formulations prescribed and administered, it could be argued that the nurses carried out an appropriate assessment at the time of the administration in the cases where the residents diagnosed with dysphagia received solid medication. The observation of signs of aspiration requires certain skills that are not attributed to general nurses and it is recognised that the liability of administering solid medication to PWD is shared between the doctor and the nurse.

This study was designed to identify potential improvements in the medication choices but the nature of the results obtained may help us in estimating some of the likely reasons for those choices.

The cost of prescribing suitable alternative formulations to PWD in our sample was estimated to be 4.6 times the cost of current practice. However, it should be considered that this would improve up to 47% of the administrations of drugs and that could theoretically reduce the aspiration rates from 77.1% to 1.9%. When considering that aspiration related to wrong food or medication texture is the most significant risk factor for pneumonia,^(89, 90) it could be expected that optimising the formulation choices for PWD would be likely to reduce the rate of expensive hospital admissions related to respiratory diseases in older people. This link has not been established before and it could be the aim of future research.

Another factor that could be affecting the formulation choices was the lack of awareness of the condition. When the formulation errors were observed, only nine of the 22 administrations belonged to residents that had been diagnosed with dysphagia. Chewing tablets and food (excessively) is one of the main signs of the presence of a swallowing disorder and these cases should be referred to the doctors or the SALT for further investigation. There is a possibility that a large group of PWD are not being diagnosed.

In summary, despite the pharmacist being recognised as the expert in medication, the doctor still remains as the prescriber and the professional selecting the formulation of the drug. The pharmacist has expert knowledge on the pharmacokinetic and the effects of tampering with drugs' formulations as well as on the alternative formulations available on the market. The doctors' lack of knowledge on these alternatives could be affecting the prescribing of medication to PWD but it offers an opportunity for the pharmacist to get more involved in the care of PWD.

This study placed the cost of the optimisation of prescribing to PWD, the lack of awareness of the condition and the lack of knowledge of alternative formulations as the most likely factors that affected the formulation choices made by the doctor. However, further research is needed to validate this hypothesis and to identify other potential factors that influence the prescribing of medication to PWD.

5.5.5. Restriction of medicines at the time of prescribing

The observation of administrations to PWD identified 54 different drugs in comparison to the 125 different ones observed in the non-dysphagic group (section 5.4.7.). These figures indicated the wider variety of conditions that dysphagia is associated to, i.e. Parkinson's and Alzheimer's disease and other forms of dementia. However, PWD received on average a number of drugs 23.67% lower than those residents without dysphagia (section 5.4.3.). These figures indicated that despite more complicated conditions being present in the group of PWD, the residents in our sample were prescribed a more limited number of drugs per patient than those without dysphagia. Nevertheless, this study was not able to identify whether these differences in the figures could be indicating under-prescribing or what the causes for this difference were. In general multi-morbidity, polypharmacy, ageism, lack of scientific evidence, fear of adverse events and economic problems may contribute to under-prescribing of indicated drugs.⁽³⁹⁵⁾ Conversely, in some residents, a limited life expectancy, the lack of a favourable risk-to-benefit ratio or a resident's

refusal might represent appropriate reasons not to prescribe a drug.⁽³⁹⁵⁾ Under-prescribing in PWD has not been explored broadly in the literature but these results agree with studies that identified the need of more creative prescribing methods in dysphagia⁽¹⁶⁷⁾ and, as a consequence, PWD might be being prescribed less medication than needed.⁽¹⁶⁸⁾ This study also brings to the discussion other factors such as doctors not being aware of more suitable formulation and the increased cost of prescribing to this group of patients.

5.5.6. Lack of standardised practice

The environmental notes revealed different approaches between the practices of the nurse participants and how the nurse-resident interaction could be compromising the administration of medication. For example, while some nurses relied on the residents to take the medication in the absence of the nurse, other nurses would not abandon the resident's room until confident that the residents had received the medication. Despite the available recommendations for the administration of medication to PWD^(215, 292, 312, 313) and the internal policies and guidance inside the care home, the differences in practice fell on the nurses as individuals and a strong initiative is needed to over-ride those individual factors that make practice differ between professionals.

The comments from the participants also revealed concerns about the clinical confidence of the nurses on the administration of medication. While some of the nurses felt they needed to prepare for the visit of the researcher in his observer role, other nurses did not feel confident to take part.

The lack of standardised practice had already been identified by the literature^(195, 228) in observational studies in other settings. However, this modest collection of field notes also added contextual factors to the causes of such practice. While this study suggests that interventions that focus on setting up standards of practice could be beneficial for the nurses' practice, those interventions should, therefore/consider qualitative and quantitative outcomes.

5.6. Limitations and strengths

One of the strengths of this study is that each administration of medicines was recorded in all the different categories of errors, allowing us to determine the frequencies of the most common errors as well as to identify the total MAE rates for PWD and without dysphagia when including and excluding time errors.

Conversely, the severity of the errors was not considered in the design of this study but it could be beneficial to include it as part of a larger study, where HCPs from different backgrounds (GPs, pharmacists, nurses, SALTs, etc.) could rate the severity of the errors identified.

The researcher observed drug rounds in the hospital in preparation for this study and compared the data collected with the nurse chief investigator of the hospital study. While this could be seen as a limitation of the study as the dataset was collected by a researcher with a pharmacist point of view, those observations in the hospital matched also the data from the research nurse and, therefore, this is also a strength of the study. However, the researcher was not observed in the care homes and, therefore, competency was not confirmed and the validity of the observations could be questionable.

Despite the small percentage of NHS care homes in England, the results of this study are not only limited to observations in private homes but also to those in the North Yorkshire area. A larger scale study could benefit from including NHS care homes as well as those from the private sector across England or the whole UK. Additionally, local guidelines, processes and systems may be different to other parts of the country, e.g. dysphagia guidelines, local support from pharmacist teams, greater or lesser SALT input, etc.

The care homes visited belonged to groups of multiples (several homes that belong to the same company) and therefore these results may not represent the practices observed in independently-owned homes. Similarly, the participating care homes were care homes with nursing and not residential homes which also limits the scope of the findings.

While the support of the medical practices was essential and effective for the recruitment of participants, the participation rates were likely affected in a negative way by the concern from the participants about being observed and this should also be considered. It is undeniable that the presence of a researcher observing the drug rounds of the nurses may condition the behaviour and practices of the participants^(274, 396, 397) so this potential example of the Hawthorn effect⁽³⁹⁸⁾ needs to be considered as one of the limitations of the scope of the results. Several of the nurses approached refused to participate in the research and, therefore, the observed sample is likely to be biased with those who are possibly more confident of their practice or wanting feedback on their practice more likely to consent.

If the study was repeated, we would need to undertake observations in a large number of homes which represented the general distribution of care homes with respect to ownership, size and resident type. Also, increasing the amount of observations during the research could make observations usual practice, and reduce the Hawthorn effect of the initial observations and enable practice to revert to normal.⁽³⁹⁹⁾

5.7. Conclusions

This study has identified numerous factors that can affect the way that PWD are receiving their medication in care homes. At a nurse level, the lack of basic pharmaceutical knowledge, inappropriate assessment and poor skills-based practice are the main concerns. However, as part of the care home, time pressure remains as the factor with highest impact on the administration of medication. External factors like the appropriateness of the formulation choices made by the prescriber are exposing PWD to a higher risk of aspiration that can potentially evolve into respiratory complications. This is in addition to the complexity of the conditions suffered by PWD, where Parkinson's and Alzheimer's disease, as well as other forms of dementia, are often present.

The weight of improving administration of drugs to PWD falls directly and almost completely on the nurses in the care homes and on the appropriate prescribing choices of the doctors. The support and expertise of other professionals like the community pharmacists is required to enhance the pharmaceutical knowledge of nurses and to provide advice to prescribers in the selection of suitable formulations.

With 22.9% of the residents observed suffering from dysphagia, this study concludes that more specific reports and inspections are required to enhance the safety of such a large group of residents. Also, the high prevalence of MAE in care homes should make the care of residents in care homes, and especially those with dysphagia, one of the main targets of the CQC to achieve safer practice.

This piece of research has identified some likely causes and consequences of the poor practice carried out in care homes and it has highlighted those concerns to some of the professionals involved. Increasing the awareness of dysphagia in healthcare professionals at the time of making clinical decisions could be the first step towards a better care of PWD in care homes.

The design of interventions that improve nurses' practice and its impact on the residents' health need to be evaluated with the correct outcome measures. The association between aspiration and inappropriate prescribing highlights the importance of considering aspiration rates as a suitable outcome measure for future studies. Nevertheless, environment notes helped to identify other factors like the clinical confidence of nurses and the workload in the care homes. In summary, further research in improving the administration of medicines to PWD should include both quantitative and qualitative outcome measures.

6. General discussion

Research on the administration of medication to PWD started over a decade ago when the problems of medicine administration to PWD in care homes with nursing were explored.⁽¹⁵⁸⁾ Since then, numerous publications have contributed to the awareness of these problems shared by nurses, carers and patients and to optimise the medicine administration to PWD in hospital wards and care homes.^(23, 195, 228, 292, 320, 400, 401) Those publications have set a milestone for national research on medicines management to PWD, demonstrating how the combination of qualitative and quantitative methods of research can provide a wider picture of the problem explored.

While most of the previous research was carried out and focused on hospital wards,^(246, 270, 281, 282, 284-286) the increasing numbers of the older population in care homes,⁽³⁸⁶⁾ the high rates of medication errors in this environment,^(196, 240, 275) and higher awareness of dysphagia in primary care,^(73, 76, 97, 159, 323, 402) provided an opportunity to explore the problems experienced by nurses in care homes with regards to the administration of medication to PWD. Following similar approaches to those of Kelly et al⁽²⁷²⁾ in hospital wards, this dissertation identified the need for improving the administration of medication to PWD in care homes and focused on establishing the elements needed to develop, evaluate and implement a pharmacist-led intervention in older PWD in care homes that improves the medicines management of dysphagia.

This final chapter will discuss:

- the barriers identified by this research in the medicines management of PWD,
- how this study provides good evidence for the need to improve administration of medication to PWD in care homes,
- the relevance of the findings of this study to the development of a complex intervention within the MRC guidelines framework.

6.1. Medicines management of PWD: barriers identified in this research

This section discusses the evidence provided by this thesis to current literature in identifying the problems faced by PWD in the management of medication.

The literature review, in chapter 2, indicated the complexity of the administration of medication to PWD. While probably other research fields rely on established research to which new papers can only contribute with updates and reviews, the process explored in this thesis is a combination of numerous elements such as flaws in knowledge, challenging multidisciplinary interactions and pharmaceutical technology. This confirms the complexity of any interventions identified as potentially suitable to enhance the care provided to PWD by nurses in care homes.

The results from the provision of a pharmacy-led service in the hospital wards, as described in chapter 3, found that, often, the administration of medication to PWD could be simplified by choosing more suitable formulations for the patients according to recommendations of current guidelines mentioned in chapter 1.^(215, 292, 312, 313) Nevertheless, it was also estimated that the cost of optimising those administrations by selecting more suitable formulations could be more than double (2.4) when using licensed medication and up to almost 10 times (9.9) when including ‘specials’ as part of the administration.

The obvious differences between the type of setting and population between primary and secondary care would not allow a statistical comparison in the cost of medication. However, the increase in the costs when recommending appropriate formulations for PWD in the care home environment were also noticeable (based on Drug Tariff 2013⁽³²²⁾ cost calculations). This is indicating that the cost involved in providing suitable licenced medication and special formulations is a likely common barrier to the administration of medicines to PWD both in primary and secondary care. Conversely, the limitations of the hospital study and the differences between populations, as previously mentioned, would only allow this discussion to suggest further research on whether the cost may impact the practitioners’ decisions when prescribing to PWD and whether the current practices observed in primary and secondary care are related.

When we consider the results from the observational drug rounds in chapter 5, the MAE rates due to inappropriate formulation choices in care homes were not only higher in PWD than in those without but also higher than the ones identified by the literature.⁽²⁷²⁾ Additionally, the PWD observed during the drug rounds were prescribed on average 3.8 drugs, which is not only 23.7% less than the observed patients without dysphagia (as discussed in section 5.5.5.) but it is also significantly lower than the average of eight medicines reported in the study by Barber in 2009.⁽²⁹⁹⁾ PWD in care homes may not be receiving all the required

medication possibly due to the reasons identified by other authors such as a limited life expectancy, the lack of a favourable risk-to-benefit ratio or a patient's refusal.⁽³⁹⁵⁾ Conversely, some of the participants of the interviews in the care homes (chapter 4) identified clearly a concern by the prescriber about prescribing liquid medicines:

“The doctor was not prepared to write this gentleman up for liquids.” (N2)

Other elements alongside the cost could be influencing the prescribers' decisions. Awareness of dysphagia has been a problem reflected in the literature^(131, 228) and throughout the research presented in this thesis. Not only the results of the interviews highlighted a lack of awareness of the condition, but also the observational drug rounds identified five patients who had not been diagnosed with dysphagia and chewed their tablets in 13 instances. Chewing medication is a sign of dysphagia and a natural mechanism often found in PWD, but these patients had not been assessed for any swallowing disorders.⁽⁴⁸⁾ Additionally, when signs of dysphagia were identified, the nurses did not feel competent to carry out swallowing assessments as they considered it someone else's 'remit'(section 4.4.2.2.4.). These facts show how the lack of awareness of dysphagia may also be accompanied by problems in the assessment of the swallowing function. If no assessment is possible, the presence or the severity of dysphagia cannot be determined.

As the literature suggests,^(159, 228) HCPs are not asking often enough about dysphagia. When considering the impact of this disorder in the treatment received by the patients, it would be sensible to suggest that routine checks of the swallowing function could be incorporated to the visits of the HCPs to the residents of care homes and reflected in the care plan or in the medication chart in order to communicate it to others care providers such as the pharmacist or SALTs.

After identifying PWD, other barriers have been outlined in this research. In accordance to Elliott & Liu (2012),⁽¹⁷⁴⁾ the 'nine Rs' should be followed by practitioners when prescribing and administering medication to patients. The interviews with nurses identified challenges between the doctors and the care home when requesting liquid formulations. For example, one of the participants commented:

“If you have a GP and I have seen them, who say right, just give these, but crush them, can you put that on the prescription please? No. Because they know that they will then be liable.” (N1)

This interaction already outlines the following concerns:

- is the patient getting the right medicine as other more suitable medications may need to be considered for that patient? (right medicine)
- is the patient going to receive this medication on time when considering that the administration is already presenting challenges to the nurses’ practice? (right time)
- is there an alternative formulation that avoids tampering? (right form)
- is the patient going to get the right dose after crushing tablet?
- if getting the right dose, is the medication going to deliver the right responses after being tampered with?
- can this advice be documented and appropriately authorised by the prescriber?
- is there a more suitable alternative route for this medication that obtains the same action?

With all of the nine Rs being questioned in one single interaction about medication with the doctor, the input of other HCPs like the pharmacist who is the only expert in formulation science, could be considered beneficial. This input was able to ease the interaction between prescribers and the nursing team, which indicates that the doctors are not always aware of the alternative formulations, doses, actions and responses of the medication prescribed in addition to the concerns on the cost of them. Conversely, it could possibly mean that the prescribers are aware of these concerns, but they expect the pharmacist to co-ordinate those changes as suggested by Dean in 2002⁽³⁶⁵⁾ in which case, the pharmacist should take a pro-active role in identifying these kind of interventions and producing the appropriate advice to the prescriber and the administrator. Beyond those suggestions, these interactions between HCPs also highlight the numerous and individualised elements that should be present when prescribing and administering medication to PWD. The implementation of interventions like the I-MAG is perceived by the nurses as a tool with the potential of providing recommendations that assure the right medication, dose, response, form, effect, documentation and action. Although I-MAGs were considered to maximise the time spent with the patient so the administration of medication could be done timely and efficiently in the hospital, further research is

required to identify whether the guides would have the same effect in the practice of the nurses in a different environment like the care home.

The next step on the management of dysphagia leads to the person administering medication. The services provided in the hospital wards offered an opportunity to explore the acceptability and the perceptions of the nurses on the implementation of a pharmacy intervention for nurses administering medication to PWD. The findings in the questionnaire completed by the nurses highlighted how they felt more confident in their practice when I-MAGs were in place, as quoted from one of the participant's comments, they "*knew the right way of administering each drug*". This lack of confidence in the administration of medication has been reflected in a lack of standardised practice throughout the studies reflected in this thesis and previous studies by Kelly and Wright.^(195, 228)

The interviews with nurses in care homes identified different practices between participants who revealed being hesitant on the most appropriate methods of administering medication as mentioned by one of the participants:

"It seems to be done differently by different people, so ah, I'm not sure." (N4)

The observational drug rounds in the care homes also demonstrated a lack of standardised practice which became obvious when interpreting the differences in the practices between nurses (reflected in the environment notes), but also when carrying out the rounds with nurses that had been selected by their work colleagues as being more 'confident' in their practice. The non-standardised practice may derive from variations in pharmaceutical knowledge and administration skills which was highlighted by the analysis of MAEs in the observational drug rounds and had also been identified in chapter 2.^(199, 223, 225) Time constraints, as identified by the literature,^(224, 225) were also one of the main concerns for nurses in the wards and in the care homes and it was an element to blame for the heavy workload of the nurses who often were the only qualified member of staff administering medication in the whole care home. The qualitative interviews also outlined other elements that, according to the participants, could affect the administration of medication to PWD such as the care home environment and the patient's health conditions. This was not only supported by literature,^(199, 223, 225) but also from the practices observed in the drug rounds, as described in the environment notes.

If all of the previously identified barriers to optimal medicines administration practices could be overcome, adherence to the treatment by the patient needs to be

explored as the complexity of dosing in the administration of medication to PWD and lack of understanding can provide barriers to adherence.⁽²³²⁾

6.2. Implications of this research in current practice

The barriers faced by HCPs in the administration of medication identified in the previous section provided an opportunity to explore the implementation of a pharmacy intervention for PWD. Whilst the I-MAG was implemented as a tool to improve the administration of medication by nurses to PWD, this research has shown how these guides have the potential of overcoming those challenges.

The presence of I-MAGs in the hospital wards increased the awareness of dysphagia within the nursing team and highlighted concepts of safety for the patients and the professionals on the hospital wards. The generation of I-MAGs by a pharmacist triggered a closer interaction between the pharmacist and other professionals on the wards such as the SALT, the consultants, the ward pharmacist and the nursing team. As a result, not only standardised practice was set in the service wards, but also a reflection of a holistic approach towards the care of PWD was reflected in the guides. The lack of pharmaceutical knowledge of the nurses was solved by the individualised recommendations reflected in I-MAGs, reducing the time constraints of the drug rounds, the risk of inappropriate tampering of medication and the workload of the nurses.

It is recognised that the practice seen in care homes derives from training within secondary care⁽¹⁹⁵⁾ and, therefore, similar problems in the nurses' practice were identified. However, the environment of the care homes uncovered additional challenges to those seen in hospital. The design of a model like the DIAMMOND allowed us to identify these additional challenges faced in the administration of medication to PWD in care homes and to estimate the impact of implementing a pharmacy intervention like I-MAGs in the care home. The theoretical acceptability of I-MAGs during the interviews in the care homes relied on the support of most of the participants but was faced by negative approaches towards change by some of the interviewees, which was not identified in the hospital. This contrast between hospital and care homes may be due to the isolated environment of the care homes as recognised by the literature⁽¹⁹⁹⁾ and by the interviews' participants. The isolation of the care home may be limiting the access to professional resources and it is seen as a disadvantage in the recruitment of skilled nurses for specialised care within the

care home. This difference between the hospital and care home environments may also reflect a limitation to the applicability of the model in secondary care.

Whilst the DIAMMOND model is untested and not-validated in practice yet, the observation of drug rounds provided an opportunity to test this model. Dysphagia awareness was placed as one of the four pillars in the DIAMMOND model obtained from the thematic analysis of the interviews, as the identification of PWD is essential to improve the way that residents receive their medication. The observations highlighted how the lack of awareness of dysphagia was also present in the practices seen in the care homes. Prescribers and nurses in primary care were not always aware of the presence of dysphagia and when identified, the communication between them was not optimal. Although the communication issues could be a reason for the identified inappropriate formulations being prescribed for PWD, further research is required to establish that association. Additionally, doctors possibly are not always aware of alternative formulations but pharmacists have an important role on suggesting suitable formulations for the patients as suggested in the interviews with the nurses. This is highlighting the need to explore the likelihood of a link between the communication of HCPs and the formulation choices made at the time of prescribing in primary care.

The time constraints and the lack of pharmaceutical knowledge identified during the drug rounds had an impact on the workload of the nurses observed in the care home and, therefore, the heavy workload of nurses was identified as one of the barriers in the administration of medication to PWD. The identification of this barrier was in agreement with the workload identified in the hospital and also with one of the elements that form part of the DIAMMOND model.

The observational drug rounds represented a strong step towards the validation of the DIAMMOND model. The time constraints during the drug rounds were reflected in high MAE rates related to time in both of our groups in agreement to the DIAMMOND. However, the likely lack of awareness of dysphagia from the prescriber and the administrators, and the inappropriate formulation choices made at the time of prescribing, were the most common cause of errors affecting the administration of medication to PWD in accordance to the same elements identified in the model.

The fourth main element of our model was the patient's health, which it may not have an identified impact on wrong administrations, but it may have affected the number of omissions made by the nurses when the residents were asleep, or when

the patients refused the medication prescribed. Indirectly influenced by the pharmaceutical knowledge of the nurses and other factors like the lack of highly qualified nursing staff available in the care homes, the workload of nurses in the care homes observed challenged the administration of medication to the residents and especially to those with dysphagia, leading to late, omitted and wrong dose administrations.

The research strongly suggests that while IMAGs may require further small amendments for the implementation in care homes (i.e. the incorporation of signatures of the members of the team to accept the recommendations, comments box and layout of the guide), they will be beneficial in this environment. I-MAGs will provide continuous professional development for the knowledge and skills of the nurses, and a holistic care of PWD due to the enhanced involvement of HCPs. This may reduce the isolating elements observed in the care home and, therefore, improve the care received by PWD.

6.3. Implications for the implementation of a pharmacy intervention for PWD in care homes

As from the beginning of this dissertation, the MRC guidelines for complex interventions have set the standpoint for all the studies presented. While the aim of this thesis is still to improve the care of PWD, the focus of this thesis is to develop a pharmacist-led intervention in care homes where community pharmacists can provide individualised administration guidance for nurses administering medication to PWD. The literature in chapter 1 already outlined the complexity of this process due to the numerous components affecting the figurate delivery of such an intervention and the qualitative and quantitative nature of them.

The implementation of a framework to develop our intervention is essential in order to evaluate the scope of the process.⁽¹⁾ As indicated in chapter 1, the framework presented by Saunders and colleagues⁽¹⁶⁾ offers a systematic approach to assess the implementation of a targeted health promotion intervention to aid in understanding the relationship between specific programme elements and programme outcomes (Table 1).

It seems, therefore, sensible to commence this section with a discussion of how the research presented has contributed to the development of such intervention, as well as to outline the elements that may have been identified but not explored and that will be the subject of future research.

Theoretical development

An in-depth review of the literature available was presented in chapter 2. While the literature related to the medicine management of PWD is limited, this review aimed to identify most of the components that may influence our likely intervention. The perceptions of nurses and carers, explored through semi-structured interviews, as presented in chapter 4, were used to develop a theoretical model that may reflect which elements are affected by implementing changes in the routines of care homes as a consequence of the intervention. This model was supported not only by a thorough and strict thematic analysis but also by previous literature on the interaction of some of the components that form the DIAMMOND model.

Testing the I-MAG service in the hospital setting using traditional randomised controlled methodology was found to be unfeasible due to the majority of patients only requiring the intervention for a small number of days and the resultant number of patients suitable for randomisation being too small to justify the cost of the research. The completion of the questionnaires by the patients highlighted the strengths of this choice of outcomes, probably due to the fact that the questionnaires were exploring issues in the medicines management that were very specific to PWD, as complex interventions may work best if they are tailored to local contexts rather than completely standardised.⁽⁶⁾ However, these outcome measures (adherence, patient's satisfaction, health services use and quality of life) may need to be adjusted to the care home environment where patients do not always have mental capacity to provide this information.

While the literature review identified criteria to determine the appropriateness of prescribing, and this is suitable tool for the UK, the results of the observation of drug rounds described in chapter 5 highlighted the association between aspiration (or signs of aspiration) and inappropriate prescribing and, therefore, this could be used in future research as an outcome measure of the changes in the prescribing due to our intervention. Differences in the MAE rate, as identified in chapter 5, could also be utilised as an outcome measure to assess the impact of training nurses in the administration of medication to PWD.

Feasibility and piloting

The DIAMMOND model offers a theoretical framing of the elements affected by an intervention. However, the validity of this model had not been tested before and a practical validation before the implementation of the intervention was more suitable for further development of the model prior to the intervention. The

observational drug rounds served as an assessment of the feasibility of our model in practice, as previously described.

The pilot study of I-MAGs estimated the recruitment of patients at the time of discharge without considering other elements such as the consent to be approached by a researcher, the limited access to the wards experienced by the researchers or the extensive impact of the lack of mental capacity on many of the patients at the time of being approached for recruitment. Although the design of the intervention should include an estimation of the sample size, it could be beneficial to re-estimate the recruitment rate once the sites for the intervention have been selected as part of the cycle between development and feasibility prior to, or as part of, a piloting phase.

The studies in this dissertation also explored the recruitment of nurse participants. While the recruitment rates of nurses in care homes was considerably lower when approached to participate in the interviews described in chapter 4, face-to-face recruitment between the researcher and the nurses in the ward for the evaluation of the I-MAG service found drastically higher rates. Equally, the direct involvement of a doctor in the recruitment of care homes for the observational drug rounds, mentioned in chapter 5, increased the participation of the care homes despite this then being compromised by a lower participation of the nurses as individuals. It could be argued that other factors such as the close environment in the hospital ward between HCPs, or that the care home managers personally knew the doctors, are the reasons for the increased recruitment rates. In summary, when recruiting patients or HCPs, the standpoint of the researcher and the participants is of crucial relevance to the recruitment rates.

Evaluation of the intervention

The questionnaire designed for the evaluation of the I-MAG service was an example of alternative outcome measures to those expected by the completion of the patients' questionnaires. While patients' outcomes are important, the pilot study had the potential to study other outcomes such as the changes in the nurses' practice, or the improvement in their knowledge or increase in confidence like that highlighted by the evaluation of the service. The findings from the responses of quantitative and qualitative questions in the evaluation provided a wider view of the concerns of the nurses and the value of the components assessed in the questionnaire.

6.4. Limitations and strengths

One of the strengths of this thesis is the combination of qualitative and quantitative methods used throughout the studies presented. Where quantitative data were explored, such as in the questionnaire or the drug rounds, the addition of qualitative components to the I-MAG service questionnaire and environment notes during the observational drug rounds added a contextual element to the analysis of the data that helped understand the environment of the practice of the nurses and carers in charge of the administration of medication to PWD. Another strength is that each study presented was analysed and evaluated before moving onto the next study in order to assure the exploration of more components that defined the design of our complex intervention.

Recruitment of participants has often been a limitation seen in the research presented in this thesis. During the I-MAG service study, the recruitment of patients was extremely low due to the improvement of dysphagia while in the ward and the difficulties experienced when trying to approach the patients. Conversely, the recruitment of participants (HCPs) for the evaluation of the I-MAG service was relatively high, but still excluded the 35% of the nurses involved during the delivery of the process. During the recruitment of care homes for the semi-structured interviews, the response rate of the care homes approached was unexpectedly low and although the sample size obtained was appropriate for our study, the results may not necessarily represent the insights of others within the same region. In addition to this, the interviews were only based in Norfolk and it is possible that the results could have benefited from exploring the insights of nurses and carers in other areas of the country. Although, demographically, North Yorkshire and Norfolk could be comparable, the results of the observational drug rounds may not necessarily be extrapolated to practice of the nurses interviewed in care homes in Norfolk. However, the methodology and the results identified in these entire studies offer strong grounds for larger-scale studies where the limiting factors discussed can be avoided and, therefore, these studies represent a contribution to the feasibility and piloting phase of the development of a complex intervention.

Time and funding have also been close-limiting factors, for further development of the intervention outlined in this thesis. Complex interventions require the exploration of numerous components and often the costs and the time involved on the development of those processes were not feasible within the framework of a

PhD term. However, these can also be seen as a strength of this research due to the fact that the studies presented have shown the importance of identifying barriers in the cost, time, interaction between HCPs and recruitment of participants that will be reflected in the design of future research to develop a pharmacy-led intervention for PWD in care homes.

7. Conclusions and further research

The research carried out in this thesis has made several contributions to the current evidence on the medicines management of PWD and to the development of a pharmacist intervention for PWD in care homes.

The pilot study demonstrated that I-MAGs were acceptable to nurses in hospitals who were positive regarding their introduction and use with the majority asking for the service to be continued. Stated benefits associated with I-MAGs were increased confidence when administering medicines, enhancing standardisation of care and improving the safety of administrations.

It was also identified that it is not possible in the hospital setting to test the hypothesis that individualised medication administration guides are a cost-effective intervention to improve the care of patients with dysphagia. Due to the limited available population, the significant attrition rate and the fact that, for many patients, I-MAGs would only be in place for a few days, it was hypothesised that care homes may be a more suitable location to test such a hypothesis.

The proposed outcome measures for the hospital-based pilot study included patient self-reported adherence, quality of life and patient satisfaction. Due to the loss of patient autonomy in care homes and the reduction in mental capacity frequently seen in residents, self-reported outcomes based on perception and ability to manage one's own medicines may not be appropriate in this setting. Literature^(39, 90) suggests that incidence of chest infection, hospitalisation and mortality may be more appropriate outcome measures in the care home environment and this may apply to our intervention when considering the impact of I-MAGs.

The hospital I-MAG service was delivered by a pharmacist trained in swallowing difficulties⁽¹⁴⁹⁾ with practice experience in primary and secondary care. The community pharmacist was identified as the most suitable professional alternative for providing an I-MAG service to care homes, but further research is required to establish the appropriate training necessary for them to provide a similar service.

The research has demonstrated that there is a significant population with medicines-related dysphagia in the care home setting, and this may be an underestimate due to the lack of routine assessment for the condition. The recruitment rate in this population may be affected by different elements to those identified in the hospital and, therefore, would need to be determined prior to any future definitive study.

The practice seen in the administration of medication by nurses to PWD in care homes is often more challenging than the one observed in hospital and it could benefit from interventions that standardise practice, enhance the clinical knowledge and skills of the nurses, and improves the communication of the HCPs involved in the care of PWD.

Factors which were found to affect medicines administration in the care home environment were time constraints, lack of dysphagia awareness, the formulation choices made at the time of prescribing, and the patients' health conditions.

The DIAMMOND model outlines other elements involved in the administration of medication to PWD and provides an overview of the likely interaction between those elements when implementing changes in the practice of the nurses in care homes. The model offers a strong theoretical background that may be useful in the design of research studies on the medicines management of dysphagia in the care home environment.

The observation of the MAE in care homes provided information about the cause of those errors and an opportunity to validate the DIAMMOND model. The provision of I-MAGs is an example of an intervention that can affect the practice of the nurses with a potential effect on the MAE rate. Therefore, changes in the MAE rates can be recommended as an outcome measure for future research in PWD, but the impact of the observer in those rates needs to be considered.

The medicines management of dysphagia requires a multidisciplinary approach and often, the practices of the HCPs involved in the care of PWD are challenged by the cost, awareness and availability of suitable formulations of medicines. The pharmacist as the HCP with highest expertise in medication can play a crucial role in the training of nurses and carers, by providing advice to the prescribers and, when possible, advising PWD on the importance of their treatment. The care home environment offers an opportunity to extend the role of the pharmacist improving the practice of HCPs and the care received by PWD.

This research also suggests that in order to improve the administration of medication to PWD, local policies and HCPs will need to focus on:

- re-assessing the methods of identifying and diagnosing dysphagia in the care home,
- estimating the individual needs of each patient when administering medication,
- enhancing the pharmaceutical knowledge and skills of nurses administering medication,
- increasing the involvement of the community pharmacist in the care home,
- providing advice to the prescriber on suitable formulation choices.

The key conclusions of this thesis, in addition to those mentioned in previous chapters, are that:

- the provision of I-MAGs by a specialised pharmacist in the hospital wards increases the nurses' confidence in their practice and the safety of the administrations of medication to PWD,
- the medicine management for PWD requires a multidisciplinary approach between nurses, pharmacists, doctors, SALTs and dieticians and, consequently, PWD could benefit from interventions that overcome the barriers between HCPs observed in current practice,
- the lack of awareness of dysphagia, the interaction between HCPs, the lack of standardised practice and pharmaceutical knowledge in the nurses' practice, and the time constraints experienced by nurses are the main barriers challenging the medicines management of PWD as perceived by nurses,
- the DIAMMOND provides a theoretical model to explore the effects of implementing a medicines management intervention for PWD in care homes,
- appropriate formulations are often not being prescribed for PWD, but the likely association with cost, lack of awareness of dysphagia or lack of knowledge on available formulations by the prescriber has not yet been established,
- the gaps in the pharmaceutical knowledge and skills of the nurses in care homes are some of the causes for the increased MAE rates in PWD in care homes when compared to those without,
- the implementation of I-MAGs in care homes could potentially increase the awareness of dysphagia, enhance the interaction between HCPs and promote standardised practice. This may increase the nurses' confidence in their clinical practice, reduce the time pressure in the care home and reduce errors.

As suggested by Campbell,⁽⁴⁾ developing complex interventions is not a linear process and it requires evaluation of new elements identified during the process. This thesis outlines several suggestions for future research that would contribute to enhance the care received by PWD and to develop additional components for the implementation of I-MAGs in care homes. Therefore, further research is needed on:

- exploring the feasibility of the provision of I-MAGs in care homes by community pharmacists ,
- exploring the perceptions of other HCPs on the implementation of I-MAGs in care homes,
- identifying the applicability of the DIAMMOND model and the impact on the practices of the HCPs of the implementation of novel interventions in the care home setting,
- exploring if any improvements in patients' health can be achieved and justified at the cost of the service in primary and secondary care,
- exploring the practicality of a training package designed by a pharmacist on the administration of medication to PWD for its use in care homes and its impact on the MAE rates,
- determining qualitative and quantitative outcome measures that may reflect significant changes in residents' health,
- the measures and records of competency for nurses on the administration of medication to PWD in primary and secondary care,
- identifying additional reasons that affect prescribers' decisions when choosing a formulation for PWD in primary and secondary care,
- identifying the link between formulation tampering and appropriate formulation selection and its impact on hospital admission rates.

8. Publications and conferences

8.1. Journal publications

Serrano Santos JM, Poland F, Kelly J, Wright D. Drug administration guides in dysphagia. *Nursing Times*. 2012;108(21):15-7.

8.2. Conferences publications

Royal Pharmaceutical Society Conference, 8/9th September, 2013, Poster presentation: Nurses' views on the implementation of Individualised Medication Administration Guides in patients with dysphagia in care homes. Abstract publication:

Dysphagia Research Society (DRS) 21st annual meeting, 14-16th March, 2013, Seattle, US Research Poster: Inappropriate formulation choices in the administration of medication to elderly patients with dysphagia in nursing homes

Health Services Research and Pharmacy Practice Conference, 23rd/24th April, 2012 Cork, Ireland. Oral presentation: Implementation of Individualised Medication Administration Guides for patients with dysphagia: results from a pilot controlled trial.

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10. Appendices

Appendix 1: Example of I-MAG

Patient's Name:	xxxxxx xxxxxxxx	Hospital Number:	1234567	
Signature		Date of IMAG:	05/08/2011	
Individualised Medicine Administration Guide (I-MAG) for Patients with Swallowing Difficulties				

I-MAGs work alongside the patient's drug charts. Ensure that you administer medicines from the patients Medicine Chart and do not rely solely on the I-MAG.

Other details about Dysphagia:

Patient chews tablets

Consistency able to swallow	Solids:	Liquids:	Vol. of Fluids used with medication
	Soft Mashable Diet	Level A (2 scoops T&E/200mL)	

Medicine prescribed:	Frequency	Advice on Administering
Concentrated Thick and Easy Mix for level A (prepare before administering medication)		Use two scoops of T&E in 100mls of Water and use this as Concentrated mix for administering drugs. (when mixed with the same amount of water carrying the tablets, it will form a Level A consistency suspension)
ASPIRIN 75mg dispersible tablet (Regular Medication)	in the morning	Disperse the tablet in 10mls of water in a medicine cup. Add 10mls of the concentrated Mix of T&E prepared before in the pot with the drug, mix it and administer to the patient immediately. Add another 5mls of the concentrated T&E Master mix and 5 ml of water to the cup, mix with any possible trace left in the cup and administer to the patient
DIPYRIDAMOLE (Persantin) 200mg MR Capsules (Regular Medication)	twice a day	If patient cannot swallow the capsule whole, recommend prescriber to prescribe liquid formulation. When giving liquid formulation, use 5mls spoon and administer to the patient immediately

Patient's Name:	xxxx xxxx	Hospital Number:	1234567
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IMAG Number: 24

If you have any queries call the Dysphagia Pharmacist:
Manuel Serrano (Switchboard / 01603 000000)
Pager 0700000000 (outside call)

Page 1 of 2

Medicine prescribed:	Frequency	Advice on Administering	
FUROSEMIDE 40mg/5mls Liquid	40mg once a day	Furosemide tablets shouldn't be crushed so liquid formulation is required while swallowing difficulties persists. When giving liquid formulation, use 5mls spoon and administer to the patient immediately	
PARACETAMOL 2x500mg Soluble tablets (When Required)	four times a day	When administered orally: Dissolve the tablets in 20mls of water. Once dissolved, add 20mls of the concentrated T&E mix prepared before and administer to the patient immediately Add another 5mls of the concentrated T&E Master mix and 5 mls of water to the cup, mix with any possible trace left in the cup and administer to the patient	
SENNA Syrup 7.5 mg/5 mL (when required)	5ml at night	Shake the bottle and administer 5mls to the patient using a 5ml spoon	
Patient's Name:	xxxx xxxx	Hospital Number:	1234567
IMAG Number: 24	If you have any queries call the Dysphagia Pharmacist: Manuel Serrano (Switchboard / 01603 000000) Pager 07000000 (outside call)		Page 2 of 2

Introduction Session to

“Will an individualised service improve medicine administration to adults with dysphagia?”

A pilot Study

We would like to invite the **Healthcare team** to a quick introduction to our clinical study on dysphagia that will be carried out in (**Participating wards' names**).

The 20 minutes introduction will be on room 22 near Guist Ward on the following dates:

- 27th of July at 13:00
- 27th of July at 15:00
- 3rd of August at 13:30
- 3rd of August at 14:30

Lunch will be provided

If you are not able to attend but you are interested in knowing more about this study we can arrange further sessions.

Please, fill in an invitation response and leave it in this envelope or contact Manuel at jmanserrano@hotmail.com or 07838198822.

Thank you

Jenny Kelly (Chief Investigator) J.Kelly@uea.ac.uk

Manuel Serrano (Dysphagia Pharmacist) jmanserrano@hotmail.com

Will an individualised service improve medicine administration to adults with dysphagia?

Introduction session

We would like some feedback from you:

Being 1 the most negative score and 10 the most positive

How would you score...?

- **The flyers displayed**
- **The time of the introduction.....**
- **The facilitator/s.....**
- **The presentation.....**
- **The subject of the study.....**
- **The location of the room.....**
- **The snacks provided.....**

Please add any comments:

.....

.....

.....

“Will an individualized service improve medicine administration to adults with dysphagia - a pilot study?”

Important changes are going to happen in the way medication is administered to patients with Swallowing Difficulties.

Please attend to one of the following training sessions on any of these locations:

- **21st of September: (participating ward) Staff room**
 - o 12pm
 - o 1pm
 - o 2pm
 - o 3pm
- **30th of September : (participating ward) Staff room**
 - o 12pm
 - o 1pm
 - o 2pm
 - o 3pm

It is essential that all and only the Staff Nurses from (participating ward) and (participating ward) attend to this training. If you are not able to attend or need more information, please contact the sister of your ward or Manuel Serrano (m.serrano-santos@uea.ac.uk) ,

tel: 07838198822 for further arrangements.

Food will be provided in all the sessions.

Will an individualised service improve medicine administration to adults with dysphagia?

Training session

We would like some feedback from you:

Being 1 the most negative score and 10 the most positive

How would you score...?

- The flyers displayed
- The time of the introduction.....
- The facilitator/s.....
- The presentation.....
- The materials provided.....
- The location of the room.....
- The snacks provided.....

Please add any comments:

.....

.....

.....

Appendix 6: Consent To Approach (CTA) form

Norfolk and Norwich University Hospitals 
NHS Foundation Trust



The patient

Or next of kin

has given verbal/written consent / assent to a clinician in the ward (please initial the patient's label) to be approached by a Research Assistant of the study “Will an individualised service improve medicine administration to adults with dysphagia?”

Please put this sheet upside down in the Dysphagia Pharmacist's tray on the ward reception desk

**“Will an individualised service improve medicine administration to adults with dysphagia?
– a pilot study “**

If you have any queries call the Dysphagia Pharmacist:
Manuel Serrano (Switchboard / 01603 286286)
Pager 07623606508 (outside call)

Appendix 7: Patient Information Sheet (Hospital Study)

Project Title: Will an individualised service improve medicine administration to adults with dysphagia?

Name of Researcher: Jenny Kelly (j.kelly@uea.ac.uk)

**INSTITUTE OF HEALTH
Teaching Centre**

Queen Elizabeth Hospital
King's Lynn
Norfolk
PE30 4ET

Telephone
01553 613751
Fax
01553 613723

Invitation

You are invited to take part in a research study. Before you decide to do so it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

Patients with swallowing difficulties (dysphagia) and / or being fed through a tube sometimes experience problems taking their medicines. This study is designed to try and find ways of reducing these problems. It aims to evaluate the effectiveness of giving nurses written information on how best to give medicines to patients with swallowing difficulties. These guides will be introduced on two wards in the hospital by a pharmacist trained in improving how medicines are given to patients with swallowing difficulties.

Why have I been chosen?

You have been chosen to take part in this study because you have swallowing difficulties and take oral medication.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you are asked to read, complete and return the two copies of the enclosed Consent form to the research assistant. The research assistant will also sign them, and will return one to you to keep. You are still free to withdraw at any time and without

giving a reason. A decision to withdraw at any time will not affect the standard of care you receive in anyway.

If you wish to obtain independent information or advice about your rights regarding being involved in this research study you can do so by contacting your local NHS Patient Advisory Liaison Service situated at this hospital.

What will my participation involve?

If you are happy to take part in this study, you will be asked to complete four brief questionnaires before you leave hospital. The research assistant will help you to complete them if you wish. Six weeks and six months after you have been discharged from hospital the research assistant will contact you again and ask you to complete the same four questionnaires that you completed in hospital. If you need help with completing them she will help you. Together with the research assistant I would like to have permission to look at your medical notes to identify if you have had any emergency admissions to hospital during the study period.

What are the possible benefits of taking part in this research?

There are unlikely to be any immediate benefits for you in taking part. However, your participation will help to evaluate the use of a new document which could improve medicine administration to patients with swallowing difficulties in the future.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm that you might suffer will be addressed. If you have any concerns please telephone Dr David Wright, who is a senior member of staff within the School of Pharmacy at the University of East Anglia on 01603 592042.

What happens after I have returned the questionnaires?

Your answers to the questionnaires, and those of other patients, will be analysed by the researcher.

Will my taking part in the study be kept confidential?

Yes. All information about your participation will be kept confidential in accordance with the Data Protection Act 1998. Thus all the information about you will be coded so that you cannot be identified from it. All personal information and your consent form will be stored by the researcher in a locked filing cabinet in an office in the School of Pharmacy at the University of East Anglia, Norwich. These will only be viewed by the Chief Instigator and the research assistant. Only the encrypted data will be analysed by the research team and this will be stored on a password-protected personal laptop computer, used solely for the purpose of research, and kept at the Chief Investigator's home. All confidential documentation will be destroyed in five years' time.

What will happen to the results of the research?

The results of the study will be written up as part of a doctoral thesis, a copy of which will be kept in the library of the University of East Anglia. They will also be published in a nursing or pharmaceutical journal to make other professionals aware of the value of the special guides to administering medicines to patients with swallowing difficulties that this project is developing and testing out.

Who is organising and funding the research?

The research is being organised through the School of Pharmacy at the University of East Anglia. The project is funded by the National Institute for Health Research for Patient Benefit Scheme.

Who has reviewed the study?

This study has been reviewed and agreed by the East Norfolk and Waveney Research Governance Committee and the Essex 2 Research Ethics Committee.

Contact details:

If you would like further information about this study you can contact Jenny Kelly on 01553 613613, or at j.kelly@uea.ac.uk, or UEA School of Nursing and Midwifery, Queen Elizabeth Hospital, King's Lynn, Norfolk, PE30 4ET

*Thank you for taking the time to consider
becoming involved in this project*

Appendix 8: Consultee Information Sheet (Hospital Study)

Project Title: Will an individualised service improve medicine administration to adults with dysphagia?

Name of Researcher: Jenny Kelly (j.kelly@uea.ac.uk)

**INSTITUTE OF HEALTH
Teaching Centre**

Queen Elizabeth Hospital
King's Lynn
Norfolk
PE30 4ET

Telephone
01553 613751
Fax
01553 613723

Invitation

We would like to invite (name) to take part in a research study. However, the clinical team do not feel that s/he is able to give informed consent to take part in this study because of his / her current mental state. The Mental Capacity Act 2005 allows a 'personal consultee' to be identified who is willing to be consulted about whether a person would want to participate in a study. We would like you to consider being the consultee for (name). Before you decide that you would like to act as consultee it is important for you to understand why the research is being done, what it will involve, and what your role as consultee will be. Please take time to read the following information carefully.

What is the purpose of the study?

Patients with swallowing difficulties (dysphagia) and / or being fed through a tube sometimes experience problems taking their medicines. This study is designed to try and find ways of reducing these problems. It aims to evaluate the effectiveness of giving nurses written information on how best to give medicines to patients with swallowing difficulties. These guides will be introduced on two wards in the hospital by a pharmacist trained in improving how medicines are given to patients with swallowing difficulties.

Why have I been approached?

We want to recruit patients with swallowing difficulties who take oral medication. You care for such a person or are interested in his or her welfare other than in a professional capacity or because you are paid to do so. You are therefore by law able to act as a personal consultee and we would like you to take on this role for (name).

What does the role of consultee involve?

If you decide that the participant should take part in the research you will be asked to complete the four brief questionnaires that the participant would have been asked to complete prior to leaving hospital. The research assistant will help you to complete them if you wish. You will be offered a diary to record health events for the participant and six weeks and six months after the participant has been discharged from hospital the research assistant will contact you and ask you to complete the same four questionnaires again. If you need help with completing them he / she will help you. Together with the research assistant I would like to have permission to look at the participant's medical notes to identify if they have had any emergency admissions to hospital during the study period.

If you wish to obtain independent information or advice about your rights in acting as a personal consultee and being involved in this research study you can do so by contacting your local NHS Patient Advisory Liaison Service, situated at this hospital. The research assistant will offer you a copy of the Department of Health's booklet 'Making decisions: A guide for family, friends and other unpaid carers, which includes a section on research. There is also a statutory Independent Mental Capacity Advocate (IMCA) service which offers assistance to people lacking mental capacity. The research assistant will discuss this service with you and can provide you with a copy of the booklet 'Making decisions: the Independent Mental Capacity Advocate (IMCA) Service' if you wish.

Do I have to be a personal consultee?

No the role is totally voluntary and you are under no obligation to take it on. If you do agree to act as personal consultee and then change your mind you can withdraw from the role at any time and this will not be detrimental to you in any way, or to the person you care for.

What are the possible benefits of taking part in this research?

There are unlikely to be any immediate benefits in taking part. However, your involvement and that of the participant's will help to evaluate the use of a new document which could improve medicine administration to patients with swallowing difficulties in the future.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm that you or the participant might suffer will be addressed. If you have any concerns please telephone Dr David Wright, who is a senior member of staff within the School of Pharmacy at the University of East Anglia, on 01603 592042.

What happens after we have returned the questionnaires?

The information from the questionnaires that you completed and those of other patients will be analysed by the researcher.

Will my involvement in the study and that of the person I care for be kept confidential?

Yes. All information about your involvement and that of the person you care for will be kept confidential in accordance with the Data Protection Act 1998. Thus all the information about the participant will be coded so that they cannot be identified from it. All personal information and the form you will be asked to sign acknowledge the information you have received will be stored by the researcher in a locked filing cabinet in an office in the School of Pharmacy at the University of East Anglia, Norwich. These will only be viewed by the Chief Instigator and the research assistant. Only the encrypted data will be analysed by the research team and this will be stored on a password-protected personal laptop computer, used solely for the purpose of research, and kept at the Chief Investigator's home. All confidential documentation will be destroyed in five years' time.

What will happen to the results of the research?

The results of the study will be written up as part of a doctoral thesis, a copy of which will be kept in the library of the University of East Anglia. They will also be published in a nursing or pharmaceutical journal to make other professionals aware of the value of the special guides to administering medicines to patients with swallowing difficulties that this project is developing and testing out.

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Contact details:

If you would like further information about this study you can contact Jenny Kelly on 01553 613613, or at j.kelly@uea.ac.uk, or UEA School of Nursing and Midwifery, Queen Elizabeth Hospital, King's Lynn, Norfolk, PE30 4ET

Thank you for taking the time to consider

Becoming involved in this project

Appendix 9: Patient consent form (Hospital Study)

Patient Identification Number:



Project Title: Will an individualised service improve medicine administration to adults with dysphagia?

INSTITUTE OF HEALTH Teaching Centre
 Queen Elizabeth Hospital
 King's Lynn
 Norfolk
 PE30 4ET

Patient Consent Form

Telephone
 01553 613751
Fax
 01553 613723

Name of Researcher: Jenny Kelly (j.kelly@uea.ac.uk)

- I confirm that I have read and understand the information sheet
- I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical or legal rights being affected.
- I agree to take part in the above study.
- I agree to allow access to my medical records for the purpose of the study.
- I would like to be sent a copy of the research findings.

Name of personal consultee	Date	Signature
Name of research assistant	Date	Signature

When completed, 1 copy for patient; 1 copy for researcher file

Appendix 10: Consultee consent form (Hospital Study)

Patient Identification Number:



Project Title: Will an individualised service improve medicine administration to adults with dysphagia?

**INSTITUTE OF HEALTH
Teaching Centre**
Queen Elizabeth Hospital
King's Lynn
Norfolk
PE30 4ET

Telephone
01553 613751
Fax
01553 613723

Personal Consultee's Checklist

Name of Researcher: Jenny Kelly (j.kelly@uea.ac.uk)

Please tick box when completed

Explanation of why they have been approached.

Discussion of the role of personal consultee, that acting as a consultee is completely voluntary, and that they are free to withdraw at any time, without giving any reason, without their medical or legal rights being affected.

Discussion of what the study involves and what their involvement in it would entail.

Discussion on whether the participant should take part in the study and if in their opinion the participant would have wanted to be involved if they had mental capacity to give informed consent.

Offered a copy of Department of Health's booklet 'Making decisions: A guide for family, friends and other unpaid carers' and 'Making decisions: the Independent Mental Capacity Advocate (IMCA) Service'.

Decision that patient SHOULD / SHOULD NOT (please circle) take part in the study.

Whether a copy of the research findings is required. YES / NO (please circle)

Name of personal consultee	Date	Signature
Name of research assistant	Date	Signature

Appendix 11: Health Service Use Questionnaire

Project Title: Will an individualised service improve medicine administration to adults with dysphagia?



Patient Code:

INSTITUTE OF HEALTH Teaching Centre
 Queen Elizabeth Hospital
 King's Lynn
 Norfolk
 PE30 4ET

Telephone
 01553 613751
Fax
 01553 613723

Health Services Use Questionnaire

We would like to monitor your use of the health and social care services, and how this changes over the period of this study. We would therefore be grateful if you could complete the following questions.

1. During the **4 weeks** prior to this admission have you seen, or been visited by, a health professional?

Yes No

If Yes, please complete the table below. If No, please go to question 2.

	Number of visits in the previous 4 weeks	Number of visits related to your swallowing problems	Where were you most commonly seen? (1= GP clinic, 2 = Home; 3= Hospital)
Physiotherapist			
Occupational therapist			
Social worker			

Speech and language therapist			
Nurse			
GP			
Pharmacist			
.....			

Q2 Have you been admitted to a residential / nursing home in the **4 weeks** prior to this admission? [If 'NO', please put '00' in the boxes]

How many times?

--	--

Name of home

Q3 Have you attended a day centre in the **4 weeks** prior to this admission? [If 'NO', answer '00']

How many times **per week**?

--	--

Q5 Have you had a home help or community care assistant in the **4 weeks** prior to this admission? [If 'NO', answer '00']

How many times **per week**?

--	--

How long approximately in **minutes** do they stay?

--	--	--

Appendix 12: Screenshot of database with individualised recommendations

	A	B	C	D	E	F
1	Drug	Medicine prescribed	Strength	Frequency	Advice on Administering ON	Advice on Administering OFF
260	84	CLOPIDOGREL	75mg tablet (Regular Medication)	once a day		Crush the tablet and put it in a medicine pot. Rinse the crusher with 10mls of water and use those 10mls to disperse the tablet in the pot. Add 10mls of the Master Mix of T&E in the pot with the drug, mix it and administer to the patient immediately. Add another 5mls of the concentrated T&E Master mix and 5 mls of water to the cup, mix with any possible trace left in the cup and administer to the patient
261	84	CLOPIDOGREL	75mg tablet (Regular Medication)	once a day		Crush the tablet and put it in a medicine pot. Rinse the crusher with 10mls of water and use those 10mls to disperse the tablet in the pot and administer to the patient immediately. Add 10mls of water in the same pot and administer to the patient immediately.
262	84	CLOPIDOGREL	75mg tablet (Regular Medication)	once a day		Crush the tablet and put it in a medicine pot. Rinse the crusher with 10mls of water and use those 10mls to disperse the tablet in the pot and administer to the patient immediately. Add 10mls of water in the same pot and administer to the patient immediately.
263	84	CLOPIDOGREL	75mg tablet (Regular Medication)	once a day		Crush the tablet and put it in a medicine pot making sure that no traces are left in the crusher. Add 20mls of the Level B T&E Suspension and give to the patient immediately. Add another 10mls of Level B T&E Suspension in the same pot, mix with any possible traces of the drug, and give to the patient.
	84	CLOPIDOGREL	75mg tablet (Regular Medication)	once a day	Crush the tablet and put it in a medicine pot. Rinse the crusher with 10mls of water and use those 10mls to disperse the tablet in the pot. Shaking may be necessary. Load the syringe with that dispersion and administer as follows. 1. Stop enteral feed. 2. Flush enteral feeding tube with the 20mls of water. 3. Load the syringe with the dispersion prepared. 4. Add 10mls of water to the medicine pot, shake it and re-load the syringe with it. Shake the syringe if required	

Service Evaluation: the use of Individualised Medication Administration Guides (I-MAGs)



- This questionnaire is designed to take less than 10 minutes to complete.
- Please tick only one box per answer
- Complete all the sections unless otherwise indicated.
- Return in the stamped addresses envelope provided

Patient's Name: xxxxx xxxxx	Hospital Number: xxxxx	
Signature	Date of IMAG: 16/11/2020	

Individualised Medication Administration Guide (I-MAG) for Patients with Enteral Feeding Tubes

I-MAGs work alongside the patient's drug charts. Ensure that you administer medicines from the patient's Medicine Chart and do not rely solely on the I-MAG.

General management of enteral tube

1. Stop the feed prior to medicine administration and flush tube with 30ml of water.
2. Use purple 20ml enteral syringes to give all medicines. Depress plunger gently to avoid damaging the tube.
3. Prepare each medicine separately, do not mix medicines unless advised to.
4. Rose tablet crusher / containers and draw up water into syringe and flush down tube to ensure all medicine is given.
5. If more than one medicine to be administered flush between drugs with at least 10mls of water.
6. Flush tube with at least 30ml of water following administration of last drug.
7. Restart feed

Vol. of fluids used with medication 30

Medicine prescribed	Frequency	Advice on Administering
ALLORUNOL 300mg	once a day	Dispense tablets in 50 ml of water immediately prior to administration. Administer after food. 1. Stop enteral feed. 2. Flush enteral feeding tube with the recommended volume of water. 3. Place tablet in barrel of an appropriate sized syringe. 4. Draw 10mls of water into syringe and allow tablet to dissolve, shaking if required. 5. Attach connector to syringe if necessary. 6. Flush medication down feeding tube. 7. Draw another 10mls of water into the oral syringe and also flush this via feeding tube (this will rinse syringe and ensure total dose is administered). 8. Finally flush with the recommended volume of water. 9. Re-start the feed, unless a prolonged break is required. Alternatively at step 3, place tablet into medicine pot and add 20mls of water and allow tablet to dissolve. Draw this into syringe with appropriate adaptor for tube connector. Ensure the measure is read and this rinsing water administered also to ensure total dose is given.

Patient's Name: xxxxx xxxxx Hospital Number: xxxxx

IMAG Number: 26 If you have any queries please contact the Dysphagia Pharmacist Page 1 of 2

Preparation

1. Did you attend to the training sessions prior to the commencement of the study?

Yes No Unsure

If you answered NO or UNSURE, please go to question 6.

2. "The training session adequately prepared me for using the I-MAGs on the ward"

Strongly agree Agree Undecided Disagree Strongly disagree

3. "The time allocated for the training sessions was appropriate"

Strongly agree Agree Undecided Disagree Strongly disagree

4. "I found the handout of the session helpful"

Strongly agree Agree Undecided Disagree Strongly disagree

5. How do you think the session could improve?

Presentation

6. Have you ever seen I-MAGs in the ward?

Yes No

If your answer is NO, please go to question 23

7. Do you think that the Medication Chart is the right location for the I-MAG?

Yes No

If your answer was NO, please indicate where you would think it should be situated:

8. What layout do you think it is more suitable?

Portrait Landscape 

9. Was the font in the text of the I-MAG easy to read?

Very easy Easy Undecided Hard Very hard

10. What would you suggest changing to improve the presentation of the I-MAGs?

Content

20. "The instructions in the I-MAG were easy to understand"

Strongly
agree

Agree

Undecided

Disagree

Strongly
disagree

21. How often were the instructions in the I-MAG different to what you would have normally done/recommended?

Every time

Very often

Sometimes

Rarely

Never

22. What other information would you like to see in the I-MAG?

Your Opinion

23. Would you like the I-MAGs to continue being produced for patients with dysphagia? Yes No

24. Could you mention three main advantages of this service?

25. And what were in your opinion the main three disadvantages?

26. Please add any more comments that you would like to make about this service?

Thank you for taking the time to answer this questionnaire. Please return it to the Dysphagia Pharmacist in the stamped envelope.

Service Evaluation: the use of Individualised Medication Administration Guides (I-MAGs)



- This questionnaire is designed to take less than 10 minutes to complete.
- Please tick only one box per answer
- Complete all the sections unless otherwise indicated.
- Return in the stamped addresses envelope provided

Patient's Name: xxxxx xxxxx	Hospital Number: xxxxx	
Signature	Date of IMAG: 16/11/2020	

Individualised Medication Administration Guide (I-MAG) for Patients with Enteral Feeding Tubes

I-MAGs work alongside the patient's drug charts. Ensure that you administer medicines from the patient's Medicine Chart and do not rely solely on the I-MAG.

General management of enteral tube

1. Stop the feed prior to medicine administration and flush tube with 30ml of water.
2. Use purple 20ml enteral syringes to give all medicines. Depress plunger gently to avoid damaging the tube.
3. Prepare each medicine separately, do not mix medicines unless advised to.
4. Remove tablet crusher / container and draw up water into syringe and flush down tube to ensure all medicine is given.
5. If more than one medicine to be administered flush between drugs with at least 10mls of water.
6. Flush tube with at least 30ml of water following administration of last drug.
7. Restart feed

Vol. of fluids used with medication 30

Medicine prescribed	Frequency	Advice on Administering
ALLORUNOL 300mg	once a day	Dispense tablets in 50 ml of water immediately prior to administration. Administer after food. 1. Stop enteral feed. 2. Flush enteral feeding tube with the recommended volume of water. 3. Place tablet in barrel of an appropriate sized syringe. 4. Draw 10mls of water into syringe and allow tablet to dissolve, shaking if required. 5. Attach connector to syringe if necessary. 6. Flush medication down feeding tube. 7. Draw another 10mls of water into the oral syringe and also flush this via feeding tube (this will rinse syringe and ensure total dose is administered). 8. Finally flush with the recommended volume of water. 9. Re-start the feed, unless a prolonged break is required. Alternatively at step 3, place tablet into medicine pot and add 20mls of water and allow tablet to dissolve. Draw this into syringe with appropriate adaptor for tube connector. Ensure the measure is rinsed and this rinsing water administered also to ensure total dose is given.

Patient's Name: xxxxx xxxxx Hospital Number: xxxxx

IMAG Number: 26 If you have any queries please contact the Dysphagia Pharmacist Page 1 of 2

I am :

Speech and
Language
Therapist

Pharmacist

Dietician

Preparation

1. Did you attend to the Informative sessions prior to the commencement of the study?

Yes

No

Unsure

If you answered NO or UNSURE, please go to question 5.

2. "The training session adequately informed me about the implementation of the I-MAGs on the ward"

Strongly
agree

Agree

Undecided

Disagree

Strongly
disagree

3. "The time allocated for the training sessions was appropriate"

Strongly
agree

Agree

Undecided

Disagree

Strongly
disagree

4. How do you think the session could improve?

Presentation

5. Have you ever seen I-MAGs in the ward?

Yes

No

If your answer is NO, please go to question 21

6. Do you think that the Medication Chart is the right location for the I-MAG?

Yes

No

If your answer was NO, please indicate where you would think it should be situated:

7. What layout do you think it is more suitable?

Portrait

Landscape



8. Was the font in the text of the I-MAG easy to read?

Very easy

Easy

Undecided

Hard

Very hard

9. What would you suggest changing to improve the presentation of the I-MAGs?

Practicality

10. How often did you find an I-MAG attached to the medication chart of patients with dysphagia?
Every time Very often Sometimes Rarely Never
11. How often did you see the warning that was located in the medication chart indicating how to use of the I-MAG?
Every time Very often Sometimes Rarely Never
12. Did you consider the I-MAGs when giving recommendations in the administration of medication?
Yes No
13. "Having I-MAGs in the ward increased the amount of time that I spent in my recommendations about how to administer medication"
Every time Very often Sometimes Rarely Never
14. "I am more confident in my practice when the I-MAGs are in place" :
Strongly agree Agree Undecided Disagree Strongly disagree
15. How often were the I-MAGs up-to-date with the information in the Medication chart?
Every time Very often Sometimes Rarely Never
16. What do you think that would make the I-MAG more practical?

Content

17. "The instructions in the I-MAG were easy to understand"
Strongly agree Agree Undecided Disagree Strongly disagree
18. How often were the instructions in the I-MAG different to what you would have normally recommended?
Every time Very often Sometimes Rarely Never
19. What other information would you like to see in the I-MAG?

Dysphagia Pharmacist

20. "The Dysphagia Pharmacist was available whenever I needed him"

Strongly
agree

Agree

Undecided

Disagree

Strongly
disagree

Your Opinion

21. Would you like the I-MAGs to continue being produced for patients with dysphagia? Yes No

22. Could you mention three main advantages of this service?

23. And what were in your opinion the main three disadvantages?

24. Please add any more comments that you would like to make about this service.

Thank you for taking the time to answer this questionnaire. Please return it to the Dysphagia Pharmacist in the stamped envelope.

Appendix 15: Cover letter for service evaluation

Norfolk and Norwich University Hospitals 
NHS Foundation Trust


University of East Anglia

Manuel Serrano
School of Pharmacy,
University of East Anglia
Norwich NR4 7TJ
m.serrano-santos@uea.ac.uk

Tel: 01603 591996

**Individualised Medication Administration Guides (I-MAGs):
Service Evaluation**

Dear Colleague:

My name is Manuel Serrano and I am studying for a PhD at the University of East Anglia under the main supervision of Professor David Wright. Since the last 10 of January, I have been working as the Dysphagia pharmacist in some of the wards of the Norwich and Norfolk University Hospital. As part of my role, I have been issuing Individualised Medication Administration Guides (IMAGs) for all in-patients with dysphagia or Enteral Feeding Tubes (EFT).

This part of the study is now finished and I would like to ask for your collaboration in evaluating the service offered during this period by completing a short questionnaire covering all the facts surrounding the delivery of this service. As there are different Health Care professionals involved in this project, some of the questions may not be relevant to you as part of your role, which is why I would like to start the questionnaire asking you what your role in the wards is. Your feedback is extremely valuable so please take some time to fill in these boxes. All information about your answers will be kept confidential. Thus all the information about you will be anonymised so that you cannot be individually identified from it.

It is important that your questionnaire reaches us before the 31st of October so, when you have finished completing the questionnaire; please return it to the Dysphagia Pharmacist or to one of the ward Clerks in the Stroke unit.

Thank you for taking the time to fill in this questionnaire. Your feedback is important.

Yours sincerely

Manuel Serrano

Appendix 16: Results from the closed questions (service evaluation)

	Nurses (n)			Pharmacists and SALTs (n)		
	Yes	No	Unsure	Yes	No	Unsure
Preparation						
Did you attend to the Informative sessions prior to the commencement of the study?	6	5	2	5	1	0
	SA/A	U	D/SD	SA/A	U	D/SD
“The training session adequately informed me about the implementation of the I-MAGs on the ward”	5	1	0	5	0	0
“The time allocated for the training sessions was appropriate”	5	0	1	5	0	0
“I found the handout of the session helpful”	5	1	0			
Presentation						
	Yes	No	Unsure	Yes	No	Unsure
Have you ever seen I-MAGs in the ward	13	0	0	5	1	0
Do you think that the Medication Chart is the right location for the I-MAG?	13	0	0	5	0	0
	Portrait	Landscape		Portrait	Landscape	
What layout do you think it is more suitable?	9	4		2	3	
	VE/E	U	H/VH	VE/E	U	H/VH
Was the font in the text of the I-MAG easy to read?	11	2	0	4	1	0
Practicality						
	Yes	No	Unsure	Yes	No	Unsure
Did you ever use the I-MAGs when administering medication?	13	0	0	4	1	0
	ET/VO	S	R/N	ET/VO	S	R/N
How often did you find an I-MAG attached to the medication chart of patients with dysphagia?	10	3	0	3	1	1
How often did you see the warning that was located in the medication chart indicating how to use of the I-MAG?	10	3	0	4	0	1
How often did you follow the recommendations on the I-MAG?	12	1	0			
“The use of the I-MAG increase the amount of time that I spent administering medication”	6	4	3	1	1	3
How often were the I-MAGs up-to-date with the information in the Medication chart?	11	2		3	1	0
	SA/A	U	D/SD	SA/A	U	D/SD
“I am more confident in my practice when the I-MAGs are in place”	8	4	1	2	3	0
Dysphagia Pharmacist						
	ET/VO	S	R/N	ET/VO	S	R/N
“The Dysphagia Pharmacist was available whenever I needed him”	9	1	3	4	1	0
Content						
	SA/A	U	D/SD	SA/A	U	D/SD
“The instructions in the I-MAG were easy to understand”	13	0	0	4	1	0
	ET/VO	S	R/N	ET/VO	S	R/N
How often were the I-MAGs up-to-date with the information in the Medication chart?	11	2	0	3	1	0
Your Opinion						
	Yes	No	Unsure	Yes	No	Unsure
Would you like the I-MAGs to continue being produced for patients with dysphagia?	12	1	0	6	0	0

Appendix 17: Ethical approval (care home interviews)

Manuel Serrano
School of Pharmacy, room 0.04
University of East Anglia
Norwich
NR4 7TJ



Research & Enterprise Services
West Office (Science Building)

University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

Email: fmh.ethics@uea.ac.uk
Direct Dial: +44 (0) 1603 59 1566
Web: <http://www.uea.ac.uk>

30th September 2011

Dear Manuel

Re: Individualised Medication Administration Guidance: Interviews in Nursing homes Ref: 2010/11-47

The resubmission of your above proposal has been considered by the Faculty Research Ethics Committee at their meeting on 29th September and we can confirm that your proposal has been approved.

Please could you ensure that any amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the committee. Please could you also arrange to send us a report once your project is completed

The Committee would like to wish you good luck with your project

Yours sincerely

Yvonne Kirkham
Project Officer

Appendix 18: Preliminary information (care home interviews)

Please tick the relevant boxes:		
Age group	20-35	<input type="checkbox"/>
	36-50	<input type="checkbox"/>
	51-65	<input type="checkbox"/>
	66+	<input type="checkbox"/>
Gender	Male	<input type="checkbox"/>
	Female	<input type="checkbox"/>
Location of the Nursing home where you usually work	Town centre	<input type="checkbox"/>
	Rural	<input type="checkbox"/>
	Suburban/residential	<input type="checkbox"/>
	Close to Medical centre	<input type="checkbox"/>
	Other(please state) _____	
Nursing Qualification	UK Qualified	<input type="checkbox"/>
	Non-UK qualified	<input type="checkbox"/>
	No Nursing qualification	<input type="checkbox"/>
	Other(please state) _____	
Employment	Full time	<input type="checkbox"/>
	Part Time: ____hours per week	<input type="checkbox"/>
Time spent working as a Nurse or Carer in the UK	(to the nearest year)_____	
Nationality	_____	

Name: _____

Preferred contact number: _____

Email address: _____

Appendix 19: Cover letter for care home (care home interviews)



University of East Anglia

Manuel Serrano

School of Pharmacy,
University of East Anglia
Norwich NR4 7TJ
Email: m.serrano-santos@uea.ac.uk

Tel: 01603 591996

The Registered Manager

Care Home address

Dear Sir or Madam

My name is Manuel Serrano and I am studying for a PhD at the University of East Anglia under the main supervision of Professor David Wright. As part of my role, I am preparing and studying the usefulness of Individualised Medication Administration Guides (I-MAGs) for patients with dysphagia. These are designed to help the nurse on the ward to give medicines to this group of patients in a standardised and safe manner. They do this by stating clearly when medicines can be safely crushed or dispersed, when alternative forms of medication should be used and how to put medicines down enteral feeding tubes.

When patients who have agreed to take part in the study are discharged from the Hospital, we are giving them I-MAGs to help them to take their medicines appropriately in their homes. I am contacting you to ask whether I could arrange to come and discuss the I-MAG and how useful it is in practice with either you yourself, or a member of your staff who may be more directly involved in administering medicines.

I would like to carry out an interview of up to one hour. I would ask about whether the information provided in the guide is useful, advantages and disadvantages of using it, and possible ways to improve it. Participants will be asked if these interviews can be recorded so that they can be accurately typed up to help me accurately identify and analyse the issues discussed and find out how to improve the usefulness of I-MAG guides. However, no individual interviewed or care home will be identifiable in any reports. The study's findings about carers' opinions of will help us decide whether it would be feasible and useful to develop further research to test the impact of using I-MAGs within care homes.

Please provide this information to the nurses or carers in your nursing home to tell them about the general nature of this study. If any of the nurses or carers in your home, including you, may be interested in participating, please send back the Initial Contact Acceptance letter. I will then contact you to agree a suitable time to provide more information to potential participants and to seek consent for interview. If convenient and after consent has been confirmed, we could then carry out the interview or arrange a different, more convenient time. I would appreciate if we could use a room or office in your nursing home for the interview. This interview will usually be carried out during the working hours of the carer or nurse, but when that may affect the routine of the home, alternative times can be arranged by using a room available at the University of East Anglia and the travel expenses involved will be covered by the researcher. Please contact me if you have any queries about any aspect of the study at:

Manuel Serrano
Medicines Management Research Group
School of Pharmacy,
University of East Anglia,
Norwich Research Park
Norwich, NR4 7TJ
Norfolk

Tel 01603591996
Mob 07838198822
m.serrano-santos@uea.ac.uk

Thank you for taking your time to consider this request.

Yours sincerely

Manuel Serrano



Manuel Serrano
School of Pharmacy,
University of East Anglia
Norwich NR4 7TJ
Email: m.serrano-santos@uea.ac.uk

Tel: 01603 591996

The effect of Individualised Medication Administration Guidance in patients with Dysphagia in Nursing Home

Invitation

You are invited to take part in a research study. Before you decide to do so it is important that you understand why the research is being done and what it will involve for you if you take part. Please take time to read the following information carefully.

What is the purpose of the study?

The aim of this study is to explore your view about using a new type of guide called Individualised Medication Administration Guides (I-MAGs) which have been designed for patients who have swallowing difficulties and who live in care homes. These guides are designed to help the nurses and carers to give medicines to patients with swallowing difficulties in a standardised and safe way. This means they say clearly when medicines can be safely crushed or dispersed in drinks, and when other ways of giving them need be used and how to give medicines through enteral tubes. We also want to see how I-MAG guides may be changed to improve their usability in the care home.

What will the study involve?

If you take part you will have a short interview of up to an hour with the researcher ((Manuel Serrano, a dysphagia pharmacist) to talk about your views on possible usefulness of Individualised Medication Administration Guides.

Where will the interview take place?

The interview will take place in a private room in the Nursing home during your work hours unless it is differently agreed to fit the routine in the home or if you prefer to be interviewed somewhere else. The travel expenses involved will be covered by the researcher.

Why have I been chosen?

You have shown interest on this study after being informed by the registered manager of the care home where you work for being the nurse or carer in charge of giving medication to patients with swallowing difficulties. Your experience is very relevant for this study. However, there is a possibility

that you may not be selected if many people have volunteered to be interviewed, even after having consented to be interviewed.

Do I have to take part?

No. It is up to you whether or not you take part. If you choose to take part in the study, you will be asked to sign a consent form before you are interviewed. Even after you have signed a consent form, you are still free to withdraw from the study at any time and without giving a reason. If you choose not to take part, this will not affect your employment or other rights in any way. If you wish to obtain independent information or advice about your rights regarding being involved in this research study you can do so by contacting Prof David Wright, School of Pharmacy at the University of East Anglia, and who is a supervisor for this study, on 01603 592042 or email D.J.Wright@uea.ac.uk, University of East Anglia, Norwich NR4 7TJ.

What will taking part in this study involve for me?

The researcher (Manuel Serrano) will ask you some questions about what it is like to work in a care home and about your views on using I-MAGs guides in your usual practice in giving medications in the care home where you work. The interview questions will aim to find out your views about what it would be like using the I-MAG guide, how it fits into the daily routines of the care home and what you think could be changed to improve how useable it is. We also wish to record the interview if you are willing, to help review and analyse the conversation.

What are the possible benefits of taking part?

There are no direct benefits for you in taking part. However, you will be helping share and highlight the experiences of nurses administer medication to patients with swallowing difficulties, so as to help reduce levels of risk of medication errors and improving patients' health chances.

What are the possible disadvantages of taking part?

There are no expected disadvantages for you in taking part; however, if you feel uncomfortable about discussing any of the questions, you can ask the researcher to discuss them in a way that you are more comfortable with or not to discuss the topic at all.

What if there is a problem?

If you have any complaint about how you have been dealt with during the study or any concerns or possible harm that you might suffer, this will be addressed. If you have any concerns please contact Prof David Wright, who is a senior member of staff within the School of Pharmacy at the University of East Anglia, and who is a supervisor for this study, on 01603 592042 or email D.J.Wright@uea.ac.uk.

What happens after the project comes to an end?

The data will be analysed by the researcher and his supervisory team and the care home will be sent a copy of the overall findings.

Will my taking part in the study be kept confidential?

Yes. All information about your participation will be kept confidential. Thus all the information about you will be anonymised so that you cannot be individually identified from it. All personal information and your consent form will be stored by the researcher in a locked filing cabinet in an office in the

School of Pharmacy at the University of East Anglia, Norwich. These will only be viewed by the Dysphagia Pharmacist and the research assistant. The data will only be analysed by the research team (Manuel Serrano and academic supervisors) and this will be stored on a password-protected laptop, used solely for the purpose of research, and kept at the researcher's home. All confidential documentation will be destroyed five years after the interview (2016). However the Dysphagia Pharmacist as main researcher has the Duty of Care if the interviewee reveals activities that have caused or are likely to lead to harm to an individual in the nursing home, the Dysphagia Pharmacist as main researcher has a Duty of Care and may need to share this information the relevant authorities (Duty of Care Disclosure)

What will happen to the results of the research?

The results of the study will be written up as part of a doctoral thesis, a copy of which will be kept in the library of the University of East Anglia. The results may also be published in an academic or professional journal. These will be used to add to scientific knowledge of this topic and to share with other professionals any findings about individualised medicine administration guides from this project.

Who is organising and funding the research?

The research is being organised and funded through the School of Pharmacy at the University of East Anglia. The information is being used for the researcher's postgraduate research degree, supervised by a multidisciplinary team of experienced researchers.

Contact details:

If you would like further information about this study you can contact Manuel Serrano on 01603591996, at m.serrano-santos@uea.ac.uk, or by writing to Medicines Management Research Group, School of Pharmacy, University of East Anglia, and Norwich, NR4 7TJ.

**Thank you for taking the time to consider
becoming involved in this project**



University of East Anglia

Manuel Serrano

School of Pharmacy,
University of East Anglia
Norwich NR4 7TJ
Email: m.serrano-santos@uea.ac.uk

Tel: 01603 591996

«Nursing_home_Name»
«Address»
«Postcode»

The effect of Individualised Medication Administration Guidance in patients with Dysphagia in Nursing Homes

Please initial the box for each statement with which you agree

- 1. I have had the opportunity to consider the information, ask questions and to have these answered
- 2. I understand that if I tell the researcher about something likely to lead to harm to an individual in the nursing home, they may need to report it to the relevant authorities.
- 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without it affecting my work conditions.
- 4. I agree for the interview to be audio taped
- 5. I agree to take part in the above study.

Name of Participant	Signature	Date
.....

Name of the Researcher	Signature	Date
.....

Appendix 22: Initial contact acceptance letter (care home interviews)



Registered Manager' Name: _____
Care Home address: _____

Date:/...../.....

F.A.O. Manuel Serrano
Medicines Management Research Group
School of Pharmacy,
University of East Anglia,
Norwich, NR4 7TJ
Norfolk

Re: The effect of Individualised Medication Administration Guidance in patients with Dysphagia in Nursing Home

Dear Manuel:

Further to the invitation letter to the study mentioned above, and after having informed the members of my team about this, I would like to be contacted to agree a time when you can give my team members more information about the study.

Yours sincerely

Name:

Appendix 23: Set of questions and sub-questions and interviews schedule

What is it like working in this care home?

- How busy is the Care home?
- How many residents?
- How many staff?
- How easy do you find the work here?
- What kind of residents lives in this care home?
- What do you think is done differently in this care homes compared to others?

What is your role within the care home?

- How long have you worked here?
- What is your job title?
- Have you worked in other care homes before and if so what kind of work did you do?
- What are your responsibilities in relation to medication here?
- What training have you received or would like to receive?
- What about training for medication?

When you give medication to residents with swallowing difficulties here what does this usually mean you need to do?

- Do you ever have to crush tablets, open capsules or change the original formulation of the medicines?
- How do you find the administration of medication by EFT?
- What kind of support do you get or would like to get on that practice?
- Do you know what the risks of manipulating medication are?
- How would you improve that?

What would you expect if you were asked to use an individualised medication administration guide to help your work with people you look after?

- Is it something you have heard before?
- How do you interpret that concept?
- How would you describe this idea?
- How would it benefit your daily practice?
- What would you like to see in such a guide?

Now you have looked at this (I-MAG presented), how do you think I-MAGs could be used in the care home?

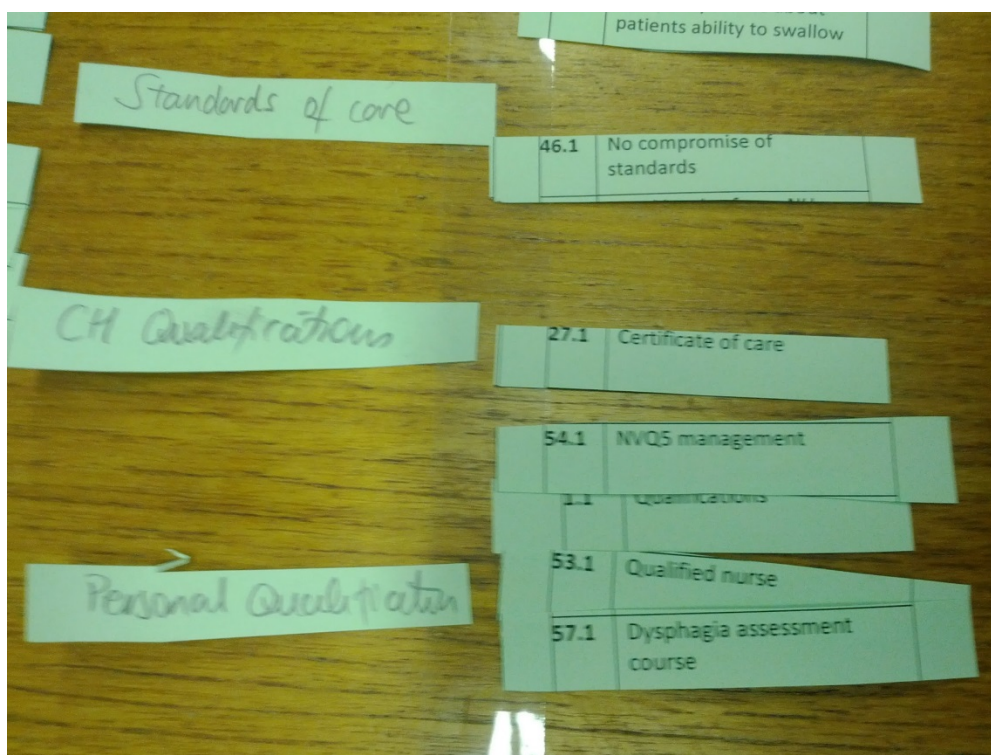
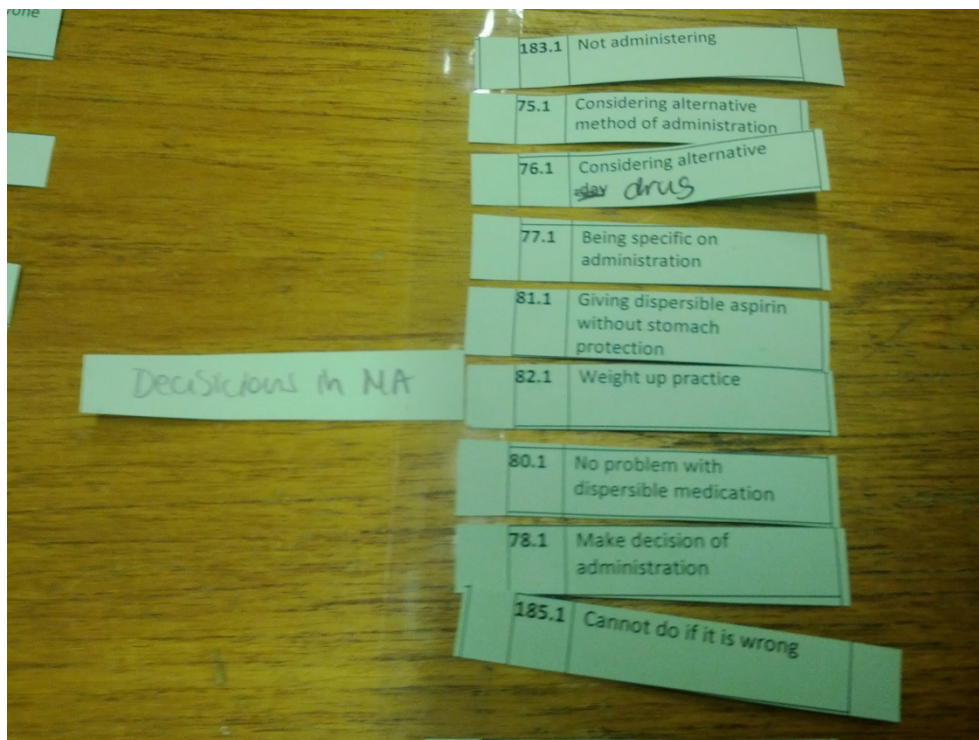
- How would you find having to use and I-MAG on the administration of medication?
- What else would like to see on it and wouldn't?
- What support do you think you would need to make the best use of this guides?
- Who do you think that could support you on its use?
- Do you think the I-MAG could have an impact the patient's health? In what ways?

Date of interview	Participant code	Date of interview	Participant code
7/11/2011	N1	23/11/2011	N9
7/11/2011	N2	24/11/2011	N10
7/11/2011	N3	25/11/2011	N11
8/11/2011	N4	25/11/2011	N12
7/11/2011	N5	30/11/2011	N13
13/11/2011	N6	29/11/2011	N14
13/11/2011	N7	2/12/2011	N15
14/11/2011	N8		

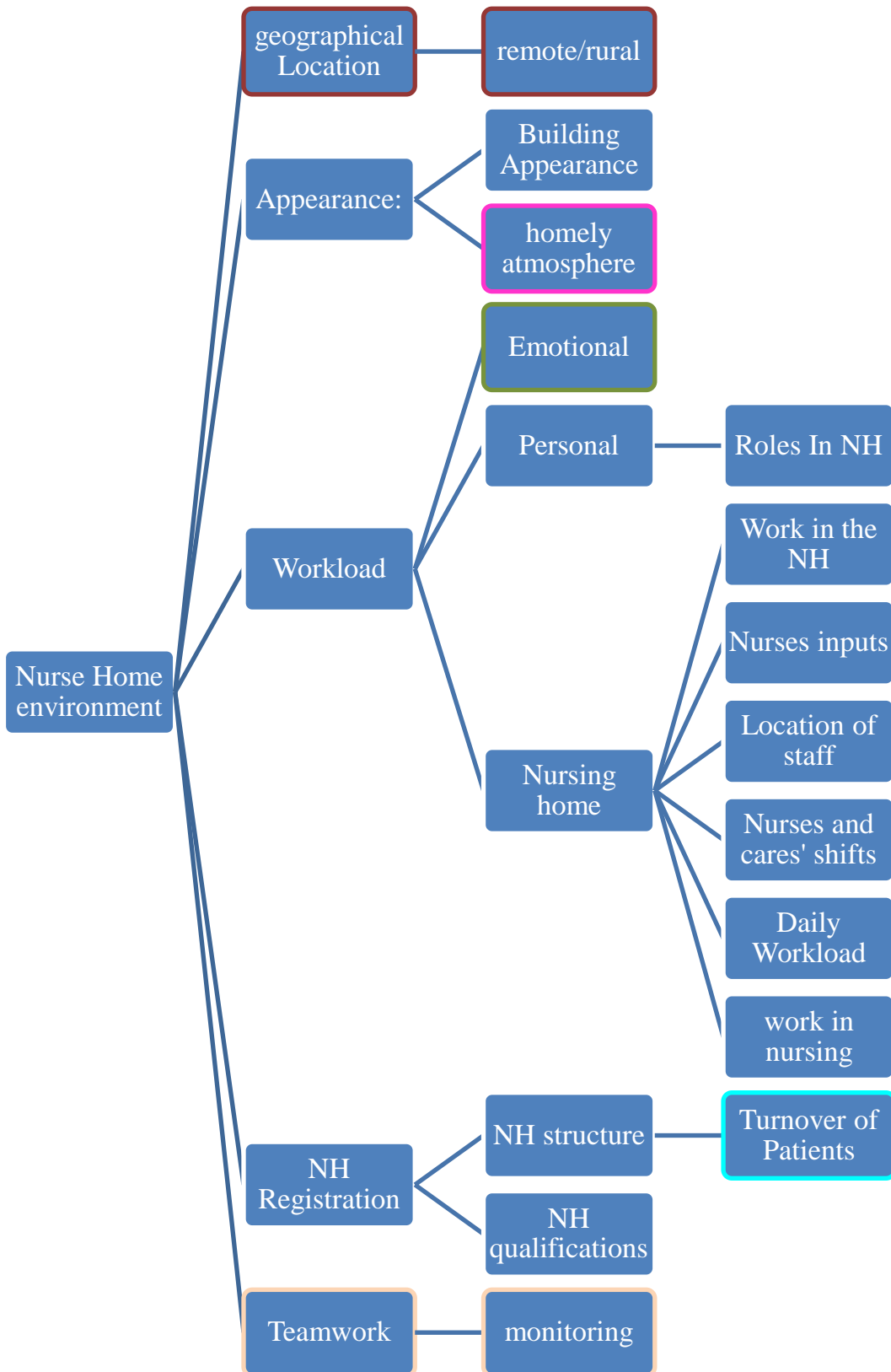
Appendix 24: Fragment of coded transcription

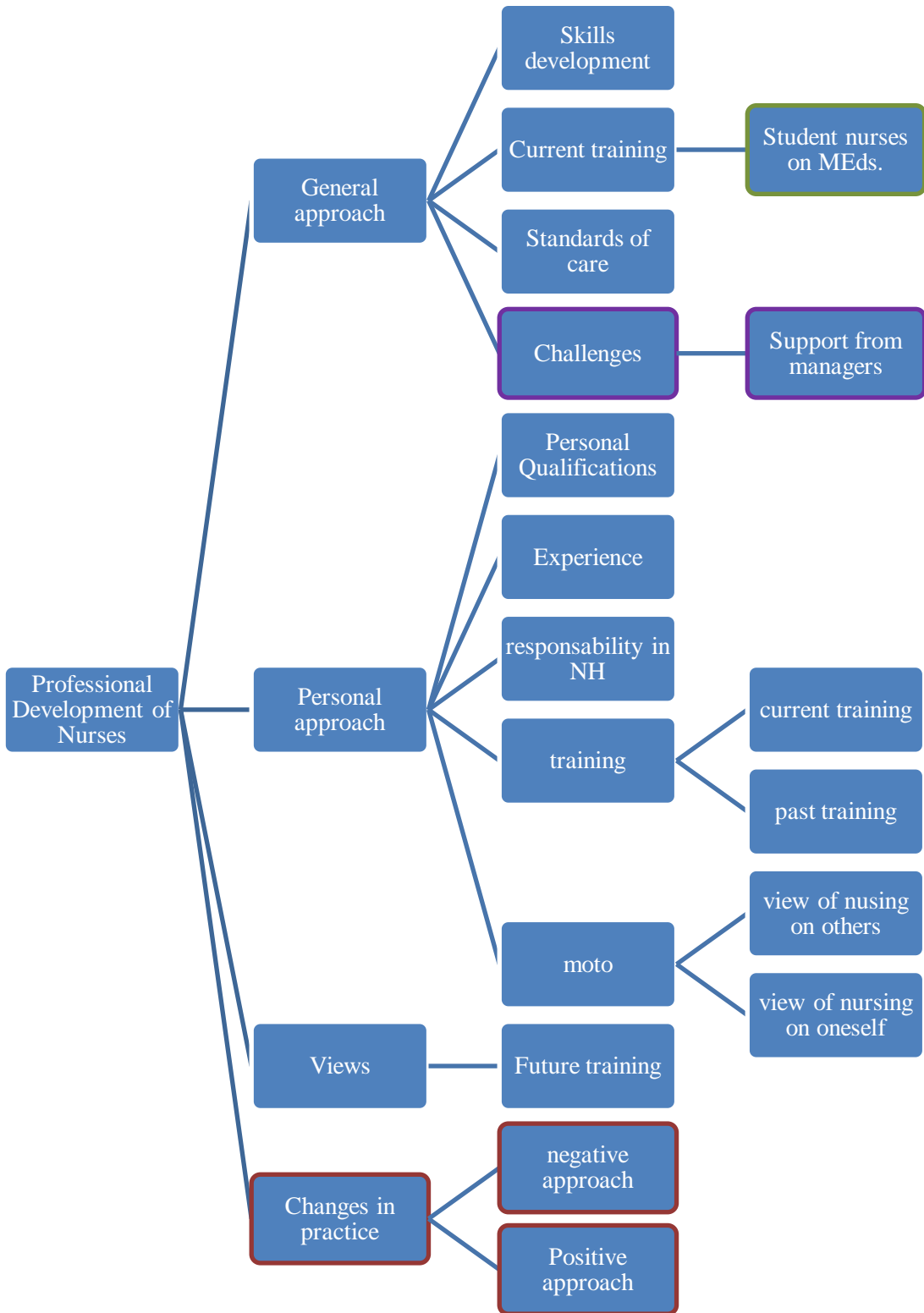
	Transcription	Codes
MS	So, could you please explain what is like working in this care home for you?	
001	I am actually the manager of the nursing home and also a registered nurse. for me this is possibly nursing at its purist essence in terms of we are looking of the whole person , I find that really rewarding and even as a manager I go home at the end of each day knowing that I have made a difference to people's lives and that is why I am here and that is what I do	Qualifications Essence of nursing Reward in care
Ms	How busy is your home?	
001	At the moment we are actually quite quiet. I have a few empty beds and I would say that we tick along quite nicely because I fortunately I have some very good staff in senior roles which means that without regimentation we work to set standards and protocols on times so I wouldn't say that we are madly busy but is due to good time management rather than anything else. Things get done appropriately	Workload Staff in senior roles time management
Ms	Ok, How many staff would you say you have to help you?	
001	On a normal shift in my nursing until I would normally have 4 carer in the morning plus a trained nurse, 3 carer in the afternoon plus a trained nurse and at night I would have I carer and a trained nurse And on my dementia unit I would have 3 carers in the morning , 3 carers in the afternoon and two carers at night	Workforce Nurse workload
Ms	Ok, so your dementia until r within different premises to here	
001	Yes , they are, within the same site but slightly different building	Swapping location
Ms	And is manager' role as the same structure as...	
001	No, ...Normally my dementia unit I keep the same staff there partly because they have the skills to handle the residences they form relationships within a period of time other staff do work there and sometimes I bring my nurses around the dementia unit staff over to the general nursing side basically to have the insights and inputs on some of my nursing patients who also suffer from dementia	Communication with the nursing team

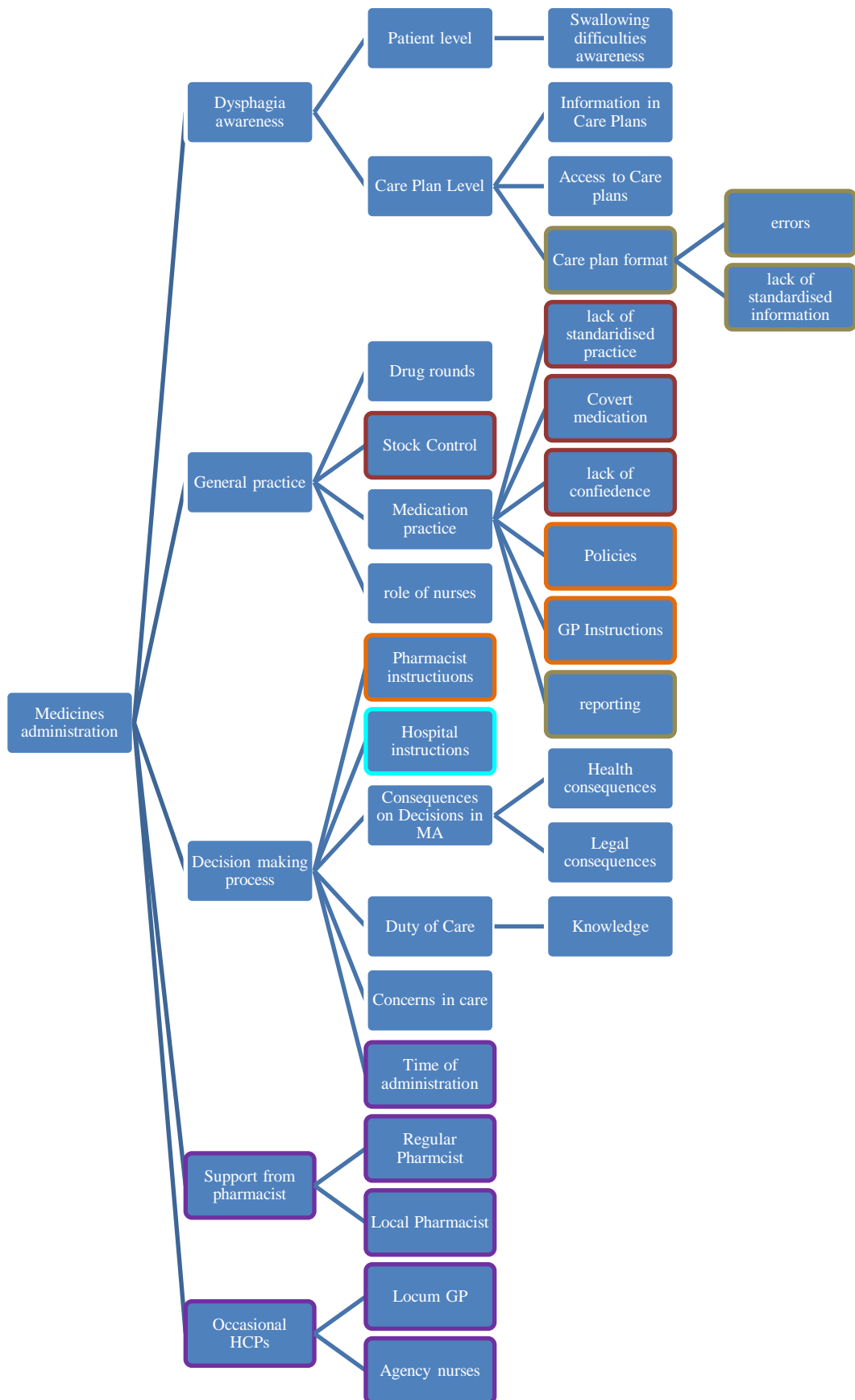
Appendix 25: Images of the coding process

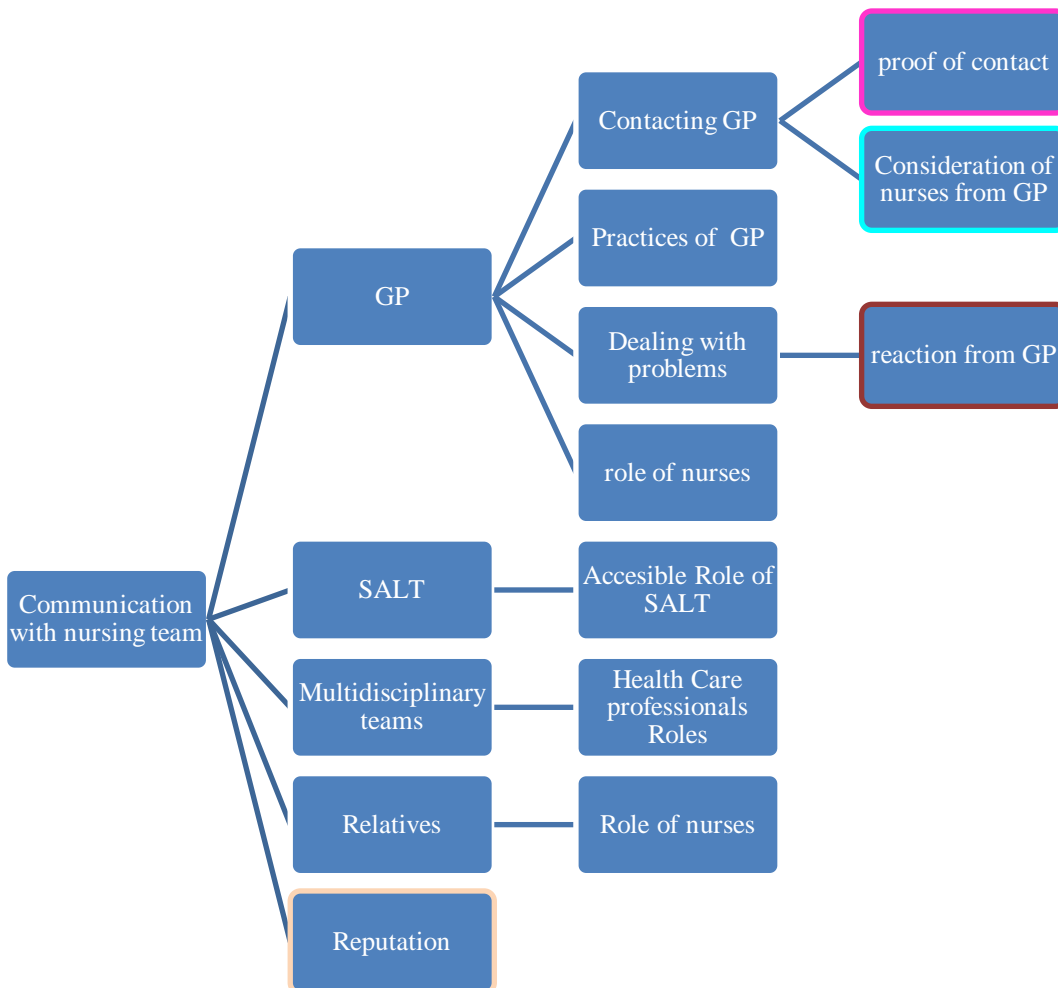
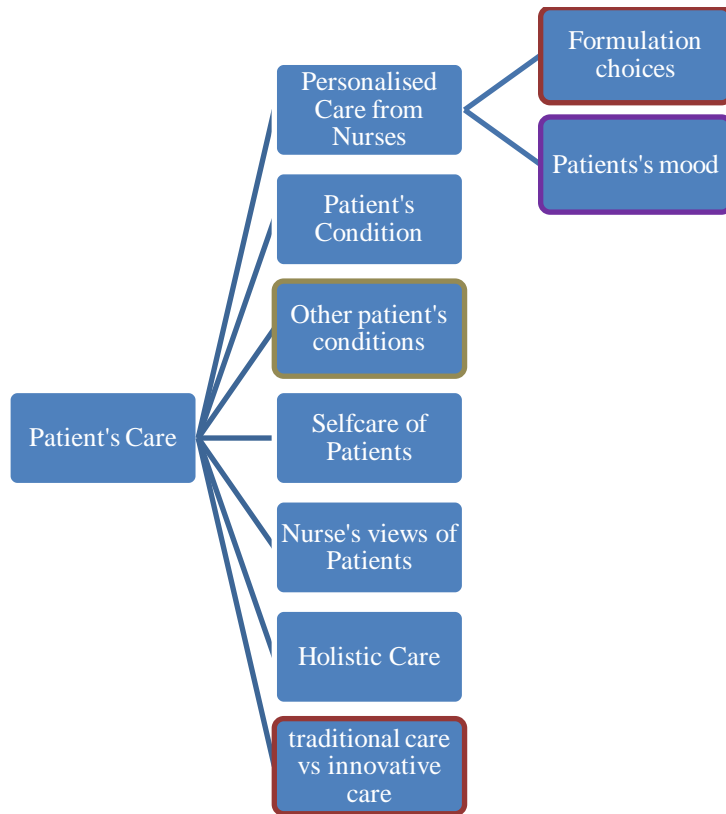


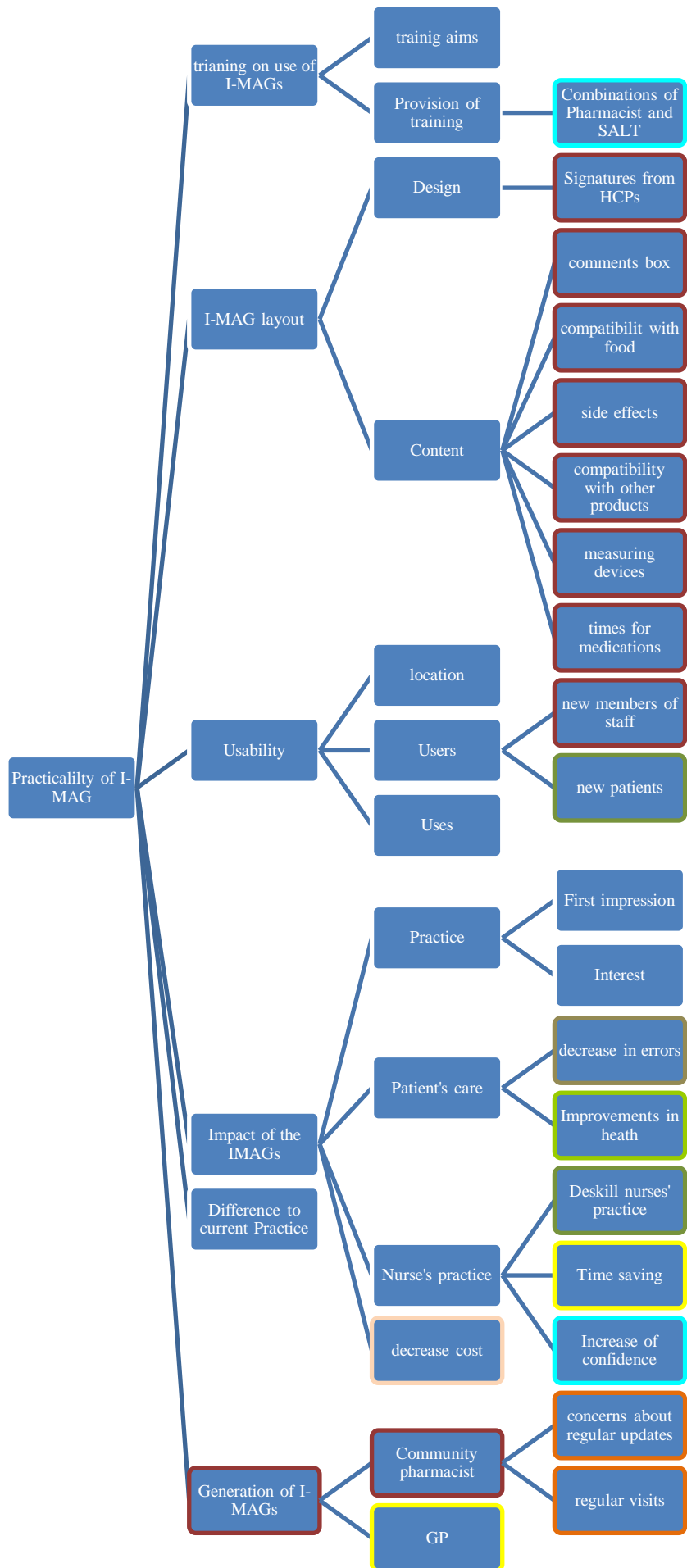
Appendix 26: Organisation of codes into themes





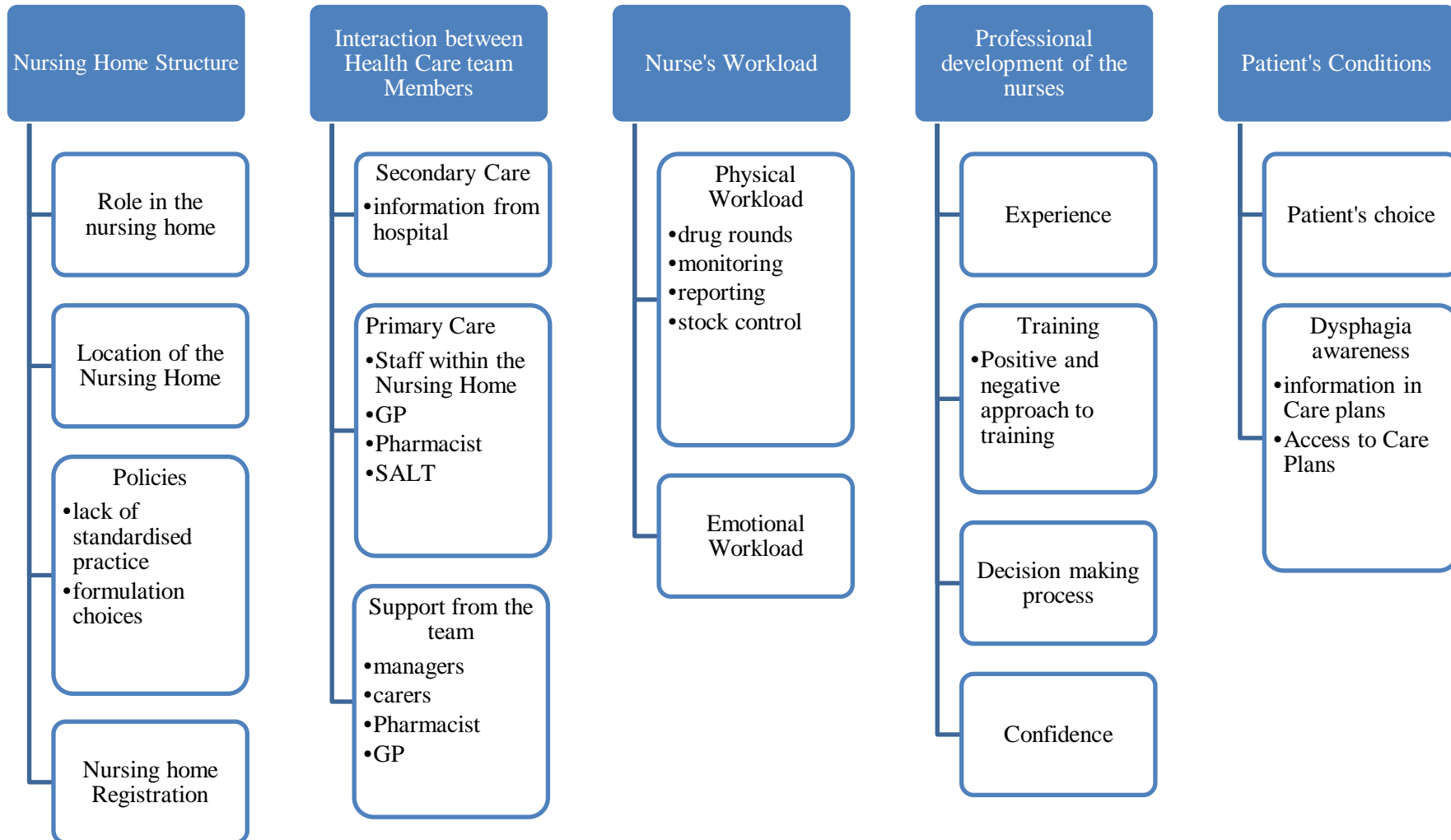




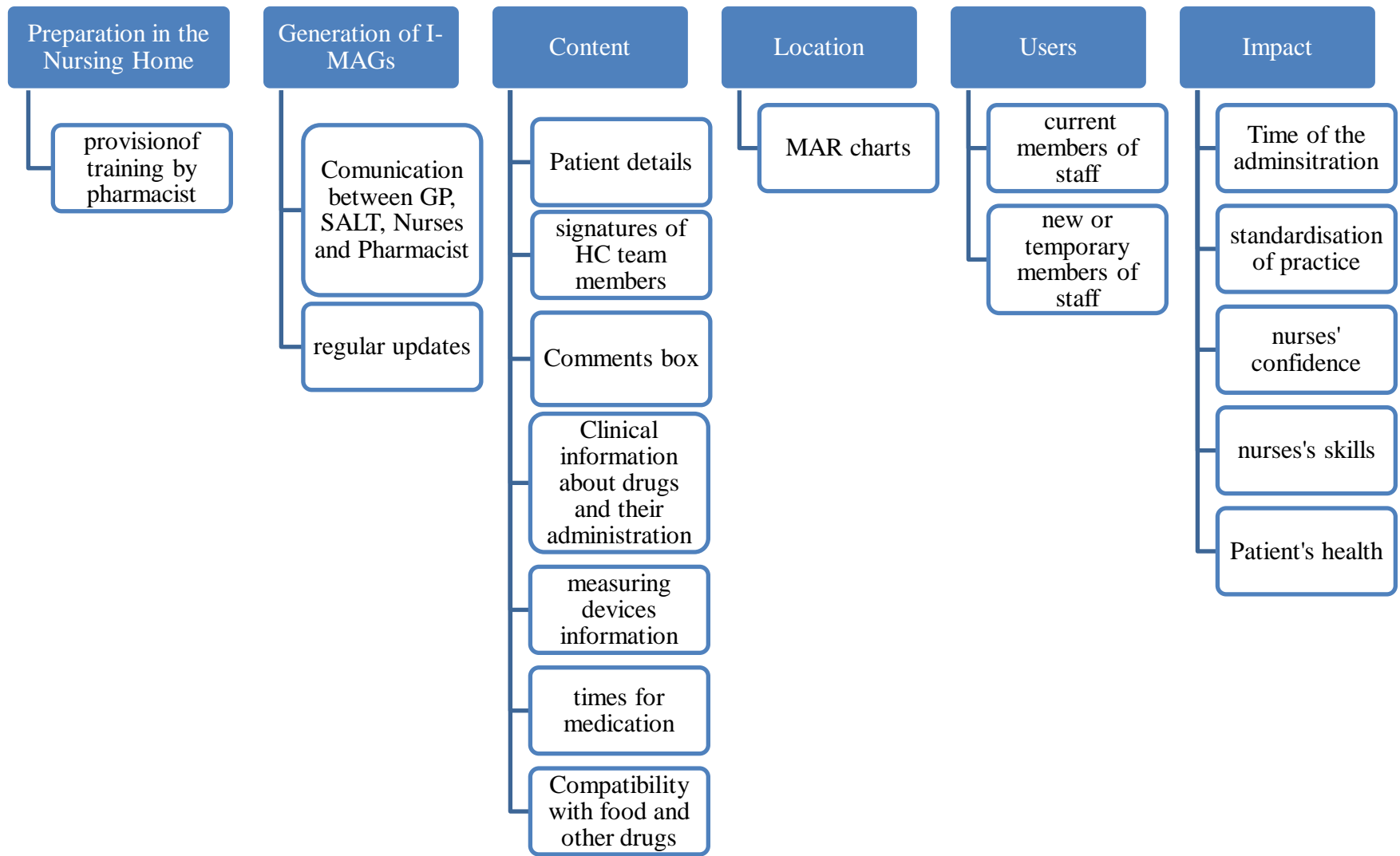




Medication administration to patients with dysphagia in nursing homes



Implementation of I-MAGs for Patients with Dysphagia in Nursing Homes



Appendix 28: Agreement of funding

UNIVERSITY OF EAST ANGLIA

Agreement for research

This agreement is made on the [1st] day of [December] 2011 between **Rosemont Pharmaceuticals Limited** of Leeds, LS11 9XE (hereinafter referred to as "Funder") and the **University of East Anglia** of Norwich, NR4 7TJ (hereinafter referred to as "UEA") for the provision of research entitled "*Evaluation of medicines administration to residents in care homes and Exploration of reasons for regular unplanned hospital admissions*"

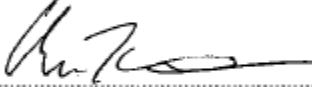
Whereas the funder and UEA have agreed that UEA shall perform the tasks as specified in the Annex attached hereto the following is hereby agreed between the parties

1. Between 01 January 2012 and 30 June 2012 UEA shall carry out the research work as detailed in the Annex under the direction of the Project Manager (*Professor David Wright*)
2. UEA shall provide suitable facilities for the project.
3. UEA may replace its appointed Project Manager at any time on prior written notice to the Funder
4. UEA agrees to inform the Funder if during the course of the research it becomes apparent that there will be any difficulties in completing the research on time.
5. The Funder agrees to pay UEA the sum of £12,800 (plus VAT if applicable) for the work within 30 days of receipt of invoices from UEA.
6. UEA shall invoice the Funder for the total sum on the signing of the contract.
7. Both parties hereby agree to limit the transfer of confidential information between the parties to the extent that is needed to conduct the work. Both parties agree to clearly mark such material as confidential and shall treat such information with the same care as if it was their own confidential information.
8. For the avoidance of doubt, any intellectual property developed by the researchers at UEA during this period shall remain the property of UEA. Nothing in this agreement shall prevent the results of the research being published by UEA or prevent UEA from entering into research collaboration with other partners.
9. UEA grants the Funder an exclusive right or option to negotiate a licence, on fair and reasonable commercial terms, to use any Foreground Intellectual Property for commercial purposes. The option or right shall remain open for the period of the contract and for 3 months beyond the end of the contract.
10. For the avoidance of doubt, nothing in this contract prevents Funder using the results of the work for non-commercial, internal research and development activities.
11. If UEA receives a request under the Freedom of Information Act 2000 to disclose any information which under this agreement is the Funder's Confidential Information then the Funder agrees to give as much assistance as may be required by UEA within the time limits laid down by the Act for UEA to effect an appropriate response to any such request.
12. Either party may terminate this agreement by giving one months notice in writing to the other. The Funder agrees to pay the UEA for all legitimate expenditure incurred up to the date of termination.
13. Any changes to this agreement should be agreed in writing by both parties.
14. If any dispute arises out of or in connection with this Agreement the parties will attempt in good faith to settle it by negotiation. If the parties are unable to settle any dispute by negotiation within

twenty-eight (28) days the parties will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure.

15. To initiate a mediation a party must give notice in writing to the other party requesting a mediation in accordance with clause 12
16. This agreement shall be governed by English Law under the exclusive jurisdiction of the English Courts.

Signed on behalf of UEA



Mr Olly Dean, Project Officer

21/12/2011

Date

Signed on behalf of **Rosemont Pharmaceuticals Limited**



Signed

Janet Flynn

Print Name

Marketing Manager

Title

19th December 2011

Date

ANNEX 1

Description of Work

Manuel Serrano, David Wright

Setting

Work to be carried out initially in co-operation with Dr Tim Longmore, York Road Surgery, Elvington, North Yorkshire and colleagues from the North Yorkshire Primary Care Research Network.

Project 1 Evaluation of medicines administration to residents in care homes

Observation of medicines administrations within up to 8 care homes (200-300 residents) to identify the exact level of dysphagia, the methods used by carers to administer medicines and how they can best be supported in giving the medicines to the residents.

This information would identify the extent of the problem, inform the development of training materials for care homes and determine exactly what should be prescribed. Following discussion with the medical practitioners responsible for the homes and implementation of any medicine changes, follow up observations could be undertaken to determine whether the error rate has been reduced and patient care improved.

Timeline and requirements

The project would take 6 months to complete. Ethical & PCT approval would need to be obtained (3 months), homes would need to be recruited and observations would take place over an 8 week period.

Outputs

Conference abstract, research paper in a pharmacy journal and an education article in a care home journal.

Project 2 Exploration of reasons for regular unplanned hospital admissions

Patients who have been admitted to hospital more than three times in the previous 12 months would be identified along with controls with similar demographics (gender, age, number of prescriptions). Anonymous patient data would be collected (Chronic medical conditions, medication, dysphagia, gender, age, residence) and would be compared between the two groups to determine which factors, if any, are different between the two groups.

It may also be useful to consider those patients repeatedly admitted with chest infection, although the importance of this won't be known until the data has been looked at.

Timeline and requirements

The project would take 2 months to complete. Ethical approval would not be required as this is a service evaluation. PCT approval and honorary contract for Manuel would be required. Statistical and research design input would be required from John Wood, who is one of Manuel's PhD supervisors.

Outputs

Research paper in a medical journal.

Project cost

£10,000 PhD Stipend for 6 months
£1,800 PhD fees for 6 months
£1,000 Travel and accommodation costs

Appendix 29: Cover letter for care home (observational drug rounds)



**[Practice's
name]**

[GP's Name

address]

Telephone number

The Registered Manager

Dear Sir or Madam

My name is *[GP's Name]* and I am one of the General Practitioners in *[Practice's name]*.

We are aware of the lack of support for patients with swallowing difficulties in our community, so *[Practice's name]* in liaison with the University of East Anglia is trying to carry out a research study in Care Homes with the aim of designing a training programme to support nurses and carers in the best practice of administration of medication to patients with swallowing difficulties and/or Enteral Feeding Tubes (EFTs). This training will focus on improving the standards of care set by the Care Quality Commission (CQC).

The study will be carried out by a research Pharmacist (main researcher) studying for a PhD at the University of East Anglia under the main supervision of Professor David Wright. As part of his role, he will observe the different methods used by the nurses and carers in the administration of medication to patients with swallowing difficulties and Enteral feeding Tubes (EFTs) in care homes.

To achieve this, the main researcher would like to observe nurses in your care home during two early morning drug rounds. He may be taking notes on the methods used in the administration of drugs to patients with swallowing difficulties or EFTs. Although the main objective is to describe what nurses do when administering oral medicines to patients with dysphagia, and to quantify the appropriateness of these interventions, he would like to observe the entire drug round and will record data when the nurse administers medicines to patients both with and without swallowing difficulties, noting the drug details and the administration process on a Data Collection Form. He will collect data on each medicine, noting the name, dose, route and formulation given to each patient together with the details on the prescription chart so that he can compare the two. He will also note

how the nurse prepares and administers each medicine. No personal data will be collected about you, the care home or the patient.

The data from the observations will be used to identify if you are receiving the best formulations for your patient's medication and to ease the design of a training programme focused on how to optimise the administration of medication for patients with swallowing difficulties in your care home.

Please provide this information and the Participants Information Sheet to the nurses or carers in your nursing home to tell them about the general nature of this study. If any of the nurses or carers in your home, including you, are willing to participate, **please send back the Initial Contact Acceptance letter to me or to the research pharmacist**. He will then contact you to agree a suitable time to provide more information to potential participants and to seek consent for the drug round. If convenient and after consent has been confirmed, we could then carry out the drug round or arrange a different, more convenient time.

Please contact us if you have any queries about any aspect of the study at:

**[GP's Name
and address]**

OR

Manuel Serrano
Medicines Management Research
Group
School of Pharmacy,
University of East Anglia,
Norwich Research Park
Norwich, NR4 7TJ
Norfolk
Tel 01603591996
Mob 07838198822
m.serrano-santos@uea.ac.uk

Thank you for taking your time to consider this request.

Yours sincerely

(GP's name]

Observational drug rounds in Care Homes

Invitation

You are invited to take part in a research study. Before you decide to do so it is important that you understand why the research is being done and what it will involve for you if you take part. Please take time to read the following information carefully.

What is the purpose of the study?

The aim of this study is to design a training programme to support nurses and carer in the best practice of administration of medication to patients with swallowing difficulties and/or Enteral Feeding Tubes (EFTs).

What will the study involve?

A researcher will be observing two early morning drug rounds in the care home where you work. The researcher may be taking notes on the methods used in the administration of drugs to patients with swallowing difficulties or EFTs.

Why have I been chosen?

You have been chosen because you work on one of the care homes involved in the study.

Do I have to take part?

No. It is up to you whether or not you take part. If you choose to take part in the study, you will be asked to sign a consent form before you are observed. Even after you have signed a consent form, you are still free to withdraw from the study at any time and without giving a reason. If you choose not to take part, this will not affect your employment or other rights in any way. If you wish to obtain independent information or advice about your rights regarding being involved in this research study you can do so by contacting Prof David Wright, School of Pharmacy at the University of East Anglia, and who is a supervisor for this study, on 01603 592042 or email D.J.Wright@uea.ac.uk, University of East Anglia, Norwich NR4 7TJ.

What will taking part in this study involve for me?

You will be observed carrying out a drug round. Although the main objective is to describe what nurses do when administering oral medicines to patients with dysphagia and where nurses struggle on these administrations, the researcher will observe the entire drug round. He will record data when you administer medicines to patients both with and without swallowing difficulties, noting the drug details and the administration process on a Data Collection Form. He will collect data on each medicine, noting the name, dose, route and formulation you give to each patient together with the details on the prescription chart so that he can compare the two. He will also note how you prepare and administer each medicine. No personal data will be collected about you or the patient.

His role whilst observing you is purely to collect data for this study and he will not be 'checking' the drugs with you. If however he observes that you are about to make a potentially serious mistake such as giving the wrong drug or dose, he will bring it to your attention in order to minimise patient harm. It will then be necessary to complete the home's standards serious event/incident procedure. You will also have to request verbal consent on behalf of the observer to the patient on the day of

the observation and before the observer joins you. If you feel the patient suffers from serious dementia and is incapable of making a decision, please contact the patient's relative to ensure they are aware that this observation is taking place.

What are the possible benefits of taking part?

There are no direct benefits for you in taking part. However, you will be helping to share and highlight the experiences of nurses administering medication to patients with swallowing difficulties and will be helping us to identify how we can help you to optimise the administration of medication to your residents.

What are the possible disadvantages of taking part?

There are no expected disadvantages for you in taking part; however, if you feel uncomfortable about discussing any of the questions, you can ask the researcher to discuss them in a way that you are more comfortable with or not to discuss the topic at all.

What if there is a problem?

If you have any complaint about how you have been dealt with during the study or any concerns or possible harm that you might suffer, this will be addressed. If you have any concerns please contact Prof David Wright, who is a senior member of staff within the School of Pharmacy at the University of East Anglia, and who is a supervisor for this study, on 01603 592042 or email D.J.Wright@uea.ac.uk.

What happens after the project comes to an end?

The data will be analysed by the researcher and his supervisory team and the care home will be sent a copy of the overall findings.

Will my taking part in the study be kept confidential?

Yes. All information about your participation will be kept confidential. Thus all the information about you will be anonymised so that you cannot be individually identified from it. All personal information and your consent form will be stored by the researcher in a locked filing cabinet in an office in the School of Pharmacy at the University of East Anglia, Norwich. These will only be viewed by the main researcher. The data will only be analysed by the research team (Manuel Serrano and academic supervisors) and this will be stored on a password-protected laptop, used solely for the purpose of research, and kept at the researcher's home. All confidential documentation will be destroyed five years after. However the main researcher has the Duty of Care if the rounds reveal activities that have caused or are likely to lead to harm to an individual in the nursing home, the main researcher has a Duty of Care and may need to share this information the relevant authorities (Duty of Care Disclosure)

What will happen to the results of the research?

The results of the study will be written up as part of a doctoral thesis, a copy of which will be kept in the library of the University of East Anglia. The results may also be published in an academic or professional journal. These will be used to add to scientific knowledge of this topic and to share with other professionals any findings about individualised medicine administration guides from this project.

Who is organising and funding the research?

The research is being organised and funded through the School of Pharmacy at the University of East Anglia and Rosemont Pharmaceuticals. The information is being used for the researcher's postgraduate research degree and supervised by a multidisciplinary team of experienced researchers.

Contact details:

If you would like further information about this study you can contact Manuel Serrano on 01603591996, at m.serrano-santos@uea.ac.uk, or by writing to Medicines Management Research Group, School of Pharmacy, University of East Anglia, and Norwich, NR4 7TJ.

**Thank you for taking the time to consider
becoming involved in this project**

Appendix 31: Nurse consent form (observational drug rounds)



Manuel Serrano
School of Pharmacy,
University of East Anglia
Norwich NR4 7TJ
Email: m.serrano-santos@uea.ac.uk

Tel: 01603 591996

{Care Home Name and address}

Please initial the box for each statement with which you agree

- 1. I have had the opportunity to consider the information provided in the Information sheet (Version 1, April 2012), ask questions and to have these answered

- 2. I understand that if I do or I tell the researcher about something likely to lead to harm to an individual in the nursing home, he may need to report it to the relevant authorities.

- 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without it affecting my work conditions.

- 4. I agree to be observed during one or more drug rounds

- 5. I agree to take part in the above study.

If you feel the patient suffers from serious dementia and is incapable of making a decision, please contact the patient's relative to ensure they are aware that this observation is taking place.

Name of Participant	Signature	Date
.....
Name of the Researcher	Signature	Date
.....



University of East Anglia

Manuel Serrano
School of Pharmacy,
University of East Anglia
Norwich NR4 7TJ
Email: m.serrano-santos@uea.ac.uk

Tel: 01603 591996

Dear Sir or Madam

My name is Manuel Serrano and I am a Research Pharmacist studying for a PhD at the University of East Anglia under the main supervision of Professor David Wright. As part of my role, I am trying to observe the different methods used by the nurses and carers in the administration of medication to patients with swallowing difficulties and Enteral feeding Tubes (EFTs) in care homes with the aim of designing a training programme to support nurses and carers in the best practice of administering medication to patients with swallowing difficulties and/or Enteral Feeding Tubes (EFTs).

I would like to observe you during two early morning drug rounds in the care home. I may be taking notes on the methods used in the administration of drugs to patients with swallowing difficulties or EFTs. Although the main objective is to describe what nurses do when administering oral medicines to patients with dysphagia and where nurses struggle on these administrations, I will observe the entire drug round and will record data when you administer medicines to patients both with and without swallowing difficulties, noting the drug details and the administration process on a Data Collection Form. I will collect data on each medicine, noting the name, dose, route and formulation you give to each patient together with the details on the prescription chart. I will also note how you prepare and administer each medicine. No personal data will be collected about you or the patient.

Please take some time to read though the Information sheet attached to this letter and, if convenient and after consent has been confirmed, we could then carry out the drug round or arrange a different, more convenient time. This observational drug round will usually be carried out during the morning.

Please contact me if you have any queries about any aspect of the study at:

Manuel Serrano
Medicines Management Research Group
School of Pharmacy,
University of East Anglia,
Norwich Research Park
Norwich, NR4 7TJ
Norfolk

Tel 01603591996
Mob 07838198822
m.serrano-santos@uea.ac.uk

Thank you for taking your time to consider this request.

Yours sincerely

Manuel Serrano



Manuel Serrano
School of Pharmacy,
University of East Anglia
Norwich NR4 7TJ
Email: m.serrano-santos@uea.ac.uk
Tel: 01603 591996

Patient Information Sheet

Observational drug rounds in Care Homes

Invitation

A researcher will be visiting the care home tomorrow to observe one of the nurses giving out medicines to a group of patients, of which you (your relative) may be one.

What is the purpose of the study?

The aim of this study is to design a training programme to support nurses and carer in the best practice of administration of medication to patients with swallowing difficulties and/or Enteral Feeding Tubes (EFTs).

Why will the nurse be observed giving drugs to me (my relative)?

The researcher wants to observe the nurse giving medicines to patients with and without swallowing difficulties and feeding tubes so that a comparison can be made.

What will my (relative's) participation involve?

You (your relative) will not need to do anything other than take your (their) medicines as normal.

Do I (my relative) have to take part?

No. It is up to you to decide whether or not to take part. If you do not wish to take part (do not want your relative to take part) please indicate this to the nurse either before or during the medicine round. If you choose not to take part (do not want your relative to take part) you do not need to give a reason and it will not affect the standard of care you (your relative) receive(s) in anyway.

Please, feel free to discuss with your relatives

Thank you for taking the time to consider becoming involved in this project

Appendix 36: Ethical approval (observational drug rounds)

Faculty of Medicine and Health Sciences Research Ethics Committee



Jose Manuel Serrano Santos
Medicines Management Research Group
School of Pharmacy
University of East Anglia
Norwich
NR4 7TJ

Research & Enterprise Services
West Office (Science Building)
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Telephone: +44 (0) 1603 591574
Fax: 01603 591550
Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

28th June 2012

Dear Manuel

Project title: "Homes Optimising Medication Administration in Dysphagia (HOMeAID)"
Reference 2011/2012-48

The amendments to your above proposal have been considered by the Chair of the Faculty Research Ethics Committee and we can confirm that your proposal has been approved.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

The Committee would like to wish you good luck with your project

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Yvonne Kirkham', is written over a light blue horizontal line.

Yvonne Kirkham
Project Officer

Appendix 37: 25 most frequently prescribed drugs

25 most frequently prescribed drugs to residents without Dysphagia	Times prescribed	%
Paracetamol	52	8.7%
Aspirin	46	7.7%
Macrogol	37	6.2%
Furosemide	30	5.0%
Lansoprazole	29	4.9%
Levothyroxine	29	4.9%
Calcium salts	21	3.5%
Citalopram	21	3.5%
Ferrous salts	21	3.5%
Omeprazole	17	2.9%
Digoxin	15	2.5%
Lactulose solution	13	2.2%
Bisoprolol	11	1.8%
Metformin	9	1.5%
Amlodipine	8	1.3%
Folic acid	7	1.2%
Gliclazide	7	1.2%
Simvastatin	7	1.2%
Atenolol	6	1.0%
Clopidogrel	6	1.0%
Co-Codamol	6	1.0%
Sertraline	6	1.0%
Codeine	5	0.8%
Isosorbide mononitrate	5	0.8%
Prednisolone	5	0.8%

25 most frequently prescribed drugs to PWD	Times prescribed	%
Paracetamol	15	10.5%
Macrogol	12	8.4%
Aspirin	10	7.0%
Citalopram	10	7.0%
Calcium salts	8	5.6%
Lansoprazole	6	4.2%
Sodium valproate	6	4.2%
Levothyroxine	5	3.5%
Co-Beneldopa	4	2.8%
Co-Codamol	4	2.8%
Folic acid	3	2.1%
Omeprazole	3	2.1%
Procal shot	3	2.1%
Sertraline	3	2.1%
Co-Careldopa	3	2.1%
Atenolol	2	1.4%
Bisoprolol	2	1.4%
Cetirizine	2	1.4%
Digoxin	2	1.4%
Fludrocortisone	2	1.4%
Fluoxetine	2	1.4%
Furosemide	2	1.4%
Lactulose solution	2	1.4%
Memantine	2	1.4%
Stalevo	2	1.4%