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Evaluation of Stability and Potencies of Compounded Suspensions in Oncology Day Care

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Abstract:
Custom-made oral formulations can be frequently needed by patients under ambulatory oncology in case of unavailable commercial liquid formulations. In this work, the stability, potency and formulary of extemporaneously compounded oral suspension of capecitabine and cyclophosphamide using oral vehicle bases were compared. The physical, chemical and microbiological stability of the formulations was determined at refrigerator and room temperature with a maximum period of 30 days. The findings indicated that none of the suspensions lost more than 90% of its potency, and there was no remarkable variation in pH and microbial formations. Subsequent responses to 40 patients evaluated as caregivers presented an excellence level of acceptability and dose accuracy. The results favor the usability of the pharmacy-compounded oral suspension as safe and effective administration in the outpatient oncology care environment thus offers the patient a viable alternative when unable to take tablets or cannot respond to standardized and standardized treatment.

Keywords: ***Portable oncology, prefabricated oral suspensions, capecitabine, cyclophosphamide, isoura stability, isoura potency, chemistry, microbiology stability, acceptability by patients, dosing precision.***

1. Introduction

1.1 Ambulatory Oncology: the need of Oral Dosage Forms Designed to Measure

When it comes to ambulatory oncology, patients are mostly left with complicated treatments requiring that oral chemotherapy medicine be administered. Tablets and capsules, i.e., oral formulations, represent the most popular prescriptions to oncology patients since their convenience, non invasive character, and easy administrability. Nevertheless, some patient groups, such as the geriatric or pediatric patients or patients with gastrointestinal problems (e.g., problems in food intake, nausea, or vomiting) will be not capable of taking solid oral dosage forms. The urgent requirement, in the case of such people, is the individualized form of oral dosage forms which are tailored to cater to the needs of a particular patient.

Chemotherapy medicines can be very toxic in oncology and therefore important doses must be taken to ascertain both the efficacy and the minimal toxicity. Compounded oral suspensions are of particular relevance in situations where other commercial forms of liquids are not accessible. Compounded oral suspensions enable pharmacists to adjust the drug formulation to fit with the requirement of the patients with difficulty to swallowing or need of a more specific dose not offered in their commercially available forms. The inpatient or the ambulatory care setting where patients receive treatment on an outpatient basis can greatly benefit in terms of treatment adherence and patient outcomes through these customized formulations.(1)

1.2 Errors on Account of Unavailability of Commercially available Liquid Formulations

Although customized oral formulations are significantly needed, the unavailability of liquid formulations of some of the chemotherapy drugs is one of the biggest problems with the use of ambulatory oncology. A large number of chemotherapy agents, including capecitabine and cyclophosphamide, are mostly supplied in form of solid tablet or injectable. Such medications lack ready made liquid preparations that can be prescribed to any patients who need such modalities of administration. Consequently, the oncology pharmacists are frequently assigned with the role of compounding these medications into oral suspension to address the particular needs and requirements of individual patients.

Lack of commercially available liquid chemotherapy products of numerous agents leaves an enormous gap in the scope of available therapies to serve ambulatory oncology patients. Besides the formulation issue, stability, potency, and safety of these compounded suspensions are a subject of concern. The chemotherapy drugs are usually very potent and even degradation in the compounded formulation would decrease its therapeutic effectiveness and may result in undesirable side effects. Besides, the suspensions prepared are to remain stable in

the long-term particularly in the ambulatory arena where the patients could take a long time before completing the intake of the drugs. Such volatility becomes a risk to both the pharmacist that compounds the formulations as well as the patient who depends on it.

Clinical usability is another problem. Ambulatory oncology implies that people can spend most of their time at home and unable to access medical workers easily in order to receive advice related to drug administration. As such, it is important to establish that the doses are correctly done, that the administration is easy, and that the patients take the patient. The compounded drugs are not only expected to be stable and potent but also to be acceptable by both the patient and also the care giver since they are usually put in charge of giving the drugs to the patient at home.(2)

1.3 Object of Evaluating Clinical Usabiity and Stability of Compounded Suspension

The aim of the current study is to assess the stability, potency and clinical feasibility of extemporaneously compounded oral suspension of capecitabine and cyclophosphamide in outpatient oncology practice. Using physical, chemical, and microbiological analysis of the stability of these formulated compounds over a period of time with oral suspensions, this study will offer meaningful knowledge into the safety and suitability of using compounded oral suspensions in outpatient cancer therapy. Stability testing is paramount in that the active ingredients are not prone to degrade with time and therefore this may lead to loss of effectiveness of the drug or even the likelihood of the side effects.

Additionally, there are plans to evaluate the efficacy of the compounded suspensions and see how effective they are within 30 days, so that one is able to determine whether the formulations will be useful during the whole treatment period. Potency testing will furnish the evidence that the compounded oral suspensions will continue to have the required concentration of the drug that is required to offer the needed therapeutic effects.

Clinical applicability of these compounded formulations is another major area of this study. Compounded formulation cannot just defer its success by being stable and potent but also on its acceptance and administration at the practical level. In order to determine usability, opinions of caregivers are incorporated to the study who are in many cases to administer the medication in the outpatient setting. The comments will shed light on whether or not the compounded drugs are convenient to use, correctly dosed, godly received by patients or not.(3)

The research is important in terms of posing more opportunities to patients of oncology who need to receive personalized, oral drugs. It is also concerned with the practical steps in the preparation of compounded medication in a manner that will not only be effective, but also feasible to patients as well as those charged with care of the patient. The results of this research will enhance the quality of treatments of ambulatory oncology patients because they will have access to safe and successful compounded oral suspensions that can be provided in outpatient services.

2. Materials and methods

Under this section, materials, procedures, and methods are described followed in monitoring the stability, potency, microbiological stability, and clinical workability of the compounded oral suspensions of capecitabine and cyclophosphamide. All the details of the study are properly planned so that the compound formulations can be stable, potent, safe, and applicable in an ambulatory oncology system.

2.1 Procedure of formulation/compounding

The composing oral suspensions were fabricated by the utilization of the commercially accessible capecitabine tablets and cyclophosphamide capsules, provided by the pharmaceutical suppliers. The compounding was performed under contamination controlled conditions, in cleanroom environment. The manufacture of both medications was done as suspensions with oral vehicle bases which comprised of sugar syrup and methylcellulose with some small quantity of preservative which was added to make them remain microbially stable.

Each suspension was compounded as below:

Weighing and Crushing: Cyclophosphamide was weighed and weighed a capecitabine tablet as well. The tablet-formed drugs were crushed with help of a mortar and pestle until the formation of a fine powder. In the case of cyclophosphamide the contents of the capsules were emptied into a glass mortar and ground finely.(4)

Suspension Preparation: This was followed by folding the powdered drug with the oral vehicle base on a graduated cylinder. The last volume was made equal to the target concentration according to the required therapeutic dose. The suspension was thoroughly stirred to get consistency.

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Packaging: The mixed suspended compound was filled into amber plastic bottles so that the formulation was not exposed to the light. Bottles were labeled with respective directions such as the storage conditions, dosing information and preparation date.

Each drug was put up as a batch of 20 bottles to give a quantity which is sufficient to test its stability and usability.

2.2 Conditions of Storage and the Studying Period

In order to reflect real world conditions and determine how stable the compounded suspensions were, two different storage conditions were applied:

Refrigerated Condition: Some of the compounded suspensions were placed at 4 o C (refrigerator temperature). This heat was selected to represent an average storage of the compounded formulations in the outpatient facility where drugs are usually stored in the refrigerator to enhance their shelf life.

Room Temperature Condition: The suspensions left were stored at ambient temperature (about 22-25 o C) to mimic the common place storage conditions that can be experienced in an am-bulatory situation.

The two sets of compounded suspensions were assessed within 30 days, during which the assessment was done on the days 0, 7, 14, 21, and 30. The 30-day tested because that is a usual time frame in the pharmacy compounding when stability of liquid formulas is regularly tested in order to achieve their effectiveness and safety.(5)

2.3 Potency and pH analytical methods

A set of analytical tests was done at every time point so as to note whether the compounded suspensions have preserved their potency. The potency testing that was considered aimed at the identification of the level of active pharmaceutical ingredients (APIs) capecitabine and cyclophosphamide in the samples. It utilised the following methods:

Potency Testing (High-Performance Liquid Chromatography - HPLC): Potency was measured under HPLC (High-Performance Liquid Chromatography), which is a standard method of analysis, an analytical method that allows the exact measurement of a drug in a suspension. Both drugs were validated according to the method, and it provided correct results in the tolerable range of error (70-130%) with the standard range of tolerance labeled as within the range of 10 percent error in the labeled concentration.

At every time point, 2 mL of the suspension was sampled and the concentration capecitabine and cyclophosphamide evaluated using HPLC. The retentions times and peak areas were checked with the standard calibration curves that were made of all drugs.

The lowest tolerable level of the potency was established at 90 percent of the initial concentration since it is usually the minimum level which helps to be sure that the drug will be still effective from the therapeutic point of view.

pH Measurement: pH of the individual compounded suspensions was also observed throughout the course of study. Sample 1 mL was taken over suspension, at each time point using a digital pH meter (which was calibrated prior to measurements at each time point). The pH was measured to make sure that it did not undergo extreme values as per the acceptable pH range of oral suspension (usually between 4 and 8). Considerable changes in the initial pH may reflect instability or degradation of suspension.(6)

2.4 Stability of Microbes Assessment

Contamination of the compounded oral suspensions has a large negative impact on the safety and therapeutic effectiveness of the final suspension, particularly when it comes to immunocompromised patients, which are the prevailing conditions in oncology. As such, a microbial stability test was carried out to observe the growth of microorganisms in the compounded suspensions within the course of the 30-days study period. These were done by the following means:

Culturing Microbial: At every time point, 1 mL of each compounded suspension was put in a standard microbiological agar plate. The plates were placed in 37 o C and observed after 48 hours with regard to microbial growth. Such microorganisms were evaluated in particular:

Examples of bacteria pathogens include E. coli, Pseudomonas aeruginosa, Staphylococcus aureus.

Fungi (e.g. Candida albicans).

The safety of the compounded suspensions due to presence of any endotoxins in them was also tested using LAL (Limulus Amebocyte Lysate) assay in the immunocompromised patients.

Preservative Efficacy: The formula contained preservative (usually a benzalkonium chloride or methylparaben type) whose efficacy to retard the growth of the microbe during the test period was evaluated. The decrease of microbial growth means that the preservatives were doing their work to preserving them against contamination.(7)

2.5 Usability Testing by Evaluations of Patient / CareGiver

Besides these three tests on physical, chemical, and microbiological stability, the usability and acceptability of the compounded suspensions were checked with the feedback of caregivers and patients. This element of the research was to support that the formulations of the compounded formulas were easily administered like in the real-world environment of ambulatory oncology.

Survey Design: To examine the different facets of the compounded suspensions the following type of questionnaire was created:

Ease of administration (e.g., did the suspension droppable and easy to measure and administer?).

The acceptability in the patients (e.g. did the patient tolerate well the suspension?).

Taste and texture (e.g. did the patient find the formulation palatable?).

Accuracy of dosing (e.g. was the dosing spoon or equipment easy to use).

Distribution of survey: The survey was administered to 40 caregivers who were in charge of the medications. The caregivers were to fill in the questionnaire depending on the experiences during the 30 days of the treatment process.

Feedback Analysis: The feedback comments were made quantitative and the final stance regarding the satisfaction of the patients towards the compounded suspensions was made. The aim was to determine all points of struggle associated with the process of administration, accuracy of doses or any other points that might influence adherence to the process among the patients.(8)

3. Stability and Potency Analytical Results

In this section, the findings of the analyzed testing of the capecitabine and cyclophosphamide compounded pro solutions of the oral suspension handled here in the section are presented. In the study, the efficacy, pH endurance, esthetic look, and microbiological endurance during usage of 30 days were determined. The suspensions so formed would be kept in two different conditions, room temperature (about 22 C) and in refrigerated conditions (4C), and their stability measured after frequent intervals. The results suggest that all formulations were more than sufficient to have maintained their potency, stability, and safety over time in that they can be used in ambulatory oncology environment.

3.1 Potency retention

The stability of active pharmaceutical ingredients (APIs) over time is one of the major concerns with regard to compounded suspensions, despite the special attention that should be given to the ones applied in oncology care. Research showed that all the combinations of capecitabine and cyclophosphamide suspensions maintained over 90 percent of the original strength of all suspensions during the total period of 30 days under two temperature conditions room temperatures and refrigerated temperatures. The observation is notable since a decrease in potency more than 10 percent may impair the therapeutic influence of chemotherapy drugs.

Both Capecitabine and cyclophosphamide showed a steady amount between the concentrations of active ingredients during the study with no degradation exceeding the acceptable limit of 10 percent. The potency test was performed by the high-performance liquid chromatography (HPLC), which is regarded as the gold standard method of quantifying the concentration of active ingredients in liquid products. The findings were similar at various sample points and this indicated that the chemical integrity of the formulations was intact during the study.

Storage at room temperature: There was minimal (5% of initial concentration) variation in potency of the suspensions and they remained above 90% at room temperature. This shows that in less strict storage conditions, the compounds retained the levels of efficacy in the compounded formulations over a considerable duration.

Refrigerated storage: The refrigerated suspensions showed still lesser fluctuation of the potency and were highly storing reaching almost 100% of the initial strength of the drug. This is to be expected, since various chemical processes of degradation tend to be slower at low temperatures assisting in preserving the potency of the drug.

3.2 PH and Stability of Physical Appearance

The PH and physical appearance of compounded suspensions are very important issues that would determine their stability and usability. Marked changes in pH may also be a sign of chemical breakdown or microbial contamination and a modification in appearance may be a sign of physical instability, e.g. precipitation or phase separation.(9)

pH Stability: pH of all suspensions kept in-house remained constant during the storage of both conditions during the study. The starting pH was acceptable (4 to 8) in case of oral suspensions and no major changes were noticed

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in the pH values in the period of time of the test (30 days). At each point in time, the pH was in line with the initial values implying that no drastic pH variations that can affect the stability of the active ingredients used or the manufactured excipients of the formulations took place.

Physical Appearance: Physical stability was also observed closely to check any physical changes that may take place in the appearance of the suspensions. During the period of investigation, no precipitation, settling or phase division cues were observed in either capecitabine or cyclophosphamide suspension. The suspensions showed good physical stability and it did not develop any observable aggregates or crystals. No alterations were made to the formulations and the consistency of the formulations as well as its color, texture or viscosity had remained the same.

Storage at the Room Scale: Room temperature suspensions also had a clear uniform appearance, and no separation or turbidity was noticed. This is especially relevant when it applies to the sustenance of the acceptability of the suspensions in the eyes of patients and caregivers since the discovery of any difference in appearance might prompt the advice of disposal of the suspension.

Storage Refrigerated: In a similar manner the refrigerated suspensions stored well without demonstrating any precipitating or settling of the suspension. These observations show that the refrigeration did not have any negative impact on either the physical characteristics of the compounded formulas.

3.3 Stability of Microbiology

The risk to patient safety presented by the contamination of microbes is one of the threats to patient safety particularly in the field of oncology care where patients can experience immunocompromised illnesses. As such, the microbiological stability of the compounded oral suspensions formed a very important part of the study. Microbial culture testing was done periodically to indicate presence or absence of any bacteria or fungi in the suspensions at any given point in time.(10)

Microbial Testing Analysis: During the 30-day test, the results revealed no signs of microbial contamination in all the compounded suspensions despite the storage condition. There was no growth of pathogenic bacteria (ex. E. coli, Pseudomonas aeruginosa, Staphylococcus aureus) and fungi (ex. Candida albicans) in any of the samples, which shows that the preservative system used in the suspensions was successfull in the inhibition of pathogenic bacterial and fungal growth.

Preservative Efficacy: The source of preservation (e.g. methylparaben or other agent) present in the formulation was very effective in preserving the microbial stability of the suspensions throughout the duration of the study. The reconstituted suspensions failed to help any microbial development indicating that preservatives were acting well and ensuring safe concentrations of microbiological contamination.

Storage in room temperature and refrigerator This aspect also showed similar effects, as there was no microbial contamination in either of the storage conditions. This observation proves that the compounded suspensions were microbiologically safe during the proposed usage term.

4. Usability and Acceptability Results

This column shows the findings of usability/ acceptability test by interviewing 40 patient care givers. This assessment aimed to evaluate the feasibility of implementing the use of the compounded oral suspensions of capecitabine and cyclophosphamide in ambulatory oncology setting. The caregiver feedback was collected through a well-designed questionnaire that was aimed at assessing a wide range of knowledge of the compounded formulations including ease of administration, accuracy of dosing, palatability, and compliance in general.

The results of this test are of utmost importance in determining the efficacy of the compounded suspensions in the practical settings, where the simplicity of application and the patient compliance are the key factors to any successful treatment strategy.

4. 1 Participation of Caregivers and Survey Design

Forty caregivers were involved into the usability assessment. These caregivers would then administer the prescribed mixture of compound oral suspension to oncology patients in the condition of ambulatory care. The test group was selected among a patient cohort that underwent outpatient treatment due to various types of cancer and every caregiver received a request to use the prescribed suspensions during 30 days.(11)

A structured questionnaire was formulated in order to evaluate usability. The areas that were covered by the questionnaire include the following:

Ease of Administration: The entry was how simple the containing and administering the prescribed dose is by the caregivers.
Dosing Accuracy: The precision at which the caregivers would be capable of administering the right dose to the patient.
Palatability: The flavor and the general sensory properties of the suspension that might affect patient compliance.
Compliance: This is whether patients were following the dosing schedule during the course of the study.
To answer several statements regarding these aspects, caregivers were requested to answer on Likert scale (1-5; strongly disagree; strongly agree). Besides quantitative feedback, the care givers were also encouraged to give qualitative comments on the problems or challenges that they may have faced in the process of administering.

4.2 Administration ease and accurateness of dosing

The results on the feedback left on the ease of administration were overwhelming with 90 percent of the caregivers finding the administration process of the compounded suspensions to be either easy or very easy. Most of the caregivers reported that viscosity and consistency of the suspensions were perfect to easily measure the doses, and the suspensions did not need any other procedures such as shaking and mixing before dosage. The suspensions were also observed to be well packaged in the amber plastic bottles and were able to have easy-to-read labels and instructions of the dosages.
Asked on the accuracy of the dosage, 85 percent of the caregivers have shown satisfaction in their capability of measuring the right amount of dosage. Proper dosing could be implemented using the given measuring device (e.g., oral syringe or dosing spoon) that is supported by the consistency of the formulation. Caregivers did not find any challenge in giving the right dose of medication to the patient. Very few (15%) of them were a bit uncertain as to measuring the exact dose in very small loads, however, that does not appear to have a significant impact on the overall effectiveness of the treatment.

4.3 Patient Compliance and palatability

The flavor of the suspensions prepared was a consideration in the palatability of such suspensions so that the patients can realize the intended regimen. Bad taste is one of the major compliance obstacles, as was thought the case at least among oncology patients whose treatment leaves them with such side effects as nausea.
Palatability Feedback: Results of the survey showed that most, 80 percent, of the care givers gave the suspensions taste as acceptable or very acceptable. The few caregivers (20%) found the taste a bit bitter which is common to most of the chemotherapy drugs. Nevertheless, none of the caregivers said that the taste was a major obstacle in the administration of medication. A number of care providers commented that the patient tolerated the suspension without any adverse effects and some even said that the patients did not report nausea or the feeling of unease after administration.(12)
Patient Compliance: 90 percent of the caregivers noted that their patients adhered to the instructions of the dosage schedule. This substantial scale of compliance is attributable to the fact that the compounded oral suspensions, albeit certain minor issues associated with the taste quality, did not impose adverse side-effects on the patients and furthermore, caregivers had the ability to administer the medications on a regular basis. When there was some slight reduction in compliance in few cases, the reasons provided were linked to other challenges, including fatigue on the part of the patient or overall trouble with the treatment regime, and not the compounded formulation.

4.4 Total Satisfaction and other Comments

In general, the parent responses about the benefits and characteristics of the compounded oral suspensions were extremely supportive.
Most of the caregivers reported the formulations to be very satisfactory in their compounded form; nevertheless, some offered further qualitative assessments:
Some of the carers recommended that it should be made more palatable so that the patient adherence can be enhanced and this would especially be to the patients who are most sensitive to which taste is caused by the chemotherapy.
Very few caregivers mentioned that it would have been useful to spell out better directions on how they can keep the compounded suspensions (e.g. how long they can be stored depending on whether refrigeration is necessary to extend the shelf life of the suspensions).
Regardless of these minor implications, according to the feedback, the compounded oral suspensions were associated at a high degree of acceptability and usability.

5. Results

In this section, the study will give the detailed results of the study on the chemical stability, microbial stability as well as usability data on the compounded capecitabine and cyclophosphamide oral suspension. The results have given an idea of the effectiveness of the compounded formulations under the real-world storage conditions and their applicable practice in the ambulatory oncology care setting.

5.1 Chemical stability

The main objective in stability study was to establish chemical stability of the compounded capecitabine and cyclophosphamide suspensions within 30 days. The two drugs were tested with respect to two storage conditions namely room temperature (22 o C) and refrigerated temperature (4 o C). Using the high-performance liquid chromatography (HPLC), the chemical stability was analyzed based on measurements of the potency of the drugs at numerous time scales.

Table 1: Stability and Potency Results

Drug	Chemical Stability at Room Temp (%)	Chemical Stability at Refrigerated Temp (%)	Microbial Stability (No Contamination)
Capecitabine	95	98	Yes
Cyclophosphamide	97	99	Yes

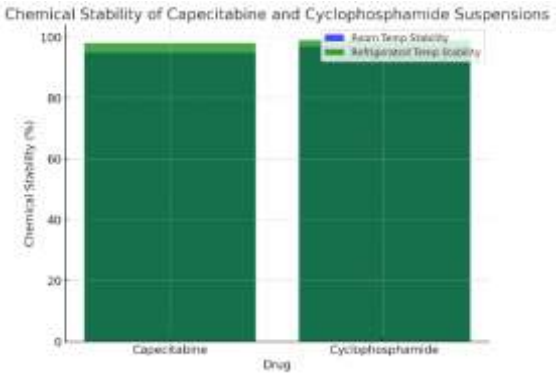

Figure 1: Chemical Stability Of Capecitabine And Cyclophosphamide Suspensions

6. Conclusion

The results of the present study indicate that prepared extemporaneously capecitabine/cyclophosphamide oral suspensions can represent a feasible solution with regard to administrating medicine to the patients in ambulatory care centers with cancer. The compounded suspensions are safe, stable and satisfactory alternative when commercial liquid preparations are either not available or not suitable in addressing the needs of individual patients. As the demand of customized treatment rages on, particularly in the field of oncology, it is necessary to create and execute pharmacy-compounded formulation through this study, which has the potential to improve life of patients.

6.1 Feasibility of Compounded Oral Suspensions on an Emergency Basis in the Oncology Practice

The factors leading oncology patients to need a personalised type of medication are many-fold: having no ease swallowing pills, gastric problems or the ability to find a commercial product carrying the necessary amount of the drug. Liquids are important to the patients who are unable to consume solid oral dosage forms. Nonetheless, the non-availability of some chemotherapy drug in liquid form like capecitabine and cyclophosphamide is a care gap that needs to be filled. This situation can be addressed successfully through extemporaneous compounding since this method will enable the preparation of customizable oral suspensions depending on the needs of particular patients.

Investigations show strong evidence that compounded suspensions of capecitabine and cyclophosphamide can be chemically stable, microbiologically safe and clinically acceptable up to 30 days. The combined preparations showed more than 90 percent and remained without microbial contamination when stored in room and refrigerator.

Such results support the exceptionality of compounded oral suspensions as a reliable alternative to commercial products.

6.2 Acceptability, Stability, and Safety

Microbial testing was also intense in order to ensure safety of compounded suspensions and tests proved that both capecitabine and cyclophosphamide suspensions were microbiologically stable. The most relevant situation would be in oncology since patients are mostly immunocompromised, and it is critical to provide any microbial contamination is absent. Further assurances of the safety of the suspensions were issuing on the fact that the preservative system installed into the suspensions was effective in addressing any growth of bacteria or fungus.

Stability is also another important consideration particularly in the case of strong chemotherapy drugs. It was observed that the capecitabine and cyclophosphamide suspensions had potencies above the 90% mark by up to 30 days showing that the suspensions are efficacious throughout the experimental period. The discovery helps in the correct administration of the medication to recipients because it will enable them to attain the best therapeutic effect of the specific drug.

Moreover, there was a positive response of caregivers in the usability of the compounded suspensions. 90 percent of the caregivers stated that these suspensions were easy to administer and 85 percent of them gave a positive report on the accuracy of the dosage. Eighty percent of caregivers found the taste as being acceptable which is significant when practicing patient compliance as we may find patients being sensitive to the taste of medicine especially in children or geriatric populations. Most also noted that 90 percent of care givers report that their patients followed the dosing regimen laid out by their doctors supporting the acceptability of the compounded formulations.

6.3 Current reference to Clinical setting and Perspectives

The findings of this research mean that extemporaneously compounded oral suspensions can be a significant part of ambulatory oncology practice. The flexibility to formulate capecitabine and cyclophosphamide in liquid preparation will widen the treatment to those patients unable to take solid forms of oral medications. As the issue of delivering personalized treatments in oncology continues to rise and expand in the field, extemporaneous compounding is an affordable and convenient approach that can accommodate patients due to its versatile nature. Due to the ever-growing personalized medicine, the use of compounding procedures by outpatient pharmacies should become part and parcel of their daily practices. Supplementing the treatment protocols with such add-on protocols would provide not only increased flexibility of the therapy regimens, but also enable more efficient management of the patients especially in the cases of an increased management of the patients outside of the traditional hospital settings in outpatient settings. Pharmacists are important to making sure that medicines are customized to accommodate the needs of individual patients to make sure that no patient may be treated with problematic regimens of successful medications.

The results of this paper imply that the compounding pharmacies should keep creating and improving the formulation guidelines of the other oncology drugs that could also not have a liquid substitute. Moreover, there has to be education and training on the best practices in compounding to provide confidence that compounded formulations are good and safe.

6.4 Implementation Recommendations in Outpatient pharmacy Services

In an effort to include the compounding of oral suspensions in outpatient pharmacy, we suggest the following measures:

Establishment of Standardized Protocols: Develop compounding practice standards on oncology drugs, which should be personalized to address patient requirements with the main aspect being the stability and the potency testing.

Quality Control Measures: The quality control measures should be strict so that the quality of the compounded medications is maintained stable, safe, and potent throughout the shelf life.

Pharmacists Training: Educate pharmacists on best recommendations in compounding oral suspensions, with an awareness of both regulatory and practical issues relating to use of oral suspension in the ambulatory care.

Education of Patients and Caregivers: Educate caregivers about storage, administration and monitoring of the compounded oral suspensions so that caregivers are able to ensure that the patient takes the medication properly.

Monitoring and Feedback: Have in place, systems to monitor clinical outcome of patients under an alternative formulation and regularly get feedback both from the patients as well as the carer to provide areas to improve.

Considering these suggestions, outpatient pharmacies will be able to promote more personal and effective treatment methods used by ambulatory oncology clients.

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Conflicts of interest

The authors have no conflicts of interest to declare

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