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Research Article

**ASSESSMENT FOR STORAGE OF LIQUID DOSAGE FORM AT  
HOME IN SOUTH JEDDAH CITY, KSA**Izhar AS<sup>1\*</sup>, Omar AA<sup>1</sup>, Alshehri AA<sup>1</sup>, Hamed YS<sup>1</sup>, Nabil AA<sup>1</sup> and Arief M<sup>2</sup><sup>1</sup>Programme Pharm D, Ibn Sina National College for Medical Studies in Jeddah, KSA<sup>2</sup>Department of Clinical Pharmacy, UCSI University, Cheras, Malaysia**Abstract:**

**Introduction:** Liquid state forms are meant for internal and external use. They are available in monophasic and biphasic forms. Monophasic liquid dosage forms are true or colloidal solution. Water is mainly used as a solvent for a majority of monophasic liquid dosage forms. Hence, the present study was conducted to observe the storage of the oral liquid formulation during the usage.

**Methods:** A retrospective observational study of 4 month duration was undertaken from Jan- April 2018. A total 100 number of participants have involved in the study. The data was interpreted and the results were articulated as counts and percentage.

**Results:** Participants store the oral liquid formulation at room temperature i.e., 25-30°C (60.15%). The data also indicates that most of the parents will administer the medication 2-3 times per day. The percentage usage oral liquid formulations (internal use) and external liquid formulations are 79.1% and 9.8% respectively. However, the majority of the participants in the study used extemporaneously preparation are used for seven days (76.95%) and only 10.12% used for one month. The data also indicates that 62.56% of participants do not read the administration guideline or labels. Different tools for the administration of liquid dosage forms, the usage of syringe/ dropper are higher percentage (29.91%) whereas the usage of household spoon and medical cup is 24.05% and 24.01% respectively. As per the survey recorded it shows that the liquid formulation changes the color in higher percentage (32.5%) and then formation of the crystals i.e. (30.05%), it might be due to the storage of the formulation at room temperature.

**Conclusions:** The results reflect a good level of correct practice. However, there is a room for improvement. The pharmacists are recommended to explain the correct directions for the storage and usage of the liquid oral formulations.

**Key Words:** Liquid oral formulations. Retrospective observational study, Statistical analysis

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**INTRODUCTION:**

Liquid state forms are meant for internal, parental or external use. They are available in monophasic and biphasic forms. Monophasic liquid dosage forms are true or colloidal solution. Water is mainly used as a solvent for majority of monophasic liquid dosage forms. The liquid which consists of two phases are known as biphasic liquids.

Monophasic liquid dosage forms: It contains only one phase.

**Liquids for internal use:** Drops, Elixirs, Linctuses, Syrups, and draughts. [1-2]

A. Liquids for external use:

**Liquid to be applied to the skin:** Liniments and lotions.

**Liquids meant for body cavity:** Gargles, throat paints, mouth washes, throat paints, mouth washes, eye drops, eye lotions, ear drops, nasal drops, sprays and inhalations

**Syrups:** Syrups containing medicinal substances are called medicated syrups and those containing aromatic or flavored substances are known as flavored syrups.

**Elixirs:** Sweet aromatic colored preparations. Main ingredients of elixir are ethyl alcohol, water, glycerin, propylene glycol, flavoring agent, syrup and preservatives. Medicated elixir contains very potent drug such as antibiotics, antihistamines, sedatives. Flavoring elixirs used as flavors and vehicles.

**Linctuses:** Viscous liquid and oral preparations that are generally prescribed for the relief of cough. They contain medicament which have demulcent, sedative or expectorant action. Linctuses should be taken in a small doses sipped and swallowed slowly without diluting it with water in order to have maximum and prolonged effect of medications.

**Drops:** Liquid preparations meant for oral administration Since these preparations contain potent medications the dose must be measured accurately.[3-4]

**Liniments:** Liquid and semi liquid preparations meant for application to the skin. Liniments are usually applied to the skin with friction and rubbing of the skin. Alcohol helps in penetration of medicament in to the skin and also increases its counterirritant or rubefacient action. Arachis oil is used in some liniments which spread more easily on the skin. Soap is also included as ingredients in some

of the liniments which helps in easy application of liniment on the skin.

Liniments contain medicaments possessing analgesic, rubefacient, soothing, counter irritant or stimulating properties. Liniment should not be applied to broken skin it may cause excess irritation. [5-6]

**Lotions:** Liquid preparations meant for external application without friction. They are applied direct to the skin with the help of some absorbent material such as cotton, wool or gauze soaked in it. Lotions may be used for local action as cooling, soothing or protective purpose. They are generally prescribed for antiseptic action **ex:** Calamine lotion

**Gargles:** Aqueous solutions used to prevent or treat throat infections. They are usually available in concentrated form with direction for dilution with warm water before use. They are brought in to contact with mucous membrane of the throat and are allowed to remain in contact with it for a few seconds. [7]

**Mouth washes:** Aqueous solutions with a pleasant taste and odor used to make clean and deodorize the buccal cavity. Generally they contain antibacterial agents, alcohol, glycerin, sweetening agents, flavoring agents and coloring agents. [8]

**Throat paints:** Viscous liquid preparations used for mouth and throat infections. Glycerin is commonly used as a base it adheres to mucous membrane for a long period and it possesses a sweet taste. [9]

**Nasal drops:** solutions of drugs that are instilled in to the nose with a dropper. They are usually aqueous and not oily drops. Nasal drops should be isotonic having neutral pH and viscosity similar to nasal secretions by using methyl alcohol

**Ear drops:** Sterile solution or suspensions of drugs that are instilled in to the eye with a dropper. The eye drops are usually made in aqueous vehicle. It should be sterile isotonic with lacrymal secretions, buffered and free from foreign particles to avoid irritation to the eye

**Eye lotions:** Aqueous solutions used for washing the eyes. The eye lotions are supplied in concentrated form and are required to be diluted with warm water immediately before use. It should be isotonic and free from foreign particles to avoid irritation to the eye.[10]

**Ear drops:** solutions of drugs that are instilled in to

the ear with a dropper. These are generally used for cleaning the ear, softening the wax and for treating the mild infections. [11-12]

**Biphasic liquid dosage forms:** It contains two phases. Ex: Suspension and emulsion

**Suspensions:** Biphasic liquid dosage form of medicament in which finely divided solid particles are dispersed in a liquid or semisolid vehicle. The solid particles act as disperse phase whereas liquid vehicle acts as the continuous phase. Suspensions are generally taken orally or by parental route. They are also used for external application. Many suspensions are supplied as dry powders which are converted in to suspensions by adding the specified amount of vehicle before use. This is done to ensure the stability of suspension. Ex: Ampicillin for oral suspensions, Barium sulphate suspensions, Insulin zinc suspension. [13-14]

**Emulsion:** Biphasic liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules in to the other. The liquid which is converted in to minute globules is called the disperse phase and the liquid in which the globules are dispersed is called the continuous phase. Normally two immiscible liquids cannot be dispersed for a long period. So an emulsifying agent is added to the system. It forms the lmm around the globules in order to scatter them indefinitely in the continuous phase, So that a stable emulsion is formed.[15-16]

Emulsions are of two types

**I. Oil in water type (O/W):** Emulsion in which oil is I the dispersed phase whereas water is in the continuous phase. The O/W type emulsions are preferred for internal use. In these emulsions gum acacia, tragacanth, methyl cellulose, saponins synthetic substances and soaps formed from monovalent bases like sodium, potassium are used as an emulsifying agent.[17-19]

**II. Water in oil type (W/O):** Emulsion in which water is in the dispersed phase whereas oil is in continuous phase. Wool wax, resins, beeswax and soaps formed from divalent bases like calcium, magnesium and zinc are used as an emulsifying agent. The W/O emulsions are mainly used externally as lotions or creams.

**III. Intravenous emulsion:** The oil soluble hormones vitamin A,D and K are administered as intravenous injection. The emulsified oils are also injected as diagnostic aids. The emulsion should have small globule size and must be sterile.

**IV. Emulsion for external use:** The emulsions for

external application may be both O/W or W/O type but O/W type emulsion is preferred. When a drug is emulsified its rate of penetration through the skin may get reduced.

Oral liquids for both these older and paediatric patients. The oral liquids is challenging, both due to the lack of pharmacopoeial and stability-indicating formulae and the fact that their stability is not only determined by the active pharmaceutical ingredient, but also the ability of excipients from the commercial product to interact with each other and the active pharmaceutical ingredient. This increases the complexity of the stability considerations to be taken into account within these oral liquids, highlighting the number of parameters to be considered in the extemporaneous preparation of oral liquids.

A number of parameters need to be considered in the formulation of a stable oral liquid. These include chemical, physical, microbiological, therapeutic and toxicological stability evaluations not only taking account of the active pharmaceutical ingredient (API), but also the excipients and packaging of the drug product. The extemporaneous preparation of oral liquids can be complex due to the addition of excipients to improve patient adherence and / or the stability of the final product. Further, due to convenience and availability of ingredients, it is common practice for oral liquids to be prepared from commercially available solid dosage forms such as a tablet or capsules. Therefore additional potential interactions may occur between the drug and the excipients in the solid dosage in the prepared oral liquid. In addition to chemical stability, physical stability, microbial stability and palatability, excipient suitability (e.g. sugar free for diabetic patients) and interactions with packaging materials need to be considered in the preparation of a suitable extemporaneous oral liquid.[20]

Instructing patients on storage of liquid dosage forms at home is a challenge for pharmacists in this situation.

Hence a study will be conducted to investigate the storage of liquid dosage form by the parents after administration of the drug to the children's. Therefore, an attempt was made to know the storage of liquid dosage form after the usage of the products.

#### **METHODOLOGY:**

This is a survey based cross-sectional study. A survey method was adopted as a means of data collection because it provided the best possible way to determine the administration of the liquid formulation

by the parents.

#### **Duration of study**

The duration of the study was of 4months from Jan 2018 to April 2018

#### **Sampling**

The data were collected from a sample size of hundred parents from different regions of the Jeddah, KSA

#### **Study procedure**

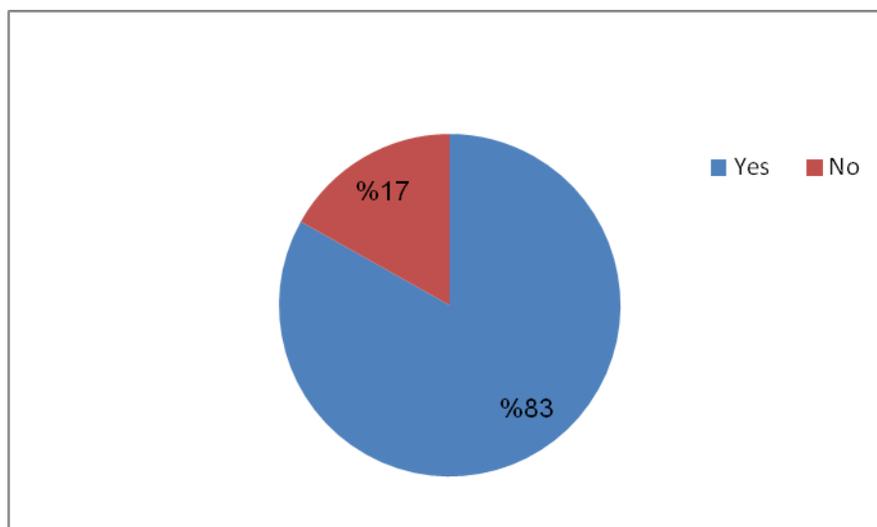
The details of the participants were collect as their name age, address along with the date in the questionnaires formatted and their information were also made record.

#### **Statistical analysis**

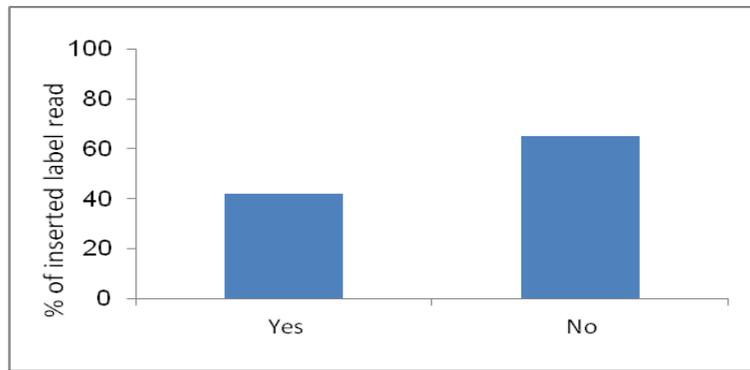
The data collected were analyzed statistically and presented as counts and percentages and presented in the form of tables and figures i.e. graphs

**Table 1: Participants' behavior concerning storage and usage of liquid formulations**

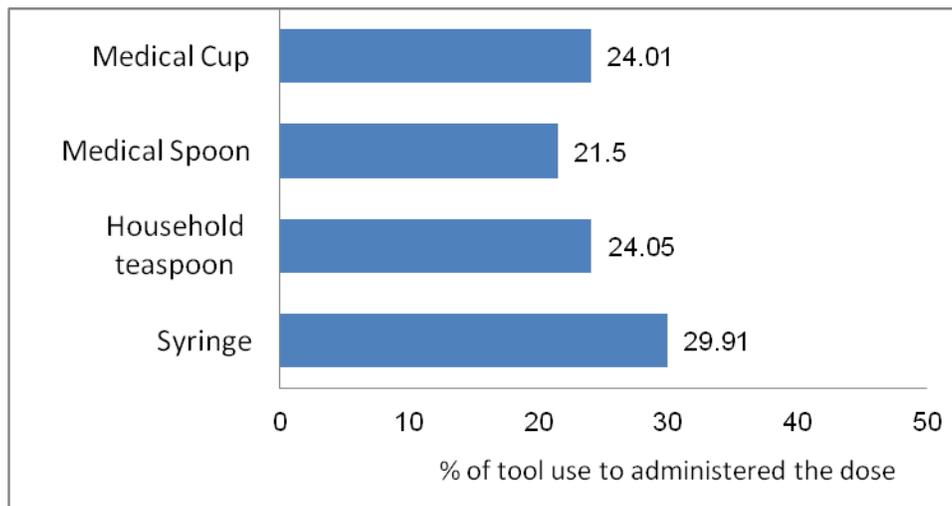
Where do you preserve liquid formulations after you open it?	
In the refrigerator	30.05%
At room temperature	60.15%
Do not care	07.01%
If there is drug deposition at the bottom of the bottle, what do you do?	
Shake the bottle and continue using it	83.95%
Add some water	16.05%
Avoid using it, then buying a new one	05.2%
What do you do if color or form of liquid formulations has changed?	
I get rid of it immediately	25.36%
I continue to use it	10.10%



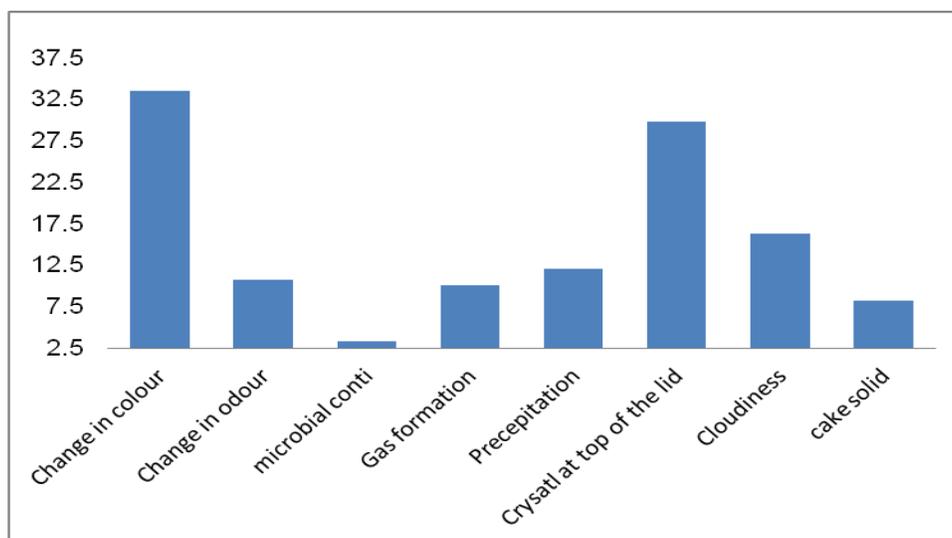
**FIG 1:** Comparison of shaking of Liquid medications while administration



**FIG 2:** Comparison of Percentage of participants reading the labels



**FIG 3:** Usage of the tools during the administration of oral liquid formulations



**FIG 4:** Observed changes in the oral liquid formulations after storage

### RESULTS AND DISCUSSION:

In this present study, 100 participants had responded the survey, most of them are parents. The age of the children was in the range of 1-5 years, the data shows that most of the parents prefer the liquid dosage form rather than solid dosage forms. From the table no 1, it is evident that most of the participant in the study store the liquid formulations at room temperature. Only 30.05% of the store at refrigerator conditions.

Apart from that, there was a significant statistical difference shown between groups' responses when they were asked if they could use any of their medicine after deposition of the medicament at the bottom of the bottle nearly 50.63% of them declared that they will shake the bottle and continue for the usage. It indicates that the participants in the study have the knowledge for shaking the liquid formulation before the usage.

When they were asked if they could use any of their medicine after changing of color or crystal formation at the top of lid. Most the participants answered they get it rid immediately, this also signifies that the participants in the study have the knowledge for shaking the liquid formulation before the usage

Storage conditions of drugs are important as drugs are chemicals that may react with external environments such as temperature, humidity, and light. This leads to changes in drugs concentration properties and therapeutic effects. Many people stored medications in kitchen or bathroom cabinet, that speeds up medication breakdown process; as in both conditions drugs may be exposed to humidity and high temperature. Instead, medicinal cabinet should be placed in a cool and dry place, away from direct sunlight, and out of reach from children. In this study a good percentage of participants 77 (41.2 %) stored medicaments at room temperature, and 28 (30.5%) of them stored liquid formulations in a refrigerator. In both cases around half of the participants followed the correct practice. Similar results are shown in one of the studies. [21] Regarding this point, more education and counseling is recommended because many people store medications in inappropriate places. To achieve higher level of awareness and correct practice regarding liquid dosage forms like suspensions use, cooperation between drugs companies, pharmacists, and doctors is needed. From figure 2, it indicates that the higher percentage (62.56%) of participants do not read the administration guideline or labels. Drugs companies are suggested to write instructions in a simple way, and may draw the directions on the label, in addition to providing suitable dose administration

devices. This study was also exploited to know how the parents or guardians will administer the liquid dosage forms.

From figure 3, it shows the usage of different tools for the administration of liquid dosage forms, the usage of syringe/ dropper is the higher percentage (29.91%) whereas the usage of household spoon and a medical cup is 24.05% and 24.01% respectively. Here, it is suggested that the prescribers should inform parents/guardians the correct instructions for the usage of the tool for the administration of the liquid formulations, also and confirm that the medications should not be shared between children. It is the responsibility of pharmacists to explain instructions to parents/guardians and confirm on them by writing, and to provide with administrative droppers, also it is important to concentrate on duration of use and storage conditions.

From figure 4 it was observed that the liquid formulation changed the color in a higher percentage (32.5%) and the formation of the crystals i.e. (30.05%), it might be due to the storage of the formulation at room temperature. However, these results can give a baseline data that can be useful in designing and implementing suitable educational programs for the storage of pharmaceutical oral liquid formulations.

### CONCLUSION:

The results reflect a good level of correct practice. However, there is a room for improvement. The pharmacists are recommended to explain the correct directions for the storage and usage of the liquid oral formulations. It is better to supply droppers with suitable calibration for dose administration, and to counsel parents about suitable storage conditions, frequency of dosing and duration of use.

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