Shared Care Guidelines for Patient Medicines Management in Breast and Colon Cancer

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Dedicated to: Lorraine Theuma for her strength and courage,
my dad and sisters, and my close friends especially Ryan, Razza, P&T.

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Abstract

The introduction of oral chemotherapy has lead to cancer patients receiving these medications through community pharmacies rather than having to visit a hospital to have their oncology medication administered. This change represents a shift from therapy being given in hospital, to therapy being given in the patient's own home. In this context, community pharmacists can provide a significant intervention by supporting patients to manage and prevent oral chemotherapy side effects, thus avoiding unwarranted trips to hospital, which saves money and time, resulting in an improvement in the patient's quality of life. The aim of this research was to compile shared care guidelines for oral chemotherapy used in the management of breast, colon and prostate cancer.

Five shared care guidelines were created for: capecitabine, everolimus, abiraterone, enzalutamide and ruxolitinib. The developed documents were validated by a panel of experts consisting of four oncologists, a principal and a senior pharmacist within the compounding section at Mater Dei Hospital, and a senior pharmacist at Sir Anthony Mamo Oncology Hospital. A patient focus group was developed during which five patients receiving oral chemotherapy from a community pharmacy were invited to participate in the focus group and given a questionnaire to capture the patient's experience about the service received from the community pharmacist. The developed shared care guidelines were presented to community pharmacists during an educational program about managing chemotherapy side effects. Scored questionnaires were handed out to the pharmacists before and after the program to determine if there was an improvement in responses.

The validation panel reported on the content and validity of the shared care guidelines developed. The educational program was carried out for 11 community pharmacists who are currently practicing in community pharmacies where dispensing of oncology oral therapy is undertaken. The mean response rate before the educational program was 5.45% whilst the mean response rate after the program was 80%. From the patient focus group issues related to information presented to the patient about what side effects to be expected, how these side effects should be handled and how these medications should be stored were identified. These points were used to develop the framework for the shared care guidelines and each guideline now consists of indications, administration, side effects and storage information.

The shared care guidelines were developed within a collaborative framework and are intended to further substantiate effective communication between healthcare professionals at different settings, namely: the hospital multidisciplinary team and the community pharmacist dispensing the oral chemotherapy drugs.

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CHAPTER 1

INTRODUCTION

1.1 Cancer Statistics

By the year 2020 cancer rates are expected to increase by 50%, according to a report published by the World Health Organisation (World Cancer Report 2003). This increase will be mainly due to smoking trends, longevity of the population in general, increasing obesity rates and sedentary lifestyle becoming more common (Donepudi et al, 2014). These reasons can be extrapolated from the fact that physical inactivity, obesity, tobacco use, and poor nutrition are known to have caused 60% of all cancer deaths in the USA (Castro et al, 2015).

With regards to cancer incidence, breast cancer is the most frequently diagnosed cancer and the leading cause of cancer death in Maltese females (Malta Cancer Registry). Its incidence has been increasing from the year 2000 to 2010 (Ellul et al, 2015). The incidence of colon cancer in Malta has also been increasing, and currently affects 26.6 people per 100,000 locally (Global Health Exchange July 2017). According to the Malta Cancer Registry, in 2014 there were 314 new cases of breast cancer, 262 new cases of colorectal cancer and 189 new cases of prostate cancer. For these cancers a number of drugs have become available that make oral chemotherapy a possibility. These three cancer types, which are relatively common in the Maltese population and for which oral drug therapy is available, were chosen as the area of focus for the study.

The increase in cancer incidence means that more healthcare services are need to be to be able to manage the subsequent increase in cancer patients and cancer treatment. The availability of oral chemotherapy leads to a situation where the patient is handling

treatment within a domiciliary environment. This reduces the strain on hospitals and in-patient settings. [1]

However this shift from intravenous to oral chemotherapy requires a shift in pharmacist services from the secondary care to the primary care setting.

1.2 Oral Chemotherapy at Home

There are many reasons why the use of oral chemotherapy is becoming more widespread in the community pharmacy scenario. These include the availability of innovative oral chemotherapy drugs, the fact that oral chemotherapeutic drugs are being used for indications other than cancer treatment and advances in chemotherapy allowing patients to live longer and thus requiring long term oral chemotherapy drugs (Depledge, 2012). Furthermore patients prefer being administered chemotherapy, whether oral or intravenous, within the comfort of their own home (Beijer et al, 2008). A report published in the UK, 'Chemotherapy Services in the Community – A Guide for PCTs' (DH Cancer Policy Team, 2010) which used evidence from France, Spain, Australia and the USA showed that patients and carers preferred home administration of chemotherapy, which was found to cost as much as chemotherapy given at hospital, or was only slightly higher. The shift towards oral chemotherapy carries advantages and disadvantages which need to be reviewed when looking at patient therapeutic management.

1.2.1 Advantages of Oral Chemotherapy at Home

A study by Mitchell et al., in 2014 in Victoria, Australia highlighted the advantages of administering oral chemotherapy when compared to giving chemotherapy via the

[1] [1] WHO. Global Health Data Exchange http://global-disease-burden.healthgrove.com/l/34492/Colon-and-Rectum-Cancer-in-Malta#References&s=ref

intravenous route. In terms of pharmacology, it has been suggested that when taken via the oral route, the body is continuously exposed to the chemotherapy and this can produce better results than when the chemotherapy is given intravenously. [2]

Another advantage is the increase in ease of administration, which causes less disruption to the patient's life partly because there are less trips to hospital. This in turn also increases the patient's autonomy with regards to their therapy, by allowing the patient to be more responsible for the administration of their own treatment and thus feel more empowered and included in their treatment plan (Simons et al, 2010). Another advantage of oral chemotherapy is that it eliminates the need for cannulation and decreases anxiety levels in the patient, which in turn reduces anticipatory nausea and vomiting. The benefits also extend to healthcare departments, as there is a reduction in the need for in-patient services. This reduces costs and frees up staff.

Whilst recognizing the advantages of patient autonomy and empowerment to control the condition and the reduction in costs for the healthcare system, it needs to be acknowledged that patient needs in the community setting are different when compared to receiving chemotherapy in the hospital setting. One of the challenges that the patient needs to overcome is related to adherence to treatment.

Through patient education and counseling provided by a community pharmacist, adherence rates can be improved. Follow up is needed to identify the patients that do not adhere to their treatment. The community pharmacist is in an ideal position to question patients about their adherence to the treatment and to support patients about the

[2] DH Cancer Policy Team, 'Chemotherapy Services in the Community – A Guide for PCTs' (Feb 2010 UK) http://webarchive.nationalarchives.gov.uk/20100604134231/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_112588.pdf

importance of maintaining a 100% adherence rate to ensure that the treatment is successful. A study by Ribed et al., in 2016, found that reinforcement of the importance of adherence to therapy is essential to improve adherence rates, with a 20% increase in adherence rates being reported in an intervention group where patients attended a pharmaceutical care program for oral chemotherapy.

1.2.2 Disadvantages of Oral Chemotherapy at Home

A study carried out in 2015 by Holle et al., highlighted limitations which can arise when using oral chemotherapy instead of intravenous chemotherapy. The disadvantages of oral chemotherapy highlighted include safe storage of the drug at home, handling and disposal of the chemotherapeutic agent, resolving difficulties in following a complex dosage regimen, identifying and reducing the potential of medication errors happening at home, avoiding any potential interactions (drug-drug and even drug–food), identifying and reporting of adverse drug events, reducing problems with novel toxicities and accessibility and costs. The patient must be educated on proper storage and disposal of chemotherapy, to avoid inadvertent exposure of the medication to other individuals particularly children and females of child-bearing potential. The patients themselves may perceive oral chemotherapy as being less potent than the intravenous drugs. Patients therefore need to be supported in terms of knowledge of oral drug potency as well as the risk and potential side effects.

Other disadvantages of oral chemotherapy include the high cost and the frequent lab monitoring needed (Patel et al, 2016). A disadvantage of giving chemotherapy at home however is that there is less patient and caregiver contact time with the healthcare providers. Adherence cannot be assured since the patient will be self-administering the treatment at home without the direct help of a healthcare professional (Bordanaro, 2014).

This disadvantage reiterates that community pharmacists need to support patients receiving oral chemotherapy in terms of information about oral chemotherapy agents, adherence and potential risks. A retrospective study carried out by Patel et al., in 2016 showed that from two cohorts investigated, the cohort that included regular pharmacist-led chemotherapy monitoring investigations had an increased adherence to laboratory monitoring.

1.2.3 Chemotherapy at Home for Pediatric Patients

In a study carried out in 2006 by Stevens et al., it was shown that physical side effects, such as nausea and vomiting were reduced, when chemotherapy was given at home rather than in a hospital setting. Parents and children also reported less disruption of their daily activities and increased their feeling of control over the situation at hand. Some of the children preferred the home setting because they could choose where to receive the chemotherapy (such as on their favorite chair, or on a comfortable couch), as well as being able to control the activities before and after receiving chemotherapy. The elimination of travelling to receive chemotherapy and the reduction in waiting time was also seen as beneficial, probably because it reduces the anxiety which is often associated with anticipatory nausea.

1.3 Community Pharmacists Intervention

Studies have been carried out to put forward pharmacist intervention at a community pharmacist level to overcome the challenges brought forward as a result of the disadvantages identified. In the study by Holle (2015) after carrying out patient assessments the pharmacist was able to recommend various courses of action, such as laboratory monitoring, and discussing supportive and chronic medications used together with chemotherapy drugs in detail. Recommendations carried out by the pharmacist resulted in the discontinuation of unnecessary therapy, modification of dosages or interval of dosing, and in some cases modification of the cancer therapy or other medications. Other interventions included providing advice on nutrition, tackling non-compliance and making adequate lifestyle recommendations (Blom et al, 2011; Holle, 2016). Patients were referred to the hospital when needed and advice was given on the safe storage of the medication at home and the safe disposal of the therapy (Holle, 2015).

The dilemma faced in the context of having community pharmacists dispensing oral chemotherapy drugs is that there are no guidelines in the local setting as to what patient support should be offered with details for the specific drugs. A survey in Rhode Island and Maine, USA carried out in 2007 by Charpentier (2012) showed that community pharmacists are not familiar with the chemotherapy being dispensed at a community pharmacy level, and feel that more education is needed to be able to provide counseling to the patients and to be able to safely dispense the medication. The community pharmacists interviewed also admitted to feeling uncomfortable with dispensing chemotherapy, especially with agents that are not regularly dispensed. Providing training to community pharmacists about oral chemotherapy would improve the overall care given to patients

and improve safety in the pharmacy and for the staff working at the pharmacy (Charpentier, 2012).

A study carried out by Abbott et al., in 2014, highlighted the requirements that are to be met to ensure that oral anticancer drugs are being dispensed safely. These requirements include ensuring that the correct medication and dosing instructions have been given to the patient, ensuring compliance by the patient or caregiver to the dosage regimen, providing information about any possible food or drug interactions and ensuring the patient knows to administer the therapy with regards to food and other drugs the patient may be taking, and also giving timely advice about side effects the patient may be experiencing.

In 2015 a website and mobile app, named "AntiC", were developed in Canada for pharmacists (Van Rooij et al., 2015) since it was felt that the current data available is lengthy and disparate and not easy for a community pharmacist to access quickly, especially in a busy pharmacy. This app is a practice tool that presented information on individual drugs using a 1-page format. The information included indication, dosage, side effect, interactions, adjustments for renal and hepatic impairment and risk stratification.

1.10.1 Managing Adherence

Community pharmacists are in an ideal position to support the patient in adhering to treatment and with ensuring they adhere to the required frequent monitoring. The reduced clinical visits as a result of administering chemotherapy at home puts greater importance on the health care professional to ensure that the patient is well aware of what side effects to expect, and when to refer back to their health care provider (Goodin et al., 2011). As with all other medication, the efficacy of the treatment will depend upon the patient

adhering to the prescribed regimen. Cancer is increasingly being viewed as a chronic disease, which further increases the importance of adhering to the treatment given to avoid relapse (Felton, 2016).

Pharmacists can offer verbal as well as written advice to help improve adherence rates. The community pharmacist is also in a position to offer counseling and follow up, which can be offered after every treatment cycle (Felton, 2016). Clinical pharmacist intervention, in a study by Simons et al., in 2011 resulted in an increase in adherence rates to capecitabine as a result of pharmacist support. In this study the intervention consisted of both written and verbal information being given to the patient by two pharmacists. This information included stating the importance of maximal adherence to the treatment and reminding patients of the dangers of being noncompliant to treatment. On initiation to the study, patients were also given detailed information about capecitabine, including its mechanism of action, potential adverse effects and how to manage them. The patient's individual treatment was discussed in detail. To test adherence, patients were given an activated MEMS vial, which records the opening and closing of the vial via a microchip.

In a study by Holle et al., in 2015, an oncology pharmacist improved adherence rates by providing frequent follow ups and medication reviews, as well as providing reinforcement about how to take the medication, and how the medication should be administered. The study also found that those patients who underwent a pharmacist intervention program were more likely to still be on chemotherapy by the end of the observation period, which is a very significant achievement (Holle et al, 2015).

Over-compliance is also possible in cancer patients, which can be a cause of morbidity and mortality, with patients taking the wrong combination of tablets, or taking more chemotherapy than needed and continuing beyond the recommended cycle of their

chemotherapy (Vidall, 2010). Through keeping patient records at the pharmacy, the pharmacist may be able to recognize cases, where more time than the recommended treatment cycle would have elapsed since the previous chemotherapy order, indicating that the patient is not adhering to the recommended treatment cycle.

Many of the novel oral chemotherapies also require frequent blood tests to monitor lab parameters. For example, abiraterone can cause a drop in serum potassium concentrations, which can only be detected through carrying out a blood test. For patients taking abiraterone blood tests should be carried out every 2 weeks for the first 3 months, and serum transaminases and bilirubin must also be monitored and compared to baseline. This demonstrates that adherence to appointments for monitoring and review including blood tests is essential to ensure patient safety. A study by Holle in 2016 showed that adherence to appointments for blood tests was significantly higher in patients that were in the pharmacist intervention cohort. Optimization of patient care can be achieved by providing intense patient education, monitoring and management, to help achieve a pro-active rather than a reactive approach. The study also recognized that there are certain sub-groups of patients that tend to have a reduced adherence rate when compared to the rest of the patient population. The lack of direct intervention and monitoring by a health professional is of concern in patients receiving oral chemotherapy at home. This is of concern since adherence cannot be assured, and the health care professional cannot be certain that the patient would report any deterioration in health, or occurrence of side effects (Mitchell et al, 2014).

Community pharmacy programs can help to bridge the gap between the continuous observation by healthcare professionals in the hospital setting, and the care being given at

home, where there is less frequent monitoring, and direct observation by a health care professional.

1.3.2 Managing Side Effects

Adverse effects need to be avoided to ensure that the patient does not stop treatment earlier and also to ensure a good quality of life for the patient A study by Bordanaro in 2014 showed that patients consider the effective treatment of side effects to be of major importance to them. Chemotherapy, compared to other medication, in general tends to have a narrow therapeutic index, which increases the likelihood of the patient developing adverse effects. This risk of developing side effects increases further when the patient is taking other medications (Goodin et al, 2011). Studies have shown that when a patient is well informed about the side effects they may encounter and are given information on how to treat and prevent these side effects, they are less likely to experience these limiting side effects and are better able to manage them, since they can be detected earlier (Simons, 2011).

When discussing side effects for a particular drug it is important for the pharmacist to use numerical rather than verbal frequency descriptors. This can help the patient understand better how likely they are to suffer from a particular side effect. Plenty of rest and a healthy diet together with a positive attitude can never be over emphasized (Hiumin et al, 2015).

1.3.3 Managing Interactions with Natural Remedies

Up to 75% of patients undergoing chemotherapy use natural remedies, in many cases without informing their doctors about them, the potentially dangerous effects of natural remedies together with chemotherapy are often not known by the patient. Pharmacists can provide information about the possible interactions, which may occur with natural remedies and chemotherapy medication (McKeon, 2012).

1.3.4 Pharmacist-led Patient Education and Counseling

Pharmacists can carry out chemotherapy teaching sessions, which have the aim of decreasing the patient's anxiety about chemotherapy, whilst at the same time increasing patients' knowledge about the treatment. In the study by Avery et al (2015), these sessions were conducted before chemotherapy was started, and were carried out again during therapy and after therapy was stopped. The study highlighted the importance of ensuring that the patient is well aware of the side effects that can be experienced with the therapy given, and how the medication should be taken.

Not all patients are the same, with some patients requiring more extensive counseling than others. These patients need to be identified in order to ensure safe and effective dosing and optimal adherence to therapy. It is also important to note that the patient requires counseling not only about the chemotherapy being given, but also about the rest of the medications which are being taken, which can sometimes reach up to ten different drugs and which are prescribed by different medical specialties to cover for chronic conditions. The oral chemotherapy drugs may be taken for long periods of time, with certain cancers such as lymphoblastic leukemia requiring treatment for around 2 years.

1.11 Community Pharmacy Educational Programs

In 2016 a meta-analysis was carried out to review the impact community pharmacists have on programs carried out in community pharmacies, such as smoking cessation, weight loss and alcohol reduction. The study found that community pharmacies are ideal places to carry out such programs, which were deemed to be successful and cost effective (Greenhalgh et al, 2016). This is partly due to the ease of accessibility of community pharmacies, the familiarity of patients with the community pharmacist and staff, and the relatively low cost of such programs.

The "Counter Weight Program" in Fife, Scotland, saw 10% of participants achieving and maintaining weight loss. During this program pharmacists were given specialized training in dealing with overweight patients, which is then used to help patients lose weight and maintain the weight loss (Morrison, 2013). A smoking cessation program carried out in the United Kingdom also provided training to pharmacists on how to recruit patients and how to provide advice and follow up to patients who wished to stop smoking. A 14.2 % success rate was achieved (Morrison, 2013). Preventing readmission to hospital has also been achieved through community pharmacy based programs, which are aimed at transitioning patients from the hospital setting into the community setting. Medication issues are one of the main reasons patients are re-admitted into hospital. These medication issues include non-adherence, drug adverse events and drug over doses (Grissinger, 2015). Community liaison programs have been set up in community pharmacies to reduce hospital readmissions and to reduce the harm that can be caused by medication errors (Grissinger, 2016).

Similar programs as those mentioned above can be carried out in community pharmacies to educate patients about the prevention and management of chemotherapy side effects.

Community pharmacists may argue that they require additional training and practice updates to align with the continuous developments in oncology pharmacotherapeutics. Empowering community pharmacists with knowledge on oral chemotherapy drugs that can easily be applied in the community setting will help contribute to patient safety and patient support hence overcoming the barrier of non-direct healthcare professional during administration of oral chemotherapy. An additional concept that may be considered is to organize home delivery programs, which in addition to ensuring access to the drugs, also considers patient support and direct services.

1.12 Home Delivery Programs

In the United Kingdom, a home delivery program already was developed for imatinib, and has been operating with success for a number of years (So, 2010). This service was described by So (2010). An annual review is carried out to discuss any major issues and patient complaints. After three years of operation, no medication errors were ever encountered and due partly to being exempt from paying VAT, over 120,000 sterling pounds were saved. Patients who agreed to start receiving imatinib at home were still under the full clinical responsibility of the prescriber. The patient would have met with the prescriber to take the first dose of imatinib, with the rest of the doses being delivered at the patient's home, thus eliminating the need for the patient to wait at a pharmacy to get their prescription filled. The patient would still meet with the clinician regularly and the prescriber would inform the pharmacist about any change in dose. The pharmacist fills in a change in dose form, screens the prescription and informs the supplier of any change in dose. The use of this home delivery system has led to a reduction in waiting time at the

outpatient pharmacy, from an hour and a half to just 30 minutes, whilst the patients using the home care delivery system completely avoid any queues.

In some countries, intravenous chemotherapy is also given at the patient's home (Chahed et al, 2009). The service, which involves the administration of chemotherapy drugs by a nurse or trained health care worker, after being reconstituted, or prepared, at hospital by a pharmacist, is gaining popularity in other European countries, and in America. Given Malta's small size, and the logistics and resources involved in delivering such medication this may not be feasible.

1.13 Barriers to Implementing an Oral Chemotherapy Service in the Community Pharmacy

A study carried out in 2016 by Butt et al., highlighted the barriers that currently exist which prevent the implementation of an oral chemotherapy service in the community pharmacy in the United Kingdom. The first barrier mentioned was the separation between the Information Technology (IT) system of the National Health Service in the United Kingdom (which in Malta can be compared to the information technology system present at Mater Dei Hospital) and the community pharmacy, which means that community pharmacists cannot access hospital patient data. There is also a lack of communication between the different settings, with no communication existing between the hospital setting and the community pharmacy setting (Butt et al, 2016). This situation is very similar to the local setting. In Malta community pharmacists have access to a database recording drugs that patients are entitled to through the national health service. However the database is not directly linked to the patient case notes and any change in treatment is

not automatically fed into the system. Change in drug therapy requires manual transcription and changes in doses are not captured.

Another barrier mentioned in the Butt et al study was the imbalance between running a profitable business and providing an adequately high level of patient counseling and guidance, with the need of one on one patient appointments being highlighted as a much needed and desired service in the community. Other barriers mentioned in the study included the lack of space to provide adequate and confidential patient counseling and the lack of space to store chemotherapy properly. Issues were also raised on how to ensure that all the locum staff was adequately trained to provide the service required. The potential danger of counter assistants dispensing the chemotherapy without providing the necessary counseling was also questioned (Butt et al, 2016). These reflections are very much relevant to the local community pharmacy setting where the physical space of the pharmacies may be limited, in most cases jeopardizing availability of a privacy area for counseling. In Malta the pharmacy to population ratio is 1:1980 resulting in community pharmacies having a small professional team where a pharmacist is available on the floor during any particular time (Wirth et al, 2011). This situation limits the possibility of one to one patient sessions unless these are pre-booked during times when the pharmacy is least busy or when the pharmacist has additional pharmacists available. The concept of having pharmacists available in the pharmacy to offer a one-to-one patient focused clinical pharmacy service is starting to be introduced and identifying which groups of patients will benefit most and elucidating economic structures to ensure sustainability of this service are to be studied.

The model, which was deemed to be the safest option for dispensing chemotherapy, was the second model, which was referred to as level 2 in the study by Butt et al in 2016,

which was carried out in the United Kingdom. This would involve the community pharmacist checking the prescription for the oral chemotherapy, ensuring that it was in line with a regime protocol and applying the basics of chemotherapy verification defined by BOPA Verification Standards 2010. Such prescriptions should be verified by pharmacists specialized in oral chemotherapy who have undergone training. Verification is only possible if the pharmacist has access to patient blood tests and records.

1.14 Outpatient Pharmaceutical Care Program

The use of oral chemotherapy may be associated with medication errors which occur during prescribing, dispensing, administration and monitoring. According to Weingart et al (2010), common medication errors identified from reported literature were: wrong dose (38.8%), wrong drug (13.6%) wrong number of days supplied (11.0%) and missed doses (10.0%). The risk of medication errors may be reduced if the pharmacist identifies problems such as dosing, drug supply and patient understanding with regards to administration. A study by Ribed et al in 2016 was carried out in Spain to investigate the impact of a pharmacist's intervention on the risk of patient's developing DRPs. Such errors can be the result of a lack of co-ordination between the different settings involved, namely the hospital and the home. To reduce the potential for errors taking place a pharmaceutical care program was set up within the study by Ribed et al (2016) to compare the percentage of errors taking place in a group of patients not being supervised by a pharmacist, and a group of patients receiving a pharmacist's intervention. Results showed that the pharmaceutical care program was able to identify and effectively prevent up to 59% of medication errors, with 57% of these errors being due to drug-drug interactions, the number 1 cause of DRPs. Other errors included dosage and administration errors.

Community pharmacists may support patients in sustaining a positive outlook during the treatment period. Studies have shown that up to 10-25% of patients diagnosed with cancer also experience depressive symptoms (Zhou, 2010). Depression and anxiety in cancer patients can result in high blood pressure, heart palpitations, increased stress, and has been shown to reduce compliance to treatment. Attempted suicide together with the other symptoms mentioned can lead to increased hospital stays and increased cost, whilst also having a negative effect on the quality of life of the patient. A poor prognosis is an expected outcome when such symptoms lead to treatment interruption. Experience through clinical practice has also lead to the observation that depressed patients are prone to experience more adverse drug reactions, when compared to patients in a healthier state of mind. Community pharmacists are in a position to identify patients who require referral for psychological support.

1.15 Safety Standards of Dispensing of Chemotherapy

Safety standards within the hospital and community pharmacy settings demonstrate a standardized approach to ensuring a consistent level of professional services offered, which are targeted to ensure patient safety. The patient-centered approach which puts patient safety as a priority is practiced by pharmacists but may not be seen to be so by external reviewers of the service, since there is hardly any documentation demonstrating the standardization of services between one pharmacist and the other in the same community pharmacy. Developing structures that provide a framework to standardize safety standards followed when dispensing oral chemotherapy may be a start towards this direction. Safety standards include the elaboration of shared care guidelines that are

agreed upon by the clinical specialists in the field and are transferred for implementation in the community pharmacy setting.

Butt et al carried out a study in the United Kingdom in 2016, which focused on the level of implementation of safety standard of different hospitals across the country. Arbitrary levels ranging from 1 to 3 were assigned. With level 1 meaning the failure to reach level 2 standards. Level 2 meant that a meeting was scheduled with the pharmacist before starting treatment and written leaflets were given to the patient about the treatment and disease. Level 3 meant that level 2 standards were met, with the addition of electronic prescribing and ordering, as well as added safety standards. The pharmacist was the main professional involved in the dispensing of oral chemotherapy and most oral chemotherapies were collected from the hospital pharmacy. Patient education and counseling by the pharmacist was rated as an important component of safe dispensing of oral chemotherapy and the optimization of patient care. This intervention by the pharmacist resulted in improved patient outcomes and improved compliance. The education provided by the pharmacist to the patient was also deemed to be crucial to avoid potential drug problems such as reduced compliance due to complex dosage regimens, the mismanagement of side effects and avoidance of interactions with other drugs and food items. Pharmacists provided patient education by giving out printed material, individualized calendars to be used to assist dosage regimens, and in some cases pre -loaded pillboxes.

1.16 Setting

The idea for this dissertation arose from the researcher's experience working as a community pharmacist, after instances of meeting carers of cancer patients in the

community pharmacy asking if there were products available to help alleviate the symptoms of mucositis and hand foot syndrome. It was clear that there was a lack of information on side effects available to patients and their carers, who would in turn seek the help of a community pharmacist since community pharmacists are easily accessible, and many times act as a first point of call for patients with a health problem.

In Malta the national health system provides for free medications for carcinoma according to a closed-formulary system managed by the Directorate for Pharmaceutical Affairs within the Ministry of Health. A number of oral chemotherapy agents are not included in the formulary yet and are not available on the national health system. Patients buy such medications privately and seek subsidy from the Malta Community Chest Fund, a charitable foundation under the auspices of the President of the Republic of Malta.

1.10 Aims and Objectives

The aim of this research was to compile shared care guidelines for oral chemotherapy used in the management of breast, colon and prostate cancer.

The objectives of the research were to:

i. Identify areas of weakness in the current system of dispensing of oral chemotherapy drugs through a patient focus group
ii. Compile shared care guidelines regarding oral chemotherapy for application in a community pharmacy setting
iii. Assess the impact of the shared care guidelines on community pharmacists knowledge

CHAPTER 2

METHODOLOGY

2.1 Study design

The methodology of the research was divided into three areas, namely; a patient focus group to identify gaps and weaknesses in the current system of dispensing of oral chemotherapy, the development and validation of shared care guidelines, and the setting up of a pharmacist education program. Ethics approval was obtained in June 2016.

2.2 Identification of Gaps and Weakness in the Current Dispensing Service

The gaps and weaknesses present in the current system for dispensing of oral chemotherapy were identified through the development and implementation of a questionnaire used within a patient focus group.

2.2.1 Questionnaire Validation

A questionnaire (Appendix 2) aiming at capturing the patients' experience about taking oral chemotherapy at home was developed for the focus group. The questionnaire consisted of 7 Likert scale statements and 5 open-ended questions. An expert panel consisting of 3 pharmacists, 1 physician, and 2 lay people validated the questionnaire. Following the recommendations put forward by the expert panel the final version of the questionnaire was disseminated to the focus group.

2.2.2 Focus Group

A focus group consisting of 5 patients chosen randomly from 4 community pharmacies dispensing oral chemotherapy was set up. The aim of the focus group was to gather information about the patients' experience with taking oral chemotherapy at home. A preliminary meeting with the managing and locum pharmacists participating in the study was held whereby the researcher introduced the study and explained the aim of the research. The managing or locum pharmacists at community pharmacies were asked to explain the purpose of the study with the 5 chosen patients participating in the focus group. The patients were given a recruitment letter (Appendix 3) and invited to participate by the managing pharmacists or locum pharmacists. Patients agreeing to participate were asked to sign the consent form (Appendix 3). Subsequently the researcher contacted the participating patients and the questionnaire was completed via telephone.

2.3 Developing and Validating the Shared Care Guidelines

A list of oral chemotherapy drugs dispensed on the local private market was compiled. Microsoft excel was used to determine the frequency of each chemotherapy agent being given in the community pharmacy setting. The five most commonly dispensed agents were found to be capecitabine, enzalutamide, everolimus, abiretarone, and ruxolitinib. As of January 2017, across the 12 pharmacies involved in the study, a total of 13 patients are taking everolimus, 3 are taking ruxolitinib, 14 are taking capecitabine, 19 are taking enzalutamide, and 7 are taking abiraterone. Making these 5 oral chemotherapy drugs the most commonly prescribed oral chemotherapy drugs across the 12 pharmacies.

The latter is more commonly used for haematological cancers. Bevacizumab, although the second most commonly prescribed chemotherapeutic drug to be dispensed in the community pharmacy setting, was excluded since it is not an oral chemotherapeutic agent[3].

A literature review was carried out to investigate the current issues encountered when dispensing oral chemotherapy and issues that arise when patients take the medication at home rather than in the hospital setting. The literature review was carried out using the Hy-Di program via the library section in the University of Malta's website. Different key words such as "pharmacist," "community," "community pharmacy," "chemotherapy," "domiciliary," "pharmacist intervention," and "home" were typed into the search bar to look through different academic papers and studies.

The layout of the shared care guidelines was chosen based on United Kingdom National Health Service protocols found online during the literature review[7]. This layout was the most user friendly and clear. The shared care guidelines were designed to be not more than three pages long and the information was laid out in a way to present the information in a concise manner that can be understood quickly and easily. The summary of product characteristics and the patient information leaflet for each of the oral chemotherapeutic agent were reviewed and summarized into the shared care guidelines. Additional references from reliable online websites such as https://www.cancercare.on.ca [4], chemoexperts.com[5], and chemocare.com[6] were also reviewed.

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[3] Only oral chemotherapy agents were included in the study, since in Malta, intravenous formulated drugs are given at hospital and not at the patient's home.

[4] Cancercare.on.ca is a website based in Ontario, Canada, which acts as an advisory for Ontario's government, on matters of Cancer and Renal Systems, using evidence-based and innovative approaches

[5] Chemoexperts.com is an American based website run by expert oncology pharmacists.

The Shared Care Guidelines developed in this study were divided into eight sections and include the following information:

- The name of the oral chemotherapy drug and its formulation
- A table containing information on the dosing cycle of the drug
- The indication/s of the oral chemotherapy drug
- A list of the supportive medications which may be given together with the oral chemotherapy drug, and information about these medications
- Counseling points such as how the oral chemotherapy drug is to be administered, what to do when the patient misses a dose, how to store the oral chemotherapy drug, and information about the drug's pregnancy category.
- Self Care tips, which are points that the community pharmacist can discuss with the patient to help the patient feel more empowered with their treatment. This section includes advice that the patient will be able to follow without the need of a health care professional.
- Side effects were listed and this section also includes information on when a doctor or healthcare professional should be contacted.
- Common drug-drug, or drug-food interactions which may occur

The shared care guidelines focus on the most commonly occurring and distressing side effects that a pharmacist would be able to manage and help prevent. Side effects that would require a doctor's intervention or an outpatients visit were only discussed briefly, so that the pharmacist would be aware of emergencies requiring a referral.

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[6] Chemocare.com is an online website run by multidisciplinary team of healthcare professionals working with cancer patients at Cleveland clinic, Ohio, United States.

[7] Capecitabine NHS protocol exp. 2016 http://www.necn.nhs.uk/wp-content/uploads/2012/12/CR009-Capecitabine-CNTW-protocol-CRP10-CR009-v1.4.pdf

Other supportive medications, which would be dispensed together with the chemotherapy, were included in the shared care guidelines. This information would be useful to the pharmacist, should the patient have questions regarding these supportive medications. These include warning the patient about the dangers of stopping prednisolone abruptly after taking the medications for a number of days consecutively without tapering off the dose and the importance of taking regular blood tests due to the increase in blood sugar that can occur when using steroids.

The Shared Care guidelines were validated by an expert panel, which consisted of 5 oncologists, and 3 clinical pharmacists. The changes made by the expert panel are discussed in the results section.

2.4 Assessing Impact of Educational Program and Shared Care Guidelines for Community Pharmacists

An educational program targeting the five most commonly dispensed oral chemotherapy drugs namely capecitabine, enzalutamide, everolimus, abiretarone, and ruxolitinib for which Shared Care Guidelines were developed, was undertaken. The target audience was pharmacists practicing within community pharmacies dispensing oral chemotherapy drugs on the private market scheme.

Prior to the implementation of the educational program, a questionnaire aimed at capturing the pharmacist's knowledge of oral chemotherapy before and after the educational program was drafted. The questionnaire was validated by an expert panel consisting of two community pharmacists, a doctor and one lay person. The recommendations put forward were taken into consideration and the final version of the

Pharmacist's Questionnaire was prepared (Appendix 1). The Pharmacist's Questionnaire consisted of 18 questions.

Pharmacists within the 12 community pharmacies participating in the educational program and through which the oral chemotherapy drugs are distributed were approached and invited to attend to the educational session. An evening session was run to accommodate the participating pharmacists who were asked to complete the Pharmacist's Questionnaire (Appendix 1) prior to the start of the session.

Subsequently the pharmacist-researcher delivered a presentation focusing on the side effects that can be managed by a community pharmacist and included information on when a patient should be referred to a specialist or doctor, and included photos of the manifestation of the side effect for better identification. The side effects chosen were mucositis, hand foot syndrome, rash, diarrhoea and constipation, nausea and vomiting. A slide about the importance of sun protection was also included. Each slide included strategies and therapies that a pharmacist can recommend, with particular emphasis being made on the prevention of the side effects. For example in the case of Hand Foot Syndrome, it was stressed that applying emollients liberally and frequently, protecting the hands and feet from extremes of temperatures, and wearing cotton gloves can help to prevent the occurrence of hand foot syndrome. Patients were also advised to avoid applying topical anesthetics, to avoid constricting the skin, and to avoid chemical and physical abrasion. A slide dealing with the occurrence of anxiety and how it can be managed was also included, since the occurrence of anxiety as side effect is very detrimental to the quality of life of the patient, as well as that of family members and carers. After the power point presentation the validated Shared Care Guidelines were presented to the pharmacists and discussed. At the end of the program pharmacists were

given a copy of the Shared Care Guidelines to keep in their community pharmacy for quick referral before dispensing chemotherapeutic drugs.

At the end of the educational program, the Pharmacist's Questionnaire (Appendix 1) was again handed out to all the pharmacists. Therefore the same questionnaire was given to the pharmacists before and after the educational program. This allowed statistical analysis on data on the pharmacist's knowledge of oral chemotherapy side effects before and after the educational program.

CHAPTER 3

RESULTS

3.1 Patient's Questionnaire

The first results discussed are the results obtained through the patient questionnaire used during the patient focus group session intended to assess the patients' experience about taking oral chemotherapy at home.

3.1.1 Patient's Questionnaire: Validation

Following the recommendations from the expert panel, the questionnaire was amended to make the wording easier for patients to understand, as they might not be familiar with medical terminology which was originally included in the questionnaire. The panel also pointed out that some of the statements in the Likert scale section and the discussion section were repeated. These questions were removed and different questions were suggested to help the discussion achieve better results.

3.1.2 Patient's Questionnaire: Focus Group Results

The focus group that was carried out at the beginning of the study brought to light problems that patients currently taking oral chemotherapy drugs at home are facing. Results from the focus group showed that only 1 patient received information about what side effects to expect from the pharmacist or any other health care professional. One patient experienced problematic mouth ulcers which she was not told could happen, and was unsure about whether this was a manifestation of the cancer or a side effect of the oral chemotherapy medication she was taking. The patient frustration was exacerbated by the fact that her oncologist was not available immediately to answer her questions, and she had to wait for an appointment before the problem could start to be resolved.

Not all the 5 patients received information about how to store the medication at home and what precaution to take with safe storage.

The focus group results presented a scenario where the same general information about oral chemotherapy drug dosing is not given to patients and that there is not a standard which is followed throughout for each patient receiving oral chemotherapy. Whilst acknowledging that different patients have different requirements when it comes to their therapy, it must be ensured that the patients receiving oral chemotherapeutic drugs have a basic understanding of what to expect from their therapy with regards to side effects and how they can be treated, when they should alert their doctor in the event of certain adverse reactions, and how to safely store their oral chemotherapy.

3.2 Validation of Shared Care Guidelines

The validation of the Shared Care Guidelines was attempted for each guideline developed. The clinical pharmacists suggested changes (n) for capecitabine (n= 4 addition of information), for enzalutamide (n= 2 addition of information, n=1 removal of information) and for ruxolitinib (n=7 addition of information, n=2 removal of information). The oncologists suggested changes (n) for capecitabine (n=4 addition of information, n=4 removal of information), for enzalutamide (n=2 addition of information), for everolimus (n=2 addition of information), for abiraterone (n=1 removal of information).

The changes suggested for capecitabine related to handling of the tablets, administration technique and supportive medication (Table 3.1). Information on the hand foot syndrome was included for capecitabine which being a precursor for 5-fluorouracil is associated with a risk for this side effect. In general, females are at a higher risk than males (Miller et al, 2014). The likelihood of developing these reactions are mostly dose dependent. The time of onset is normally between 2 - 21 days from initiating therapy. The patient should be advised to avoid using hot water to bathe, avoid tight fitting clothing or shoes and gloves, patient should be advised to avoid vigorous exercise. Highly potent topical corticosteroids, wound management, frequent emollient use, pain control and keratolytics are to be encouraged (Miller et al, 2014). Severe diarrhoea with capecitabine requires immediate cessation of therapy. The patient should be warned to avoid lactose containing foods, as well as alcohol, as this can exacerbate the situation. Adequate hydration needs to be ensured using oral rehydration salts and water. The patient should also be advised to eat small frequent meals (Stein et al, 2010). Diarrhoea is of particular importance in summer and in warm, hot countries like Malta, where patients are more prone to dehydration in summer secondary to the hot weather.

The changes suggested for enzalutaminde related to presentation of the drug and the potential for drug interactions. Enzalutamide is hepatically metabolized by CYP 2C8 and CYP 3A4, with the generation of an active metabolite (Gibbons et al 2015). There is great potential for interactions between enzalutamide and other drugs. The oncologists validating the shared care guideline suggested that the ten most commonly used drugs that can interact with enzalutamide should be listed in the shared care guideline. Only seven drugs were included in the shared care guideline, since the other 3 most commonly used drugs that interact with enzalutamide are not available in the community setting, and are

only used in hospital (Table 3.2). A number of the drugs that were listed are pain management medications. A study carried out by Schumacher et al., in 2014 brought to light many of the problems cancer patients deal with when it comes to managing their pain medication.

For ruxolitinib, due to the lack of evidence about the use of "magic mouthwash" for treating oral mucositis, information about this formula was removed. The clinical pharmacists suggested that an emphasis is made about the importance of patients going to regular check-ups, since some of the more serious side effects of ruxolitinib can only be detected by blood tests and skin tests (Table 3.3).

Everolimus has the potential for interacting with a variety of drugs due to its metabolism process and the oncologists suggested to list the ten most commonly used drugs that interact with everolimus. One oncologist suggested the use of bicarbonate of soda rinse to be added, as it is often used locally to help relieve symptoms of mucositis to good effect (Table 3.4). Stomatitis may occur with the use of everolimus and capecitabine. Patients should be advised on proper oral hygiene and the avoidance of alcohol-containing dental products and spicy and acidic food (Peterson, 2013). Information on managing rashes was included for the everolimus guideline particularly highlighting the need to use sun protection that is very relevant for the local scenario.

For abiraterone the oncologists suggested removing the advice of drinking cranberry juice to help treat urinary tract infections since recent studies show that there is a lack of evidence for using cranberry juice to treat urinary tract infections (Jepson, 2012).

Table 3.1: Changes to Capecitabine Shared Care Guideline

Recommendations made by Clinical Pharmacists	
Information to Include	
- Patient or carer handling the medication should wear gloves to protect themselves from coming in contact with chemotherapy.	
- Tablets should not be crushed or chewed, as this would result in an immediate release of the active ingredient which can cause damage to the mouth	
- More information about the drugs that interact with capecitabine should be added	
- Add information for special population groups	
Recommendations made by Oncologists	
Information to Include	*Information to Remove*
Dosing may be continuous, and not taken as a cycle with 14 days 'on' and 7 days 'off' in some cases, depending on the condition being treated	Capecitabine should not be taken if the patient has missed the dose by more than 30 minutes, as this is not done in practice.
"Administration of drug: 12 hours apart within 30 minutes of a meal"	"Administration of drug : 1 tablet, 12 hours apart, 30 minutes after a meal"
	Remove "1 tablet" as more may be required, change wording to "the prescribed dose"
Domperidone as a take home medication as per hospital protocol	Metoclopramide as a take home medication
Add the note "as long as afebrile" to the information about taking paracetamol for pain relief, to ensure that fever is not masked by paracetamol, since any fever occurring whilst using capecitabine needs to be investigated immediately, and paracetamol may mask any rise in temperature.	

Table 3.2: Changes to Enzalutamide Shared Care Guideline

Recommendations made by Clinical Pharmacists	
Information to include	*Information to Remove*
Medication is available as soft capsules	Medication is not available as tablets
Details about possible drug interactions should also be included since the drug is a potent enzyme inducer.	
Recommendations made by Oncologists	
Information that should be added	Information that should be removed
The following 7 drugs were listed to be avoided due to potential drug interactions: - Buproprion - Tramadol - Oxycodone - Hydrocodone - Ranolazine - Everolimus - Ivabradine The other theee most commonly used drugs suggested were medications found in a hospital setting only, so it was decided that they should not be listed as the shared care guidelines are to be used in the community setting.	

Table 3.3: Changes to Ruxolitinib Shared Care Guideline

Recommendations made by Clinical Pharmacists	
Information to include	*Information to Remove*
Perform a complete blood count which will include a white blood count differential before initiating treatment	Correct identification of the locally available Proprietary Name
How the drug should be stored safely	Magic Mouth Wash information, as there is a lack of evidence about its benefits.
Drug should only be handled by the patient, or by carer wearing protective gloves	
Explain meaning of anaemia, neutropenia and thrombocytopenia	
Regular blood tests are recommended to help control cholesterol levels	
Regular skin testing should be done	
List flatulence, constipation and abnormal liver function tests as potential side effects.	

Table 3.4: Changes to Everolimus Shared Care Guideline

Recommendations made by Oncologists	
Information to add	*Information to Remove*
Provide a list of the 10 most commonly used drugs that interact with everolimus: - Fluvoxamine - Clarithromycin - Carbamazepine - Diltiazem - Verapamil - MMR Vaccine - Phenytoin - Yellow Fever Vaccine - Dexamethasone - Itraconazole	
Add note about using bicarbonate of soda rinses for the management of Mucositis.	

3.3 Impact on Community Pharmacist Knowledge

Following the validation process, the Pharmacist Questionnaire was adjusted to include three new questions in the demographics section that capture principal area of practice, hours of practice and years of practice as a pharmacist. Four questions were added at the end of the questionnaire to get the pharmacist's opinion on the Shared Care Guidelines format and on the format of the educational program presented. These questions were rated on a Likert scale and a comments section was made available.

Eleven community pharmacists attended the educational program. All the pharmacists attending were female, and working as full time community pharmacists, their ages ranged from 24 – 42 years. One pharmacist did not complete the Pharmacist's Questionnaire. Before the start of the educational program, the 10 pharmacists completing the questionnaire answered in total 12 questions correctly (average 1.2 questions out of 18 questions, range 0-3). After the educational program and exposure to the Shared Care Guidelines, the 10 pharmacists answered in total 177 questions correctly (average 17.7 questions out of 18 questions, range 16-18) (Figure 3.1). This means that after the program 8 out of 11 pharmacists answered all the questions of the questionnaire correctly. Of the other 3 pharmacists, 1 didn't answer any questions before and after the educational program, 1 other pharmacist got 1 question wrong after the educational program, with the question being "How often should everolimus be taken?" and the 3 rd pharmacist got 2 questions wrong after the educational program, these 2 questions were "which side effect of everolimus should be reported promptly?" and "The patient has taken their dose of capecitabine and vomited, should they take the dose again?"

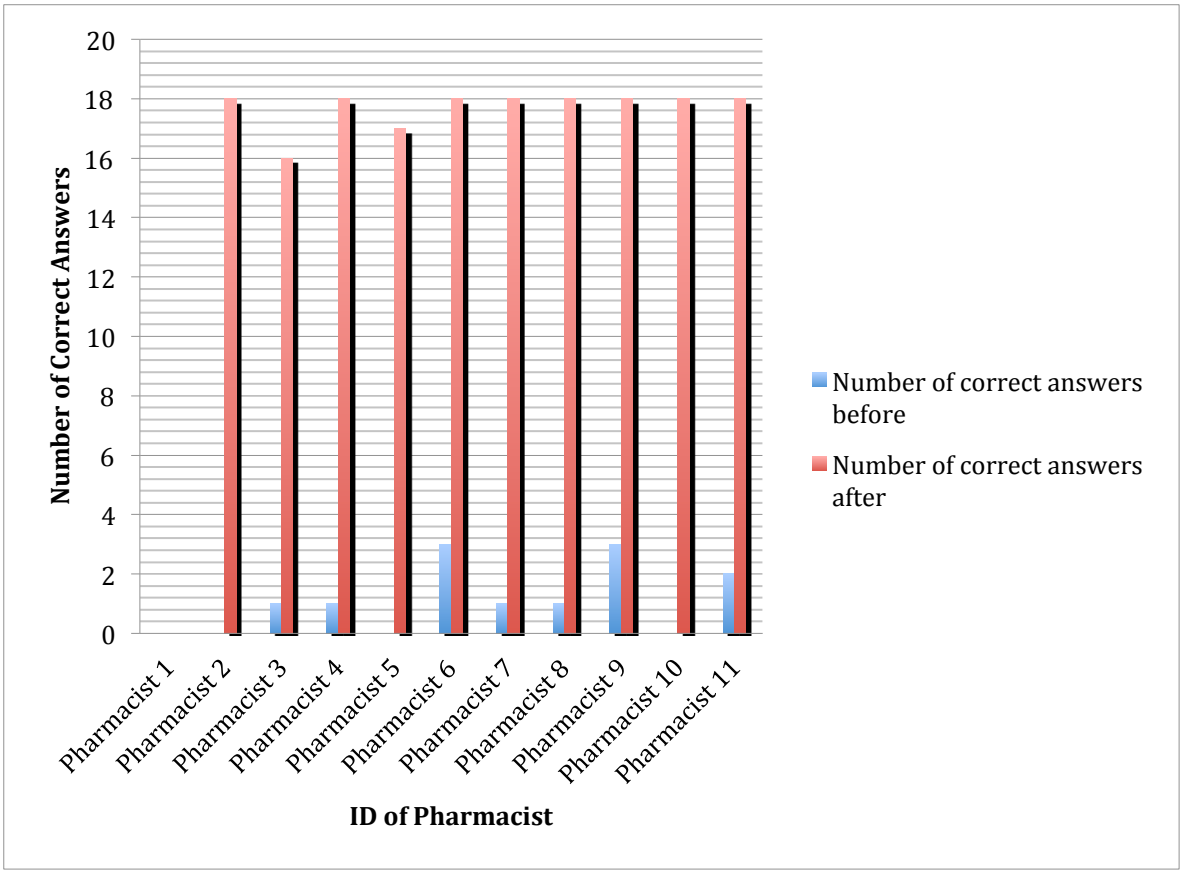

Figure 3.1: Correctly answered questions in the Pharmacist's Questionnaire before and after the educational program (n=11) y axis = number of correct answers, x axis = ID of the pharmacist answering the questionnaire

CHAPTER 4

DISCUSSION

4.1 Standardising care

Oral chemotherapies being given in the community pharmacy setting is quite a recent development, which explains why patients are seeking help from community pharmacists to help manage chemotherapy side effects. In this situation community pharmacists in different countries may require tools and resources to support them to keep up-to-date with relevant important aspects that need to be highlighted during dispensing and patient counselling. Standardising the service is essential so as to reduce variability in the professional services received by patients. Standardization contributes to pharmacist empowerment since through tools made available for standardization, pharmacists are gaining access to up-to-date, clinically relevant issues that need to be discussed with the patient. Uninformed patients and carers are more susceptible to safety hazards, which can easily go unchecked in the domiciliary setting since there are no health care professionals to oversee drug dosing and storage (Vidall, 2010).

Results from the answers of the questionnaire showed that before the educational program community pharmacists had very limited knowledge on the side effects of the oral chemotherapy drugs selected, which were the most commonly dispensed by the group of pharmacists involved. The percentage of completed questionnaires and correct answers given after the educational program show that the Shared Care Guidelines and the educational program had a positive direct impact on the community pharmacist's knowledge of oral chemotherapy. During the program the researcher was told that most of the information given was new to the participants, who felt that the shared care guidelines offered a practical approach to improving the community pharmacist's knowledge and offering a better service to cancer patients in the community.

In this research the impact of using the Shared Care Guidelines in the practice setting in the community pharmacy was not attempted and the retention of the knowledge in the longer term was not studied.

The Shared Care Guidelines developed had a similar layout to NHS-UK protocols available online for chemotherapy medications. This was done to retain a structure that was tested elsewhere and in use within a practical scenario. The innovation in the developed Shared Care Guidelines in this study was that they were developed for drugs available locally and aligned with information and experience from the clinical pharmacists and oncologists practicing in the local oncology center. The characteristic of the guidelines was that they were kept specific to community pharmacy and kept concise so as to improve their practicality within a scenario where a community pharmacist is dispensing the drug in a real-setting of the pharmacy.

Novel Oral chemotherapeutic drugs are being introduced into the market regularly, with mounting pressure being applied on hospital and state run health services. Community pharmacists can be seen as being the ideal people, since they are in an accessible position, to help alleviate some of the pressure being placed on hospitals. Measures need to be put in place to ensure that the transition from the hospital setting into the domiciliary setting is smooth, with community pharmacists being the ideal link between the two settings Community pharmacists however may be unfamiliar with the novel chemotherapeutic agents coming onto the market, this can lead to pharmacists shying away, within a high pressure practice setting, from giving standard advice to their patients about what side effects to expect, how to manage these side effects, how to take their medication, what other drugs should be avoided to prevent interactions.

Shared Care Guidelines are one way of reducing some of the pressure placed on hospitals, whilst at the same time improving the community pharmacist's knowledge about novel oral chemotherapies. The shared care guidelines themselves can also be used as educational tools to help pharmacists improve their knowledge about novel therapies.

The shared care guidelines written for this study focused on side effects that a community pharmacy can manage, and included criteria on when a patient should be referred to a more specialist setting. The Shared Care Guidelines were kept concise, to aid easy and quick collection of information in the community pharmacy setting. At the same time however the information given had to be exhaustive and detailed to suit the needs of the community pharmacist when dispensing the treatment. The guidelines also included notes on supportive therapy to be used alongside the chemotherapy. The information given on these supportive medications was limited to keep the shared care guidelines concise, which can be seen as 1 limitation of the shared care guidelines.

4.2 Limitations

A limitation of this study is that the economic advantage to carrying out this pharmacist educational program, through money and time saved by reducing trips to hospital, thus reducing workdays lost by the patient and possibly the carer was not studied. A positive impact on the quality of life of the patient was determined. This could be an area which can be explored for future study. The long-term effects of using the Shared Care Guidelines in the pharmacies was not studied.

A patient focus group methodology was used for the researcher to understand the weaknesses in the current system and extensive patient study adopting the questionnaire

within a larger sample of patients was not attempted since the focus of the study was the development of the guidelines.

4.3 Recommendations for Future Studies

A study to compare the occurrence and management of side effects for patients receiving pharmacist's intervention from a pharmacist who has undergone the educational program and has access to the Shared Care Guidelines, to patients that are not exposed to a pharmacist with this background.

Shared Care Guidelines can be developed for 'conventional' products like tamoxifen and anastrazole which are available on the local national health scheme as well as for other novel oral chemotherapy drugs that are less commonly used compared to the drugs included in this research.

4.4 Conclusion

Patients receiving oral chemotherapy drugs from community pharmacists presented the lack of knowledge on side effects to expect and how to handle them as a weakness to the current system adopted for the dispensing of these drugs that are not very commonly used since they are available only on the private sector. The Shared Care Guidelines developed are innovative in that they are concise so as to be practical and applicable for the community pharmacy setting and can be used by the pharmacist during the dispensing and patient counseling session. One advantage of the guidelines is that they are not only evidence-based and developed based on the Summary of Products Characteristics and the

Patient Information Leaflet but they were developed based on a multidisciplinary collaborative method. Clinical pharmacists and oncologists participated in the validation process of the Shared Care Guidelines developed in this study so as to ensure that the guidelines presented evidence-based clinically relevant information. The educational program consisting of an overview on the Shared Care Guidelines and access to the Shared Care Guidelines to pharmacists dispensing these drugs indicated a positive on the knowledge of the pharmacists about the drugs.

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Appendix 1

Questionnaire for Pharmacists

What is your area of practice?

_____

Do you work full-time or part-time?

_____

How many years have you been practicing as a pharmacist?

_____

Capecitabine (Xeloda)

1. How should capecitabine be taken? (frequency per day and relation with food):

_____
_____

2. How long is the duration of the cycle for capecitabine?

_____

3. Mention the 5 common side effects you should warn patients starting capecitabine about, and which would warrant referral to a doctor.

_____
_____
_____
_____

4. The patient has taken their dose of capecitabine, and vomited, should they take the dose again?

_____
_____

Enzalutamide (Xtandi)

5. What is the dosage regimen of enzalutamide?

_____
_____

6. Mention the 4 main toxicities of enzalutamide.

_____
_____
_____
_____

Everolimus (Afinitor)

7. What is the dosage regimen for everolimus?

_____
_____

8. With regards to administration with food, what advice should you give your patient? What food in particular should they avoid?

_____
_____

9. What medication and topical product should you recommend to your patient to take home?

_____
_____

10. What particular side effect should be reported promptly?

_____

Abiratarone (Zytiga)

11. With reguards to administration with food, how should abiraterone be taken?

_____
_____

12. What medication should patients on abiraterone be given?

_____

13. What parameter should be monitored?

_____

14. How should a patient manage a missed dose?

_____
_____

15. Mention 4 main toxicities of abiraterone.

_____

Ruxolitinib (Jakavi)

16. What monitoring should be carried during therapy with ruxolitinib?

_____

17. What are the 2 indications of ruxolitinib?

_____

18. Jakavi increases the likelihood of which cancer?

_____

On a Scale from 1 – 5 how useful did you find this program to be?

1 2 3 4 5

Do you think similar programs should be carried out in the future for novel therapies?

_____

Do you like the format of the protocols? Why?

_____
_____

Do you have any comments you wish to make regarding the program?

_____
_____
_____

Appendix 2

Questionnaire for Patients (English)

1= Do not Agree, 5 = Fully Agree

1) Pharmacist addressed my health concerns

1 2 3 4 5

2) I was given information about the medication

1 2 3 4 5

3) Any questions I had were answered

1 2 3 4 5

4) Pharmacist checked if I understood how to take my Medication

1 2 3 4 5

5) Pharmacist gave recommendations for my overall health

1 2 3 4 5

6) I was satisfied with the overall care I received

1 2 3 4 5

7) I felt encouraged to keep my pharmacist up to date with my progress.

1 2 3 4 5

Discussion

8) Did you receive information on what side effects to expect and how to treat them?

9) How thorough was the information given to you before coming to the pharmacy?

10) Did you receive information on possible Drug-Drug/ Drug-Food interactions?

11) Do you prefer verbal or written information?

12) Did you receive information on how to safely handle the medication, and any precautions you should take whilst storing it at home?

Kwestjonarju ghal pazjenti (bil – Malti)

1 = Ma Naqbilx, 5= Naqbel Hafna

1) L-ispizjar/a indirizza/t it-thassib li ghandi dwar sahhti.

1 2 3 4 5

2) Jien inghatajt informazzjoni dwar il-medicina.

1 2 3 4 5

3) Il-mistoqsijiet kollha tieghi gew imwiegba.

1 2 3 4 5

4) L-ispizjar/a ccekja/t jekk fhimtx kif niehu l-medicina.

1 2 3 4 5

5) L-ispizjar/a tani/taghtni pariri dwar sahhti ingenerali.

1 2 3 4 5

6) Kont sodisfatt bil-kura ingenerali li nghatajt.

1 2 3 4 5

7) Nhossni motivat/a li nzomm l-ispizjar/a infurmat/a bil-progress.

1 2 3 4 5

Diskussjoni

8) Inghatajt informazzjoni fuq l-effetti sekondarji li tistenna u kif titrattahom?

9) Kemm kienet dettaljata l-informazzjoni li nghatajt qabel ma gejt l-ispizerija?

10) Ircivejt informazzjoni dwar interazzjoni bejn medicina/medicina u medicina/ikel?

11) Tippreferi informazzjoni bil-kliem jew bil-miktub?

12) Rcivejt informazzjoni fuq kif tiehu hsieb l-medicina b’ mod sikur, u kif ghandek izomm din t-tip ta medicina d-dar?

Appendix 3

CONSENT FORM (English)

I am a Maltese citizen and I am over eighteen (18) years of age.

I have been asked to participate in a research study entitled:

"Shared care guidelines for patient medicines management in breast and colon cancer."

The purpose and details of this study have been explained to me by **Rebecca Theuma** and any difficulties which I have raised have been adequately clarified.

I give my consent to the Principal Investigator and her delegate to either make the appropriate observations. I am aware of the inconveniences this will cause.

I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from this study in which I am participating may be reported or published; however I shall not be personally identified in any way, either individually or collectively, without my express permission.

I am under no obligation to participate in this study and I am doing so voluntarily.

I may withdraw from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to me.

I understand that any complications and / or adverse effects which may arise during the study will be recorded and any treatment which this may entail will be given within the government health services.

I am **not** receiving any remuneration for participating in this study.

In case of queries during the study I may contact: Rebecca Theuma, Tel. no. 21571338/77974664

Signature of Participant: _____
Name of participant:
ID no.

FORMOLA TAL- KUNSENS (Malti)

Jiena cittadin/a Malti/ja u ghandi ‘l fuq minn tmintax-il (18) sena.

Jien gejt mitlub/a biex nippartecipa fi studju ta’ ricerka bit-titolu:

"Shared care guidelines for patient medicines management in breast and colon cancer”.

L-iskop u d-dettalji ta’ dan l-istudju gew spjegati lili minn **Rebecca Theuma** u jekk kelli xi diffikultajiet dawn gew iccarati.

Jien qed naghti il-kunsens tieghi biex nippartecipa f’ intervisti ma’ Rebecca Theuma, u naghtiha permess biex tuza’ l-informazzjoni li tohrog minn dawn l-intervisti.

Nifhem li r-rizultati ta’ dan l-istudju jistghu jintuzaw ghal ghanijiet medici jew xjentifici, u li r-rizultati miksuba minn dan l-istudju jistghu jigu ippublikati, madanakollu id-dettalji personali tieghek m’huma ha jinghataw lil hadd minghajr il-permess miktub tieghek.

Jien minix taht l-ebda obbligu biex nippartecipa f’dan l-istudju u qed naghmel dan b’mod volontarju.

Jien nista’ nirtira minn dan l-istudju f’kwalunkwe hin, minghajr ma naghti ebda raguni. Dan mhux ser jinfluwenza bl-ebda mod il-kura u attenzjoni li hi normalment moghtija lili.

F’kas ta mistoqsijiet nista’ nikuntatja lil Rebecca Theuma fuq in-numri 21571338, jew 77974664.

Firma tal-partecipant:_____

Isem tal partecipant:

Numru ta l-identita:

Firma ta’ l-investigatur:_____

Isem ta linvestigatur: Rebecca Theuma

Numru ta L’identita: 0231391M

Firma ta’ Principal Supervisor Profs Lilian Azzopardi:
_____

Recruitment letter

538, Cabanas
Ghajn Zejtuna Rd.
Mellieha
MLH2700

Dear Sir or Madam,

I am Rebecca Theuma , a 2nd year Pharm D student at the university of Malta, under the supervision of Profs. Lilian Azzopardi and Dr. Louise Grech.

I am currently carrying out a study, the aim of which is to investigate the role of the community pharmacist in dispensing oncological medication, managing the side effects of these drugs, and offering advice on how to take these drugs, all in the setting of a community pharmacy, thus avoiding unnecessary trips to hospital.

Currently oral oncological drugs are being dispensed from a community pharmacy of the patient's choosing. These drugs require special handling, and advice on how to take these drugs needs to be given by a specialist in the field. There are no shared care guidelines about chemotherapy for breast and colon cancer available in the community pharmacy setting, and pharmacists require training to identify any possible significant drug interactions and situations that require referral. Strategies to increase monitoring by the pharmacist to ensure adherence to therapy will also be tackled.

In order to carry out the study effectively, I will need to interview patients to identify areas they feel require improvement, and services they would like to be made available to them at a community pharmacy level with regards to their care.

After these areas are identified I will, through research, tackle these issues by drawing up protocols and standard operating procedures to be used in the community pharmacy setting. I will also establish an educational programme pertaining to oncology treatment in the community pharmacy setting to be undertaken by community pharmacists. The aim will be to increase the knowledge of the community pharmacist about this medication and its management.

I am writing this letter to ask your permission to be interview you, and ask you about what areas you think can be improved or added, to help make your

treatment easier and more comfortable.

I thank you in advance,

Rebecca Theuma
0231391M
rthe0003@um.edu.mt
Mob. no. 77974664

L-UNIVERSITÀ TA' MALTA

Msida – Malta
Skola Medika
Sptar Mater Dei

UNIVERSITY OF MALTA

Msida – Malta
Medical School
Mater Dei Hospital

Ref No: **45/2016**

Monday 8th August 2016

Ms. Rebecca Theuma
538, Cabanas
Ghajn Zejtuna Rd.
Mellieha MLH2700

Dear Ms. Rebecca Theuma,

Please refer to your application submitted to the Research Ethics Committee in connection with your research entitled:

Shared care guidelines for patient medicines management in breast and colon cancer

The University Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

Email: umms@um.edu.mt • ***Web:*** http://www.um.edu.mt/ms

Approval for access to patients/data

538, Cabanas
Ghajn Zejtuna Rd.
Mellieha
MLH 2700

To whom it may concern,

I am Rebecca Theuma , a 2nd year Pharm D student at the university of Malta, under the supervision of Profs. Lilian Azzopardi and Dr. Louise Grech.

I am currently carrying out a study, the aim of which is to investigate the role of the community pharmacist in dispensing specialised medication, managing the side effects of these drugs, and other medication associated with care, and offering advice on how to take these drugs, all in the setting of a community pharmacy.

Currently oral specialised drugs are being dispensed from a community pharmacy of the patient's choosing. These drugs require special handling, and advice on how to take these drugs needs to be given by a specialist in the field. There are no shared care guidelines on medication used in such specialised treatment, and pharmacists require training to identify any possible significant drug interactions and situations that require referral. Strategies to increase monitoring by the pharmacist to ensure adherence to therapy will also be tackled.

In order to carry out the study effectively, I will need to interview patients to identify areas they feel require improvement, and services they would like to be made available to them at a community pharmacy level with regards to their care.

After these areas are identified I will, through research, tackle these issues by drawing up shared care guidelines about specialised therapy to be used in the community pharmacy setting. I will also establish an educational programme pertaining to such treatment in the community pharmacy setting to be undertaken by community pharmacists. The aim will be to increase the knowledge of the community pharmacist about this medication and its management.

Written patient consent will be sought and all data will be treated confidentially.

I am writing this letter to ask your permission to be able to recruit patients for my study, through their consent.

I thank you in advance,

Rebecca Theuma
0231391M
rthe0003@um.edu.mt
Mob. no. 77974664

Signature: _____

Name: _____

Date: _____

Approval for access to patients (Malti)

538, Cabanas
Ghajn Zejtuna Rd.
Mellieha
MLH 2700

Ghaziz Sinjur/Sinjura,

Jien Rebecca Theuma, studenta tat-tieni sena tal-Pharm D. fl-Universita' ta Malta, taht is-supervizzjoni ta' Profs. Lilian Azzopardi u Dr. Louise Grech.

Bhalissa qed inwettaq studju bil-ghan li ninvestiga r-rwol tal-ispizjara fil-komunita' meta pazjenti jinghataw medikazzjoni u trattamenti. L-istudju jinvestiga ukoll kif, u meta, jigu trattati l-effetti mhux mistennija ta' dan it-trattament, u kif tinghata informazzjoni fuq kif jittiehdu il-medicini. Il-pjan hu li dan is-servizz jibda jinghata mill-ispizerija tal-belt jew rahal tal-pazjent, u b' hekk jevita' li l-pazjenti jmorru l-isptar.

Biex dan l-istudju jkun effettiv, ser jigu identifikati ammont ta' pazjenti li jmorru fi spizerija biex jiehdu trattament orali specifici. Dawn ser jkunu mitluba jirrispondu numru ta' mistoqsijiet biex jigu identifikati problemi li l-pazjent jesperjenza, u kif dawn jistghu jigu evitati.

La darba dawn l-problemi jigu identifikati, permezz ta' studju u ricerka, ser nikteb "protocols" u "standard operating procedures" li jistghu jintuzaw fl-spizeriji ghal dawn it-tip ta trattamenti. Wara dan il-process l-ispizjara ser ikollhom programm edukattiv ghad-dispozizzjoni taghhom fuq certu medicini fl-ispizerija tal komunita'. L-ghan hu li l-ispizjara jkollhom aktar rizorsi fuq dawn t-trattamenti u l-immanigjar taghhom.

Qed niktiblek din l-ittra biex nitolbok permess biex, jekk ghandek pjacir, niltaqa' mieghek u nistaqsik ftit mistoqsijiet fuq problemi li qed ikollok tghaddi minnhom waqt t-trattament tieghek, x jista' jigi rrangat, u x' tahseb li ahna bhala spizjara nistghu naghmlu biex nghinuk u naghmlu t-trattament tieghek aktar komdu u facli.

Grazzi bil-quddiem,

Rebecca Theuma

0231391M

rthe0003@um.edu.mt

Mob. no. 77974664

Appendix 4

ENZALUTAMIDE (Xtandi®)

UNIVERSITY OF MALTA
L-Università ta' Malta

Available as 40 mg soft capsules

CYCLE

DAY 1 - 28	
Enzalutamide taken 4 capsules daily	No Stopping

Indications: Castrate – resistant prostate cancer
Disease Progression following Docetaxel

COUNSELLING POINTS

Administration of drug: 4 tablets daily, at the same time, with water and with or without food. Tablets must NOT be crushed, chewed, opened or dissolved.

Missed Dose: Dose is to be taken as soon as possible, if the whole day has passed wait for the next scheduled dose and do not double up.

Storage: 20 – 25 Celcius

Pregnancy Category X, **barrier contraception required during treatment and for 3 months after last dose**. Pregnant women should **not** handle the medication.

SELF-CARE TIPS

Patients are at an increased risk of infections, and should be advised to avoid crowds, people with colds, and to wash their hands often.

Drink plenty of fluids unless told otherwise by doctor.

Consumption of alcohol should be kept to a minimum.

Enzalutamide is a strong CYP3A4 enzyme inducer.

SIDE EFFECTS

- *Hypertension:* An increase in blood pressure can occur in about 7% of patients, but rarely requires cessation of therapy. Antihypertensive treatment may be added however.

- *Hot Flushes:* If these symptoms are very severe, advise patient to speak to a doctor, as medication can be prescribed to help deal with hot flushes. Wearing light clothing and staying in cool environments can be helpful.

- *Headache*

- *Risk of Seizures*

Contact doctor or nurse immediately if you experience fever > 100 ^{o}F or 38^{o}C

INTERACTIONS

Enzalutamide is a potent enzyme inducer, and can interact with a variety of drugs. **Always** check for interactions before recommending any OTC medications. Interacting drugs include Omeprazole. Enzalutamide interacts with drugs that inhibit or induce CYP3A4, CYP2C8 as well as other drug metabolizing enzymes. The following is a list of commonly used drugs that interact with enzalutamide:

Buproprion
Tramadol
Oxycodone
Hydrocodone
Ranolazine
Everolimus
Ivabradine

ABIRATERONE (Zytiga[R])

UNIVERSITY OF MALTA
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Available as 250mg tablets
Must **not** be taken with food

CYCLE

DAY 1-28	
Take x4 250mg tablets everyday	No Stopping

Indications: Castrate – resistant metastatic prostate cancer
Chemotherapy naïve for metastatic disease

Supportive Medication: Prednisolone 10mg or 5 mg a day as tolerated.

COUNSELLING POINTS

Administration: Food increases absorption of abiraterone up to ten-fold. Take the medication at least 2 hours after eating, and wait 1 hour before eating, should be swallowed whole with water.

Missed dose: In the event of a missed dose resume normal dosing the following day.

Interactions: Caution! Abiraterone is metabolized via CYP2D6 and CYP3A4. Always check for interactions with other medication.

Side Effects

- *Swelling*: If swelling occurs ask patient to weigh themselves daily, and to keep a record, to keep their feet elevated and avoid standing for long periods of time, reduce salt intake and avoid tight fitting clothes. If swelling is severe stockings can be considered.

- *Urinary Tract Infection*: Cranberry juice and blueberry juice can be recommended, give usual advice for preventing UTIs.

- *Hepatotoxicity*: Refer immediately in cases of: severe fatigue, worsening jaundice, abdominal pain, nausea and vomiting, bleeding which doesn't stop after a few minutes, weight gain over 2 kgs in 1 week, new rashes.

SELF-CARE TIPS

This medication can cause a rise in triglycerides. Advise patient to eat a diet high in fiber and low in fatty foods. Weight gain and alcohol consumption can further increase the levels of triglycerides in the blood. Advise the patient to exercise regularly if they are able to.

This medication can cause hypokalemia, this may cause muscle weakness, fatigue and cramps, and is diagnosed by carrying out blood tests. Advise hypokalaemic patients to avoid caffeine & alcohol, and eat plenty of fresh fruits and vegetables, especially oranges, leafy greens and potatoes.

This medication can cause a rise in blood pressure, such that blood pressure should be monitored regularly.

NB. Healthcare professional to be contacted if patient hasn't passed urine for over 8 hours.

PREDNISOLONE

As mentioned above, prednisolone is given together with abiraterone, in a dose of 5 up to 10mg, to reduce the mineralocorticoid effects of abiraterone.
Prednisolone should:

- Only be taken once a day, and if the patient misses the dose, they should not double up on their next dose.
- Always to be taken with food or after a meal.
- Taken before 12pm to help promote better sleep.

Patient should be told to wash hands frequently due to an increased risk of infection, and to avoid sun exposure. Sun screen should be applied every day.
Prednisolone may cause an increase in blood sugar.
Prednisolone must not be stopped abruptly, but the dose has to be tapered down.

EVEROLIMUS (Afinitor®)

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Available as 2.5mg, 5mg, and 10mg tablets

CYCLE

Day 1 – 28	
Usually 10 mg Everolimus taken once daily	NO STOPPING

Indications: Breast Cancer
Neuroendocrine Cancer
Renal Cancer
Pancreatic Cancer
Other Cancers

COUNSELLING POINTS

Administration of dose: once a day, with a glass of water, with or without food, but NOT after a high fat meal. Do not chew or crush tablets. Take at the same time each day.

Risk of non-infectious pneumonitis: Report promptly any new or worsening respiratory symptoms.

Immune response to vaccination may be altered: The use of live vaccines should be avoided whilst treating with everolimus.

Everolimus is a substrate for CYP 3A4: Advise the patient to speak to a healthcare professional before starting any medication. Grapejuice should be avoided.

Pregnancy category **D.**

Loperamide, Metoclopramide and emollients are recommended take home medications.

SIDE EFFECTS

Mucositis (mouth sores): Keep mouth and lips moist. Rinse with water with baking soda or salt. Use soft bristled toothbrush. Use saliva substitute if needed. Avoid alcohol-containing mouthwash.
Apply orabase[R], apply vitamin E (puncture capsule) using a swab, take antacids as needed. Avoid: spicy, hot, very hot/cold, rough, textured foods, citrus juices and alcohol.
A magic mouth wash can be used, use the below recipe.

Diarrhoea: Drink as much fluids as you can, including Gatorade[R], and take small and frequent servings of the following food items: banana, rice, noodles, white bread, skinned chicken, turkey or mild white fish.

Rash: Advise patient to; pat themselves dry rather than rubbing vigorously, avoid perfumed soaps, take showers or short cool baths instead of long hot baths, wear cotton clothes washed in mild detergent, avoid the sun and wear gloves in colder conditions. Use moisturizers regularly, always rinse and dry hands carefully. Baby or mineral oil can be applied after showering.

RUXOLITINIB (Jakavi[R])

Available as 5, 10, 15 or 20 mg tablets
To be swallowed whole with water, with or without food, do not chew, crush or break.
There is no fixed dose of ruxolitinib, and the maximum dose is 25mg BD.
A complete blood count must be carried out before initiating treatment with ruxolitinib. A CBC is carried out every 2-4 weeks until the ruxolitinib dose is stabilized.

DOSING

Indefinite	
Jakafi is given twice a day.	No Stopping

Indications: Myelofibrosis & Polycythemia Vera

Missed Dose: If a dose is missed, do not attempt to double up on your next dose. Just take the next dose as planned.

Pregnancy category C to be used only if benefit to mother outweighs risk to fetus. Breast feeding should be avoided, and barrier methods should be used to prevent pregnancy.

COUNSELLING POINTS

Report any signs of bleeding or bruising. Complete Blood Counts will be taken since ruxolitinib can cause anaemia, thrombocytopenia and neutropenia.

Patients should always inform their healthcare professional about any medication they may be taking, even over the counter medication, due to the potential of drug-drug interactions when using ruxolitinib.

Avoid eating grapefruit, pomegranate, starfruit and Seville orangs and drinking their juice when taking ruxolitinib.

Store at room temperature 20 – 25 ^{0}C

SIDE EFFECTS

- *Blood Counts*: Thrombocytopenia, anaemia and neutropenia may develop, for this reason complete blood counts will be performed. The dose of ruxolitinib may be altered according to the results of the blood counts. In very severe cases, treatment may be interrupted.

- *Infections*: ruxolitinib should not be started unless serious active infections are resolved. Urinary tract infections can also occur.

- *Tuberculosis:* has been reported in patients taking ruxolitinib. Report any new onset cough.

- *Shingles:* Herpes Zoster can also develop, advise the patient to report the occurance of a rash, so treatment can be initiated as soon as possible

- *Hypercholesterolaemia:* may result when being treated with ruxolitinib. Advise patients to take care not to put on weight, and to eat a healthy diet high in fruits and vegetables and to avoid animal fat. Regular blood tests should be carried out.

The 3 most frequent non-hematological side effects are: bruising, headache and dizziness.
Flatulence, constipation and abnormal liver function tests have also been reported. Regular skin investigations are needed since non melanoma skin cancer has been reported.
Patient should be advised to report promptly any minor impairment in thinking and speaking.

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CAPECITABINE (Xeloda®)

Available as 150 or 500 mg tablets

CYCLE

DAY 1 - 14	DAY 15 - 21
Capecitabine taken BD acc. To BSA	STOP

Repeat for 8 cycles if tolerated

Indications: Adjuvant Dukes C colon cancer
Advanced / Metastatic colorectal cancer
Advanced / Metastatic breast cancer

COUNSELLING POINTS

- Administration of drug: 1 tablet, 12 hours apart, 30 minutes after a meal. To be swallowed whole with water. Never crush, break, open or chew the tablets. Dosing may be continuous in certain cases.

- Missed Dose: Do not attempt to double up on your next dose to make up for a missed dose. Do not take extra doses at the end of the treatment cycle.

- Post Dose Vomiting: If vomiting occurs a few hours from taking the tablet, do not take another tablet, wait until the next scheduled dose.

- Storage & Handling: Store in a cool dry place, at a temp less than 30^{o}C. Medication should be handled by the patient only, ensure gloves are always worn by anyone handling the drug.

- Appointment with oncologist every 3 weeks

SIDE EFFECTS

To Discuss with Patients: Diarrhea, Nausea & Vomiting, Stomatitis, Hand Foot Syndrome, fever, infection. If the patient experiences any of these side effects, they should contact their oncologist or chemotherapy day unit immediately.

- *Hand Food Syndrome:* HFS causes the palms of the hand and soles of the feet to become red and tender, peeling of the skin can also occur which can interfere with daily activities, always give advice on how to avoid developing HFS. In the case of HFS developing the following advice can be given:

Procedure	Explanation
Cooling	Place affected area on an ice pack wrapped with a towel or a bag of frozen peas. Alternate on and off for 15-20 minutes at a time.
Lotions	Use emollients as often as you can. However take care not to rub too hard during treatment. Soak your hands in cool water for 20 minutes, then apply lotion at least once a day.
Pain Relief	Paracetamol can be used, make sure patient is afebrile, do not suggest anything else unless the oncologist prescribes it.
Vitamins	Vitamin B6 may be beneficial.
When to call your doctor	If you notice palms and soles getting red and tender

- *Diarrhoea:* Diarrhoea is a common problem that may require intervention with fluids and electrolytes. Loperamide can be given 2 to 4 mg four times a day. Refer to a doctor if diarrhea is moderate/severe (watery stools 4-6 times a day).

Abstract for oncology conference 2016

Developing Shared Care Guidelines for breast and colon cancer

Rebecca Theuma, Louise Grech, Stefan Laspina, Godfrey Laferla, Lilian M. Azzopardi

Introduction:
Transitional care between the oncology setting in hospital and the community pharmacy is imperative if the system is to operate safely and effectively. Shared care guidelines ensure effective joint pharmacotherapy decision making within a collaborative framework between the primary and secondary care settings. The aim of this research is to compile shared care guidelines for oral chemotherapy used in the management of breast and colon cancer taking into consideration the role of the dispensing community pharmacists.

Method:
A literature review was carried out to identify international share care guidelines in order to design the template for the proposed local Maltese Oncology Shared Care Guidelines for breast and colon cancer (MOSCG). A list of oral chemotherapy drugs prescribed for breast and colon cancer respectively was compiled. A draft MOSCG was compiled for capecitabine and is being evaluated by an expert panel consisting of oncologists, nurses, hospital and community pharmacists.

Results:
The draft MOSCG for Capecitabine was developed in a short template of not more than 2 pages consisting of concise but detailed information. The template is contains information on the dosage form availability; indications and uses; the dose, duration and frequency of administration; counseling points in relation to drug administration, missed doses, storage and handling. A separate section includes information on side-effects which can occur together with recommendations required in order to deal with post-dose chemotherapy side effects. The template indicates to the pharmacists when patients should be referred directly to the oncology center for further management.

Conclusion:
The proposed MOSCGs developed within a collaborative framework will further substantiate effective communication between different healthcare professionals at different settings such as the hospital multidisciplinary team and the community pharmacists dispensing on a daily basis oral chemotherapy drugs.