Medicine use in swallowing-impaired patients: Pharmacists' knowledge, practice and information needs

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By

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ABSTRACT

Dysphagia, or swallowing impairment, is a growing problem that affects 13.5% of the general population. The ability to swallow is essential for patients taking oral medicines, so this presents a challenge for swallowing-impaired (SI) patients as tablets and capsules will usually require modification prior to ingestion. Pharmacists should play a central role in advising SI patients about their medicine use, as well as problems that may impact on safety, adherence and therapeutic outcome. However, little is known about pharmacists' level of knowledge, their practice and their information needs when dealing with SI patients and their use of medicines. The aim of this study was to investigate pharmacist knowledge, practice and information needs relating to the support of SI patients and their medicine-related needs.

The study design included both quantitative and qualitative methods. A quantitative questionnaire was developed to collect data on the knowledge, practice and information needs of pharmacists and was piloted in 10 pharmacists, which resulted in minor modifications. The questionnaire was converted to a web-based survey and emailed to all pharmacists registered with the South African Pharmacy Council. Two knowledge scores were generated by summating correct responses: knowledge of dysphagia (KOD) and knowledge of medicine use (KOMU) in SI patients. Correlation analysis was used to investigate the strength of the relationship between specific variables with KOD and KOMU using the Pearson correlation coefficient.

Qualitative semi-structured interviews were conducted with pharmacists from community, hospital and primary healthcare clinics in both a small town and a major metropole. The aim was to gain deeper understanding of issues arising from the survey, and to explore preferences for topic-specific information materials. All interviews were audio-recorded and transcribed verbatim. Thematic analysis was used to analyse the data.

A total of 439 pharmacists responded to the survey, with 67% being females. The mean KOD score out of a maximum score of 10 was 6.1 ± 1.8. KOD was inadequate (≤5) in just over one-third (37.8%) of pharmacists. The mean KOMU score achieved (maximum score 17) was 9.4 ± 2.0, with inadequate knowledge (≤10) being established in just over two-thirds of pharmacists (70.8%). Age, length of registration as a pharmacist, and years of practice in a setting with direct patient interaction were significantly but weakly correlated with KOMU,

whereas KOD showed no significant association with these variables. Qualification significantly influenced both KOD and KOMU; the highest group with adequate knowledge had either a Masters or a PharmD degree.

Fewer than half the pharmacists (44%) never ask patients about their swallowing ability, and most (86%) reported no knowledge of locally available viscosity enhancers. Almost all pharmacists were interested in receiving information materials on assisting SI patients with their medicine use.

Three major themes emerged from the semi-structured interviews. Pharmacists recognised their knowledge deficit and felt that lack of both undergraduate training and formal training during practice, as well as limited exposure to SI patients, were contributing factors. Barriers to their practice with SI patients included lack of time, lack of institutional support and lack of easily accessible references on the pharmacists' role in supporting medicine use in SI patients. Lastly, most pharmacists were not prepared to take ownership of medicine-related problems in SI patients and had conflicting opinions of the pharmacists' role, usually shifting the responsibility of medicine use in SI patients to nurses.

This is the first study to investigate pharmacist knowledge of medicine use in SI patients. The findings indicate that pharmacists do not have the requisite knowledge when dealing with SI patients and their medicine-taking issues despite being the most highly trained healthcare professionals in this field. Lack of undergraduate training, in-house training and limited exposure to SI patients were reported to contribute to poor knowledge. Current practice revealed that there appears to be poor communication among different healthcare professionals, pharmacists were reluctant to work with and/or train nurses on appropriate medicine use in SI patients, and there appeared to be ambiguity surrounding the role of a pharmacist. This research identified that pharmacists regard this topic to be highly relevant to their everyday practice and are keen to receive more information and training relating to this area of study. Information materials were designed and will be made accessible to all pharmacists registered in South Africa.

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DEDICATION

"Every experience, no matter how bad it seem, holds a blessing of some kind. The goal is to find it."

Buddha

This thesis is dedicated to all swallowing-impaired patients…

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LIST OF ACRONYMS

API	Active Pharmaceutical Ingredient
CPD	Continuing Professional Development
FIP	International Pharmaceutical Federation
HCP	Healthcare professional
KOD	Knowledge of dysphagia
KOMU	Knowledge of medicine use
MAE	Medicine Administration Error
MR	Modified Release
PSSA	Pharmaceutical Society of South Africa
SA	South Africa
SAACP	South African Association of Community Pharmacists
SAAHIP	South African Association of Hospital and Institutional Pharmacists
SAPC	South African Pharmacy Council
SI	Swallowing-impaired
SODF	Solid Oral Dosage Form
SSI	Semi-Structured Interview
UK	United Kingdom
WHO	World Health Organisation

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CHAPTER 1
INTRODUCTION

1.1 Background to research

Swallowing impairment or dysphagia refers to difficulty and discomfort during the act of swallowing. Dysphagia is a growing problem that affects 13.5% of the general population (1). It generally occurs in all age groups but the prevalence increases with age (2). The ability to swallow is imperative to all patients, especially those in need of solid oral dosage forms (SODFs). The oral route is the most widely used route of administration, with tablets and capsules being the SODFs of choice for their convenience, accuracy of dosing, ease of handling, consistent quality and relatively low price (3). The administration of SODFs presents a challenge for swallowing-impaired (SI) patients, with tablets and capsules often requiring modification in order to be ingested.

SI patients are more prone to medicine administration errors (MAEs) due to the need to match the dosage form to swallowing ability (4). To address their medicine-related needs, healthcare professionals (HCPs) require the appropriate knowledge to support and advise these patients. Pharmacists should inhabit a central role in assessing the medication regimen of SI patients for potential problems that might impact on patient safety, adherence and therapeutic outcome. Despite the growing interest in swallowing impairment and related healthcare needs, limited research has investigated pharmacist knowledge and their potential information needs regarding dosage form modifications.

1.2 Aim and objectives

The aim of this research was to investigate pharmacist knowledge and practice relating to swallowing impairment, advising SI patients on medicine-taking, safe practice for dosage form modification, and to assess pharmacist information needs. This will be achieved through the following objectives:

- To describe current pharmacist practice with SI patients.
- To evaluate pharmacist knowledge of medicine-taking issues in SI patients and how they should be addressed.

- To identify the information needs of pharmacists relating to medicine administration in SI patients.
- To develop information for pharmacists to support their counseling of SI patients on general issues related to medicines administration.

1.3 Significance of the study

As there is a dearth of research on the knowledge and role of the pharmacist in medicines management of SI patients, this study should afford valuable insight into the current state of knowledge of pharmacists in this area, and how pharmacists perceive their roles in caring for this patient group. The findings should be of value to pharmacy curriculum developers in informing undergraduate education curricula as well as continuing professional development (CPD) modules for pharmacists. Pharmacy organisations, both local and international, could use the knowledge generated by this research in evaluating the role of the pharmacists in patient care, and in strategising to improve patient care through pharmacist intervention. The information materials developed in response to pharmacists needs and desires could, if well designed, increase their general knowledge of dysphagia, which in turn may enhance their practice and improve patient care in a particularly vulnerable patient group.

1.4 Conceptual framework

For this study I did not use a predetermined theoretical framework, but was guided by fundamental factors influencing the professional role of a pharmacist. These factors include good pharmacy practice guidelines at a national and global level, undergraduate education, continuous professional development, and the knowledge, skills and attitudes of pharmacists. (Figure 1.1).

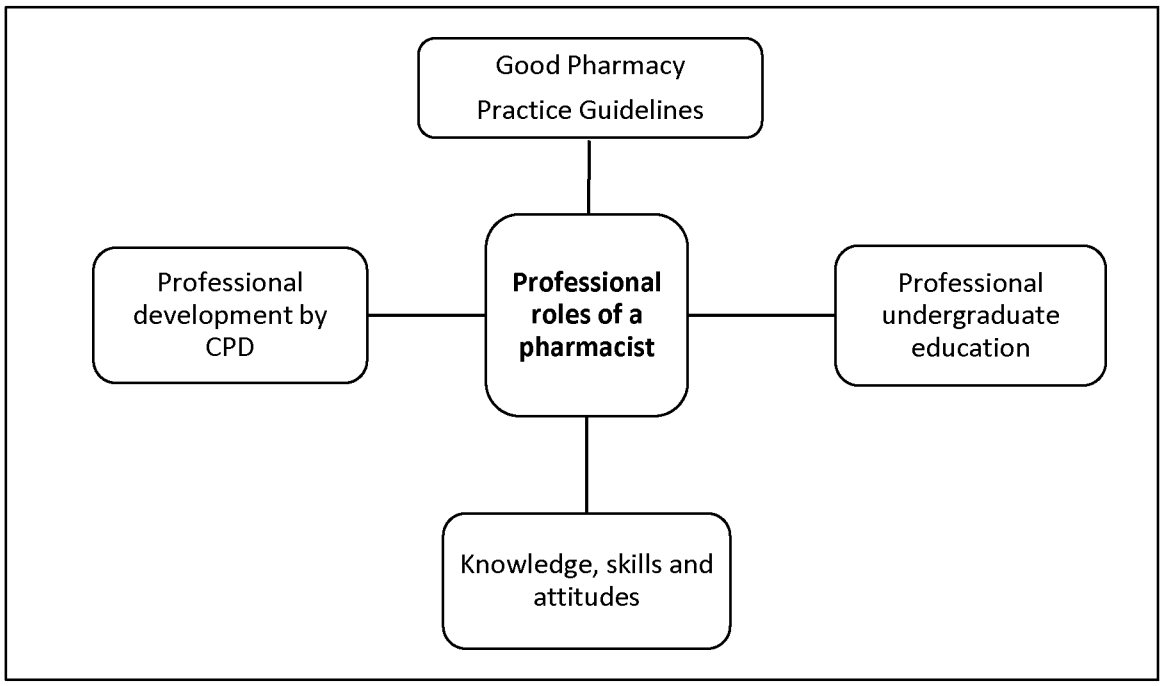

Figure 1.1 Fundamental factors influencing the role of a pharmacist

The World Health Organisation (WHO) envisages healthcare as "…the highest attainable standard of health as a fundamental right of every human being." This implies a clear set of legal obligations on states to ensure appropriate healthcare conditions (5). Barriers to quality health include poor access to quality medical products, lack of access to trained health professionals, an inadequate health workforce, and poor standards of education of HCPs (6).

Medicines are an integral part of healthcare services, and pharmacists, as the custodians of medicines, play a key role in providing quality healthcare and medicine-related services, thereby ensuring that this fundamental human right is fulfilled. The WHO and the International Pharmacy Federation (FIP) together describe the role of pharmacists as promoting and supporting safe, effective, and rational use of medicines (6). Within the pharmacy profession, there is increasing recognition that providing consumers with medicines alone is not sufficient to achieve therapeutic outcomes. To address these medication-related needs, pharmacists are accepting greater responsibility for the outcomes of medicine use and are evolving their practices to provide patients with enhanced medicines-use services (6).

The WHO eight-star pharmacist concept incorporates eight personality traits into the development of a pharmacist's role. Figure 1.2 depicts the core standards needed to satisfy the role of a pharmacist

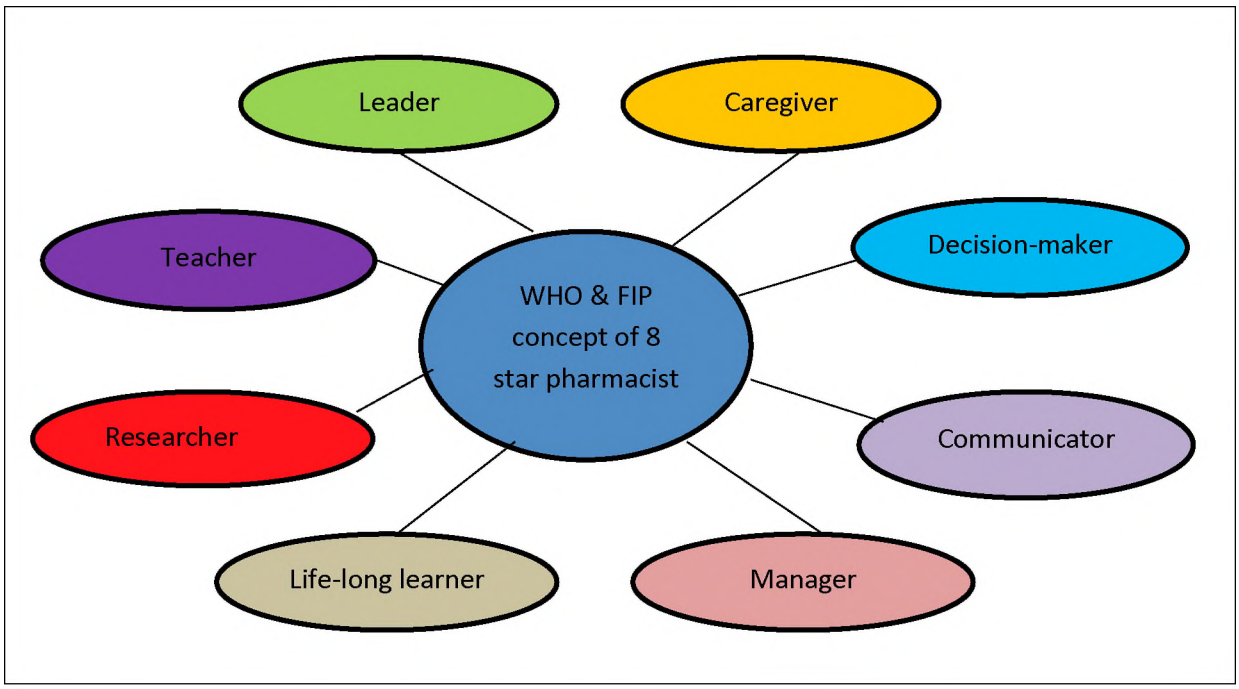

Figure 1.2 The WHO and FIP eight star pharmacist (7).

The South African Pharmacy Council (SAPC) is the national regulatory body governing pharmacists and pharmacy practice in South Africa (SA). Their mission includes protecting the public by improving health outcomes, assisting in promoting access to sustainable quality pharmacy services by embracing the use of innovation and technology, ensuring quality pharmaceutical services by developing, enhancing and upholding universally acceptable education and practice standards through stakeholder engagement and promoting the dignity of the profession through professional ethics and conduct, and ongoing competence (8).

Undergraduate training should equip the pharmacist with adequate knowledge and expose students to the practice environment in order to develop professional skills. The knowledge base of diseases and their management is constantly expanding, along with the number of people who have access to healthcare. The range and complexity of treatment options has also increased significantly, making it essential that pharmacists adopt life-long learning as a principle of their practice. This has become increasingly important given the increase in the

elderly population with a concomitant rise in age-associated diseases and age-related changes that can influence the management of medicines.

The knowledge, skills and attitudes of pharmacists all influence the quality of care that patients receive. Undergraduate pharmacy education programmes usually offer a general education in pharmacy practice. However, different practice sites often demand different knowledge, skills and expertise of the pharmacist. Ideally, on-site practice-based training should be offered to support the pharmacist in developing these skills (9). Inadequate practice-related knowledge may be due to lack of self-initiated post-training education and training. Self-directed lifelong learning is essential for pharmacists to remain current and to adapt to practice in a new setting.

Mandatory CPD and the recording of related activities was introduced by the SAPC in 2015. Ongoing CPD is also a requirement of continued registration as a pharmacist in many other countries. CPD can be defined as ongoing learning, or means, by which persons maintain, broaden and improve their professional development throughout their professional life (10). CPD enables pharmacists to develop in their area of practice, and assists in keeping them abreast of developments in all areas of pharmacy practice and the pharmaceutical sciences.

1.5 Overview of phases of the study and chapter summaries

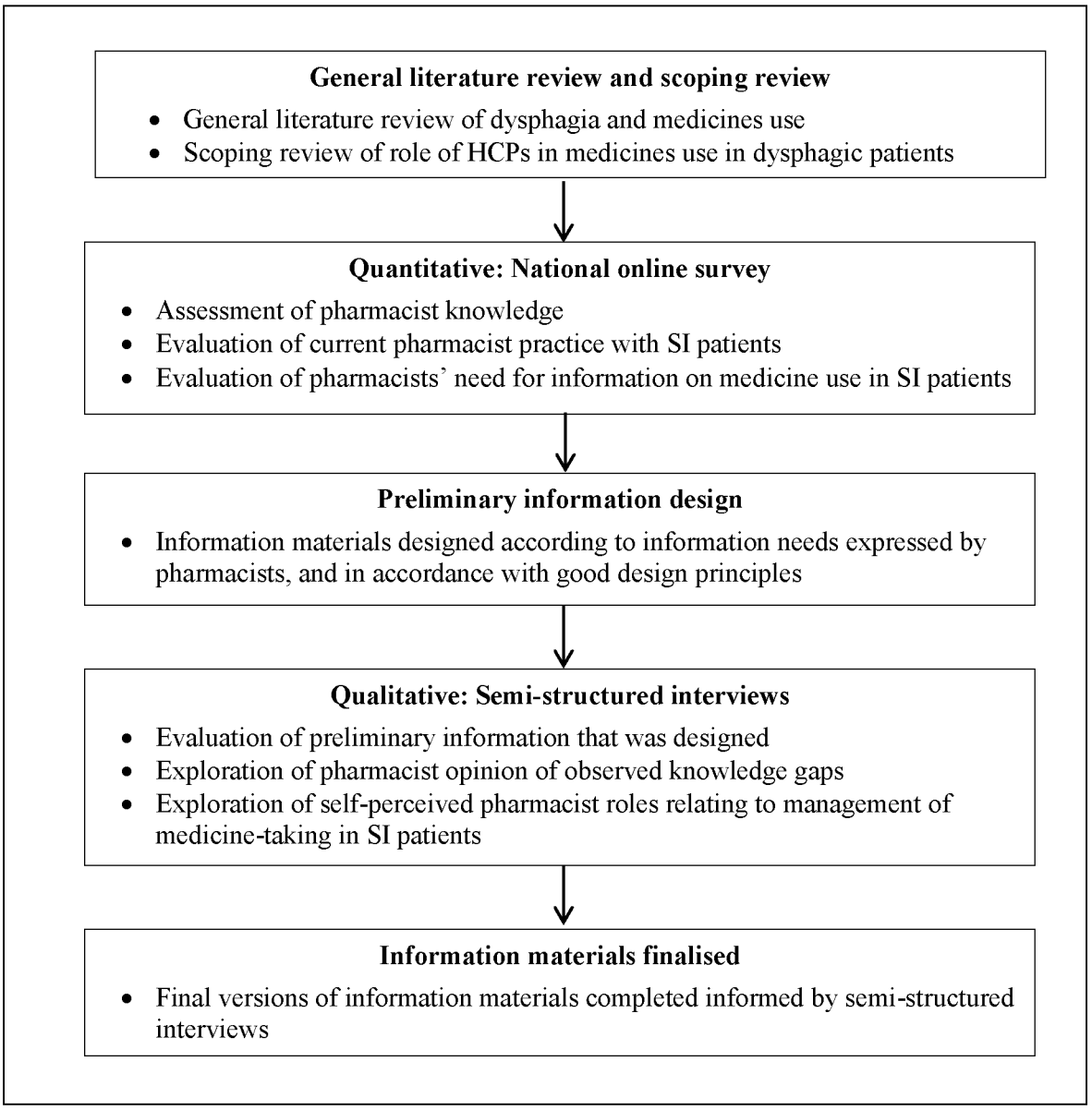

Figure 1.3 Flow diagram of study phases

Chapter 2 is a literature review that begins with a description of the burden of dysphagia and describes the pathophysiology, consequences and management of the disease condition. The problem of SODFs in SI patients is introduced, and the prevalence and implications of SODF modification discussed.

Chapter 3 introduces the concept of the pharmacist's role in assisting SI patients with their medicinesmanagement. A scoping review conducted for this project to investigate the role of HCPs and medicine use in SI patients is described and the findings discussed.

Chapter 4 describes the study design and methodology used for the quantitative phase of the study, providing details of ethical considerations, study setting, population, data collection and analysis. The development of the online national survey as the main research tool is described.

Chapter 5 reports the quantitative results of the online national survey. Results obtained regarding pharmacists' knowledge of dysphagia and of medicine use in SI patients are presented. Results pertaining to current pharmacist practice with SI patients is described.

Chapter 6 reports the qualitative results of the study, starting with reasons for inadequate knowledge on the topic, information needs of pharmacists, opinions on a multidisciplinary approach and ending with pharmacists' perceptions of their role in managing medicine use in SI patients.

Chapter 7 discusses the process by which information material for pharmacists was designed. Results obtained from qualitative SSI on preliminary information design are discussed and the final information design and distribution process is described.

Chapter 8 discusses the study findings and contextualises them within the literature. Lastly, the limitations of the study are described.

Chapter 9 concludes the thesis by reflecting on the study aims and objectives in relation to the findings, explores practical application of the findings and provides recommendations for future research.

CHAPTER 2
LITERATURE REVIEW: DYSPHAGIA AND MEDICINE USE

2.1 Introduction

This chapter presents background information on dysphagia as a disease condition and medicine use in SI patients. Topics covered in this chapter include the process of swallowing and swallowing impairment, demographic transition and ageing, comprehensive information on dysphagia (prevalence, types, presentation, causes, diagnosis, consequences and management) and information pertaining to medicine use in SI patients.

2.2 The swallowing process

Swallowing is a function that affects the physical and mental health of individuals. It is the product of a complex series of events that require an intact nervous system and adequate musculature to initiate, facilitate, and conclude a safe swallow (11). People swallow 600 times daily and under normal circumstances swallowing is performed with no prior thought or effort (12).

The process of swallowing is known as deglutition and consists of voluntary and involuntary components. Anatomically, swallowing can be broken down into three phases: oral, pharyngeal and oesophageal (Figure 2.1). The oral phase includes preparatory as well as early transfer stages. Food enters the oral cavity and is followed by mastication and the formation of a bolus of suitable size and consistency (2). As the bolus enters the back of the throat, the second stage of swallowing, known as the pharyngeal phase commences, in which the tongue propels the bolus into the oesophagus. Lastly the oesophageal phase involves the passage of food down the oesophagus through the lower oesophageal sphincter to empty into the stomach (13). The oral phase is voluntary, whereas the pharyngeal and oesophageal phases are mediated by an involuntary reflex called the swallowing reflex.

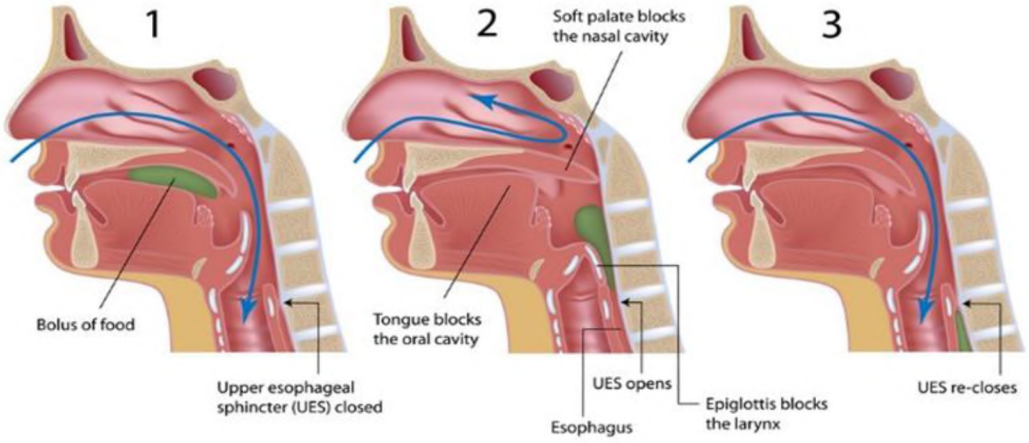

Figure 2.1 The swallowing process (14)

Table 2.1 gives a summarised version of the physiological mechanisms which occur within each phase of swallowing (2).

Table 2.1 Physiological mechanisms occurring during swallowing

Phase	Physiological Mechanism
Oral	Food enters oral cavity
	Mastication and bolus formation
Pharyngeal	Soft palate elevates to seal nasopharynx
	Larynx and hyoid bones move anterior and upward
	Epiglottis moves posteriorly and downwards to close
	Upper oesophageal sphincter relaxes and opens
	Tongue propels bolus into oesophagus
	Pharynx contracts and closing of the upper sphincter
	Larynx reopens
Oesophageal	Oesophagus contracts sequentially
	Lower oesophageal sphincter relaxes

A normal swallow provides efficient, unidirectional flow of the ingested bolus, while avoiding undesired deviation into the nasal cavity or respiratory tree. The interruption, at any stage of these precise and synchronized movements, results in the phenomenon known as dysphagia.

2.3 Dysphagia

Dysphagia or swallowing impairment can be defined as difficulty or discomfort during the act of swallowing (15). Dysphagia often arises from a structural or neurological dysfunction. The underlying complexity of the swallowing process provides a medium for different

disease conditions and/or medication to affect the structure of the oral cavity, pharynx and/or oesophagus resulting in dysphagia (16). Figure 2.2 demonstrates changes in the anatomical structure of an SI patient.

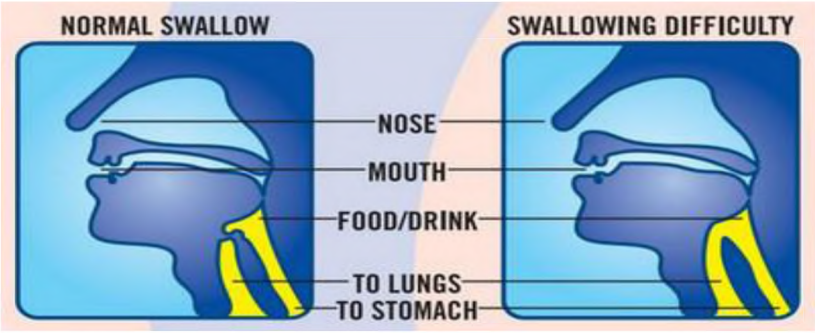

Figure 2.2 Normal versus SI patient anatomy (17)

Dysphagia is a growing problem that affects 40%–70% of patients with stroke, 60%–80% of patients with neurodegenerative diseases, 13% of adults aged 65 and older, and 60%–75% of patients who undergo radiotherapy treatment for head and neck cancer. Literature suggests that one in 17 people will develop some form of swallowing impairment in their lifetime (2). Dysphagia is difficult to ascertain given the variations in how swallowing impairments are defined and the assessment measures used to identify them. Dysphagia cuts across so many diseases and age groups that its true prevalence in adult populations is often underestimated (18).

The number of people aged 65 years and older will increase significantly in the coming decade (19). This trend follows the demographic transition model which proposes a decline in mortality, followed by reduced fertility, leading to an interval of first increased, and then decreased, population growth and finally, population ageing. The increase in life expectancy poses a challenge to HCPs as older people are frequent users of healthcare services (20), accounting for 50% of prescribed medicines (4). Medication management is more challenging and complex in the elderly patient due to the presence of more chronic diseases and polypharmacy (21,22), with the higher prevalence of dysphagia exacerbating the problem.

2.3.1 Types of dysphagia

The two types of dysphagia, known as oropharyngeal and oesophageal, are classified according to the anatomical region affected. Oropharyngeal dysphagia, affecting both the oral

and pharyngeal phase of swallowing, occurs due to failure to move food into the oesophagus or to spit food out resulting in gagging, drooling, regurgitation of food through the nose and a sensation of food being stuck to the back of the throat. Any impairment or malfunction of the passage of food down the oesophagus into the stomach will result in oesophageal dysphagia, with a common symptom being discomfort or pain in the chest area (13).

The presentation of dysphagia can differ among individuals depending on the phase of swallowing implicated. Although it is commonly assumed that patients can accurately localise dysphagia to the level of actual obstruction, this is not always the case. About one-third of patients identify a site well above the level of obstruction documented by radiographic studies (12). Signs and symptoms of oropharyngeal dysphagia include the following: coughing or choking with swallowing, difficulty initiating swallowing, food sticking in the throat, sialorrhoea, unexplained weight loss, change in dietary habits, recurrent pneumonia, change in voice or speech, and nasal regurgitation. Signs and symptoms of oesophageal dysphagia include the following: sensation of food sticking in the chest or throat, change in dietary habits, recurrent pneumonia, symptoms of gastro oesophageal reflux disease, including heartburn, belching and sour regurgitation (23). Other associated symptoms of dysphagia include general weakness and mental status change.

2.3.2 Causes of dysphagia

The three major causes of dysphagia are ageing, selected diseases and medicines. Ageing results in decreased lingual strength and pressure generation, as well as diminished pharyngo-laryngeal sensory sphincter relaxation (24). The major age-related alterations occur in each phase of swallow. Alterations in the oral phase include reduction in strength of masticatory muscles and tongue movement as well as deterioration of dental apparatus. These changes may lead to difficulty in bolus preparation and in propelling the bolus towards the pharynx. Alterations in the pharyngeal phase include delayed triggering of the pharyngeal swallowing reflex and opening of upper oesophageal sphincter. These changes will alter the length of pharyngeal swallowing time and will drop the bolus into the larynx or pharynx. Alterations in the oesophageal phase include upper and lower oesophageal sphincter dysfunction, which results in oesophageal retention in the proximal oesophagus leading to gastro-oesophageal reflux (25).

Pathophysiologically, the causes of dysphagia can be broadly grouped into four disease categories: neurological diseases such as stroke, Parkinson's, Alzheimer's and dementia, musculoskeletal conditions such as cerebral spinal muscular atrophy and myasthenia gravis, metabolic conditions including diabetes and Cushing syndrome, and oncological conditions such as head and neck cancer (26). Medication can also induce dysphagia. Table 2.2 gives a summary of the disease conditions that contribute to dysphagia (27).

Table 2.2 Diseases conditions contributing to dysphagia

Disease conditions	
CNS	**Musculoskeletal**
Stroke	Spinal muscular atrophy
Alzheimer's	Myasthenia gravis
Parkinson's	Zenker diverticulum
Dementia	Osteoarthritis
Motor neuron disease	Polymyositis
Amyotrophic lateral sclerosis	Inflammation myopathies
Multiple sclerosis	**Metabolic**
Schizophrenia	Diabetes
Depression	Hyper and hypothyroidism
Infectious brain disease	Cushing syndrome
Polyneuropathy	**Oncological**
Down's syndrome	Brain and neck tumours
Traumatic brain injury	

A number of classes of medicines, as well as individual medicines, are associated with the development of dysphagia (Table 2.3) (27).

Table 2.3 Medicines contributing to types of swallowing impairment

Oesophageal injury	Xerostomia	Dysphagia
Antibiotics	Antipsychotics	**Antipsychotics**
Tetracycline	Antidepressants	Haloperidol
Macrolides	Antiemetics	Olanzepine
Penicillin	Anxiolytics	Clozapine
NSAIDs	Antihistamines	Risperidone
Acetylsalicylic acid	Anticholinergic	**Anticholinergics**
Piroxicam	Antihypertensives	Nitrazepam
Indomethacin	Bronchodilators	Clonazepam
Bisphosphonate	Diuretics	**Chemotherapy**
Alendronate		Vincristine

2.3.3 Outcomes of dysphagia

Impairment of the swallowing process may result in negative health outcomes. These can be physical, such as malnutrition, resulting from inability to consume adequate nutrition to maintain a healthy weight, dehydration due to inability to drink enough fluids to maintain adequate hydration, chest infection if bacteria from food enter the lung as a result of difficulty swallowing, and aspiration pneumonia due to inhalation of foreign matter, which is a major cause of morbidity and mortality among the elderly who are hospitalized or in nursing homes (28,29).

Apart from physical difficulties, dysphagia has a wide range of social and psychological consequences. Eating and drinking in society are considered a social platform, and are often the highlight of celebrations and religious holidays among family and friends. Dysphagia can negatively impact these social opportunities, affecting the relationships patients have with friends and family. Patients with dysphagia can become isolated, feel excluded and judged by others, and be anxious and distressed at mealtimes (30). Dysphagic patients often have low self-esteem, diminished self-confidence, an overall negative outlook, and decreased work capacity, motivation and leisure (31,32). A study conducted in four different countries demonstrated that although 84% of SI patients thought that eating should be an enjoyable experience, only 45% considered it so. Over a third (36%) avoided eating with others because of their dysphagia. Anxiety and panic attacks during mealtimes were experienced by 41% because of food sticking in the throat or because of experiencing a feeling that they were choking (32). Swallowing-impairment therefore has a major negative influence on patients' overall quality of life (33).

2.3.4 Management of dysphagia

Dysphagia can be managed using compensatory or rehabilitative strategies, or a combination of both. Compensatory methods aim at reducing the effects of impaired bolus flow using postural adjustments, diet modification and oral hygiene. Postural changes consist of moving the head to the non-affected side, enabling redirection of the bolus through the oral cavity (head tilt), tilting the head to the weaker side to ensure that this side is closed off and the bolus redirected to the stronger side (head rotation), moving the chin down so that the bolus

is directed anteriorly which prevents premature spillage (chin tuck) and tilting the head back which utilises gravity to clear the oral cavity (25,34,35).

Dietary modification to ensure a dysphagia diet allows for the safe modification of liquids and solids by modifying their consistency (36). As thin liquids can cause difficulties to SI patients due to loss of muscle control, increasing their viscosity using thickeners decreases the flow rate, allowing SI patients more time to protect their airways.

There are three different consistencies of liquids:

- nectar-like which is similar to a thick milkshake or tomato juice,
- honey-like which approximates the thickness of bee honey, and
- spoon-thick with a consistency similar to pudding or a thick yoghurt (37,38)

Typically the least viscous liquid (nectar-like) is used for mild dysphagia, whilst increasingly thicker liquids are used for the management of moderate to severe forms of dysphagia (39).

Similarly, with solid or semi-solid food, the consistency can be altered to allow the patient to control the speed of transit of the bolus (40). According to the dysphagia diet there are three levels based on severity of dysphagia.

- Level 1 - for moderate to severe SI patients, consists of pureed food that easily stays together where little or no chewing is required.
- Level 2 - for mild to moderate SI patients, composed of foods that are soft, moist and easily form a bolus, where some chewing is required.
- Level 3 - for mild SI patients, consists of all food except hard, sticky and crunchy food. Food needs to be moist and cut into bite size pieces (41–43).

Guidelines for safe swallowing during mealtimes include the following (25,44,45):

- maintain an upright position (90°) while eating,
- eat slowly,
- avoid mixing liquids and solids in the same mouthful,
- eat in a relaxed atmosphere, and
- maintain good daily oral hygiene and ensure regular dental examinations as poor oral hygiene can increase the risk of infection

Rehabilitative swallowing interventions are designed to directly improve dysphagia and are exercises targeted to train specific muscles or muscle groups (25,46). These various therapies are aimed at increasing tongue base retraction and pressure during the pharyngeal phase closing the airways prior to and during the swallow (47) and increasing tongue base and throat muscle motions which enhances posterior pharyngeal wall movements aiding transport through the pharynx (25). Increasing the duration of cricopharyngeal opening through amplifying the extent and duration of laryngeal elevation (25) and repetitive head raising motions improve hyoid and laryngeal elevation which allows longer opening of upper oesophageal sphincter are also therapies used for treating dysphagia (48).

2.4 Solid oral dosage form use and modification in patients with swallowing impairment

Medicines are integral to disease management. However, key to optimising drug therapy is ensuring that the patient receives the desired medicine at the right dose by the right route at the right time (49). The oral route is the most widely used route of administration. Tablets and capsules are the SODFs of choice for their ability to cheaply and accurately deliver a specific quantity of active pharmaceutical ingredient (API) (50). There are several advantages related to the use of SODFs such as dose accuracy, a variety of different release profiles, facilitated drug distribution, non-invasiveness and ease of use by patients (3,20,51). The manufacturing of SODFs is generally less complex and thus cheaper than other types of dosage forms. Stability problems are rare, a variety of non-toxic excipients are available, and masking of taste is accomplished more easily than for liquids (52).

As SODFs need to be swallowed in order to reach the dissolution site and exert their full therapeutic effect (53), an important requirement for adequate efficacy is that they should be safely swallowed (54). However, in SI patients, tablets or capsules may cause choking, with the subsequent risk to the airway resulting in fatal consequences. There is an increased risk of a tablet or capsule becoming lodged in the throat resulting in incorrect drug dispersal and changes in efficacy, together with possible oesophageal damage (54,55). Problems such as these are likely to compromise adherence (56), resulting in suboptimal health outcomes.

Various aspects of SODF formulations have an effect on swallowing. Tablet size was found to affect the swallowability and oesophageal transit in adults; smaller tablets are generally easier to swallow and show faster oesophageal transit than larger tablets (56). Tablet shape

also affected swallowing, torpedo-shaped tablets or capsules are easier to swallow. Surface characteristics were found to have a major influence as smooth coatings were preferred in comparison to chalky texture tablets. Liu *at al.* found that density and type of formulation can affect the swallowability and oesophageal transit of tablets and capsules (57). Visual characteristics such as colour of SODFs are associated with flavour perceptions (58). Tablet colour has been linked with taste. A study found pink coloured tablets to be considered sweet and yellow tablets to be salty (59).

There is a need to match medication therapy to swallowing ability in individual patients, and this can present a challenge. There are three categories of SI patients: those with partial dysphagia who have some ability to swallow, those with complete dysphagia who require the placement of an enteral feeding tube, and those with total dysphagia who do not have any access to their gut because an enteral tube has not been sited. There are also those patients who would not normally be classified as being swallowing-impaired, but who still have difficulty swallowing tablets; these patients tend to chew tablets which can have the equivalent effect of crushing the medication (60). Advanced skills and knowledge are required in managing medicine use in patients with swallowing difficulties to ensure adherence and desired therapeutic outcomes. There is a higher potential of MAEs in these patients owing to their inability to conclude a safe swallow (61).

Approaches to managing problems with swallowing SODFS include modification of the tablet or capsule, substituting the drug with one that is in the same therapeutic class (55), or suggesting an alternate route of administration (16).

2.4.1 Adverse drug events, medicine errors and medicine administration errors

Adverse drug events are defined as injuries that result from medication use. The annual incidence of adverse drug events resulting from medication errors in hospitalised patients in United States of America is estimated at 400,000, approximating one medication error per patient per hospital day (62). Medicine errors can occur in any of the five stages of the medication process: ordering/prescribing, transcribing and verifying, dispensing and delivering, administering, and monitoring and reporting (63). MAEs are defined as "mistakes associated with medicines that are made during the medication process". A multinational

systematic review interrogating the prevalence and nature of MAEs found the median MAE rate to be 19.6% in healthcare settings (64).

A component of MAEs is the modification of SODFs. Studies have found patient- or carer-reported prevalence of medication modification in the general community to be between 43% (65) and 68% (66) with almost half of the patients seemingly unaware of the dangers associated with modifying SODFs (67–69). The incidence of institutional SODF modification has been found to vary from 26% in a United Kingdom hospital (70), to 34% in 10 South Australian aged care facilities. In the latter case, 17% of the modifications were of medications that should not be altered, with 18% of all medicines administered to the residents being medicines for which there are concerns about modification (69). In another Australian study, 79% of all the 97 hospitals investigated in a single study reported that medication was modified at the bedside (50).

SODF modification is reportedly a routine component of clinical practice, particularly with SI patient populations. SI patients experience over three times the frequency of MAEs as compared to patients with no swallowing difficulties (31). A study conducted by Kelly *at al.* identified a statistically significant rise in the risk of MAEs for patients with dysphagia due to SODF modification (61). Incorrect medicine preparation and the use of inappropriate formulations were identified as the main causes for errors in SI patients. It is clear that modifications occur even in situations where alternative formulations are available and/or in situations where the modification is prohibited by the manufacturers' guidelines (69,71).

2.4.2 Tablet crushing and capsule opening

The most common SODF modifications are tablet crushing and capsule opening. Studies have shown that between 24.1% and 31.0% of all tablets prescribed for adult patients in primary care are split prior to administration (65) with data from long-term care indicating that 35.4% of older adults receive at least one split medication (72). Disconcertingly, Paradiso *at al.* (69) reported that 18% of all medicines administered to the residents of 10 aged-care facilities were medicines for which there are concerns about modification. Modifying drug products and dosage forms in a pharmacy has to be done based on the available information about the specific product. The available information in product labels often only includes the warning 'do not crush the tablet', without any further details that

would allow a good judgement on the risk-benefit (73). In a study set in community pharmacy, Lau *at al.* (68) found that 17.5% of 369 pharmacy customers reported swallowing difficulties, 11% reported modifying medication dosage forms and, disconcertingly, almost half (44%) of those surveyed did not think there would be problems with modifying medicines.

2.4.3 Problems associated with tablet crushing and capsule opening

Enteric coatings on tablets are polymers that remain intact in the stomach, but dissolve and release the drug in the more alkaline pH of the small intestine. Enteric coatings are applied to tablets to either delay the release of drugs that are inactivated by the stomach contents, to prevent irritation to the stomach, or to delay the onset of action to a specific site within the gastrointestinal tract. Crushing enteric coated tablets may result in the drug being released too early, destroyed by stomach acid, or irritating the stomach lining. There are also problems with tablets/capsules which contain enteric-coated beads (74). Since it is common practice to mix the contents of the capsule with fruit juice and other acidic mixers, should the enteric coated granules be crushed or chewed during the mixing/administering process the API will be subject to degradation prior to reaching the site of action (75).

Other types of tablet coatings may be used to protect photo-labile drugs from the effects of light and destroying this coat will result in the drug becoming susceptible to degradation (16). For drugs which have a particularly bitter taste, a sugar or film coating is used to help mask the taste of the active substance. Crushing such tablets may produce a preparation which is unpleasant to taste and which may affect the willingness to take the medicine (16).

Modification of dosage forms may not only have undesirable effects on the user, but may also affect the administrator, if this is not the patient. Crushing products with carcinogenic or teratogenic properties may expose carers and HCPs to health risks through powder aerosolisation. Several drug substances may also cause irritation to eyes, skin and mucous membranes if the powder is aerosolised and inhaled (76).

There are significant legal implications related to making any changes to the original dosage form registered by the manufacturer. Crushing, breaking and opening of tablets/capsules before administration will result in the altered product being unlicensed (76). Unlicensed

medication poses a risk of causing harm to the patient, but in such circumstances the manufacturer bears no responsibility for any resulting harm as the product is now dispensed in an unlicensed form. The responsibility for any adverse effects is now borne by the prescriber and/or the dispenser (77), or any associated HCPs who altered the medication (54). If the patient's health deteriorates due to dosage form modification as advised by an HCP, the HCP who offered the advice can be sued for negligence (55,76,77).

2.4.4 Administration, co-mixing and the use of viscosity enhancers

After modification, administration of the modified SODF occurs. According to literature, the method by which SODFs are administered is often suboptimal. Individuals with dysphagia find the turbulent and fast flow of liquids difficult to control during passage through the pharynx, resulting in impaired airway protection. One of the methods of managing this challenge is to thicken liquids in order that they flow more slowly, allowing the individual time to co-ordinate safe swallowing (39). It has been shown that viscosity enhancers can be used to thicken liquids to improve bolus control and contribute to a safe swallow (38,78). Typically, the least viscous is used for mild dysphagia, whilst increasingly thicker liquids are used to manage more severe forms of the condition (39).

The co-administration of food/drink with modified SODFs to facilitate ease of swallowing is common practice. Co-administration of immediate release crushed tablets with food-based vehicles or thickening agents provides a functional approach to medicine administration as it reduces the discomfort caused by SODFs for patients with swallowing difficulties, but with it comes the potential for unexpected drug release and dissolution profiles. A study conducted among 97 Australian hospitals found that in 21 of the 97 hospitals, two or more medications were often crushed and mixed together. Mixers used included jam, water, honey, juice, custard, yoghurt and mixing into the patients' food (50). A study conducted by Akram and Mullen in the UK (79) found that psychiatric nurses commonly mixed mental health drugs with a variety of food to facilitate administration. For example, Atomoxetine and Phenytoin capsules were emptied into various flavours of yoghurt and crushed bananas, and Risperidone and non-psychiatric drugs such as prednisolone and antibiotics were mixed into diluted blackcurrant juice or concentrated orange juice (79).

Crushing a tablet and/or sprinkling the contents of a capsule over food, or mixing in a drink, is a common practice which may lead to errors in preparation or delivery of dose as bioavailability may be altered (75,80). Fruit juices such as grapefruit, orange or apple juice have shown altered absorption profiles of numerous medicines (81–83). Many vehicles such as fruit juice (pH 4-4.5) and fizzy drinks (pH 2-2.5) are easily accessible and are used as a dispersion medium for crushed tablets and capsule contents; however the physicochemical properties of the drug should be considered in these vehicles. Since these vehicles do not contain any suspending agents and lack solubility properties, the drug will not be uniformly distributed, leading to inaccurate dosing (75).

The presence of food affects gastric emptying. There is evidence that absorption of whole digoxin, penicillin and metformin tablets may be reduced when consumed with guar gum as a source of dietary fibre and dissolution rate of benzoic acid tablets is reduced when tested in dissolution media thickened using xanthan gum or guar gum (80).

Generally, crushing tablets or opening capsules and mixing with a small quantity (e.g. two tablespoons) of food such as pudding, yoghurt or apple sauce does not significantly alter bioavailability (80). Where the addition of a vehicle is considered clinically necessary to aid medication delivery, yoghurt as compared to jam, honey and juice is the most appropriate as it can produce the mechanical profile required for oral processing in dysphagic patients without critical implications to drug dissolution (80).

In order to encourage and facilitate safe swallowing, commercially available viscosity enhancers have been introduced onto the market. These include starch-based powders, gum-based powders, gel thickeners and pre-thickened liquids and purees. Starch-based powder thickeners are usually made of modified corn starch and/or maltodextrin and can be mixed with any beverage to the desired consistency. These include Thick and Easy®, Resource Thicken-Up® and Thick-It®. Gum-based powder thickeners usually contain xanthan and/or cellulose gums and in comparison to starch-based powders will not contribute any meaningful amount of carbohydrates to the food/drink. Examples of products available include Thick and Easy Clear® and Resource Thicken-Up Clear®. Gel thickeners such as Simply Thick® have an advantage over powders in that they do not coagulate and form lumps. Pre-thickened liquids are products that have been thickened with modified corn-starch and fortified with vitamins and minerals. They require no additional ingredients or mixing

and include water, milk, and several juices or juice drinks. Pre-thickened beverages are available in economical bottles and convenient single-serving options, with examples being water, milk and a variety of juices (84).

2.4.5 Use of alternate routes of administration

An alternative to modifying the SODF is to consider a different route of administration. This may be either enteral or parenteral. Enteral means to do with the GI tract and includes oral, buccal, and rectal. Parenteral refers to injections such as intravenous, intramuscular, and subcutaneous, but could also include topical and inhalation preparations.

Enteral tube feeding is used in patients who cannot attain an adequate oral intake from food and/or oral nutritional supplements, or who cannot eat/drink safely (85). Tube feeding can be given through different types of tubes which 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 and jejunum (86). For patients who require short-term enteral nutrition, nasoenteric feeding tubes are commonly used as they are easier to place and less costly than other enteral access routes. The most commonly used is the nasogastric tube that is inserted nasally, with the distal end of the tube in the stomach.

Administering medication via an enteral feeding tube requires thought and exercise of clinical judgement**.** Most medicines are not licensed for this mode of administration and professionals responsible for prescribing, supplying and administering them accept liability for their use. Some medicines interact with enteral feeds causing a reduction in drug or feed absorption or a tube blockage. This can be avoided by using once daily dosing if possible, changing to an alternative medicine and/or administering medicines during a break in feeding (87).

The preparation of medication for administration to patients with feeding tubes is a particularly error-prone and challenging process (88). One study found that 85.5% of nurses crushed tablets and opened capsules to convert them into an applicable form for enteral tubing (89). This is incorrect practice as several issues must be considered prior to concurrent administration of oral medication and enteral formulae. Crushed tablets can result in clogged feeding tubes requiring tube replacement, drugs may bind to the tube reducing drug absorption and decreasing drug effectiveness, and there could be drug-enteral nutrition

incompatibility. Crushing enteric coated tablets, controlled-release tablets, and mutagenic and teratogenic SODFs can lead to a decrease in the medicines' effectiveness, unpredictable side-effects, irritation of gastric mucosa, and harm to the administrator (90,91).

CHAPTER 3
A LITERAURE REVIEW ON THE ROLE AND PRACTICE OF PHARMACISTS AND OTHER HEALTH PROFESSIONALS IN MEDICINES MANAGEMENT OF SWALLOWING-IMPAIRED PATIENTS

3.1 Introduction

This chapter describes a scoping review that was conducted to investigate the role of various HCPs in assisting SI patients with their medicine-taking practices and to explore their knowledge of this topic. A scoping review consisting of part of this chapter has been submitted to the International Journal of Pharmacy Practice for consideration for publication. The original submission has been modified and the modified manuscript re-submitted for further review. This chapter expands on the original focus of the scoping review with additional discussion on the professional roles of the pharmacy profession.

3.2 The professional role of pharmacists

The WHO and the FIP together developed the Joint FIP/WHO guidelines on good pharmacy practice that describe the role of pharmacists as promoting and supporting safe, effective, and rational use of medicines (6,92). However, this role may take different forms in different parts of the world, and even within the same country (92). A recent study conducted in Canada identified that a majority of pharmacists felt that their primary roles were to prevent or manage medication problems (89%), provide advice to patients about their medication or health concerns (89%), and assess patients' concerns or symptoms (88%) (93). In contrast, a study conducted in 2009 in the same country, identified that community pharmacists describe their roles primarily in terms of medication distribution (94).

In SA, the regular activities reported by public and private hospital pharmacists are usually dominated by medication dispensing and stock control (95). According to Schindel *et al.* (93), confusion pertaining to the role of a pharmacist affects how pharmacists enact their roles. The scope of practice of a pharmacist is broad enough to encompass all aspects relating to medicine and health-related needs of citizens, however, some pharmacists are hesitant and shy away from adhering to their full scope of practice despite having the authority, knowledge and expertise in the field (93).

Elvey *et al.* (96) commented on the lack of clear direction regarding the pharmacist's contribution to patient care. There is a reported resistance among some pharmacists to relinquish their drug distribution roles and to be actively involved in taking on newer roles and responsibilities (93). Some barriers to change relating to their professional role have been attributed to the attitude of pharmacists (97), with pharmacists appearing to be reluctant in changing their practice from the supply of medicines to incorporate more patient contact and clinical responsibility (98).

3.2.1. Good pharmacy practice in South Africa

According to the local pharmacy regulatory body, the SAPC, the pharmacy profession is a dynamic, information-driven, patient-orientated profession aiming to fulfil the health care needs of South African citizens (99). This regulatory body's good pharmacy practice guidelines inform the scope of practice of pharmacists in ensuring that the above responsibilities are met. The scope of practice guidelines of relevance to this project include (100):

- provision of pharmaceutical care by taking responsibility for the patient's medicine-related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions: evaluation of a patient's medicine-related needs by determining the indication, safety and effectiveness of the therapy; dispensing of any medicine or scheduled substance on the prescription of a person authorised to prescribe medicine; furnishing of information and advice to any person with regard to the use of medicine; determining patient compliance with the therapy and follow-up to ensure that the patient's medicine-related needs are met; and the provision of pharmacist-initiated therapy;
- compounding, manipulation, preparation or packaging of any medicine or scheduled substance or the supervision thereof;
- distribution of any medicine or scheduled substance;
- re-packaging of medicines.

3.2.2 Moving from dispensing to pharmaceutical care

The WHO and FIP are promoting an expanded role for pharmacists in order to facilitate patient care and improve drug therapy outcomes (6). An integral tenet of pharmaceutical care is that pharmacists accept and take the appropriate steps in ensuring safe and appropriate medicine use (93). Some countries have taken proactive steps to bridge the gap, resulting in the pharmacist's role transitioning from the preparation and supply of medicines to assessing and managing the drug therapy needs of patients (93,101). Innovative practice models have emerged in Canada that include the integration of pharmacists into primary healthcare teams, pharmacists practicing in specialist clinics, and medication management services in community pharmacies (93,102).

As the role of the pharmacist shifts to an increasing responsibility for patient care, collaboration with fellow HCPs increases (93). However, in SA there is no legislative guidance enabling collaborative practice in which pharmacists are able to continue management of a patient's medicine therapy after initial diagnosis and prescription by a medical practitioner (95). Research shows that patient outcomes are significantly improved through collaborative practice. According to one nurse practitioner: "I do lots of joint visits with our pharmacist just because I'm stronger in the area of physical assessment and giving diagnosis and she's stronger in the area of medication and treatment and medicine interactions. And we find that very complementary" (93). At present, SA is transitioning towards universal health care. This provides pharmacists the opportunity to play a crucial role in managing system and policy development to ensure the provision of equitable patient care (95).

3.3 Knowledge and practice of healthcare professionals relating to oral medicine use in SI patients: A scoping review

With reference to the scope of practice of pharmacists and the underlying philosophy governing their practice, pharmacists should adopt a critical role in ensuring that the medicine needs of SI patients are met. Although pharmacists are usually the first point of contact for ambulatory patients, Nguyen *et al.* (103) noted that there is limited research focusing solely on pharmacist perspectives, experiences, and knowledge of dosage form modification.

The current involvement of different HCPs and their respective roles and practice of supporting SI patients with their medicine-taking practice appear to be unclear. Additionally, little is known about their level of knowledge, the adequacy of their training, and the availability of information sources or guidelines to support them in their practice of advising SI patients with the modification and use of medicines (104). McGillicuddy *et al.* (105) in their systematic review of the qualitative literature on SODF modification, found that the key factors influencing the knowledge and attitudes of HCPs about the practice of modifying SODFs included inter- and intra-patient individuality and variability, and the complexity inherent in every aspect of the decision-making process of modifying SODFs. They also noted the lack of a formal, systematic communication process between HCPs and strongly advised that the decision-making process should be a multidisciplinary one based on evidence-based recommendations.

The primary aim of this scoping review was to investigate the knowledge (evaluated or self-perceived) and practice of HCPs relating to supporting and advising SI patients with their medicine-taking practice in either hospital or community/ambulatory care settings. Secondary aims were to describe the roles of the various HCPs in either individual or collaborative practice, to identify their reference sources (written and/or interaction with fellow HCPs) and to describe their training and information needs.

3.3.1 Method

The framework proposed by Arksey and O'Malley (106) and modified by Levac *et al.* (107) was used for this scoping review. Scoping reviews aim to map the literature on a particular topic or research area and provide an opportunity to identify key concepts, gaps in the research, and types and sources of evidence to inform practice, policymaking, and research (108,109). They also allow for a range of study designs and accommodate diverse outcomes. This is relevant to the current topic, where we anticipated only limited literature, and for which we aimed to gain a better understanding of HCP involvement, their knowledge and their opinions on training and of information resource usage.

3.3.1.1 Search strategy

Electronic databases including Scopus, Web of Science, Medline and Google Scholar were independently searched by both authors from inception to November 2016. A repeat search was conducted in July 2017 using the same search strategy. Key words and terms were identified and were incorporated into a search strategy suitable for individual databases. An example of the search strategy used for Medline, Scopus and Web of Science was: (pharmacist OR nurse OR doctor OR physician OR healthcare professional OR speech language therapist OR physiotherapist OR swallowing therapist) AND (dysphagia OR swallowing disorder OR swallowing impairment) AND (medication OR tablet OR capsule OR solid oral dosage form OR dosage form modification) AND (knowledge OR practice). The reference lists of included papers were hand-searched, and citation searching was undertaken to identify any further potentially relevant articles. Prominent authors in the field were identified and author searches performed to identify additional articles.

3.3.1.2 Study selection

Following removal of duplicates, screened titles were screened to remove those irrelevant to the review. Abstracts of the remaining articles were assessed in order to remove studies that did not meet the stipulated inclusion and exclusion criteria. Finally, the full-text of studies identified from the abstract screen were obtained and independently assessed by the researcher and her supervisor. Any disagreement pertaining to inclusion of studies was discussed until resolved.

3.3.1.3 Eligibility

Inclusion criteria for studies were as follows: (i) written and available in English; (ii) described a research study; (iii) included either qualitative or quantitative study methodology, or a combination of methods; and (iv) described knowledge and/or practice of HCPs when dealing with SI patients and their medicine taking. Studies that included medicine administration via the enteral route, reviews, opinion pieces, commentaries and editorials were excluded.

3.3.1.4 Data extraction

An extraction form specific to this study was developed. Apart from factual information such as author names, year of publication and country in which research was conducted, data extracted included aim and/or objectives, profession of participants, study design, study setting, method of data collection, knowledge, practice, information needs, availability of information/current resources, prior training, and training needs. The researcher and her supervisor then independently assessed each study and extracted the relevant data. Any disagreements were discussed until consensus was reached. For this review, severity of the dysphagia was not considered, and the term "swallowing impairment" relates to any difficulty experienced when swallowing SODFs. The general term "modified-release" (MR) is used to describe all extended-release products (controlled-release, sustained-release) as well as delayed-release products (e.g. enteric-coated).

3.3.1.5 Data analysis

Statistical pooling of data was not conducted due to the heterogeneity in study design, methodologies, outcome measures, instruments used to measure knowledge and a limited number of articles. Results of included studies are summarised descriptively.

3.3.2 Results

3.3.2.1 Study selection

Initially, 142 articles were identified, with 110 remaining after excluding duplicates. These 110 were then screened by title, which excluded 74, leaving a total of 36 articles for abstract review. The abstract screening process eliminated a further 21 articles, resulting in 15 full-text articles that were assessed for eligibility. Seven of these articles met the stipulated criteria for inclusion. A search of reference lists yielded two additional eligible articles, resulting in a total of nine articles being included. A repeat search was conducted in July 2017 but did not yield any additional articles.

Study designs of included studies were cross-sectional (103,110–112), intervention–based (113,114), qualitative(115), mixed-methods (79,110) or observational (110,113,116). The size

of the HCP study samples in these studies ranged from six to 448, and publication dates ranged from 2006 to 2015. Four of the studies were undertaken in Australia (103,113,115,116), two in the United Kingdom (UK) (79,110), and one each from Qatar (114), Oman (112) and Germany (111). All studies were conducted in institutions, including hospitals and aged care settings. Knowledge and/or practice of HCPs were addressed in all nine studies: seven included nurses only (79,110,112–116), one included doctors and nurses (111), and the remaining one included pharmacists, doctors and nurses (103). Availability/lack of current information sources (written and/or HCP) was reported in six studies (79,103,110,111,115,116). The need for adequate information and training was stressed in all nine papers.

3.3.2.2 Knowledge and practice of HCPs

Data on knowledge and practice were collected from self-completed questionnaires (79,103,110–112,114), self-reported verbal opinions of knowledge (79,110,115,116), and observer-rated compliance with guidelines (113,116). The range of topics included the following:

- identification of SODFs that should not be modified (103,111,114),
- modifying MR dosage forms (103,112,114),
- purpose and different types of MR dosage forms (114),
- MR dosage form suffixes (111,114),
- consequences of crushing or cutting MR dosage forms (103,114),
- crushing and administering multiple medications (110),
- compliance with guidelines for modifying SODFs (113),
- choosing a suitable vehicle for dispersion and considering the viscosity (79,110,115,116),
- drug stability issues (103),
- the use of protective gloves when crushing SODFs (112),
- potential harm to administrator when modifying SODFs (103),
- legal considerations (79),
- prevalence of dysphagia (103),
- vehicle used for dispersion (79,116),
- assessment of patients to establish the need to modify SODFs (115),

- problems caused by conditions associated with dysphagia (110)'
- alternative formulations that can be given (110).

Knowledge was reported as inadequate in all three of the health professions studied.

Two intervention studies assessed nurse knowledge pre- and post- an education and training intervention (113,114) One of these studies that aimed to improve knowledge and drug administration in SI patients (114) reported an overall increase in knowledge scores, including identification of MR codes (0% to 40%), and an increase from 51% to almost 90% for knowledge relating to the purpose and consequences of crushing MR preparations. In the other study aimed at assessing compliance with guidelines for the preparation of medication for SI patients (113), knowledge improvement was evident from an increased proportion of medication safely prepared (45% - 91%) and in medication prepared optimally (33% - 60%).

Three articles reported a knowledge deficit in nurses after the completion of a knowledge questionnaire (103,111,112), and four described self-reported nurse concern regarding their lack of knowledge in this area (79,110,115,116). Knowledge of nurses was found to be inadequate in the following areas: identification of MR suffixes (103,112,114), safety risks associated with destroying the tablet coating (103,111), knowledge of the legal and professional issues associated with medicine modification and potential safety risks for the person manipulating the SODF (103).

Knowledge questionnaires also identified poor knowledge in both doctors (103,111) and pharmacists (103). Doctors also had inadequate knowledge of MR suffixes, and of the safety risks for the preparing person (111), with the results similar to those found in nurses. In the only study that included all three classes of HCPs (103), 40% of nurses, 62% of doctors and 73% of pharmacists identified stomach irritation as a potential problem when MR tablets were modified in all patients regardless of the condition being treated. Half of the participants expressed concern with modifying drugs that have a narrow therapeutic index. Pharmacists (75%), nurses (37%) and doctors (34%) correctly identified that certain drugs (in this case azathioprine) can cause harm to the administrator, but few participants identified that modifying antibiotics can also constitute a risk to the administrator. Overall, knowledge levels were found to vary greatly within the nursing profession, as well as between nurses, pharmacists and doctors (113,115).

Data on practice extracted from included studies related largely to the modification of SODFs and their administration to SI patients by nurses. Additional practice areas included systematic patient assessment to identify swallowing problems, and multidisciplinary practice. Nurse-reported difficulties associated with the practice of administering medicines to SI patients included problems preparing the medicine, the time-consuming nature of modifying and then administering medicines to older patients, particularly those with swallowing difficulties, and a lack of both knowledge and advice (110,111). One paper described the practice environment of nurses as a complex and 'messy' one, with multiple demands on nurses that often then affords inadequate time for a systematic, orderly approach to medicine modification (115).

Nurses indicated having significant concerns regarding administering medicines to patients with dysphagia (110). A study from Oman found that 77% of nurses regularly crush oral solids for SI patients, but only half check the pharmaceutical characteristics of oral solids before crushing. Although a high 87% reported being aware of certain SODFs that should not be crushed, only 38% correctly stated how these could be identified (112). Of 160 observations during medication rounds at aged care facilities, 32% of instances of SODF modification by nursing staff were identified as inappropriate (116). A UK study reported that, of 24 SODFs that were crushed, in seven of the cases a liquid formulation was available and could have been substituted (110).

Other reported problems included crushing multiple medications prescribed for SI patients in the same vessel and mixing with a vehicle (112,116), not cleaning the equipment between patients (116), medication spillage (116) and medication loss due to incomplete administration of the vehicle containing the medicine (116). More than half of nurses (~52%) rarely/never use gloves during crushing (112).

When asked to identify any knowledge gaps, nurses acknowledged their lack of knowledge pertaining to medicines in general, and particularly medicine modification and use in SI patients (79,110–114,116). This included identifying medicines that were safe to crush (110–112), appropriate vehicles for dispersion of crushed tablet (79,110,112), and dosage variation due to altered bioavailability when changing from a solid to a liquid formulation (110).

Nurses were found to be more likely to ask patients about their ability to swallow medications, as compared to doctors and pharmacists (103), whereas doctors were most likely to only target patients who were predisposed, or who had pre-existing conditions that would precipitate swallowing problems (103).

Collaborative practice was identified as key to improving practice, and its current absence is evidenced in the finding that 16% of nurses assume the prescriber has considered the characteristics of the SODF before prescribing it (112). In addition, nurses noted receiving conflicting advice from the different health professions when approaching them for guidance (115). Collaboration among nurses and pharmacists, with pharmacists providing more pharmaceutically-based information for nurses was seen as a desirable practice in improving medicine modification (115). This has been implemented in some facilities where all medication issues are discussed with a multidisciplinary team (including a pharmacist) at the weekly team meeting, with team decisions then being communicated to nurses on the ward (79). Others have reported that although there did not appear to be a formal interdisciplinary collaboration process to assist in making decisions, the nurses discussed individual medication needs with pharmacists and doctor (115).

3.3.2.3 Information sources consulted for guidance

All studies included the information sources that were consulted. A major concern reported in a few papers was the lack of information available, notably pharmaceutical information on safe medication modification to support nurses, and guidance on how to access and use available resources (79,115,116). Different professional disciplines (nursing, medicine and pharmacy) involved in residential care had conflicting opinions as there was no formal guide to best practice (115). Where adequate resources were available, it was noted that none of them were used in practice during observed medication rounds, and a lack of knowledge on how to locate and use these resources was evident (116).

Written reference sources that were consulted included hospital electronic drug information systems, facility-produced guidelines, information produced by Trusts (in the case of nurses practising in the UK), or national formularies (111,113,115,116). Nurses in one study commented that, despite written sources usually being available, they were more comfortable

seeking advice from another HCP (113). Doctors and pharmacists reportedly consulted either reference texts, or asked advice from each other.

The pharmacist was cited as a reference source in all nine studies. Most nurses chose to consult a pharmacist first when requiring information about crushing MR and coated tablets (103,112,116). After a training intervention, all nurses cited the pharmacist as first choice for a consult (113). One study found that a speech and language therapist was preferred for advice over a pharmacist (110).

3.3.2.4 Information needs identified

The findings from our review indicate that nurses need practical information to support their medicine modification practice. This includes specific pharmaceutical information, guidelines regarding optimal preparation e.g. the maximum exposure time for drug mixtures, tablets/capsules that can/cannot be modified, safety aspects for the preparing person, and a protocol to help standardise the mixing process (79,111,115). In addition, these need to be easily accessible and well-structured resources (such as freely accessible databases) that offer detailed information (111). Annotated advice on the medicine chart was seen as helpful, but not all charts had space for pharmacist notes (110).

3.3.2.5 Education and training

Only two of the included studies mentioned training (of nurses) prior to the study. Almost a third of nurse participants reported that their pre-registration training had not provided adequate preparation for administering medicines to SI patients. The remainder commented that the training they received had occurred at the bedside and that no formal theory was presented in lectures (110). This was supported by findings from the second study that describes exposure to the practice of co-mixing during undergraduate placements. However, this information was usually anecdotal rather than evidence based, and depended primarily on the experience of the placement tutor.

The need for education and training was emphasised in all included studies. In one intervention study (114), feedback from nursing staff was extremely positive as they appreciated the practical solutions provided which aided better compliance with guidelines

and overall improved patient care. Ongoing CPD and education for nurses was the most frequently reported need (79,103,115), along with appropriate undergraduate and postgraduate training to assist nurses in their medication administration role (79,110,115).

Nurses felt that they would benefit from basic education and training in drug stability issues (79), updates on dysphagia and its management from speech and language therapists, updates on medicines management, medication modification, and medicine safety aspects (110). Improved staff training on how to locate and use available resources is needed to reduce the observed high incidence of inappropriate medication crushing (116). Practice can be improved if training is targeted, practical and meaningful (113).

3.3.3 Discussion

This scoping review is the first to interrogate the knowledge and practice of the different healthcare professions involved in supporting SI patients in medicines use. The HCPs investigated were nurses, pharmacists and doctors. Both measured and self-reported nurse knowledge was poor, whereas the limited research investigating pharmacist and doctor knowledge suggested inadequate knowledge. Only nurses were actively involved in the hands-on practice of medicine modification. The small number of studies meeting the inclusion criteria for the review highlights the lack of systematic, evidence-based research in this area.

Limitations associated with this review included the small number of studies included, and the variable study methods and diversity of evidence which precluded the extraction of consistent, quality data relating to knowledge and practice. The dominance of one profession, nursing, in the included papers limits the generalizability of the review findings. A further limitation is associated with the search strategy; only the word 'modification' of dosage forms was used, whereas other descriptors such as crushing, dispersion and tampering were not included.

Despite major gaps being identified in their knowledge, nurses were at the forefront of the health professions in modifying medicines and administering them to SI patients. This is understandable given their constant presence on hospital wards and in aged care homes where they are the health professionals most closely involved in hands-on care of patients/residents.

Previous research reports inadequate nurse knowledge of pharmacology, solid dosage form characteristics, drug management (regulation, storage, dispensing), and drug dose calculation (117–119). In keeping with these reports, our review findings indicate that both measured and self-reported nurse knowledge of both pharmaceutical and pharmacological aspects of medicines appears to be limited. Nurses lacked knowledge on drug stability, degradation and bioavailability issues, formulations that should not be crushed, the consequences of crushing these preparations, codes indicating MR dosage forms used by pharmaceutical manufacturers, and identification of a MR dosage form that does not contain a suffix in its name (79,103,111,112,114). This knowledge inadequacy implies that in practice almost two out of three SI patients would be exposed to risks associated with inappropriate tablet crushing (112).

An Australian audit of oral medicine modification by nurses for SI patients found that 55% of the medications were not prepared in compliance with national guidelines (20). The appropriate modification of medicines requires a focused, systematic assessment of the medicine along with the swallowing ability of the patient. However, the limited time nurses have to devote to modifying medicines prior to administration is exacerbated by multiple competing demands along with the complexity of practices encountered during medication rounds (115). These are all likely to affect their ability to systematically consider the individual medicine requirements of patients/residents and seek appropriate advice if necessary.

The gap between theoretical knowledge and its impact on practice has been widely debated and discussed in the nursing literature, with changes in knowledge and skills not necessarily resulting in change in practice (120–123). Health professionals tend to obtain information and knowledge from multiple sources, including different types of literature, fellow HCPs, CPD courses, and their own experience (124) and then integrate this with their practical knowledge and clinical judgement to attend to patients' needs (125,126). It is possible that those nurses who are aware of their own lack of knowledge and its resultant possibly poorer health outcomes may be safer practitioners than those nurses who are unaware of their incompetence. This review shows that if nurses know to seek expert guidance in the event of a knowledge lack, then a pharmacist is consulted.

The sparse data available on knowledge in doctors (two studies) and in pharmacists (one study) could possibly be attributed to an assumption that this is less relevant for doctors, and that pharmacists already possess this expertise. However, inadequate knowledge was also found in these two professions. In doctors this has a knock-on effect as nurses tend to adopt a 'doctor knows best' strategy, relying on doctors to prescribe appropriately for SI patients (79). Improved prescriber awareness of the size and availability of different formulations, as well as the difficulties associated with their administration would positively inform appropriate prescribing (79).

Pharmacists are theoretically well positioned to directly support SI patients with their medicine-related needs based on their extensive training, and, as custodians of medicines and their management (127), should provide expert opinion to all other health professionals on medicine modification and use in SI patients. The review findings, however, do not appear to reflect such practice.

Poor patient-provider communication was identified as a major theme by McGillicuddy *et al.* (128) in their systematic review on medicine-taking in older SI patients. Patients do not appear to readily offer information about their swallowing difficulties to their HCPs (54,66,68,103,129), and, conversely, HCPs rarely enquire about patients' swallowing ability (103,105,130). This may reflect inadequate awareness on the part of the HCPs as they tend to under-estimate the prevalence of dysphagia (110) as well as under-estimating the prevalence of medicine modification in the general community (103).

Pharmacists appear to be the main reference source for information on this topic. Several authors, as well as national or local organisations, have issued guidelines and educational charts informing practice, or lists of specially formulated SODFs that should not be modified (55,115,131,132). However, this information may not be readily accessible, and nurses may not be adequately trained in its use (114).

From this review, pharmacists were not shown to be directly involved in the practice of modifying and administering medicines to SI patients, or in counselling them. However, a role for pharmacists was described in the training of fellow health professionals for an intervention which significantly improved nurse knowledge (113). Pharmacists were also included in a multidisciplinary team which made decisions to ensure optimal management of

SI patients (79). The prevalence of direct pharmacist involvement (individually or as part of a team) in medicines management of SI patients, and their confidence and knowledge to adopt such a role is unknown.

Review findings highlight the need for education and training, as formal training in caring for SI patients and their medicine-taking needs does not appear to be included in medical, nursing or pharmacy undergraduate curricula (110). Nurses reported that the knowledge they acquired of dysphagia and medicines management was not formally included in their lectures, but rather learnt anecdotally through their experiences at the bedside (110). An estimate is that, by 2050, people aged 65 and over will account for about 25% of the total population of developed countries (20). Increased medicine use as well as the increased likelihood of dysphagia in this sector of the population implies that the knowledge and skills required to support medicine use in these patients should be addressed either at the undergraduate level, or be included in continued professional development offerings.

3.3.4 Conclusion

A knowledge deficit in medicines management of SI patients was identified in nurses, pharmacists and doctors. As nurses are the HCPs currently most involved in medicine modification and administration in SI patients, this has serious implications for potential medication–related errors. Best practice and positive outcomes were evident in collaborative, multidisciplinary practice models. Pharmacists are the preferred source for information and advice in this area. However, current research does not describe pharmacists as occupying a key role in directly supporting and counselling SI patients in their medicine-taking practice. Pharmacists appear suited to an educational role, delivering in-house training to other HCPs, especially nurses.

CHAPTER 4
METHOD: ASSESSING PHARMACIST KNOWLEDGE, PRACTICE AND INFORMATION NEEDS

The focus of this chapter is to describe the study design that was employed to explore, identify and supplement the knowledge, practice and information needs of pharmacists pertaining to medicine usage in SI patients. It explicitly describes the overall plan, with a detailed step by step procedure as to how the study was conducted, including study design, study setting, study population, ethical considerations, data collection tools, data collection process and analysis.

4.1 Objectives

The objectives of this phase were:

- To develop a questionnaire to evaluate pharmacist knowledge of dysphagia and medicine use in SI patients, elucidate current practice with these patients, and assess information needs relating to this topic.
- To investigate the association of knowledge with selected variables (age, education, gender, practice experience, current practice site and years of practice at a site with direct patient interaction).

4.2 Development of the pharmacist survey

The research instrument used to collect data was a questionnaire (Appendix A) designed to meet the study objectives. According to literature, most pharmacy practice researchers self-develop the research instrument instead of adapting a previously developed tool, as this allows for the study objectives to be met fully (133). Questions were developed to collect information on pharmacists' current knowledge, practice and information needs relating to medicine use in SI patients. This process was informed by the literature and a number of dysphagia websites. A consultant team was established consisting of a current dysphagic patient who is also a pharmacist, the Chief Pharmacist for stroke and care of the elderly at Northwick Park Hospital, North West London Hospitals NHS Trust; and a Professor of Pharmacy, College of Medicine and Dentistry, James Cook University, Australia. This team, which had specialist skills and insight into the care of dysphagic patients, as well as their

medicines use, participated in online discussions relating to question content, applicability and readability.

The questionnaire consisted of five sections. Each section had been designed to collect specific data required by the researcher. The five sections were as follows:

- Section 1: Demographic and educational background information.
- Section 2: Knowledge of dysphagia.
- Section 3: Current exposure to and experience of dealing with SI patients and their medicine-related issues.
- Section 4: Knowledge relating to acceptable modification of dosage forms, availability of alternate dosage forms and counseling SI patients on medicine-taking.
- Section 5: Information needs, interest in receiving information pertaining to the topic, and method of receiving such information.

Section 1 allowed for collection of pharmacist data relating to age, year of registration as a pharmacist, years of practice in community/institutional/other practice site, current practice site, direct interaction with patients, the inclusion of the topic of medicine usage in SI patients in the undergraduate curriculum, highest qualification.

Section 2 included questions for collecting data on pharmacist knowledge of the condition of dysphagia, its prevalence, and the health outcomes associated with dysphagia.

Section 3 interrogated current pharmacist practice relating to this topic. Questions covered the frequency of interaction with SI patients, experience of dealing with these patients, frequency of asking patients (general and elderly) about swallowing ability, patients voluntarily offering information about their swallowing ability, practice relating to a patient being prescribed a tablet or capsule who was unable to swallow it, knowledge and availability of viscosity enhancers, acting as an advisor to other health professionals, extent of direct patient contact on the wards, and naming the health professional most commonly advising SI patients.

Section 4 assessed pharmacist knowledge pertaining to appropriate medicine use in dysphagic patients. Questions covered potential problems, as well as legal issues, associated

with dosage form modification, media that allow for safe dispersion of a crushed tablet, and knowledge and availability of viscosity enhancers. This section also included a case study of an SI patient prescribed Nexiam® who required pharmacist input and medicines management. Pharmacists were required to choose the best possible solution from five options to addressing the patient's problem.

Section 5 obtained pharmacist feedback regarding the need for information, the type of information desired and the mode via which to access such information. Questions elicited pharmacist opinion of the most important classes of medicine to cover, format and mode of access of this information, and personal preference for information distribution.

In order to maximize participant response and generate nationwide awareness, the questionnaire was converted into an electronic form using Google forms. As electronic platforms such as email can serve to facilitate mass communication, this method was used to distribute the survey.

4.2.1 Validity and reliability of a research tool

The validity of an instrument is the extent to which it actually measures what it is designed to measure (134). With reference to a questionnaire, validation refers to the extent to which the questions collect accurate data relevant to the study objectives. It is the extent of systematic or built-in error in a questionnaire (135). The validation process involves testing the instrument in the population for which it is to be used to ensure that the responses are a true response of the variables. There are different types of validity: face validity, criterion validity, construct validity and content validity (133).

Face and content validity are often referred to as translational or representational validity (136). This type of validity exploits how well the idea of a theoretical construct is represented in an operational measure (questionnaire) (134). Face validity aims to determine questions that might be ambiguous or misinterpreted, that may not be an accurate reflection of the variable of interest, and those that participants would be unable or reluctant to answer (133). It is often approached in a casual manner, however it remains the most widely used form of validity in developing countries (134). Content validity, assesses the extent to which an instrument covers all the relevant issues (133). The development of a content-valid

questionnaire is achieved by rational analysis of the questionnaire by experts in the desired research field. These experts review all questions in terms of readability, comprehensiveness and clarity (134,137).

Construct and criterion validity are forms of this type of validation. Construct validity is the degree to which an instrument measures the variable that it is intended to measure. It is a measure of how meaningful the instrument is when in practical use (134).

Criterion validity measures how well one measure predicts an outcome for another measure (138). It is a measure of how well the results of a questionnaire align with another instrument or predictor (139). There are two types of criterion validity: predictive (assesses the questionnaire's ability to forecast future outcomes using a correlation coefficient) and concurrent (assesses the newly developed questionnaire against an existing ideal standard) (134,140).

Reliability of a study instrument offers insight into whether it performs in a consistent and predictable manner. It refers to the extent to which the results obtained by a measurement or procedure can be replicated (134). Methods for reliability testing include test-retest, and internal consistency. Internal consistency is most commonly assessed using Cronbach's alpha, which makes the assumption that items measuring the same construct should correlate (141).

4.3 Pilot study

A pilot study is used in research to determine if the research instrument is feasible in the designated practice setting in terms of study procedure and data collection, is acceptable to participants of the study, and to explore if the study procedures gather reliable and valid data effectively and efficiently (142).

The objective of this pilot study was to assess face and content validity of the questions, the user-friendliness of the online survey, time of completion, and to elicit feedback on any further issues.

4.3.1 Development of a short questionnaire to assess pharmacist opinion

A short questionnaire was developed for the pilot study to investigate participant opinion on the usability and clarity of the survey, and to gain preliminary insight into opinions relating to the importance of the research topic (Appendix B). Response to the questions was recorded using a 1-5 Likert scale. An odd number of intervals was selected to ensure the inclusion of a middle point, allowing respondents the option towards a neutral position and not forcing them to express a positive or negative view (133).

4.3.2 Pilot study setting, participants and recruitment

The pilot study was conducted in Grahamstown, Eastern Cape, SA. Five pharmacists and five pharmacy interns were recruited using convenience sampling. Recruitment occurred either telephonically or via personal communication during which the researcher briefly explained why the research was being conducted, the impact it may have on knowledge and practice, and explained what was required from their participation in the pilot study. If pharmacists agreed to participate, the researcher organised individual interviews with each participant at his/her current practice site at a time that was convenient to both the interviewer and interviewee.

4.3.3 Study interviews

Individual interviews were conducted in July 2016. Participants were asked to read the invitation letter (Appendix C) and to sign the consent form (Appendix D) if they agreed to participate in the study. They were then shown the online survey and were asked to complete the survey on the researcher's laptop. During this process, the researcher observed each participant as s/he worked through the online survey and made note of any difficulties encountered. These were verbally expressed and were audio-recorded by the researcher. Upon completion of the online questionnaire, participants were handed a short questionnaire (Appendix B) which they were requested to complete. Any additional comments and suggestions were audio-recorded by the researcher. Permission to audio-record during the interview was included in the consent form. Feedback obtained from this pilot test was used to make minor changes to the survey questions to improve their clarity. These have been described below.

4.3.4 Pilot study results

Demographic information can be found in Table 4.1. Ages ranged from 24-55 years with wide variability in years of practice and in practice sites.

Table 4.1 Demographic information of pharmacist personnel

Participant	Age	Practice site
1	40	Public hospital
2	54	Public primary care clinic
3	55	Private community pharmacy
4	39	Academia
5	35	Corporate pharmacy
6	25	Public hospital
7	27	Corporate pharmacy
8	25	Private hospital
9	25	Public primary care clinic
10	24	Public primary care clinic

Opinions of the quality and acceptability of the online questionnaire are presented in Table 4.2.

Table 4.2 Participant responses to questionnaire acceptability

Participant	Understanding of questions[1]	Interest in questionnaire[1]	Aspects of topic being covered[1]	Visual impact[1]	Relevance to practice[1]	Time of completion (mins)
1	4	3	5	5	5	17
2	4	5	5	5	5	13
3	4	5	4	5	5	22
4	5	4	5	5	5	13
5	5	5	5	5	5	12
6	5	5	5	5	5	20
7	4	5	5	5	5	13
8	5	4	5	5	5	16
9	4	4	5	5	5	12
10	4	4	5	5	5	35
Mean ± SD	4.4 ± 0.5	4.4 ± 0.6	4.9 ± 0.3	5.0 ± 0.0	5.0 ± 0.0	15.5 ± 8.1

[1] *Responses collected using a 1-5 Likert scale where 5=excellent, 4=good, 3=average, 2=fair, 1=poor*

The results from the pilot study indicated that understandability of questions was good/excellent and the survey was considered to be user-friendly. Nine of the 10 participants found the survey to be interesting and felt that all aspects of the topic had been covered. The topic was considered to be highly relevant to pharmacist practice. The average time of completion was 17 ± 7 minutes which was considered an acceptable time.

4.4 Modification of the survey questions

The following modifications to the questionnaire were implemented.

Question 2.2

Pilot: What would you say the frequency of swallowing impairment is in the general community?

1 in 17	1 in 84	1 in 125	1 in 500

It was suggested to add an "I do not know option" to prevent pharmacists guessing the correct answer, which could introduce bias towards the results. This was implemented.

Question 3.7

Pilot: What would you most commonly do to solving the problem of patients being unable to swallow tablets?

	Crush tablet/ break tablet
	Substitute with alternate dosage form (if applicable)
	Refer to another healthcare professional

Participants had two suggestions: to include an additional option of "substitute with alternate route of administration if available" and to include an "if applicable" to the crush/break tablet statement. Both suggestions were adopted.

Question 3.8

Pilot: What is the most commonly used action used to solve the problem of being unable to swallow capsules?

	Open capsule, empty the contents and mix with some medium
	Substitute with alternate dosage form (if applicable)
	Refer to another healthcare professional

A suggestion that we should include "substitute with alternate route of administration if available" was implemented.

Question 3.10

Pilot: How often do you sell viscosity enhancers?

Regularly	Sometimes	Never

Hospital pharmacists suggested we add a N/A option as this question does not apply to their practice. This option was adopted for the final questionnaire.

Question 4.6

Pilot: If a tablet can safely be crushed, which of the following would you recommend as the medium in which to mix or disperse the crushed tablet? You can choose more than one option.

Water	
Syrup	
Thickened liquid	
Fruit puree	
Jam	
Honey	
Yoghurt	

It was noted that, as not all options are diabetic friendly, we should note this aspect in the statement. The words "…and the patient is not diabetic…" were included.

Question 5.6

Pilot: If there is widespread interest in the information we will be developing, we would consider making it available to all pharmacists online via a website. What do you think is the most appropriate website to use?

	A new website designed specifically for pharmacists in SA
	PSSA website*
	SAAHIP website
	SAACP website
	Other suggestions

A suggestion to include the SAPC website had been included in the final version.

4.5 Online pharmacist survey

Modifications to the survey were implemented following the pilot study. All changes were done on the Google form document. On completion, a link containing the final version of the questionnaire was automatically generated.

4.6 Sample size calculation

The sample size required for the online survey was based on the total number of registered pharmacists in SA which, at the end of 2015, was 13,479 (143). Allowing for a 5% margin of error and a 95% confidence interval, a minimum of 374 participants was required (144).

4.7 Distribution of online survey

The SAPC was contacted to request the contact details of all registered pharmacists. A mailing list of these pharmacists was created using the information received from the SAPC in order to contact pharmacists at a national level.

All pharmacists were sent an email on 9 September 2016. Approximately 13,500 emails were sent. The email contained the invitation letter (Appendix E) which included a brief summary of the project, assured the participant of confidentiality, and noted potential benefits of the project. At the end of the invitation letter there was a link to access the survey. Clicking on the designated link and completing the survey constituted formal consent to participate in the survey.

The editor of the South African Pharmaceutical Journal, which is the official journal of the PSSA, had also been contacted and had been requested to publish information about this study and the survey in order to enhance pharmacist awareness and thus maximize pharmacist response. The piece had been published in a circulating PSSA newsletter on the 15 September 2016 (Appendix F). Rhodes University pharmacy alumni had also been sent an email requesting participation (Appendix G). One reminder email (Appendix H) to request completion of the survey was sent after a four week interval (13 October 2016). The link was accessible for a period of three months (9 September-9 December). All information remained confidential throughout the process.

4.8 Analysis of data

All responses were automatically captured on a spreadsheet and were converted to numerical responses by the researcher. Frequencies for all questions were generated. Two knowledge scores were generated by summating correct responses: knowledge of dysphagia (KOD) and

knowledge of medicine use (KOMU) in SI patients (scoring details are provided in Chapter 5, Sections 5.3 and 5.4). The mean and standard deviations were calculated for these two scores. Correlations of KOD and KOMU with age, length of registration as a pharmacist and years of direct patient interaction were calculated. The association of practice-related responses with KOD and KOMU was investigated using ANOVA and independent T-tests.

The total KOD score was 10 and was divided into two categories: inadequate knowledge (0-5) and adequate knowledge (6-10). The total KOMU score of 17 was divided into similar knowledge categories: inadequate (0-10) and adequate (11-17). Associations of KOD and KOMU categories with demographic and practice-related information were investigated using Pearson Chi square testing. Significance was set at $p < 0.05$.

CHAPTER 5
RESULTS: PHARMACIST SURVEY

This chapter reports the findings from the quantitative aspect of our study. Results from the questionnaire assessing pharmacist knowledge of dysphagia as well as dysphagia and medicine-use are presented. Significant correlations and associations with knowledge scores are also described.

5.1 Demographic and personal information (Section 1: Finding out a bit about you, your training and practice)

In total, 439 pharmacists completed the survey during the three-month access period. This figure illustrates that the minimum number of respondents needed for this study (Chapter 4 - section 4.6) had been exceeded. The characteristics of the participants are shown in Table 5.1.

Table 5.1 Demographics and practice-related information

Demographics	Frequency n (%)	Mean ± SD
Gender		
Male	144 (32.8)	
Female	295 (67.2)	
Age (yrs)		41.8 ± 12.6
Highest qualification		
BPharm	322 (73.3)	
Masters	64 (14.6)	
PharmD	2 (0.5)	
PhD	14 (3.2)	
Other	37 (8.4)	
Current practice site		
Privately owned community pharmacy	110 (25.1)	
Corporate pharmacy	66 (15.0)	
Public hospital	78 (17.8)	
Private hospital	39 (8.9)	
Public primary care clinic	14 (3.2)	
Consultant/specialist pharmacy service	24 (5.5)	
Other	108 (24.6)	
Registration as a pharmacist (yrs)		18.2 ± 12.9
Experience interacting with SI patients (yrs)		1.8 ± 12.6
Direct patient interaction		
Yes	319 (72.7)	
No	120 (27.3)	
Meds usage in SI patients was in curriculum		
Yes	85 (19.4)	
No	354 (80.6)	

Two-thirds (67.2%) were female, and 73.3% had a pharmacy degree as their highest qualification. The most common practice site was community pharmacy (40.1%), whereas only a quarter (26.7%) of participants practised at a hospital. Most pharmacists (72.2%) reported direct interaction with patients, and 80.6% had received no undergraduate training regarding this topic.

5.2 Pharmacist practice and experience in dealing with SI patients (Section 3: Your practice relating to swallowing-impaired patients)

Table 5.2 shows responses relating to pharmacist practice in dealing with SI patients.

Table 5.2 Practice-related responses

Practice and experience with SI patients	Frequency n (%)
Interaction with SI patients about meds	
Yes	309 (70.4)
No	130 (29.6)
How often do you see SI patients	
Regularly	34 (7.7)
Sometimes	298 (67.9)
Never	107 (24.4)
Number of SI patients dispensed to over past 5 years	
0-5	216 (49.2)
6-20	135 (30.8)
21-50	43 (9.8)
>50	45 (10.3)
Ask patients about swallowing ability	
Always	32 (7.3)
Sometimes	232 (52.8)
Never	175 (39.9)
Ask elderly patients about swallowing ability	
Always	58 (13.2)
Sometimes	188 (42.8)
Never	193 (44.0)
Patients volunteer info about swallowing ability	
Always	45 (10.3)
Sometimes	270 (61.5)
Never	124 (28.2)
Action if patient unable to swallow tablets	
Crush/break tablet	116 (26.4)
Substitute with alternate route of administration	61 (13.9)
Refer to another HCP	7 (1.6)
Substitute with alternate dosage form	255 (58.1)
Action if patient unable to swallow capsules	
Open capsule, empty contents and mix with some medium	148 (33.7)
Substitute with alternate route of administration	51 (11.6)
Refer to another HCP	9 (2.1)
Substitute with alternate dosage form	231 (52.6)

Used a viscosity enhancer to aid swallowing	
Yes	61 (13.9)
No	378 (86.1)
Sold viscosity enhancers	
Regularly	3 (0.7)
Sometimes	53 (12.1)
Never	267 (60.8)
N/A	116 (26.4)
Know of locally available viscosity enhancers	
Yes	60 (13.7)
No	379 (86.3)
HCPs asked you about medicine problems in SI patients	
Yes	150 (34.2)
No	289 (65.8)
Hospital pharmacist - do you see patients in the ward	
Yes	67 (15.3)
No	83 (18.9)
N/A	289 (65.8)
Hospital pharmacist - asked for advice by other HCP	
Yes	98 (22.3)
No	63 (14.4)
N/A	278 (63.3)
Which HCP most commonly advises SI patients about medicine-taking?	
Pharmacist	317 (72.2)
GP	41 (9.3)
Specialist doctor	8 (1.8)
Nurse	42 (9.6)
Speech therapist	16 (3.6)
Specialist physiotherapist	15 (3.4)

More than two-thirds (70.4%) of pharmacists had interacted with SI patients about medicine taking, with only 7.7% seeing SI patients regularly. In exploring the frequency of dispensing medication to SI patients over the past five years, half (49.2%) reported a zero or low frequency (0-5 patients). Only 10.3% of the pharmacists reported dispensing medication to more than 50 SI patients over five years.

Very few pharmacists (7.3%) always ask patients about swallowing ability, 44% claim to never ask elderly patients about swallowing ability, and 61.5% responded that patients sometimes volunteer information without any prompting.

If a patient is unable to swallow a tablet, 58.1% of pharmacists stated that they would substitute an alternate dosage form, whereas 26.4% chose the option "crush/break the tablet". Seven pharmacists (1.6%) would refer the patient to another HCP. Similar responses were found for actions to take if a capsule could not be swallowed.

Most pharmacists (86.1%) were unaware that a viscosity enhancer can be used to aid swallowing. Only three pharmacists regularly sold viscosity enhancers, with 60.8% reporting never having sold a viscosity enhancer. Knowledge of local availability of viscosity enhancers was lacking in 86.3% of participants.

One-third (34.2%) reported that other HCPs have asked their advice on this topic. When asked which HCP they thought should advise SI patients on their medicine-taking, the following responses were received: pharmacist (72.2%), nurse (9.6%) and GP (9.3%).

5.3 Knowledge of dysphagia (Section 2: Your familiarity with swallowing impairment)

Table 5.3 presents results of the knowledge test pertaining to dysphagia as a disease state and its prevalence and impact on patients.

Scoring for the four questions was as follows:

- Questions 1, 2 and 3: Single correct answer worth one mark.
- Question 4: Eleven options, of which seven were correct. Maximum mark is seven. Selecting only the seven correct options, and not selecting the four incorrect options, resulted in the following scores: 11 correct choices = 7 marks, 10 correct choices = 6 marks, 9 correct choices = 5 marks, 8 correct choices = 4 marks, 7 correct choices = 3 marks, 5-6 correct choices = 2 marks, 3-4 correct choices = 1 mark and 0-2 correct choices = 0 marks.

Table 5.3 Pharmacist knowledge of dysphagia (KOD)

Knowledge of dysphagia	Frequency n (%)	Maximum score
1. Knows meaning of dysphagia		1
Yes[1]	403 (91.8)	
No	36 (8.2)	
2. Frequency of dysphagia in the community		1
1 in 17	49 (11.2)	
1 in 84	80 (18.2)	
1 in 125	71 (16.2)	
1 in 500	67 (15.3)	
Do not know	172 (39.2)	
3. Effect of dysphagia on overall health status		1
Major	297 (67.7)	
Moderate	131 (29.8)	

Minor	10 (2.3)	
No effect	1 (0.2)	
4. Consequences associated with dysphagia		7
Choking	399 (90.9)	
Toothache	416 (94.8)	
Aspiration pneumonia	225 (51.3)	
Reluctance to eat in public	318 (72.4)	
Dehydration	257 (58.5)	
Crohn's	439(100.0)	
Tonsillitis	367 (83.6)	
Feelings of social isolation	254 (57.9)	
Fatigue	274 (62.4)	
Malnutrition	356 (81.1)	
Decreased self-esteem	300 (68.3)	

[1]Correct responses are highlighted

Most pharmacists (91.8%) knew the meaning of the term "dysphagia", but only 11.2% knew the frequency of this condition. Two-thirds (67.7%) correctly answered that dysphagia has a major effect on health status, with only 2.5% incorrectly thinking that it has only a minor or no effect on a patient's health status. For the question relating to consequences of dysphagia, most participants correctly identified choking (90.9%) and malnutrition (81.1%) as symptoms. The psychological consequences associated with dysphagia were less well known: reluctance to eat in public (72.4%), feelings of social isolation (57.9%) and decreased self-esteem (68.3%).

Table 5.4 presents the frequency of the KOD scores. The maximum KOD score was 10. Obtaining a score ≤ 5 denoted inadequate pharmacist knowledge and ≥ 6 meant adequate knowledge.

Table 5.4 Distribution of KOD scores

Scores	Frequency n (%)
1	1 (0.2)
2	9 (2.1)
3	33 (7.5)
4	63 (14.4)
5	60 (13.7)
6	71 (16.2)
7	87 (19.8)
8	87 (19.8)
9	26 (5.9)
10	2 (0.5)

The mean KOD score achieved was 6.1 ± 1.8. The majority of pharmacists (55.8%) achieved a score of either six, seven or eight out of 10. Only two pharmacists received the maximum score. Pharmacist KOD was adequate in two-thirds (62.2%) of pharmacists.

5.4 Knowledge of medicine use (KOMU) in SI patients (Section 4: Advising swallowing-impaired patients on medicines usage)

Pharmacist knowledge of appropriate medicine use in SI patients is presented in Table 5.5.

Scoring for the eight questions was as follows:

- Questions 1, 4, 7, 8, 10: Single correct answer. One mark.
- Question 3: Four options, of which two were correct. Maximum mark is four. Selecting only the two correct options and not selecting the two incorrect options resulted in the following scores: 4 correct choices = 4 marks, 3 correct choices = 3 marks, 2 correct choices = 2 marks and 1 correct choice = 1 mark.
- Question 6: Seven options, of which all were correct. Maximum mark is three. Selecting all seven resulted in the following scoring: 7 correct options = 3 marks, 5-6 correct options = 2 marks, 3-4 correct options = 1 mark and 0-2 correct options = 0.
- Question 9: Five options, of which three were correct. Maximum mark is five. Selecting all three correct options and not selecting two incorrect options resulted in the following score: 5 correct choices = 5 marks, 4 correct choices = 4 marks, 3 correct choices = 3 marks, 2 correct choices = 2 marks and 1 correct choice = 1 mark.

Table 5.5 Responses to knowledge of medicine use (KOMU) in SI patients

Knowledge of medicine use in SI patients	Frequency n (%)	Maximum Score
1. Potential problems with crushing/breaking tablets		1
Yes	425 (96.8)	
2. Types of SODFs that should not be modified		4
Unscored	286 (65.1)	
Film-coated	118 (26.9)	
SR/extended release	418 (95.2)	
Enteric-coated	378 (86.1)	
3. Legal issues to consider when modifying SODFs		1
Yes	305 (69.5)	
4. Medium in which to disperse crushed tablet		3
Water	304 (69.2)	
Syrup	163 (37.1)	
Thickened liquid	121 (27.6)	

Fruit Puree	107 (24.4)	
Jam	55 (12.5)	
Honey	80 (18.2)	
Yoghurt	255 (58.1)	
5. An increase in viscosity makes it easier to swallow	352 (80.2)	1
6. Medium you think allows for the safest swallow		1
Apple puree	167 (38.0)	
Water	255 (58.1)	
Apple juice	17 (3.9)	
7. Case study: Nexiam®		5
Can safely be crushed	379 (86.3)	
Cannot be crushed as it is SR tablet	134 (30.5)	
Cannot be crushed because it is acid labile	85 (19.4)	
Cannot be crushed as it contains enteric coated pellets	252 (57.4)	
Cannot be crushed as it is light sensitive	421 (95.9)	
8. Preferred action to the case study		1
Place tablet into a glass of water, stir until dispersed	211 (48.1)	
Substitute alternate PPI that can be crushed	220 (50.1)	
Place in a glass of fizzy drink, stir until dissolved	8 (1.8)	

[1]Correct responses are highlighted

The majority (96.8%) agreed that there are potential problems with crushing/breaking tablets. For the question on SODFs that should/should not be crushed, 73.1% incorrectly answered that film-coated tablets should not be crushed, and 13.9% were unaware that an enteric-coated tablet should not be crushed. The need to take legal issues into consideration when modifying SODFs was answered correctly by over two-thirds (69.2%) of pharmacists.

Seven different media in which to disperse a modified SODF we5 lines, not 11...re offered as options, all of which were correct. The most common options selected were water (69.2%), yoghurt (58.1%) and syrup (37.1%). A fifth of participants (19.8%) did not know that an increase in viscosity makes it easier to swallow. Of the three options provided for the medium that allows for the safest swallow, only 38% correctly selected apple puree.

Question 7 consisted of a 5-question case study about Nexiam®. A minority (13.7%) of pharmacists incorrectly answered that Nexiam® can safely be crushed, and only 30.5% were aware that Nexiam® is a sustained-release tablet. Just over half (57.4%) knew that Nexiam® contains enteric coated pellets, with only 19.4% being aware that it is acid-labile. With reference to the action pharmacists would take, half responded that they would substitute an alternate proton pump inhibitor that can be crushed (which is incorrect), and the remaining

half correctly responded that they would place the tablet into a glass of water and stir until dispersed.

Table 5.6 presents the frequency of KOMU scores. The maximum KOMU score achievable was 17. The mean KOMU score achieved was 9.4 ± 2.0. Just over half (54%) received a score between 9 and 11. No pharmacists received the maximum score. The highest score achieved was 15, which was obtained by only two pharmacists. Obtaining a score ≤ 10 denoted inadequate pharmacist knowledge and ≥ 11 meant adequate knowledge. Pharmacist KOMU was found to be inadequate in more than two-third of pharmacists (70.8%).

Table 5.6 Distribution of KOMU scores

Scores	Frequency n (%)
5	8 (1.8)
6	16 (3.6)
7	60 (13.7)
8	55 (12.5)
9	83 (18.9)
10	89 (20.3)
11	65 (14.8)
12	34 (7.7)
13	21 (4.8)
14	6 (1.4)
15	2 (0.5)

5.5 Associations of selected variables with overall knowledge score

Table 5.7 presents KOD and KOMU correlations with selected demographic and practice related information. KOD showed no significant correlation with the selected variables. KOMU showed weak but significant correlations with age, length of registration as a pharmacist and years of practice with direct patient interaction. The correlation between the KOD and KOMU scores was weak but significant.

Table 5.7 Correlation of selected variables with KOD and KOMU

Correlations	KOD score	KOMU score
Age		
Pearson correlation	0.052	0.220
Significance	0.276	0.000*
Registration as a pharmacist (yrs)		
Pearson correlation	0.088	0.209
Significance	0.066	0.000*
Experience in a setting with patient interaction (yrs)		
Pearson correlation	0.057	0.165
Significance	0.235	0.001*
KOMU		
Pearson correlation	0.261	0.261
Significance	0.000	0.000*

* A significant correlation at P<0.05.

When age was categorised into four categories (22-29; 30-39; 40-59; 60-80 years), no significant association was found between the KOD score and age categories. However, there was a significant association (P<0.001) between the KOMU score and age categories. Upon performing Tukey's post-hoc analysis with the latter, a general trend noted was that, as age increased, knowledge of medicine use in SI patients increased. The lowest age group was found to be significantly different from both the higher age groups of 40-59 (P<0.001) and 60-80 years (P=0.001).

The association of the two scores with years of registration as a pharmacist was also investigated after the duration of registration was divided into four categories (1-5; 6-15; 16-30; 31-60 years). No significant association was found with the KOD score, but a significant association (P<0.001) was noted between the KOMU score and the categories of registration duration. The latter was followed up with Tukey's post-hoc analysis, and a general positive upward trend was noted in the KOMU score as duration of registration increased. The two lower groups displayed significantly poorer knowledge (1-5; P=0.012 and 6-15; P<0001) than the group registered the longest.

Similarly, for the four groups showing years of practice in a setting with direct patient interaction (1-5; 6-15; 16-30; 31-60), no significant association was found between KOD and these categories, but there was a significant (P=0.004) association between KOMU and the years of practice in a setting with direct patient interaction categories. Tukey's post-hoc analysis showed that, as the years of practice in a setting with direct patient interaction as a

pharmacist increased, KOMU increased. Those pharmacists who have been practising for a longer time (31-60) had significantly better knowledge than those practising for 1-5 years (P=0.006).

5.6 Association of selected variables with adequate / inadequate knowledge

This section presents the findings of interrogating associations with knowledge data, this time with each participant categorised into having either adequate or inadequate knowledge. Table 5.8 presents KOD adequate/inadequate category correlations with selected variables.

Table 5.8 Associations with adequate/inadequate KOD categories

Variables	P-value
Gender	0.000*
Highest qualification	0.019*
Current practice site	0.137
Direct interaction with patients	0.934
Medicine usage in SI patients in curriculum	0.643

* Significant correlation at P<0.05.

There was a significantly higher proportion of female respondents with adequate knowledge of dysphagia (P<0.001). Qualification significantly influenced knowledge (P<0.019), with the highest proportion with adequate knowledge being those with a Masters degree. Neither practice site, having direct contact with patients, nor having had dysphagia addressed during undergraduate training influenced knowledge of dysphagia.

Table 5.9 Demographic and practice-related associations with KOMU

Variables	P-value
Gender	0.373
Highest qualification	0.001*
Current practice site	0.972
Direct interaction with patients	0.998
Medicine usage in SI patients in curriculum	0.204

* Significant correlation at P<0.05.

Table 5.9 presents KOMU adequate/inadequate category correlations with selected variables.

CHAPTER 6
QUESTIONING KNOWLEDGE GAPS AND EXPLORING THE PHARMACISTS' ROLE IN SUPPORTING DYSPHAGIC PATIENTS

This chapter reports method and findings from the qualitative exploration of pharmacist opinion and feedback from semi-structured interviews (SSIs) related to the knowledge gaps observed from the national online survey, as well as self-perceived roles pertinent to the management of medicine-taking in SI patients.

6.1 Objectives

The objectives of this qualitative post-survey phase were:

- to explore reasons for the lack of knowledge of dysphagia and of medicine use in SI patients
- to gain insight into pharmacists' perceptions of their role in medicines management of SI patients
- to obtain opinions of preliminary information designed for pharmacists in response to needs identified in the national survey (results are reported in Chapter 7).

6.2 Method

6.2.1 Study design, setting and population

Semi-structured interviews, which are conducted with individual participants and are used to collect qualitative data, consist of predetermined open-ended questions based on the topic to be explored (145).

The study setting was community or institutional pharmacies in two sites: Durban, a large metropolitan area in the province of KwaZulu-Natal, and Port Alfred, a small town in the Eastern Cape. Pharmacists were recruited from both corporate and private community pharmacies, and from private and public hospitals. The choice of a small town as well as a large city, in two different provinces, was made in an attempt to ensure a degree of heterogeneity and to enable site triangulation. Only pharmacists who had direct interaction

with patients were included. Participants included both those who had completed the online survey, and those who had not responded.

Convenience sampling was employed to recruit pharmacists. This type of recruitment sampling is known as purposive sampling and allows for the researcher to target a specific population with intention to elicit feedback relevant to the study (146). This was done telephonically, and a mutually acceptable date chosen for the interview. A question guide was developed to use during the interviews (Appendix I).

6.2.2 Interview process

The researcher (MM) and a moderator introduced themselves to the participant, thanking them for agreeing to participate. The interviews were conducted in a private room to allow for audio-recording and confidentiality. The participant was given an invitation letter (Appendix J) to read describing the study, and a consent form to sign (Appendix K). Permission to audio-record the interview was noted in the consent form.

The interview commenced with the participant being shown the preliminary designs of the information materials to elicit feedback (this is fully reported in Chapter 7, along with the results). Thereafter, the inadequate knowledge results obtained from the survey were briefly described, and pharmacists were asked their opinion as to why such poor scores were obtained. Pharmacists' perception of their role and responsibility in ensuring safe medicine use in SI patients was then explored

Interviews were conducted until data saturation was deemed to have occurred. Saturation is described as a phenomenon whereby additional participants do not add additional insight to the topic of discussion (147). Data saturation was considered to have been achieved after interviewing 12 participants.

6.2.3 Analysis of data

Thematic analysis is defined as the method by which patterns or themes within the data are identified, analysed and reported (148).

Step 1: Transcription of data

Data were transcribed verbatim by the researcher from the audio-taped discussions. This activity assists in grasping similarities and differences in opinions mentioned by different participants. The transcripts were validated against the audio-recordings to ensure that all data were captured accordingly. The transcripts were scrutinized several times to enable a thorough understanding of the data and to identify emerging initial themes.

Step 2: Coding of data

To organise and understand the data, codes relevant to the topic were developed. These codes were applied to segments of the data based on key words/statements and recurrent issues that arose from the data itself. During this process, some data segments were coded repeatedly, uncoded or sometimes coded once, changed and combined. Coding was done independently by two researchers who later met to compare and discuss any disparities.

Step 3: Identifying themes

Once all data were coded, themes and sub-themes were identified from the coded data segments. This was done by analysing the text segments in each code and extracting common and significant themes.

Step 4: Defining and naming themes

The selected themes were critically reviewed and refined to ensure that they incorporated all relevant ideas/suggestions contained in the data segments. Afterwards, clear definitions and names were decided for each theme to ensure authenticity and an accurate reflection of the entire data set.

Step 5: Final description

Themes and specific quotations which captured significant issues generated were placed within a narrative to provide a thorough description of the research findings.

6.3 Results

Twelve pharmacists were interviewed before data saturation had occurred.

6.3.1 Demographic and practice-related information

Demographic and practice-related information of pharmacist participants is presented in Table 6.1. Practice sites were selected based on the possibility of direct patient interaction. This included pharmacists from public and private hospitals (7), private community

pharmacies (2), corporate community pharmacy (1) and primary healthcare clinics (2). The mean age was 39.7 ± 14.2 years, with nine of the 12 participating pharmacists being female.

Table 6.1 Demographic and practice information of pharmacists

Participant	Age (yrs)	Gender	Practice Site
1	25	Female	Private community pharmacy
2	27	Male	Corporate pharmacy
3	36	Female	Public hospital
4	30	Female	Public primary healthcare clinic
5	33	Female	Private hospital
6	25	Male	Public hospital
7	32	Male	Public hospital
8	45	Female	Public hospital
9	58	Female	Public hospital
10	72	Female	Private community pharmacy
11	54	Female	Public primary healthcare clinic
12	39	Female	Private hospital

6.3.2 Themes

Three major themes emerged from analysis of the data: knowledge deficit and the need for formal education and training, barriers to pharmacist practice with SI patients, and lack of clarity on the pharmacist's role in supporting medicine use in SI patients.

6.3.2.1 Knowledge deficit and the need for formal education and training

All the pharmacists agreed that the topic of medicines management in SI patients was highly relevant to their practice. *'Yes, it is [relevant], I find it very interesting because it is not something that you actually regularly see. We have encountered it, but I don't think it's something that has been thought through so well in the past, so it's definitely relevant.'* (P09). Despite its relevance, there was general agreement that there was a knowledge deficit on the topic. Lack of formal training as part of the undergraduate training programme was reported to be the main factor contributing to the knowledge deficit. '*Universities choose certain areas that they focus [on] very hard, and the rest say: listen, you have to do it yourself, so I think that's the only reason why pharmacists would not have much knowledge on that subject.*' (P06); *'Yes very much so, our undergraduate training. I mean, I certainly don't remember anything about this from our undergraduate training and even after studies. No training or exposure.'* (P11).

A further contributing factor was that this topic was never addressed in any courses or modules presented after their undergraduate training when they were in practice. '*During my practice I have never attended any swallowing dysfunction course.*' (P04). Lack of awareness was raised by a few pharmacists as the reason for low knowledge scores. *'I just think lack of awareness, I mean we haven't really been made aware of dysphagia. Some pharmacists most probably don't know anything about it. Scary but shows the need for this study.*' (P11)

A few pharmacists noted lack of exposure to SI patients as a possible reason for poor knowledge. *'To be honest it's not very common for people to come in with swallowing issues. For all the time I've been working no one has come to me and said they have a problem swallowing, so to me it's kind of new. I mean it would be nice to know more, I can't go my whole career and not come across at least one SI patient.*' (P01).

Some felt that universities could not be expected to cover every aspect of pharmacy practice as CPD, which is intended to ensure further practice-related training, was mandatory for continued registration: '*You can't really blame the university because as time progresses things change, that's why CPD is so important. All these CPDs that you go to, this has never been a topic that I've heard of before. So yeah change the focus from diabetes and hypertension and stuff to things not regularly addressed.*' (P09). Others suggested that this topic could be the focus of a CPD event: '*I would be keen to attend a CPD event [on this topic] and I'm sure there are many other pharmacists that would be keen.*' (P05).

All pharmacists recognised the importance and relevance of training on medicine use in SI patients, '*I think it's a totally unthought-of area in pharmacy and it's a challenging area.*' (P08). They felt that they would benefit from further training: '*Also, exposure during practice that would be in-house training or anyone like yourself going around and exposing pharmacists to this topic would be good.*' (P07). Pharmacists also commented that different practice sites demand different skills, and that pharmacists then need to ensure that they develop new skills to fulfil their expanded roles: '*Every workplace you work in you focus on different things so I would say appropriate CPD training on this would be very useful.*' (P12).

6.3.2.2 Barriers to pharmacist practice with SI patients

The healthcare setting in which pharmacists practised appeared to influence interaction with SI patients, with lack of time cited as a major barrier. *'To be honest, in retail it's more rushed. When the patient comes in, the pharmacist, instead of taking the full route, often just treat[s] the symptoms and not the source of the problem. It comes down to the pharmacist being too busy.'* **(**P02). Pharmacists also linked time constraint restrictions to financial considerations, suggesting that '*…in the state, because it's not a money-making exercise, you tend to spend a bit more time with your patients compared to retail where it is a business.'* (P08).

Some hospital pharmacists reported that lack of proper administration and time-management within the hospital setting represented a barrier to optimal practice: '*Being a clinical pharmacist has always been a passion for me, [but] unfortunately we don't have the time and [support of] management to say, let's go administer or watch if nurses are administering medication properly.'* (P05); '*Ward rounds and dispensing medicines is very time consuming, you don't have the dedicated pharmacists to do that.*' (P07). In some cases, pharmacists felt that complying with their employer's expectations relating to their workload could negatively influence patient care: *'There's sometimes a tendency to be in such a hurry to give them their medicines that you don't stop and think about how the patients going to handle it.* (P08).

The extent to which pharmacists interact with SI patients was reported to coincide with the knowledge they possessed. They acknowledged their lack of experience and felt that, with better knowledge and greater confidence in dealing with these patients, they would be more likely to encourage interaction. '*You do come across them [SI patients] and at that point in time you sit with the dilemma how am I going to deal with this? You are not fully equipped as to what to do exactly and help the patient adequately.*' (P09).

Although all participants would have received adequate undergraduate pharmaceutical training to solve most medicine modification issues, they lacked the confidence in applying this knowledge. As an example: *'...the patient is on Rifafour® [a fixed dose combination tablet containing four medicines for tuberculosis] which is a coated tablet and if you take the package insert, for example, no one is telling you there if you can crush it or you can't crush it… [The patient] can't go without the medicine and the only way they can get it is if they*

crush the medicine. So now crushing it is just a shot in the dark 'cos we don't know if he is going to get the [correct] amount.' (P06).

Only one pharmacist displayed good product knowledge that directly applied to appropriate medicine use in SI patients. *'Nexiam® and Trustan®, if you put the tablet or let it disperse in water the tablet will disintegrate into granules or the pellet form which has to be swallowed whole.* However, this pharmacist also stated that '*A lot of new generation medication usually comes in film-coated preparations of that nature, where you can't actually crush the tablet.*' (P02). Although modifying film-coated tablets may not be encouraged, it is acceptable in the absence of other alternatives and in the interests of a patient-centred service.

Cost to the patient was a factor reported as a being a major issue in trying to solve medicine-taking problems in this population: '*...for example 3 tablets will cost you R150. The equivalent version of that antibiotic in syrup form that a child would usually take will cost you about R300-400. Even though you have to compromise in terms of delivering the medication into the body, you have to compromise as well in terms of price'.* (P02)

Lack of easily accessible reference sources in the facility also appeared to influence pharmacist interaction with SI patients. *'Pharmacists tend to forget the pathophysiology of dysphagia itself and the treatment of it, so they may not know how to handle a patient like that. Checking reference books is time-consuming and may not be available at that time in the setting.'* (P02); '*You don't always have all the information available as well, and different people have different reason for dysphagia, and that we don't have the knowledge about. Definitely a gap there.*'(P09).

6.3.2.3 Lack of clarity on the pharmacist's role in supporting medicine use in SI patients

Pharmacists had conflicting opinions on the role that they could potentially play in the medicines management of SI patients. A few recognised that their role as a pharmacist includes taking ownership of all medicine-related problems experienced by patients. *'I think when it comes to medicine related issues it is most certainly a pharmacist's role, I'm not saying the nurses mustn't do anything because they have a role with postures and diet and stuff with the patients, but when medicine is concerned, it is a pharmacist's role. We can't not take responsibility for anything that concerns medicine.'* (P11).

Some pharmacists were reluctant to take responsibility for SI patients and seemed to shift the responsibility onto nurses. In response to the question of who they felt was responsible for managing medicine-related problems in SI patients, comments included *'Uhm, no one in particular, no I don't think you could blame and label the pharmacist as being the champion for this because we don't administer medicines in the hospital, we dispense it but we don't administer it. It's primarily the nurses administering it, they are dealing with patients personally each day and I really feel they are the ones who should take championship of this.'* (P07), and *'It would be the nursing staff.'*(P08).

Pharmacists mostly felt that their role involved only the supply of the medicine. *'We are only responsible to supply the medicine within the hospital. Once we give them the medicine we have no idea what goes on in the ward, so whether [nurses] have the information or not, or knowledge, we don't know.'* (P07). However, they did acknowledge that nurses probably do not have the requisite knowledge in order to appropriately and safely modify medicines. . *'I can't say that all of them don't have the knowledge, [but] whether they use the knowledge adequately is a different question.'* (P09); '*It's very difficult to say [if they have the requisite knowledge] because you don't really see them doing it [administering the medicine]. My instincts tell me they don't.'* (P08).

A few pharmacists both recognised the problem of inadequate nurse knowledge and felt it was their responsibility to train and work together with nurses to ensure correct medicine use in SI patients. *'I think we should take responsibility, I mean there is no use giving out medication if it is not going to have the desired effect. It is our responsibility to ensure correct administration and usage of the medication. I'm not saying we should be the absolute policeman but we should maybe work together with the nurses and check their knowledge. We have the pharmaceutical-related knowledge, not nurses. We can help nurses, no question. We should be doing more to help I would say.'* (P11). Others felt that there were too many barriers to training nurses and/or working with them such as lack of inter-professional harmony, time constraints, nurses' shift-work, and lack of proper administrative management. *'Nurses are very difficult [to train], because of the shifts, so if we train the day shift we will be missing [training] the night shift staff.'* (P08).When asked if they would be willing to take the initiative to train nurses, pharmacists responded with *'No, not at the moment. We are short-staffed and over-worked as it is.'* (P07), and *'There's a lot of politics, time is also an*

issue. Everyone says there should be a good working environment between the different HCPs, but that doesn't always work out.' (P09).

Some pharmacists felt that this practice area of medicines management in SI patients requires an inter-professional approach involving a range of HCPs, and they expressed a positive attitude towards working in collaboration with other HCPs. *'I think it's a multidisciplinary approach, it's not only the pharmacist and nurse involved, it's the doctor, dietician, physiotherapist, and, yeah, a team effort.'* (P09); *'I would say perhaps include doctors, it would be useful to us pharmacist if doctors could identify dysphagia.'* (P02); *'A multidisciplinary approach is needed, I think that's the way to go. Often there aren't really pharmacists around or available. I do think that we and other HCPs should work together.'* (P11).

CHAPTER 7
DESIGN OF INFORMATION FOR PHARMACISTS

The focus of this chapter is to present results obtained from the national survey and during SSIs pertaining to pharmacist information needs and to describe the information design process.

7.1 Introduction

Managing medicine use in SI patients is a complex challenge as it requires knowledge of a diverse range of issues such as safe dosage form modification, excipient compatibility, food-drug interactions, appropriate dispersion media, availability of alternate dosage forms, and the use of viscosity enhancers. Extensive information resources addressing the management of dysphagic patients are available online, however the information appears on a range of different websites, and under the banner of various organisations. Time is required to search for, identify, integrate and apply all this information, taking into consideration individual patient clinical variables.

7.2 Theory of designing information

In a study investigating pharmacist requirements for drug information sources, Romangoli *et al.* (149) concluded that pharmacists preferred information that contained visuals, references, links to other resources and was available online. Information is generally more acceptable if it is quick and easy to use (149). Principles such as text coherence, integration of text and pictures, and highlighting of important features of the text are known to positively impact text comprehension (150).

Text coherence considers the logic and consistency of text structure. It is directly linked to text comprehension. If a reader is able to easily comprehend the information, a connection is established between new knowledge and prior knowledge on the subject matter. Integrating text and pictures has been proven to increase recollection and comprehension of information as the working memory is able to build strong connections between corresponding text and pictures if used simultaneously (151). Highlighting important features is done by using different text as compared to regular text. This is done by changing the size, type and colour

of font. This results in the highlighted text drawing the reader's attention, thereby leading to increased recollection (150).

7.3 Aim

The aim of this phase of the study was to develop information materials pertaining to medicines use in SI patients, and to evaluate pharmacist opinion of its format and content.

7.4 Method

A two-stage process was adopted for the design of the information materials. Stage 1 involved consideration of pharmacist responses generated from the quantitative online survey in order to develop preliminary designs. In Stage 2 these preliminary designs were evaluated by pharmacists during qualitative SSIs.

Stage 1: Preliminary design of information materials

Design of the preliminary information materials was initially informed by pharmacist responses that were generated from the national online survey. The final section of the survey investigated the information needs of pharmacists relating to medicine use in SI patients. These results are reported in Table 7.1.

Table 7.1 Pharmacist interest in receiving information

Interest in receiving information	Frequency n (%)
Interest in receiving easily accessible information	418 (95.2)
Type of information requested	
General recommendations on SODF modification	343 (78.1)
Specific recommendations for SODF modification	341 (77.7)
List of locally available brand and generic formulations	330 (75.2)
List of viscosity enhancers	350 (79.7)
General counselling guidelines	367 (83.6)
Classes of medications for which information requested	
Antibiotics	315 (71.8)
Anti-hypertensive agents	287 (65.4)
Anti-diabetic agents	301 (68.6)
Proton pump inhibitors	239 (54.4)
Analgesics	205 (46.7)
Cardiovascular system agents	269 (61.3)
CNS disorder agents	177 (40.3)

Preferred method of receiving information	
CPD evening meeting	100 (22.8)
A group training session	89 (20.3)
Pdf documents received via email	266 (60.6)
Pdf documents online via a website	243 (55.4)
Not interested in this information	12 (2.7)
Most appropriate website to use	
New website	224 (51.0)
PSSA website	157 (35.8)
SAAHIP website	34 (7.7)
SAACP website	12 (2.7)
SAPC	148 (33.7)
Other	
Facebook page	1 (0.2)
ICPA website	1 (0.2)
Medscape	1 (0.2)
SASOCP	4 (0.9)
WhatsApp groups	1 (0.2)

The majority of the pharmacists (95.2%) expressed an interest in receiving easily accessible information on this topic. The most popular topics were general counselling guidelines (83.6%), list of viscosity enhancers (79.7%) and general recommendations on SODF modification (78.1%). Just over two-thirds (68.6%) requested information on anti-diabetic agents, 71.8% on antibiotics and 65.4% on antihypertensive agents.

The preferred mode of accessing this information was as PDF documents via email (60.6%) followed by PDF documents on a website (55.4%). The most popular option to display such information was to create a new website designed for South African pharmacists (51.0%), on the PSSA website (35.8%), or the SAPC website (33.7%).

The topics for the information materials to be developed included:

- Background information on dysphagia
- General dysphagia guidelines
- Dysphagia and safe medicine use

In developing the information materials, content was largely informed by available online resources. The researcher extracted relevant information from websites dedicated to providing information on dysphagia (152–154) and from product catalogues such as Thick It®, a commercially available viscosity enhancer. Information was taken from different sources to ensure that the designed material was concise and thorough. Once extracted, the

information was summarised and developed into a PowerPoint presentation. It was modified taking into account design, layout and overall appearance which was informed by the literature on information design (149,150) and was guided by the design principles of text coherence, integration of text and images and highlighting of important points (150). Images were selected based on their relation to the text and to facilitate ease of understanding. Tables and bullet points were used to ensure that the flow of information was not monotonous and to highlight significant points. Individual documents did not exceed five pages.

Stage 2: Investigating pharmacist opinion of preliminary designs

In this stage, the opinion of individual pharmacists from different practice settings was explored using a qualitative data collection method. The study design, setting, population and interview process for the SSIs have been described in Chapter 6 (Section 6.2.1). Only two of the three documents were assessed, as the third dealt with medicines management in SI patients. The third document was intended to take the form of a table containing information about individual medicines in the form of SODFs, the generic and associated trade names, whether it can safely be modified, the reason if it cannot be modified, alternative suitable dosage forms and possible alternative route of administration. The decision of which medicines to include in this table was informed by both the quantitative data generated from the online survey, and from the SSIs.

The two documents (background information on dysphagia; general dysphagia guidelines) were shown to pharmacists on a laptop. Pharmacists were allowed unrestricted time to navigate through each document. The researcher observed each pharmacist closely as they browsed through the information, noting any non-verbal cues and facial expressions, and answering any questions. Pharmacists were then asked for their opinion of content, layout, design and type of information, and the preferred method to access such information.

Pharmacists were informed that the document still to be designed would focus on selected medications and their use in SI patients, and they were asked their opinion on which classes of agents or specific agents they regarded as being important to include. Triangulating the findings from the national survey and SSIs, it was decided that classes of medicines to include in the information material would include: antibiotics, antihypertensive agents,

antidiabetic agents, proton pump inhibitors, analgesics, cardiovascular system agents, agents used to manage central nervous system disorders, agents used in TB and HIV/AIDS therapy.

Table 7.2 presents pharmacist opinions relating to the design of the information materials.

Table 7.2 Pharmacist opinion of designed materials

Aspect	Yes	Example quote[2]
Content		
Information adequate	12	- 'Definitely relevant, especially in hospital pharmacy. You get a lot more patients than in retail.' P12
Information relevant to practice	12	- 'Yeah definitely [adequate and relevant], as I said I wasn't aware of most of the things in the information. Very informative.' P01
Design		
Preference for colour		- 'You know, colour is always more interesting let's face it.' P10
Colour	10	
Black and white	2	- 'Pictures are nice, they create a bit more interest.' P09
Visuals included	12	
Layout and readability	11	- 'It was very easy to read and I actually felt like reading more.' P10
Mode of distribution		
Email	9	- 'Well, everything is done via email or electronically, so any form of electronic communication should be fine. If you are trying to reach the patient, then maybe posters to raise awareness.' – P02
Dedicated website for SA pharmacists	1	
PDF version	8	
PowerPoint version	4	
Poster	7	

[1]Quantitative data collected from national survey
[2]Qualitative data collected from pharmacist SSIs

All pharmacists reported that the information was adequate and relevant to their practice. Most pharmacists (83.3%) preferred the use of colour to black and white and all pharmacists requested the use of visuals. The majority of pharmacists (75%) reported their preferred mode of distribution to be via email, with two-thirds preferring a PDF version (66.7%), and one-third wanting a PowerPoint version (33.3%). All pharmacists maintained a positive opinion of the designed material.

7.5 Final design and distribution of information

Following the pharmacist interviews, minor changes were made to the final information documents. A list of additional websites to access information on the topic had been included. No changes were made to images and layout.

The mailing list which had been created for the online national survey will be used to send an email to pharmacists in early 2018 with an attachment of one PDF file which will include the three individual information documents designed (Appendix L).

CHAPTER 8
DISCUSSION

This is the first study dedicated to investigating knowledge, practice and information needs of pharmacists involved in supporting SI patients and their medicines use. Previous studies have explored knowledge, attitude and beliefs relating to the core issue of SODF modification in a range of HCPs, including pharmacists (103), with most focusing solely on nurses' knowledge of SODF modification (79,110–112,114). However, no research has focused on exploring the range of issues related to knowledge in only the pharmacy profession.

This study revealed a knowledge deficit in pharmacists which affects their ability to competently manage medicines use in SI patients. However, pharmacists recognise the relevance and importance of this topic and, in acknowledging their inadequate knowledge, reported a need for information relating to this area. Pharmacists seemed conflicted about their role when dealing with this patient group.

8.1 Knowledge of dysphagia and medicine use in SI patients

Pharmacists lacked knowledge of both the condition of dysphagia and also, more disconcertingly, of issues related to the modification of SODFs and their use in SI patients. This supports the findings of the only other study to report pharmacist knowledge of SODF modification (103).

Given the shift towards an ageing population, healthcare systems are faced with significant challenges. Older patients are the most frequent users of healthcare services and they suffer from more chronic conditions, some of which result in dysphagia such as stroke and a range of neurodegenerative diseases. It is well established that increasing age leads to an increase in prescribed medicine (155) as the appropriate use of medicines has a fundamental role to play in increasing life expectancy, maintaining health and improving quality of life in older patients. The increasing incidence of head and neck cancer patients who have had radiation and surgery is another patient group in which some degree of dysphagia is common. Pharmacists need to be properly equipped to ensure that optimal therapeutic outcomes in these vulnerable patients are achieved.

In a high-risk group such as SI patients, it is particularly important for pharmacists to have some knowledge of the condition and its implications for medicine use. However, more than a third of the survey population had inadequate overall knowledge of dysphagia. Lack of awareness of its prevalence was demonstrated by just over 10% being able to correctly identify its frequency in the general community. Although dysphagia has major implications on overall health status, only a third of the survey pharmacists showed adequate awareness of this. Pneumonia can be a life-threatening condition, particularly in the elderly and in immuno-compromised patients. In SI patients, aspiration pneumonia is the most common and life-threatening outcome, a fact known by only half the study population.

Pharmacists' lack of knowledge of dysphagia itself is not unexpected, unless they work with these patients regularly. Pharmacists did acknowledge their lack of awareness and knowledge of dysphagia and expressed appreciation for the researcher's efforts in compiling informative, succinct, illustrated information. They were receptive to receiving information on the topic, were keen to learn more and acknowledged the need for such information on this topic.

A particularly disconcerting finding was that almost three quarters of the pharmacists had inadequate overall knowledge of the many issues related to medicines management and use in SI patients, despite being the most highly trained HCP in this area. Although all pharmacists would have received extensive undergraduate education on the characteristics of dosage forms, it was alarming to find that 5% still incorrectly reported that modified-release (MR) tablets could be modified. This supports a previous study reporting an even higher proportion of pharmacists (17%) who did not know that crushing Morphine CR® would result in faster drug absorption (103). Results pertaining to enteric-coated tablets were similarly concerning, with the national survey findings reporting 86% who correctly indicated that enteric-coated tablets should not be modified, compared with Nguyen's 91% (103).

It was interesting to note the confusion surrounding the practice of modifying film-coated tablets. Film-coating improves stability by acting as a physical barrier to environmental storage conditions for medicines containing substances that are light sensitive or affected by oxidation. It also contributes to improving taste and appearance of tablets (156). Ideally, therefore, the coating should not be destroyed. However, the pharmacist should be equipped to make an informed decision taking into account the functional limitations and needs of the patient, which, in the case of SI patients, would inevitably involve crushing the tablets. If this

is done immediately prior to administration, the stability of the API is not likely to be compromised. It was apparent from the SSIs that pharmacists do not appear to have the confidence to make decisions and implement them, particularly when this issue is not specifically addressed in the package insert. For example, one pharmacist commented *'...Rifafour® which is a coated tablet, if you take the package insert for example, no one is telling you if you can crush it or you can't crush it or what's going on there...'* If medicine-taking issues such as this are not addressed by the pharmacist, it means that the patient then has to solve the problem. The actions taken by the patient are likely to be uninformed, predisposing the patients to adverse outcomes.

A recent survey of patients in Mexico reported that 80% of patients had either crushed or split a tablet prior to administration (157). Similarly, Schiele *et al.* (54) found that almost 60% of SI patients modified their medication at some time in order to facilitate swallowing, with half of the modifiers seemingly unaware that SODF modification may not be allowed and can cause severe health problems. Older people and patients with a lower level of education tended to know less about these consequences (54). A survey conducted by Lau *et al.* (68) reported similar findings in which almost half of all the survey respondents (ambulatory patients between 18 to over 60 years) from five different community pharmacies in Australia felt that modifying medications would not be associated with any problems. Moreover, when people did elaborate on potential issues associated with medication modification, many could not explain why the pharmacokinetics or pharmacodynamics of the medication might be affected, implying lack of comprehension of the potential risks and dangers associated with SODF modification (68).

Proton pump inhibitors are one of the most commonly prescribed medicines in primary care (158), and therefore pharmacists should be equipped to ensure optimal use of this class of medicines. The case study with Nexiam® tablets included in the survey highlighted the lack of pharmacists' product-specific knowledge. Nexiam® tablets contain enteric-coated pellets which release the API over a prolonged period. Just under a third of pharmacists were able to correctly identify that Nexiam® is a sustained release tablet, with almost half being unaware that Nexiam® contained enteric-coated pellets. Interestingly, the only pharmacist who displayed good knowledge on Nexiam® during the SSIs had done a project on tablet coating. Drugs with extended-release properties usually contain a suffix attached at the end of the medication name (CD - controlled delivery, CR - controlled release, LA - long acting, SR -

sustained release, TR - timed release, XL - extended release, XR - extended release). Nguyen *et al.* (103) identified that HCPs rely heavily upon the suffix attached to medication names to identify potential problems associated with their modification. Similarly, in the current study with the low levels of identification of extended-release properties, it would appear that pharmacists do the same, as the trade name of Nexiam® does not include a suffix.

The modification of narrow therapeutic index SODFs can have serious therapeutic implications, as some active ingredient could be lost during both crushing and subsequent dispersion within a suitable medium, with some API being left behind in the container after administration, leading to a sub-therapeutic dose. Nguyen *et al.* (103) identified that 37% of study pharmacists expressed concern with modifying drugs that have a narrow therapeutic index. Although not directly addressed in the survey, there was an open-ended question asking about potential problems associated with modifying SODFs. No pharmacists mentioned that special consideration should be given to narrow therapeutic index drugs when modifying SODFs.

General findings from the national survey and SSIs found that older pharmacists who had been in practice for longer than newly qualified pharmacists had better overall knowledge of dysphagia and medicine use. This better knowledge of the area could be due to increased exposure to different patients and disease conditions.

8.2 Current pharmacist practice when dealing with SI patients

Pharmacists play a key role in ensuring the optimal therapeutic benefit of medicines, and this should include screening the patient for any potential barriers to successful medicine-taking. Poor patient-provider communication was identified as a major theme by McGillicudy *et al.* (128) in their systematic review on medicine use in older SI patients. Similarly, the current national survey findings revealed that 40% of pharmacists never asked patients about swallowing ability, a figure comparable with that of 43% of pharmacists who rarely/never ask about swallowing ability reported by Nguyen *et al.* (103). Similarly, patients tend not to offer information about any functional limitations such as swallowing difficulties (54). Only 10% of the survey pharmacists reported that patients volunteer swallowing ability information, agreeing with the 7% finding from Nguyen *et al.* (103). Prior studies have found that patients tend not to volunteer information as they perceive swallowing difficulties to be a normal and

inevitable part of the ageing process and thus help is not sought, while others feel ashamed, or do not think their HCP is able to help anyway (54,159).

Screening patients about their swallowing functionality should therefore be a routine component of a brief patient history prior to dispensing, particularly those patients who are readily identifiable as being at-risk, either from physical observation, an existing patient history, or the prescribed medication. McGillicuddy *et al.* (128) proposed the use of a validated screening tool in daily practice that would help to overcome the communication deficit evident at present, thereby identifying patients experiencing difficulty with their oral medication regimen.

According to Wright (160), strategies to be implemented if a patient has difficulty swallowing SODFs include considering the use of an alternative SODF, an alternative route of administration, switching to liquid or dispersible oral formulations, an alternative medication or discontinuation of medication (160). Only if none of these options are available is modification of the SODF considered. The national survey found that 26% of pharmacists reported that they would crush or break a tablet if a patient presented with a swallowing problem.

Another noteworthy finding was the lack of awareness of viscosity enhancers and their commercial availability in SA. It was alarming to find that one pharmacist, during an SSI, did not know what a viscosity enhancer was. With improved insight into agents that are able to facilitate the swallowing process, commercially available viscosity enhancers are being used increasingly to improve outcomes in SI patients, and pharmacists should therefore be familiar with these key agents and their use.

8.3 Inter-professional collaboration

Interdisciplinary collaboration and teamwork is an approach said to lead to greater efficiency in healthcare (115), as decisions made in a team context have a wider variety of possible solutions to health-related problems (161). From the SSIs, pharmacists displayed a reluctance to collaborate and work with nurses, or to train them in order to promote optimal therapeutic outcomes. Literature findings indicate that pharmacists appear to be the main reference source for advice on appropriate medicine use in SI patients (103,112,113,116), particularly

in a hospital setting. However, pharmacist-reported results from the national survey revealed that only 20% of other HCPs involve hospital pharmacists in medicine-related problem-solving, linking with findings from the SSIs where one pharmacist reported *'...we can't help patients if they [nurses] don't tell us what's going on.'* Lack of communication between HCPs is a major issue that hinders the provision of optimal care to patients with difficulty swallowing SODFs. According to Hollenbeck *et al.* (162), decision-making within groups composed of members of unequal status is less effective, with communication problems between HCPs possibly being due to differences in hierarchical status.

A further concern was the overall lack of integrated and coherent education and training between the different health disciplines (115). This study identified that pharmacists are not directly involved in modifying medicines; however, being the custodian of medicines places the responsibility on pharmacists to train and ensure competence in HCPs such as nurses who are directly involved in medicine administration. Downey *et al.* found that nurse knowledge on appropriate medicine use in SI patients increased when trained by pharmacists (113). Just over 70% of pharmacists who answered the national survey felt that pharmacists should be the HCP providing advice on medicine-related problems. This indicates an opportunity for pharmacist/nurse collaboration in which pharmacists share their knowledge about the special characteristics of SODFs and alternative options if applicable.

This study, conducted during the introductory phases of the transition of the pharmacist's role from the contemporary 'dispensing role' to a more 'patient-centred approach', suggests the need for a collaborative, multidisciplinary approach to managing medicine use in SI patients, ideally including the doctor, pharmacist, nurse, speech and language therapist and dietician. Putter *et al.* (163) emphasised the need for effective team building which brings together members from different parts of the healthcare team.

8.4 Information needs, education and training

The knowledge gaps and the self-reported training needs highlighted by this research stress the demand for education and training programmes relating to medicine use in SI patients. No intervention study designed specifically to improve pharmacists' knowledge of medicine use in SI patients has been reported. However, two intervention studies for nurses, one aiming to improve knowledge and drug administration in SI patients, and the other aiming to assess

compliance with guidelines for the preparation of medicines for SI patients, involved formal education and training, and were found to improve nurse knowledge of medicine use in SI patients (113,114).

Pharmacists' desire for easily accessible information on this topic was noted in a high 95% of surveyed pharmacists. The preferred mode of access was PDF documents via email or a website, followed by just under a third reporting that a CPD event would be useful. CPD enables pharmacists to develop in their area of practice and keep abreast of new developments in all areas of pharmacy practice knowledge and of technology relating to the use of medicines. Most pharmacists from the SSIs felt that this topic should be incorporated into CPD, either as a module or presented during a CPD training event.

8.5 The role of pharmacists in assisting SI patients with medicine use

This study suggests that pharmacists lack clarity on their role and responsibilities, and they appeared reluctant to acknowledge and accept responsibility for ensuring safe and effective medicine use. With the currently expanding role of the pharmacist, an integral tenet of pharmaceutical care is that pharmacists accept responsibility for and take appropriate action towards ensuring the safe and effective use of medicine (93). However, it was apparent from the SSIs that some pharmacists were not yet ready to adopt a patient-centred approach, and preferred to remain in their dispensing role.

The need for a formalised leadership development process is crucial in bringing together members from different parts of the healthcare team (163). Hospital pharmacists, particularly, seemed to perceive their role to be solely within the walls of the pharmacy, although a few did express a desire to move beyond this role and extend their services to the wards, where they could interact with both in-patients and nurses. Most notably, however, they felt disempowered to take the initiative to make this happen, and blamed the health system within which they worked for hampering any such efforts. Lack of time to take on expanded roles was also universally noted as a barrier to any additional initiatives.

A survey in the United States of America conducted in 2004 reported that only 30% of current pharmacy practitioners would actively seek a leadership position (164). In an updated 2011 survey, White and Enright (165) noted that this percentage had increased from 30% to

45%. However, the SSIs revealed that most study pharmacists appeared to lack leadership qualities, appearing reluctant to take the initiative to improve a medicine-related situation that they acknowledged was not optimal and which could cause potential harm to vulnerable patients. Pharmacists need to acknowledge that the development of leadership skills does not require an advanced degree, rather leaders need to be grown and nurtured (163).

8.6 Strengths and limitations of the study

Strengths of this study include the use of both quantitative and qualitative methodology. The quantitative survey enabled the measurement of a construct such as knowledge, and stimulated questions which required further understanding and interrogation. A qualitative study was then used to explore the new issues which were identified, enabling a deeper interrogation of areas of interest and generating rich data. The qualitative interviews also allowed for new perspectives on the topic being investigated to be revealed.

The quantitative aspect of this study was questionnaire-based and relied on honest reporting from pharmacists, so it is possible that some responses may not reflect actual current status of knowledge and practice. Due to the survey being an online survey, some pharmacists reported difficulties accessing the content as some web browsers had identified the link as spam. This may have resulted in less than optimal numbers completing the survey.

Respondents from the qualitative phase of this study were drawn from a convenience sample from only two sites in the country. The findings, therefore, are not necessarily generalisable to all registered pharmacists in SA, or to pharmacists in other countries.

CHAPTER 9
CONCLUSION AND RECOMMENDATIONS

The purpose of the current study was to investigate pharmacist knowledge and practice relating to swallowing impairment and safe practice for dosage form modification, and to assess pharmacists' information-related needs. The main finding is that pharmacists do not have the requisite knowledge to manage medicines use and to adequately counsel SI patients as they have little understanding of the condition of dysphagia and also, more concerning, of issues related to SODF modification and their safe use. Limited or no undergraduate training in this area and lack of exposure to this patient group were reported as the main factors influencing pharmacist knowledge levels.

Despite their place in healthcare as the experts in medicines and their use, some pharmacists incorrectly stated that MR tablets can be modified, and that film-coated tablets should not be modified. Many pharmacists could not correctly explain the pharmacodynamic and pharmacokinetic properties associated with SODF modification, signifying that they are not aware of the risks associated with SODF modification.

An interesting finding was the association between knowledge, age, and duration of practice, with older pharmacists having more years of practice experience displaying better knowledge of both dysphagia and medicines modification and use.

The survey findings revealed a lack of patient-centred practice with pharmacists rarely enquiring about swallowing ability. This is particularly concerning given the 13.5% of people who are likely to have some difficulty with swallowing, allied with a reported reluctance to offer such information.

Lack of integration of knowledge into current practice emerged as a reliable predictor of poor practice. During SSIs it was observed that although all participants would have received adequate undergraduate pharmaceutical training to solve most medicine modification issues, they lacked the confidence in applying this knowledge.

A key finding was that pharmacists lacked clarity on their role and appeared reluctant to accept responsibility for ensuring safe medicine use in SI patients. Pharmacists, particular

those in a hospital setting, did not consider it their role to ensure the safe administration of medicines as they saw this as the responsibility of nurses, despite acknowledging the likelihood of poor medicines knowledge amongst nurses. Significant by its almost universal absence, was mention of collaborative, multidisciplinary practice and a team approach to medicines management in SI patients. Pharmacists were reluctant to work more closely with nurses and to initiate nurse training in medicines and their use, despite acknowledging the need to do so.

Pharmacists appeared unprepared to adopt a patient-centered approach, preferring to remain situated within their dispensing role. They felt disempowered to take a leadership role and reported factors such as the health system and lack of time as barriers to expanding their role. In general, pharmacists appeared to lack leadership qualities and appeared reluctant to initiate and facilitate interventions aimed at ensuring safe medicine use in SI patients.

The relevance of this topic to pharmacist practice is clearly supported by pharmacists' acknowledgement of their knowledge gaps along with their stated needs for further information. They reacted positively to the designed information materials and expressed preference for a pdf document and a CPD event on this topic.

Recommendations for future research

An expansion of this project could investigate comparative pharmacist knowledge of medicines management in SI patients in different countries.

Particularly useful would be research aimed at establishing some consensus on the role of the pharmacist in serving this patient group.

Future research should investigate the role of the pharmacist as a trainer of fellow HCPs in improving medicines management and use in selected high-risk patient groups, with a particular focus on in-house, continuing education for nurses focusing on safe medicine modification practices.

Further research could explore how pharmacists perceive and interpret their role in different practice environments.

A project investigating the construct of leadership could explore pharmacists' attitudes and perceptions of the importance of this construct within the pharmacy profession, as well as in individual practice.

Particularly valuable would be research investigating a collaborative practice model intervention, longitudinally tracking its impact on MAEs and the opinions of team members on multidisciplinary practice.

Implications of study

- As patients often do not disclose problems with swallowing, pharmacists should routinely screen for this, particularly in older patients.
- Pharmacists should supplement their knowledge to ensure that they are equipped to manage and advise on medicine use in SI patients.
- In practice, counselling of SI patients should not only include advice on safe modification of medicines, but also on the importance of the appropriate viscosity of the dispersion medium in ensuring a safe swallow.
- Good product knowledge is key to recommending alternative dosage forms such as liquids, or dispersible tablets.
- In settings where nurses are responsible for medicine administration, pharmacists should ensure that appropriate information and guidelines are available for nurses to access. Pharmacists could further support safe practice by proactively presenting short training courses. Relevant topics to ensure adequate knowledge in this field include a basic knowledge of dysphagia, its incidence, and its impact on patients, characteristics of formulations that should not be modified, identification of such formulations, best practice related to modifying SODFs and dispersing in a medium of a suitable viscosity, medicine stability and related legal issues.
- Pharmacists could also take the lead role in the establishment of a collaborative, multidisciplinary team to support safe medicine use in SI patients.

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APPENDICES

APPENDIX A
NATIONAL ONLINE SURVEY

Section 1: Finding out a bit about you, your training and practice

1.1 Name (leave blank if you wish to remain anonymous)

1.2 Age

1.3 Gender

M [1]	F [2]

1.4 The year you registered as a pharmacist

1.5 Years of practice in community/institutional pharmacy, or any other practice site where you interact directly with patient's _____

1.6 Current practice site:

	Privately owned community pharmacy [1]
	Corporate pharmacy [2]
	Public hospital [3]
	Private hospital [4]
	Public primary care clinic [5]
	Consultant/specialist pharmacy service [6]
	Other [7]

1.7 Do you interact directly with patients?

Yes [1]	No [2]

1.8 Was medicine-usage in swallowing-impaired patients covered in your undergraduate training?

Yes [1]	No [2]

1.9 Select your highest qualification obtained?

	BPharm [1]
	Masters [2]
	PharmD [3]
	PhD [4]
	Other[5]

Section 2: Your familiarity with swallowing impairment

2.1 Did you know what the term "dysphagia" meant prior to reading the invitation letter?

Yes [1]	No [2]

2.2 What would you say the frequency of swallowing impairment is in the general community?

1 in 17 [1]	1 in 84 [2]	1 in 125 [3]	1 in 500 [4]	I Do not know [5]

2.3 What effect do you think swallowing impairment has on the overall health status of a patient?

Major effect [1]	Moderate effect [2]	Minor effect [3]	No effect [4]

2.4 Choose the option(s) that describe(s) possible outcomes associated with swallowing impairment

	Choking [1]
	Toothache [2]
	Aspiration pneumonia [3]
	Reluctance to eat in public [4]
	Dehydration [5]
	Crohn's disease [6]
	Tonsillitis [7]
	Feelings of social isolation [8]
	Fatigue [9]
	Malnutrition [10]
	Decreased self esteem [11]

**Note: 7 of the 11 choices are correct.*
Score criteria: 0-1 correct=0; 2-4 correct=1; 5-6 correct=2 & 7 correct=3

Section 3: Your practice relating to swallowing-impaired patients

This includes swallowing impairment due to surgery, a disease state, and children who are unable to swallow tablets.

3.1 Have you ever interacted with swallowing-impaired patients about taking medicines?

Yes [1]	No [2]

3.2 How often do you see patients with swallowing impairment?

Regularly [1]	Sometimes [2]	Never [3]

3.3 Can you give a rough estimate of the total number of swallowing-impaired patients you have dispensed medicines to or counselled on medicines use over the past 5 years?

0 – 5 [1]	6 – 20 [2]	21 – 50 [3]	> 50 [4]

3.4 How often do you ask patients about their swallowing ability?

Always [1]	Sometimes [2]	Never [3]

3.5 How often do you ask elderly patients about their swallowing ability?

Always [1]	Sometimes [2]	Never [3]

3.6 How often do patients volunteer information about their swallowing ability without any prompting?

Always [1]	Sometimes [2]	Never [3]

3.7 What is your most common approach to addressing the problem of a patient being unable to swallow tablets?

	Crush tablet/ break tablet (if it is safe to do so) [1]
	Substitute with alternate route of administration [2]
	Refer to another healthcare professional [3]
	Substitute with alternate dosage form (if available) [4]

3.8 What is your most common approach to solving the problem of a patient being unable to swallow capsules?

	Open capsule, empty the contents and mix with some medium [1]
	Substitute with alternate route of administration [2]
	Refer to another healthcare professional [3]
	Substitute with alternate dosage form (if available) [4]

3.9 Have you ever advised your patients about the use of a viscosity enhancer to aid swallowing?

Yes [1]	No [2]

3.10 How often do you sell viscosity enhancers?

Regularly [1]	Sometimes [2]	Never [3]	N/A [4]

3.11 Are you familiar with any locally available viscosity enhancers?

Yes [1]	No [2]

3.12 If yes, could you give the names of any viscosity enhancers available in South Africa?

3.13 Have you ever been asked for advice from other healthcare professionals about solving a medicine-related problem in swallowing-impaired patients?

Yes [1]	No [2]

3.14 If you are a hospital pharmacist, do you see patients in the ward?

Yes [1]	No [2]	N/A [3]

3.15 If you are a hospital pharmacist, have you ever been asked for advice from other healthcare professionals about solving a medicine-related problem in swallowing-impaired patients?

Yes [1]	No [2]	N/A [3]

3.16 Which is the healthcare professional you think most commonly advises swallowing-impaired patients about their medicine-related problems? Choose only one option.

	Pharmacist [1]
	General practitioner [2]
	Specialist doctor [3]
	Nurse [4]

	Speech therapist [5]
	Specialist physiotherapist (for swallowing impairment) [6]

Section 4: Advising swallowing-impaired patients on medicines usage – how familiar are you?

4.1 Are there any potential problems associated with crushing/breaking tablets or capsules for swallowing-impaired patients?

Yes [1]	No [2]

4.2 If yes to the above, briefly mention some possible problems.

4.3 Select which type(s) of oral dosage forms should not be modified.

	Unscored tablets [1]
	Film-coated tablets [2]
	Sustained/extended release tablets/capsules [3]
	Enteric-coated tablets or capsules [4]

4.4 Are there any legal issues to consider when modifying a dosage form?

Yes [1]	No [2]

4.5 If yes to the above question, comment on any possible legal implications when modifying a dosage form.

4.6 If a tablet can safely be crushed, and the patient is not diabetic, which of the following would you recommend as the medium in which to mix or disperse the crushed tablet? You may choose more than one option.

Water [1]	
Syrup [2]	
Thickened liquid [3]	
Fruit puree [4]	
Jam [5]	
Honey [6]	
Yoghurt [7]	

**Score criteria: 0-1 correct=0; 2-4 correct=1; 5-6 correct=2 & 7 correct=3*

4.7 An increase in the viscosity of the medium makes it easier to swallow.

True [1]	False [2]

4.8 Select from the list below which medium you think allows for the safest swallow. Choose one option only.

Water [2]	Apple puree [1]	Apple juice [3]

4.9 Case Study: A female patient, 54 years old, with an 18 year history of oral cancer has undergone a variety of treatments including radiation and head and neck surgery in different sites (tongue, neck, jaw). She has an immobile tongue, impaired swallowing reflex, and she has compromised eating and drinking functionality. Her most recent problem is GORD for which she has been prescribed Nexiam® (esomeprazole) 40 mg once daily. She asks if she can crush the tablet as she cannot swallow it whole. In response, choose one or more options from the list below.

	Nexiam® can safely be crushed [1]
	Nexiam® cannot be crushed because it is a sustained release tablet [2]
	Nexiam® cannot be crushed because it is acid-labile [3]
	Nexiam® cannot be crushed as it contains enteric coated pellets [4]
	Nexiam® cannot be crushed as it is light sensitive [5]

4.10 Choose your preferred action in addressing the patient's problem.

	Place tablet into a glass of still water and stir until dispersed [1]
	Substitute with a different proton pump inhibitor that can be crushed [2]
	Place in a glass of fizzy drink and stir until dissolved [3]

5. Interest in receiving information on this topic

5.1 Would you be interested in receiving information on this topic which has been designed specifically for pharmacists?

Yes [1]	No [2]

5.2 What type of information do you think might be useful to you and other pharmacists? You may choose more than one option.

	Yes	No
General recommendations on dosage form modification and potential problems [1]		
Specific recommendations for dosage form modification in commonly used medicine classes [2]		
List of locally available brand and generic formulations for selected drugs that can be used for swallowing-impaired patients [3]		
List of viscosity enhancers that are locally available [4]		
General counselling guidelines for swallowing-impaired patients [5]		
Other [6]		

5.3 Which classes of medicines do you think are the most important to focus on? You may choose more than one option.

	Antibiotics [1]

	Antihypertensive agents [2]
	Antidiabetic agents [3]
	Proton pump inhibitors [4]
	Analgesics [5]
	Cardiovascular agents [6]
	Agents used to treat CNS disorders: depression, Alzheimer's, Parkinson's etc. [7]
	Other [8]

5.4 We will be developing information for pharmacists to use when advising swallowing-impaired patients about medicine usage. This information covers different topics and could be available to you as a file on your computer, could be printed as a poster or could be the topic of a CPD evening etc. Would you like to have access to such information?

Yes [1]	No [2]

5.5 If yes, what would be your preferred method of receiving or accessing this information? You can choose more than one option.

	A regular CPD evening meeting as the topic for that evening [1]
	A group training session with a trained presenter for pharmacists in your area [2]
	Pdf documents received via email at your request [3]
	Pdf documents accessible online via a website [4]
	Not interested in this information [5]

5.6 If there is widespread interest in the information we will be developing, we would consider making it available to all pharmacists online via a website. What do you think is the most appropriate website to use?

	A new independent website designed specifically for pharmacists in SA [1]
	PSSA website [2]
	SAAHIP website [3]
	SAACP website [4]
	SAPC website [5]
	Other [6]

If you are interested in maintaining contact with us, please state your email address.

E-mail: _____

APPENDIX B
QUESTIONNAIRE FOR PILOT STUDY

1. Were you able to easily understand all the questions? If not, could you tell me which question(s) you feel require modifying and why. On a scale of 1 -5 how understandable did you find the questions.

2. Did you find the survey monotonous or did it manage to keep you interested? On a scale of 1- 5 how interested did the survey keep you?

3. Do you think the questions covered all aspects of the topic? On a scale of 1-5 rate your thoughts about aspects of the topic covered in the questionnaire.

4. Any questions you feel should be added?

5. On a scale from 1- 5 rate your thoughts of the online survey in terms of its visual impact – colour, font, font size, user-friendly etc?

6. Do you think this research focus is relevant to your practice? On a scale of 1-5 rate the relevance of the research.

7. Do you have any suggestions that might encourage pharmacists to respond to the survey?

APPENDIX C
INVITATION LETTER FOR PILOT STUDY

RHODES UNIVERSITY FACULTY OF PHARMACY

Title of project: The pharmacist and medicine use in swallowing-impaired patients: Pharmacist awareness, knowledge and information needs

You are invited to participate in a pilot research study focused on pharmacist awareness, knowledge and information needs pertaining to swallowing impaired (SI) patients. The questionnaire that follows will take approximately 10-15 minutes to complete. If you agree to participate, please complete the consent form attached.

Purpose of research:

The administration of medicines to swallowing impaired patients is a complex challenge as they are more prone to medicine administration errors due to the need to match the dosage form to swallowing ability. Given the key role of pharmacists in medicine usage, we aim, with this survey, to assess your (pharmacist) awareness and knowledge related to medicine usage in swallowing-impaired patients and to gain some insight into your information needs on this topic. Ethics approval was obtained from the Rhodes University Pharmacy Ethics committee (PHARM 2016-11).

Privacy and disclosure of information:

Personal information collected will only be available to the researcher and her supervisor and will be used for statistical purposes only. Under no circumstances will your name or personal details be disclosed in any publications. If you choose to remain anonymous, there is the option to do so.

Further information:

If you require any further assistance, encounter any problems or wish to enquire further about this research, please contact:

Postgraduate researcher: Ms Mehrusha Masilamoney
Mobile: 061-1060701 Email: g12m3506@campus.ru.ac.za
Supervisor: Professor Ros Dowse:
Mobile: 083-5569796 Email: r.dowse@ru.ac.za

APPENDIX D
CONSENT FORM FOR PILOT STUDY

Consent Form for pilot study questionnaire

Rhodes University: Faculty of Pharmacy

Participant Consent Form

Title: Pharmacist and medicine use in swallowing-impaired patients: pharmacist knowledge and their information needs.

Please read the invitation letter before completing this consent form. After having read the statements below, please provide a tick next to each of the statements and the sign the form.

	I have read and fully understood the invitation letter.
	The co-ordinators have assured that my personal details will not be revealed in any publication.
	I voluntarily agree to be a participant based on the conditions stated in the invitation letter.
	I voluntarily agree to be audio-recorded during the interview.

_____ _____

(Print name of participant) (Signature of participant)

_____

Date

_____ _____

(Print name of interviewer) (Signature of interviewer)

_____

Date

APPENDIX E
NATIONAL ONLINE SURVEY INVITATION EMAIL

Dear Pharmacist

You are invited to participate in a research study entitled "Pharmacists and medicine use in swallowing-impaired patients: pharmacist knowledge and information needs".
The aim of this research is to evaluate pharmacist knowledge and information needs of medicines administration in swallowing-impaired (SI) patients.

- Data will be collected via an online survey.
- The questionnaire will take approximately 10-15 minutes of your time to complete.
- Participation in this research is voluntary.
- Your identity will be confidential.
- If you agree to participate, your answers will be stored confidentially and anonymously.
- The project has received institutional ethical approval.

The feedback from this survey is integral to continuing with the next phase of this project as it will help us to contribute to your knowledge and practice with this group of patients.

TO PARTICIPATE IN THE SURVEY PLEASE CLICK ON THE LINK BELOW:

https://docs.google.com/forms/d/e/1FAIpQLSfmIc2Lm4CL6MqL6x-r9F1HKnQmLLHoWA9iDoq1llQXimWG2Q/viewform

If you require any further assistance, encounter any problems or wish to enquire further about this research, please contact:

Postgraduate researcher
Ms Mehrusha Masilamoney
Mobile: 061-1060701
Email: g12m3506@campus.ru.ac.za

Supervisor:
Professor Ros Dowse:
Mobile: 083-5569796
Email: r.dowse@ru.ac.za

APPENDIX F
ADVERTISEMENT OF NATIONAL ONLINE SURVEY IN PSSA NEWSLETTER

Pharmaceutical Society of South Africa
PSSA Newsletter #32/2016 – 15 September 2016

The PSSA – pharmacy in action!

Your participation is needed
Research into current practices forms the basis of suggestions for improvement in pharmacy practice. Two current Rhodes University students are involved in research and would appreciate it if pharmacists would help them by participating in completing online questionnaires.

Swallowing-impaired patients
Pharmacists are invited to participate in a research study entitled "Pharmacists and medicine use in swallowing-impaired patients: pharmacist knowledge and information needs".

The aim of this research is to evaluate pharmacist knowledge and information needs of medicines administration in swallowing-impaired (SI) patients.

- Data will be collected via an online survey
- The questionnaire will take approximately 10-15 minutes of your time to complete
- Participation in this research is voluntary
- Your identity will be confidential
- If you agree to participate, your answers will be stored confidentially and anonymously
- The project has received institutional ethical approval

The feedback from this survey is integral to continuing with the next phase of this project as it will help us to contribute to your knowledge and practice with this group of patients.

To participate in the survey please click on the link below:
https://docs.google.com/forms/d/e/1FAIpQLSfmIc2Lm4CL6MqL6x-r9F1HKnQmLLHoWA9iDoq1IlQXimWG2Q/viewform

If you require any further assistance, encounter any problems or wish to enquire further about this research, contact:

Postgraduate researcher
Mehrusha Masilamoney
Email: g12m3506@campus.ru.ac.za

Supervisor
Professor Ros Dowse
Email: r.dowse@ru.ac.za

APPENDIX G
EMAIL TO RHODES PHARMACY ALUMNI

Dear Rhodes Pharmacy Alumnus

If you a pharmacist registered with the SAPC, you will have already have received two emails from us about a project called "Pharmacists and medicine use in swallowing-impaired patients: pharmacist knowledge and information needs".

This email is a special appeal from Ros Dowse and me (Mehrusha, MPharm student) to you, fellow Rhodians, to help us top up the number of responses to the above survey. We are currently sitting at 417 (thank you if you are one of these), but we REALLY want to try and achieve 500 – so every single additional response will count! PLEASE help us achieve this – it is a project that we hope will directly contribute to expanding pharmacist awareness and knowledge of this topic, as I will be developing information for pharmacists based on feedback from this survey.

I have appended the more detailed original email should you wish to re-read it.

Here is the link to the survey:

https://docs.google.com/forms/d/e/1FAIpQLSfmIc2Lm4CL6MqL6xr9F1HKnQmLLHoWA9iDoq1llQXimWG2Q/viewform

Thank you in advance for your support – we can get to that number with your help!

Warm regards.

Mehrusha and Ros

Postgraduate researcher
Ms Mehrusha Masilamoney
Mobile: 061-1060701
Email: g12m3506@campus.ru.ac.za

Supervisor:
Professor Ros Dowse:
Mobile: 083-5569796
Email: r.dowse@ru.ac.za

APPENDIX H
REMINDER EMAIL FOR NATIONAL ONLINE SURVEY

MPharm research study: Pharmacists and medicine use in swallowing-impaired patients

Dear Pharmacist

This serves as a friendly reminder to inform you that your participation in our research study entitled "Pharmacists and medicine use in swallowing-impaired patients: pharmacist knowledge and information needs" is needed. Kindly ignore this email if you have already accessed and answered our survey.

The aim of this research is to evaluate pharmacist knowledge and information needs of medicines administration in swallowing-impaired (SI) patients.

- Data will be collected via an online survey.
- The questionnaire will take approximately 10-15 minutes of your time to complete.
- Participation in this research is voluntary.
- Your identity will be confidential.
- If you agree to participate, your answers will be stored confidentially.
- The project has received institutional ethical approval.

The feedback from this survey is integral to continuing with the next phase of this project as it will help us to contribute to your knowledge and practice with this group of patients.

TO PARTICIPATE IN THE SURVEY PLEASE CLICK ON THE LINK BELOW:

https://docs.google.com/forms/d/e/1FAIpQLSfmIc2Lm4CL6MqL6x-r9F1HKnQmLLHoWA9iDoq1llQXimWG2Q/viewform

If you require any further assistance, encounter any problems or wish to enquire further about this research, please contact:

Postgraduate researcher
Ms Mehrusha Masilamoney
Mobile: 061-1060701
Email: g12m3506@campus.ru.ac.za

APPENDIX I
GUIDE FOR SEMI-STRUCTURED INTERVIEWS

Title: Pharmacist and medicine use in swallowing-impaired patients: pharmacist knowledge and their information needs.
Researcher: Mehrusha Masilamoney
Year: 2017
Participant: _____ Site: _____

Content	
	Information adequate
	Information relevant
Comment:	
Design	
	Black and white
	Colour
	Pictures
	Layout adequate
Comment:	
Distribution	
	Email
	Dedicated website for SA pharmacists
	PDF version
	PowerPoint version
	Poster
Comment:	

APPENDIX J
INVITATION LETTER FOR SEMI-STRUCTURED INTERVIEWS

RHODES UNIVERSITY FACULTY OF PHARMACY

Title of project: The pharmacist and medicine use in swallowing-impaired patients: Pharmacist awareness, knowledge and information needs

You are invited to participate in a research study focused on pharmacist knowledge, information needs and in the assessment of preliminary information material pertaining to swallowing impaired (SI) patients. The interview that follows will take approximately 15-20 minutes to complete. If you agree to participate, please complete the consent form attached.

Purpose of research:

The administration of medicines to swallowing impaired patients is a complex challenge as they are more prone to medicine administration errors due to the need to match the dosage form to swallowing ability. Given the key role of pharmacists in medicine usage, we aim, with this interview, to assess your (pharmacist) insight on why knowledge related to medicine usage in swallowing-impaired patients is low and to gain some insight into your desired information needs on this topic. Ethics approval was obtained from the Rhodes University Pharmacy Ethics committee (PHARM 2016-11).

Privacy and disclosure of information:

Personal information collected will only be available to the researcher and her supervisor and will be used for statistical purposes only. Under no circumstances will your name or personal details be disclosed in any publications. If you choose to remain anonymous, there is the option to do so.

Further information:

If you require any further assistance, encounter any problems or wish to enquire further about this research, please contact:

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Supervisor:
Professor Ros Dowse:
Mobile: 083-5569796 Email: r.dowse@ru.ac.za

APPENDIX K
CONSENT FORM FOR SEMI-STRUCTURED INTERVIEWS

Rhodes University: Faculty of Pharmacy

Participant Consent Form

Title: Pharmacist and medicine use in swallowing-impaired patients: pharmacist knowledge and their information needs.

Please read the invitation letter before completing this consent form. After having read the statements below, please provide a tick next to each of the statements and the sign the form.

	I have read and fully understood the invitation letter.
	The co-ordinators have assured that my personal details will not be revealed in any publication.
	I voluntarily agree to be a participant based on the conditions stated in the invitation letter.
	I voluntarily agree to be audio-recorded during the interview.

_____ _____

(Print name of participant) (Signature of participant)

_____

Date

_____ _____

(Print name of interviewer) (Signature of interviewer)

_____

Date

APPENDIX L

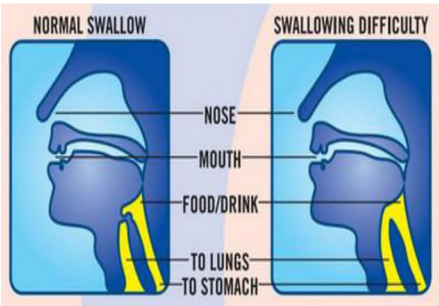
INFORMATION DESIGNED FOR PHARMACISTS

Background information on dysphagia

What is dysphagia?

Swallowing impairment or dysphagia refers to difficulty and discomfort during the act of swallowing. Dysphagia is a common problem, with research estimating that one in 17 people will develop some form of dysphagia in their lifetime.

Dysphagia statistics



Dysphagia is a growing problem that affects 40–70% of patients with stroke, 60–80% of patients with neurodegenerative diseases, 13% of adults aged 65 and older and 60–75% of patients who undergo radiotherapy treatment for head and neck cancer.

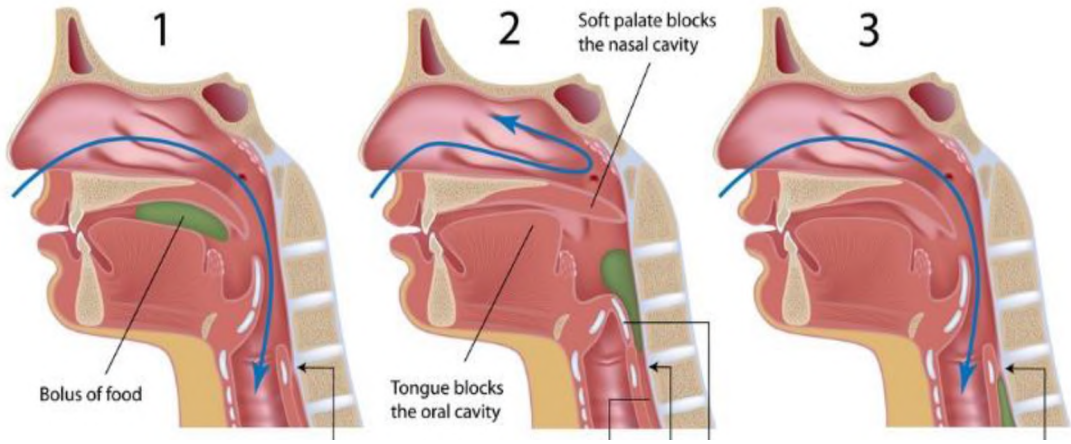
The swallowing process

The process of swallowing is known as deglutition and can be broken down into three phases; oral, pharyngeal and oesophageal.

The oral phase: Includes food entering the oral cavity followed by mastication and bolus formation.

The pharyngeal phase: As the bolus enters the back of the throat, the second, involuntary stage of swallowing commences in which the tongue propels the bolus into the oesophagus.

The oesophageal phase: Involves the passage of food down the oesophagus through the lower oesophageal sphincter to empty into the stomach.



Causes of dysphagia

Aging
A common cause of dysphagia can be attributed to aging.

Diseases
Pathophysiologically, the causes of dysphagia can be broadly grouped into four disease categories:

- ❑ neurological
- ❑ musculoskeletal
- ❑ metabolic
- ❑ oncological

Diseases causing dysphagia	
Neurological	**Musculoskeletal**
Stroke	Spinal muscular atrophy
Alzheimer's	Myasthenia gravis
Parkinson's	Zenker diverticulum
Dementia	Osteoarthritis
Motor neuron disease	Polymyositis
Amyotrophic lateral sclerosis	Inflammation myopathies
Multiple sclerosis	
Schizophrenia	**Metabolic**
Depression	Diabetes
Infectious brain disease	Hyper and hypothyroidism
Polyneuropathy	Cushing syndrome
Down's syndrome	
Traumatic brain injury	**Oncological**
	Brain and neck tumours

Medicines

Dysphagia can also be medicine induced. The table that follows lists a few drugs contributing to the different types of swallowing impairment.

Oesophageal injury	Xerostomia	Dysphagia
Antibiotics	Antipsychotics	**Antipsychotics**
Tetracycline	Antidepressants	Haloperidol
Macrolides	Antiemetics	Olanzepine
Penicillin	Anxiolytics	Clozapine
NSAIDs	Antihistamines	Risperidone
Acetylsalicylic acid	Anticholinergic	**Anticholinergics**
Piroxicam	Antihypertensives	Nitrazepam
Indomethacin	Bronchodilators	Clonazepam
Bisphosphonate	Diuretics	**Chemotherapy**
Alendronate		Vincristine

Signs and symptoms

- ❑ History of choking
- ❑ Coughing before, during or after the swallow
- ❑ History of chest infection
- ❑ Change in breathing pattern or shortness of breath when eating or drinking
- ❑ Wet, bubbly voice quality
- ❑ Weight loss
- ❑ Prolonged mealtimes
- ❑ Refusal to eat or drink
- ❑ Regurgitation

Consequences of dysphagia

Impairment of the swallowing process may result in negative physical health outcomes such as choking, malnutrition, dehydration, aspiration pneumonia and other life threatening catastrophes.

Patients often isolate themselves during mealtimes.

Dysphagia can also lead to a wide range of psychological outcomes feelings of isolation, decreased self-esteem and self-confidence, and an overwhelming sensation of hopelessness

General dysphagia guidelines

DIET

Dysphagia and mealtime strategies

In order to avoid negative health outcomes the consistency of food and beverages may require alteration. This is referred to as the dysphagia diet.

The dysphagia diet features different textures of foods and liquids and is used for people who have problems with chewing and swallowing.

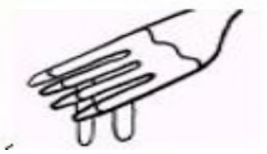
The dysphagia diet employs the following interventions:

- Modification of consistency of fluids
- Modification of consistency of food
- Modification of posture during mealtimes

The purpose of a dysphagia diet is to ensure ease when chewing, move food in the mouth and reduce the risk of food going into the windpipe or trachea, which leads to the lungs.

Liquid consistency

Due to loss of muscle control, thin liquids such as water can cause swallowing problems for people with dysphagia. Some will tolerate thin liquids; however, to minimize risk for choking and aspiration it is recommended that liquids be thickened to a certain consistency.

Nectar	Honey	Pudding
		
Nectar-like: similar to a thick milkshake, tomato juice or unset gelatin.	**Honey-Like:** consistency has a thickness like bee's honey.	**Spoon-Thick** : consistency is like a pudding or a thick yoghurt.

Food consistency

The National Dysphagia Diets have three levels. The level of diet a person follows depends on the severity of their dysphagia.

National Dysphagia Diet - Level 1

National Dysphagia Diet - Level 1

For people with moderate to severe swallowing difficulty who have a poor ability to protect their airway.

This diet allows pureed food that is smooth and easily stays together. It is important to use high calorie, nutrient dense food such as cheese sauce, gravy and whole or buttermilk in this diet.

National Dysphagia Diet - Level 2

National Dysphagia Diet - Level 2

For people with mild to moderate swallowing difficulty. Some chewing ability is required.

This diet consists of foods that are moist, soft and easily formed into a bolus. Meats should be ground or minced and should be keep moist with sauces and gravies.

National Dysphagia Diet - Level 3

National Dysphagia Diet - Level 3

For people with mild swallowing problems.

This diet consists of all foods, except very hard, sticky or crunchy foods. Foods should be moist and should be cut up into bite size pieces.

Thickening and Thinning Agents

Foods can be thickened or thinned to individual requirements. Many foods can be used to change a liquid to a different consistency. The amount of thickening agent needed to reach a certain food consistency varies depending on the food being thickened and on the thickening agent used.

How to thin liquids

- Add hot milk-based liquids (hot milk or cream) to puréed soups, puréed vegetables, or cooked cereal.
- Add other hot liquids (broth, gravy, sauces) to mashed potatoes, puréed or ground meats, and puréed or chopped vegetables. Butter or melted margarine may also be used.
- Add cold milk-based liquids to cream, yogurt, cold soups, puréed fruits, or puddings and custards.

How to thin food:

Add one of the following:

- Broth
- Gravy
- Juice
- Melted hot butter/margarine
- Milk (hot or cold)
- Plain yogurt

How to Thicken Liquids and Foods

- Add baby rice or commercial thickener to hot milk-based liquids.
- Add potato flakes, mashed potatoes, or flaked baby cereal to other hot liquids (soups, sauces, gravies).
- Add plain, puréed fruits, or a commercial thickener to cold liquids.
- Add potato flakes, mashed potatoes, thick sauces or gravies, canned, puréed or strained meat, or a commercial thickener to puréed soups.
- Add baby cereal, cooked cream of rice or wheat cereal, or a commercial thickener to puréed fruits.
- Add mashed white or sweet potatoes, potato flakes, sauces, or commercial thickener to puréed vegetables.

General guidelines for safe swallowing

- Maintain an upright position (as near 90° as possible) whenever eating or drinking.
- Take small bites — only ½ - 1 teaspoon at a time.
- Eat slowly. It may also help to eat only one food at a time.
- Avoid talking while eating.
- When one side of the mouth is weak, place food into the stronger side of the mouth. At the end of the meal, check the inside of the cheek for any food that may have been pocketed.
- Try turning the head down, tucking the chin to the chest, and bending the body forward when swallowing. This often provides greater swallowing ease and helps prevent food from entering the airway.
- Do not mix solid foods and liquids in the same mouthful and do not "wash foods down" with liquids, unless you have been instructed to do so by the therapist.
- Eat in a relaxed atmosphere, with no distractions.
- Following each meal, sit in an upright position (90 ° angle) for 30 to 45 minutes.

Symptoms of aspiration occurring during eating

- Coughing or wheezing during or right after eating.
- Excess saliva.
- Shortness of breath or fatigue while eating.
- A wet-sounding voice during or after eating or drinking.
- Fever 30 to 60 minutes after eating.

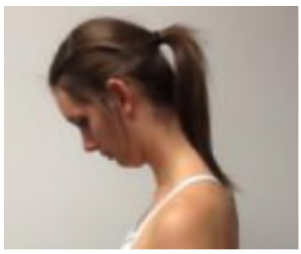
Postural techniques

Specific postural techniques are used to compensate for particular types of dysphagia by changing the way food moves through the pharynx

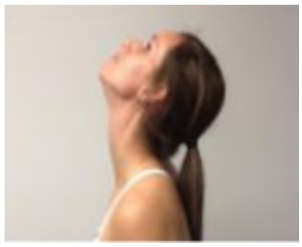
Head tilt
Move the head the non affected side, bolus is redirected through oral cavity and bolus transport improves.

Head rotation
Twist head to the weaker side so weaker side is closed off and bolus travels to the stronger side.

Chin tuck
Put chin down to move bolus anterior, this prevents premature spillage.



Head back
Bypass oral stage by utilizing gravity to clear the oral cavity.



Jaw opening exercise

Used to improve upper oesophageal sphincter opening during the swallow.

Instructions:

- Hold jaw in the maximally opened position for 10 seconds.
- Rest for 10 seconds.
- Repeat 5 times.
- Do 2 sets a day.

Dysphagia and safe medicine use

Solid oral dosage form (SODF) modification

Formulation of SODFs

SODFs can either be uncoated, sugar-coated, film-coated, enteric-coated or formulated to modify drug release (modified release). It is important to understand the reasons for the different SODF formulations before deciding whether it is safe or appropriate to modify them.

- **Sugar coating -** a sugar coating a thick, hard coating of sugar surrounding the tablet. This is a traditional method used to hide the flavour of particularly unpleasant tasting drugs, and can prevent light or moisture from affecting the drug's stability.
- **Film coating -** these are very thin layers of an inactive excipient coated thinly onto the tablet to again protect the tongue from the flavour of the contents, enhance appearance and protect the contents from moisture and light.
- **Enteric coating -** these coatings have been designed for the following three reasons: to protect the stomach from the drug, to protect the drug from the stomach, and to release the drug only once it has passed through the stomach to the small intestine.
- **Modified release -** the release of the drug from the tablet has been modified in some way. Usually this is to slow the release so that the medicine does not have to be taken too often and therefore improves compliance. The other benefit from modifying release is that the drug release is controlled therefore reducing the chance of side effects and increasing the likelihood of therapeutic effectiveness for longer periods of time.

Therapeutic options for patients with difficulty swallowing SODFs

DRUGS FOR ACID RELATED DISORDERS

PROTON PUMP INHIBITORS

Esomeprazole – The drug is acid labile. All formulations shown below are sustained-release, contain enteric-coated pellets, and cannot be modified.

Options:

- Nexiam Granules
- Nexiam MUPS Tablets
- Trustan MUPS Tablets
- Nesopram Gastro-Resistant Tablets
- Nexipraz Gastro-Resistant Tablets
- Nexmezol Tablets

Administration if difficulty swallowing

These can be mixed with water, fruit juice or yoghurt to give a dispersion of small granules for administration orally. The granules must not be crushed or chewed.

Omeprazole - The drug is acid labile. All formulations shown below are sustained-release, contain enteric-coated pellets, and cannot be modified.

Options:

- Altosec Capsules
- Omez Capsules
- Omiloc Capsues
- Sandoz Omeprazole Capsules
- Adco-Omeprazole Tablets
- Losec MUPS Tablets

Administration if difficulty swallowing

Capsules can be opened and the contents mixed with water, fruit juice or yoghurt to give a dispersion of small granules .Tablets can be dispersed in water, fruit juice and yoghurt to give a dispersion of small granules. The granules must not be crushed or chewed.

H2-RECEPTOR ANTAGONISTS

Ranitidine: Below are options that do not require off-label modification. Cheaper immediate-release tablets containing ranitidine can be crushed and dispersed.

Options:

- Zantac 75 Effervescent Tablet
- Zantac Effervescent Tablets
- Zantac Syrup

Administration if difficulty swallowing

Effervescent tablets and oral solution are available for administration orally.

CVS AGENTS - DRUGS FOR HYPERTENSION

CALCIUM-CHANNEL BLOCKERS

Amlodipine - All are immediate-release tablets and can be modified.
Options:

- Adco-Norpene
- Almadin Tablets
- Amlate Tablets
- Amloc Tablets
- Amtas Tablets
- Austell Amlodipine Tablets
- Calbloc Tablets
- Caduet Tablets
- Ciplavasc Tablets
- Copalia Tablets
- Norvasc Tablets

Administration if swallowing-impaired
Amlodipine tablets can be dispersed or crushed and mixed with water, fruit juice and yoghurt for administration orally.

Nifedipine - Some are sustained-release and cannot be altered. Shown below are the immediate-release tablets that can be modified.
Options:

- Bio-Nifedipine Tablets
- Cardifen Capsules

Administration if swallowing-impaired
Immediate-release tablets and capsules can be crushed/opened and the contents mixed with water, fruit juice and yoghurt for administration orally.

DIURETICS

Furosemide: Some are sustained-release and cannot be modified. Immediate-release tablets can be modified. Below are options that do not require off-label modification.
Options:

- Lasix Solution

Administration if swallowing-impaired
Oral solutions are available for administration.

Indapamide – Some are sustained-release and cannot be altered. Below are immediate-release tablets that can be modified.

Options:

- Adco-Dapamax Tablets
- Cipla-Indapamide Tablets
- Hydro-Less Tablets
- Indalix Tablets
- Mylan-Indapamide Tablets

Administration if swallowing-impaired

Immediate-release tablets can be crushed and mixed with water, juice or yoghurt for oral administration.

DRUGS FOR DIABETES

BIGUANIDES

Metformin HCL - Some are modified-release and cannot be altered. Below are immediate-release tablets that can be modified.

Options:

- Accord Metformin Tablets
- Austell-Metformin Tablets
- Bigsens Tablets
- Diaphage Tablets
- Glucophage Tablets
- Metforal Tablets

Administration if swallowing-impaired

Immediate-release tablets and can be crushed/opened and the contents mixed with water, fruit juice or yoghurt for administration orally.

SULPHONAMIDES AND UREA DERIVATIVES

Gliclazide - Some are modified-release and cannot be altered. Below are immediate-release tablets that can be modified.

Options:

- Adco-Glucomed Tablets
- Austell-Gliclazide Tablets
- Glycron Tablets
- Glygard Tablets
- Mylan-Gliclazide
- Sandoz Gliclazide 80

Administration if swallowing-impaired

Immediate-release tablets can be crushed and mixed with water, fruit juice or yoghurt for administration orally.

CNS AGENTS - DRUGS FOR EPILEPSY

Carbamazepine - Sustained-release and cannot be modified. Below are options that do not require off-label modification. Immediate-release tablets can be modified.

Options:

- Tegretol suspension

Administration if swallowing-impaired

Oral solution are available for administration.

Sodium Valproate - Sustained-release and cannot be modified. Below are options that do not require off-label modification.

Options:

- Convulex Syrup
- Epilim Crushable tablets
- Epilim liquid

Administration if swallowing-impaired

Oral solution and dispersible tablets are available for administration.

CNS AGENTS - DRUGS FOR PAIN

Morphine - Sustained-release and cannot be altered. Below are options that do not require off-label modification.

Options:

- Mist Morphine Oral Solution

Administration if swallowing-impaired

Oral solution are available for administration.

Aspirin- Below are options that do not require off-label modification. Immediate-release tablets can be modified.

Options:

- Disprin Dispersible Tablets

Administration if swallowing-impaired

Dispersible tablets are available for administration.

Paracetamol - Immediate-release tablets can be modified. Below are options that do not require off-label modification.

Options:

- Calpol Suspension
- Go-Pain P Syrup
- Napamol Syrup
- Panado Syrup
- Painamol Syrup
- Empaped Suppositories
- Panado Effervescent Tablets
- Parafizz Effervescent Tablets

Administration if swallowing-impaired

Oral solutions, suppositories and dispersible tablets are available for administration.

CNS AGENTS - ANTIPSYCHOTICS

TYPICAL ANTIPSYCHOTICS

Chlorpromazine - Immediate-release tablets can be modified. Below are options that do not require off-label modification.

Options:

- Largactil Syrup

Administration if swallowing-impaired

Oral solutions are available for administration.

ATYPICAL ANTIPSYCHOTICS

Quetiapine - Some are sustained-release and cannot be altered. Below are immediate-release tablets that can be altered**.**

Options

- Dopaquel Tablets
- Mylan Quetiapine Tablets
- Quetoser Tablets
- Truvalin Tablets

Administration if swallowing-impaired

Immediate-release tablets and can be crushed/opened and the contents mixed with water for administration orally.

CNS AGENTS - ANTIDEPRESSANTS

SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS

Fluoxetine - Below are options that do not require off-label modification. Immediate-release tablets can be crushed and dispersed.

Options:

- Prohexal Dispersible Tablets

Administration if swallowing-impaired

Dispersible tablets are available for administration.

Sertraline - Below are immediate-release tablets that can be modified.

Options:

- Aspen Sertraline Tablets
- Austell-Sertraline Tablets
- Dyna Sertraline Tablets
- Serlife Tablets
- Serta Tablets
- Zolid Tablets

Administration if swallowing-impaired

Immediate-release tablets and can be crushed/opened and the contents mixed with water, fruit juice or yoghurt for administration orally. Crushed tablets will have a bitter taste and may have a local anaesthetic effect.

TRICYCLIC ANTIDEPRESSANTS

Amitriptyline HCL - Below are immediate-release tablets that can be modified.

Options:

- Sandoz Amitriptyline Tablets
- Trepiline Tablets

Administration if swallowing-impaired

Immediate-release tablets and can be crushed/opened and the contents mixed with water, fruit juice or yoghurt for administration orally.

ANTIBIOTICS

PENICILLIN + BETA LACTAMASE INHIBITORS

Co-amoxiclav - some are sustained-release and cannot be altered. Below are options that do not require off-label modification. Immediate-release tablets can be modified.

Options:

- Amoclan Suspension
- Augmentin Suspension
- Augmentin ES Suspension
- AugMaxil Suspension
- Auro Amoxiclav Suspension
- Bio-Amoxiclav Suspension
- Clamentin Suspension
- Ranclav Suspension
- Sandoz Co-Amoxyclav Suspension
- Forcid Soluble Tablets

Administration if swallowing-impaired

Oral solutions and dispersible tablets are available for oral administration.

CEPHALOSPORINS

Cefaclor - some are sustained-release and cannot be altered. Below are options that do not require off-label modification.

Options:

- Vercef Suspension

Administration if swallowing-impaired

Oral solutions are available for oral administration.

MACROLIDES

Clarithromycin - some are sustained-release and cannot be altered. Below are options that do not require off-label modification. Immediate-release tablets can be crushed and dispersed.

Options:

- Claren Suspension
- ClariHexal Suspension
- Klacid Suspension
- Klarithran Suspension

Administration if swallowing-impaired

Oral solutions are available for oral administration

SULPHONAMIDES + TRIMETHOPRIM

Co-trimoxazole - Below are options that do not require off-label modification. Immediate-release tablets can be altered.

Options:

- Bencole Suspension
- Cozole Suspension
- Doctrim Suspension
- Purbac Suspension

Administration if swallowing-impaired

Oral solutions are available for oral administration.

FLUOROQUINOLONES

Ciprofloxacin - Below are options that do not require off-label modification. Immediate-release tablets can be altered.

Options:

- Ciprobay Suspension
- Cilodex Suspension

Administration if swallowing-impaired

Oral solutions are available for oral administration.

TB DRUGS

COMBINATION DRUGS

Rifampicin/isoniazid - Film-coated tablets

Options:

- Rimactazid Tablets
- Rifinah Tablets

Administration if difficulty swallowing

The Rimactazid can be chewed or dispersed in water (SAMF). This information is not given for Rifinah which is also film-coated. An off-label use is to crush the tablet and mix with water, fruit juice or yoghurt for administration orally.

Rifampicin/isoniazid/pyrazinamide/ethambutol - Film-coated tablet. Despite the film coating, this can be modified. The modified form is an off-label use to be used in special cases only.

Options:

- Rifafour

Administration if difficulty swallowing

Tablets can be crushed and dispersed in water to give for administration orally.

HIV/AIDS DRUGS

COMBINATION DRUGS

Lopinavir/Ritonavir - Film-coated tablets. Ideally these should not be modified, however Kaletra solution is not available, they can be altered, resulting in an off-label use to be used in special cases only.

Below are options that do not require off-label modification.

Options:

- Kaletra Solution

Administration if difficulty swallowing

Oral solution is available.

Emtricitabine/tenofovir/efavirenz - Film-coated tablet. Despite the film coating, this can be modified. The modified form is an off-label use to be used in special cases only.

Options:

- Atripla Tablets
- Atroiza
- Tribuss
- Odimune

Administration if difficulty swallowing

Tablets can be crushed and dispersed in water to give for administration orally.

List of websites for further information

Condition of dysphagia

National Health Systems - https://www.nhs.uk/conditions/swallowing-problems-dysphagia/

World Gastroenterology.org - http://www.worldgastroenterology.org/guidelines/global-guidelines/dysphagia/dysphagia-english

American-Speech- Language-Hearing Association - http://www.asha.org/public/speech/swallowing/Swallowing-Disorders-in-Adults/

Mayo Clinic - https://www.mayoclinic.org/diseases-conditions/dysphagia/symptoms-causes/syc-20372028

General counselling guidelines

Jackson Siegelbaum Gastroenterology - https://www.gicare.com/diets/dysphagia-diet/

Thick-it® - http://thickit.com/understanding_basics_dysphagia_nutrition/

Saint Luke's Health Sytem - https://www.saintlukeshealthsystem.org/health-library/dysphagia-diet-0

Dyshagia Diet - https://www.dysphagia-diet.com/

American Speech and Language Association - http://www.amyspeechlanguagetherapy.com/dysphagia-diets.html

Medication use with dysphagia

Keele University - www.dysphagia-medicine.com

Swallowing Difficulties - http://swallowingdifficulties.com/