ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

ORIGINAL ARTICLE

# Effectiveness of Shelf-Life Extension Program as a Contributor to Central Drug Store Stockpiles Maintenance: Ministry of Health Experience in the Gaza Strip During Crisis

**Heba Al Basha[1] * , Yousef Aljeesh[2] , Shereen Ayoub[3] , Nahed Hegazy[4]**

***Received: 27/05/2023*** ***Accepted:27/08/2023*** ***Published:1/10/2023***

**OPEN ACCESS**

**Doi:**

https://doi.org/10.52865/NXJR3154



**Competing Interests**: The authors declare that this manuscript was approved by all authors in its form and that no competing interest exists.

**Affiliation and Correspondence**:

1-Heba Al Basha Ministry of Health, Gaza, Palestine,
2-Yousef Aljeesh Islamic University, Gaza, Palestine,
3-Shereen Ayoub Ministry of Health, Gaza, Palestine,
4- Nahed Hegazy Israa University, Gaza, Palestine,
***Corresponding Author email:**
bashamatter@gmail.com

## ABSTRACT

**Background:** The Shelf-Life Extension Program (SLEP) was one of the most effective alternative plans, which could respond appropriately to crises of drug shortage and near expired drugs.
**Aim of the study:** The purpose of this research was to evaluate the SLEP in the MOH in the GS as a contributor to central drug store stockpile maintenance during crises from the point of view of the GDP pharmacists.
**Methods:** The study used quantitative descriptive and qualitative approaches. The study sample is a set of all the key members in the DCD and CDS working in the SLEP consisting of 21 persons.
**Data collection:** The researcher developed his tool to evaluate the SLEP. The questionnaire was validated by a group of experts and a pilot study was implemented on 5 participants. Cronbach alpha coefficient was 0.938 for the GDP questionnaire.
**Results:** The results of the findings from the GDP's questionnaire showed that the highest domain was " Extended Drug Labeling" with a weighted mean of 85.7%, followed by "Follow up the stock quantity for items that extended in the CDS" with a weighted mean 83.2%, and the weakest domain was "The impact of the SLEP on drug shortages in the MOH" with weighted mean 80.2%. There are statistically significant gender differences.
**Conclusions and recommendations:** The study concluded a high-level evaluation of the effectiveness of the SLEP by the GDP workers with an average score of 82.4, The study recommended that the GDP should establish regulations about the SLEP for expired drug handling for all health workers.

***KEYWORDS:*** *Shelf-Life Extension Program (SLEP), drug shortage, Cost – benefit, expired date, shelf life*

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

**INTRODUCTION*:***

In our time, crises have become a part of our lives, they're difficult to predict, and we need good preparation to cope with them, to ensure preparedness for war or other contingencies. Drug shortage is considered the main challenge facing the Ministry of Health (MOH) in the Gaza Strip (GS) due to the absence of financial support and irregular donations, these causes inspire Drug Control Department (DCD) to review a program to afford the minimum drug need (MOH, 2015).

Over the past decades, increasing evidence suggests that drugs may still be potent beyond their date of expiration; this idea is new to the MOH in the GS. It's known that the Central Drug Store (CDS) in the MOH plays a significant role in managing emergency drug shortages and donations. Drugs stocked in governmental CDS departments have an ongoing problem of expiration; many such stockpiles are the results of external donations. So it had been necessary for DCD to possess an efficient alternative plan, which may respond appropriately to the crisis of drug shortage and near-expired donated drugs (MOH, 2015).

The MOH in the GS is actively testing many drugs to determine their actual shelf lives (MOH, 2015). This effort arose when the CDS began to stockpile large quantities of donated drugs in 2012 for emergency and war relief (MOH, 2015). The shortage of drugs rather than the high cost of replacing expired drugs and also the absence of alternatives in the CDS has prompted a government medical team in DCD to extend the validity of some expired drugs in CDS to be used in hospitals, according to the World Health Organization (WHO) – guidance (Kopp S., 2011).

Shelf life is the period, from the date of manufacture, that a drug product is predicted to stay within its approved product specification while stored under defined conditions. Shelf life is usually expressed in units of months, i.e. 24 months, 36 months, to a maximum of 60 months (Capen, R., et al 2012). An expiration date is the time frame during which the product will continue to be stable when kept in a proper storage environment. Therefore, the date after which it is anticipated that the object may no longer retain its usability is known as the expiration date. If the product is not stored according to the manufacturer's directions, it may be anticipated that it will deteriorate more quickly. ( Bajaj, S. et al., 2012). The Shelf Life Extension Program (SLEP) is a joint program of the US Department of Defense (DOD) and the Food and Drug Administration (FDA) that aims to reduce the cost to the military of maintaining stockpiles of certain pharmaceuticals by researching the expiration of drugs. It tests medications for safety and stability for extended periods in controlled storage conditions ( Lyon et al., 2006).

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

Pharmaceutical manufacturers determine a drug's shelf life, or expiration date, through stability testing. This type of testing ensures that a drug's potency and integrity are intact over a specific amount of time, which becomes the expiration date. Several factors can influence these dates, including the type of active ingredients, storage conditions, preservatives, and the kind of container the drug is packaged. It is important to note that the manufacturers' expiration dates apply only to the original packaging of the drug and that once opened these dates no longer apply (Bajaj S, et al. 2012).

At various stages of the product development process, stability testing is a standard practice used on pharmacological compounds and products. Accelerated stability testing (at relatively high temperatures and/or humidity) is used in the first phases to identify the kinds of degradation products that could be discovered during long-term storage. The shelf life and expiration dates of a product are determined through testing under less rigorous conditions, i.e. those suggested for long-term shelf storage, at slightly increased temperatures. (Kiron et al., 2014).

The United States Federal Shelf Life Extension Program (SLEP) extends the expiration dates on qualifying drugs and other materials in federal stockpiles. SLEP is administered by the U.S. Department of Defense (DOD) in cooperation with the U.S. FDA. The program is an acknowledgment that the actual shelf life of drugs and other medical products may be longer than their stated expiration date, depending on their storage conditions. The purpose of SLEP is to defer replacement costs of stockpiled drugs by extending their useful life (FDA, 2019).

SLEP is currently available only for federally-maintained stockpiles, although there have been ongoing deliberations between the federal government and the states about extending SLEP to state-maintained stockpiles or creating a separate SLEP-like program for state stockpiles.

The decision on the use of medicines past their original shelf-life rests exclusively with the relevant national authority. Such decisions should take into account: (WHO, 2011)

- The quantity of stock (by manufactured batch) under consideration,
- The conditions under which the medicines have been stored since manufacture,
- Availability of alternative stocks or medicines,
- Source of scientific opinion,
- Cost and method for over-labeling or relabeling packages,
- Cost- and risk-benefit of shelf-life extension;

Where shelf-life has been extended, such medicines should only be used in case of national or

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

international emergency, and where no alternatives are available.

Where shelf-life is extended, medicine packs must be relabeled or over-labeled to show the new expiry date (WHO, 2011).

Consistent with the GDP Gaza Strip annual reports, the percent of zero stock drugs in Gaza's CDS were (2012: 33.5%; 2013: 30%; 2014: 26%; 2015: 22%; 2016: 37%; 2017: 28%%; 2018: 44% ) (MOH, 2012-2018). The drug shortage crisis of the health sector within the GS is required to seek out alternative solutions to reduce this crisis and to the suitable use of the available stockpile within the CDS. The SLEP was one of how the MOH worked to manage the drug shortage and reduce the loss of drug stockpiles within the CDS. Where the Drug Control Department (DCD) within the MOH conducted a study to determine the benefit of the SLEP then it did an extension of the shelf life for a few needed drugs to be utilized in the governmental hospitals (MOH, 2015).

This study, as far as the researchers know, is the first one proposed to clarify the various dimensions of the SLEP, which can conduct a comprehensive evaluation of the SLEP consistent with the requirements of the WHO and successively assess the work of the DCD and therefore the CDS. This research is believed to have a local interest and also a global one from the scientific side about the effectiveness of SLEP. The study may contribute to managing the shortage crisis by taking the right practical steps, thus improving the healthcare services and health status of the community, also this can contribute to enabling policymakers to make decisions towards solving the obstacle of drug shortage.

## Methodology

### Design of the Study

To achieve the goals of the study, this study was designed as a quantitative descriptive and qualitative one. The systematic questionnaire was used to collect data about the SLEP in the Drug Control Department (DCD) and CDS at GDP. The questionnaire was developed to be interviewed with pharmacists on GDP and it was designed to evaluate the different aspects of SLEP. Interviews were used to follow up on responses received by the MOH stakeholders.

The population of the Study

The study targeted all the key members on the management level of GDP who have a responsibility to develop a shelf-life extension program and meet the eligibility criteria in GDP (CDS & DCD) included in the sample. The 21 pharmacists (16 from CDS- 5 from DCD) deal with the extended drugs in the GDP.

### Instrument of the Study

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

We used self-developed questionnaires, which were constructed based on the framework and WHO international guidelines to measure the effectiveness of SLEP based on the guidance of the WHO and whether they have been achieved. The GDP questionnaire consists of six sections, the first part consists of questions related to the antity of stock if taken under consideration, the second part contains questions that assess the conditions under which the medicines have been stored since manufacture, the third part contains questions to assess availability of alternative stocks or medicines, the fourth part asked about the source of scientific opinion, the fifth part for measuring cost and method for over-labeling or relabeling packages and the last part explained the impact of the SLEP on the shortage of drugs in MOH stores.

Interviews were used to follow up on responses received by the MOH stakeholders regarding the SLEP.

**Validity of the Instrument**

The questionnaire was sent to the panel of experts working in MOH another expert in the field working in WHO, an Emergency Doctor working in Palestinian Civil Defense, experts from Al Quds and Islamic University, and an expert in International Cooperation to determine the consistency and relevance of the questionnaire to the objectives of the study. All feedback on the instruments has been taken into account. In addition, a pilot study was performed before the start of data collection.

**Data analysis**

The GDP questionnaire consists of six sections where descriptive results of the Socio-demographic characteristics of the study participants and the effectiveness of the shelf-life extension program were analyzed using mean, standard deviation, the weight of each item, and the rank of the items. We used statistical tests containing percentages and frequencies and used a one-sample t-test to analyze the items of the questionnaire.

**Reliability**

The reliability of an instrument is the degree of consistency with which it measures the attribute it is supposed to be measuring.

The researcher used Cronbach's alpha test to find the reliability for each dimension and the total score of the scale.

**Period of the Study**

The data was collected from April to May 2020.

**Ethical Considerations**

The researcher was committed to all ethical considerations required to conduct research. Also, official

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

approval was obtained from the MOH-Gaza, and official approval was obtained from the Islamic University of Gaza (IUG), Every participant in the study received a complete explanation about the research purposes and confidentiality. Every participant in the study population was informed about the optional participation in the study.

**Case study**

**Drug Control Department Study**

Only just in case of emergencies for the newly expired medications, which haven't any substitute, are highly important for use within the governmental hospitals, Standard Operating Procedure (SOP) is available. The below illustration, Figure 2.2, reveals that in the CDS Request for SLE of expired items, the SLE committee in DCD makes physical inspection conformity if yes SLE report consists of stability studies, method of analysis, and previous reports and studies, If no disposal, then availability of analysis if yes sampling, if no disposal, accredited pharmaceutical analysis laboratories, certificate of analysis if confirmed extension for 6 months if not confirmed disposal.

-Labeling in the CDC, the above steps are just a summary of the steps to follow in the local SLEP.

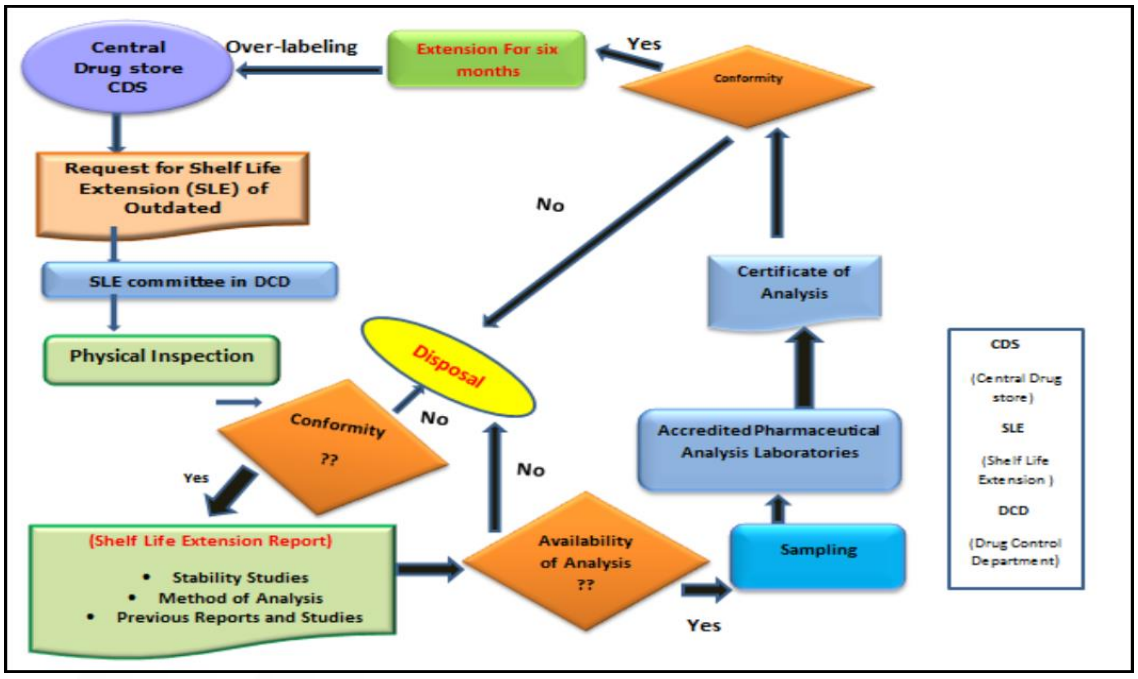


Figure: Main Steps in SLEP (DCD 2015)

Items that pass comprehensive testing (Physical, chemical, and/or microbiological) are extended for three months and if necessary re-extended after 3 months following stability testing. In the DCD study, twenty-six batches were on the list of extensions, but two items (Mesna and Milrinone) were excluded

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

from the list due to the inability to analyze. Out of 24 batches extended, there were two complaints, (amiodarone and thiopental). The major dosage forms were ampoules and vials (75%), Tablets (8.33%), Powder (8.33%), and solution (8.33%). The process of SLEP saved more than 164,000. DCD recommends Prior coordination with health authorities before sending drug donations and increasing the period of shelf life extension to six months to be more significant. (MOH 2017. DCD – GDP).

**Stability of Active Ingredients in Long-Expired Prescription Medications**

The US (FDA) allows that most drugs marketed in the US contain between 90% to 110% of the amount of the active ingredient stated on the label. (Cantrell L, et.al. 2012)

Drug expiry dates usually range from 12 to 60 months after their production. However; FDA regulations do not necessitate the estimation of how long drugs remain potent after that, allowing manufacturers to randomly set expiration dates without determining the actual long-term drug stability.

The SLEP controls the long-term stability of federal drug stockpiles. 88% of 122 various drugs stored under proper environmental conditions had their expiry dates extended by more than 1 year, with an average extension of 66 months and a maximum extension of 278 months. 12 of 14 drugs remained of full potency for a minimum of 336 months and 8 of these for at least 480 months. Despite the FDA's inability to confirm optimal storage conditions for samples, the findings support the efficacy of large extending expiration dates for many drugs, the efficacy of which has been shown by SLEP in a more controlled manner. (Cantrell L, et.al. 2012).

The most important contribution of this research included the potential cost savings resulting from extending the product expiration date. Every dollar spent on SLEP to show longer than labeled drug stability results in $13 to $94 saved on financing costs. Despite the Americans already spend more than $300 billion annually on prescription drugs, extending drug expiration dates may result in significant cost savings.

**Stability Profiles of Drug Products Extended Beyond Labeled Expiration Dates**

The American Medical Association has questioned whether expiration dates significantly reduce the actual shelf life of drug products. The results of the SLEP were evaluated to provide comprehensive data to address this issue. The SLEP has been implemented by the FDA for the DOD for 20 years. SLEP is expected to provide a comprehensive source of pharmaceutical stability data. Extended stability profiles for 122 different drug products (3005 different batches). These drug products were grouped into five categories based on the occurrence of initial extension failures and termination failures

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

(extended batch ultimately failed after re-testing). Based on testing and stability evaluation, 88% of the batches were extended at least 1 year after their original expiration date for an average extension of 66 months, although the additional stability period was highly variable. The SLEP evidence supports the fact that many drug items if correctly stored, can be extended beyond the expiration date. Due to batch-to-batch variability, the stability and quality of extended drug products can only be assured by periodic testing and systematic evaluation of each lot. (Lyon RC, et.al. 2006)

**Stability Studies of Expired Tablets of Metoprolol Tartrate and Propranolol Hydrochloride. Content Determination**

There has been a documented increase in interest in the issue of medication stability. From an economic perspective, the durability of medicinal items appears to be quite important. There are, however, a few studies that have examined the stability of medications after their expiration dates. The purpose of this study was to compare the contents of pills whose expiration dates had not yet passed with those whose contents had. Metoprolol tartrate (50 mg) and propranolol hydrochloride (10 mg) were also present in the tablets under investigation. With UV detection, the HPLC method was used to determine the content. The proposed method's linearity, sensitivity, intermediate accuracy, and precision were assessed. For all of the examined pills, there were no differences in assessment outcomes. The study's findings suggest that Storage of the studied batches of tablets for a longer amount of time than the manufacturer's recommended expiration date did not affect their contents(Magdalena, et al. 2009).

**United States Food and Drug Administration and Department of Defense Shelf-Life Extension Program of Pharmaceutical Products: Progress and Promise**

A 1986 intra-agency agreement between the DoD and the FDA led to the development of the DoD-US FDA SLEP, which aims to prolong the shelf life of medicines that are about to expire. Early on in the development process, considerable focus was placed on program execution, labeling specifications, and the financial advantages of this program. The initiative offers the FDA's Center for Drug Evaluation and Research tremendous scientific knowledge and pharmaceutical resources in addition to the major economic advantages. This exceptional scientific database, which includes examples of product shelf life, problems with their long-term stability, and various physical and chemical tests to identify such failures, provides a wealth of regulatory research opportunities to enhance public health. The database also acts as a scientific tool for analyzing mechanisms and identifying test failures that result in the creation of new formulas or more durable packaging. It is acknowledged that SLEP plays

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

a crucial role in preserving the public's welfare and national security by ensuring that pharmaceutical items on hand continue to meet quality criteria after the "expiration date" set by the sponsor. Research on the SLEP is an illustration of the regulatory science required to best ensure product functioning after the initial shelf life. This article's main goal is to outline the SLEP's history, background, and most importantly public health advantages (Khan SR, et al. ).

**Results**

The results presented in this chapter were obtained from the statistical analysis of the tool used in this study; the GDP questionnaire.

**Descriptive Results**

Findings from descriptive analysis show the characteristic variables of the respondents and effectiveness-related variables

Socio-Demographic Characteristics of the Study Participants

This part presented the results obtained from the participants who are working in the GDP. Their total number was 21 participants. The participants' characteristics, including age, qualification, job title, and years of experience, were analyzed. The majority of participants in the age group of 40–47 of 12 (57.1%) and 9 (42.9%) were aged 30–39 years, the mean age was 39.571±4.863 years. Also, 12 (57.1%) of study participants have bachelor's degrees. In addition, 11 (52.4%) were heads of departments and 8 (38.1%) were subordinates. Moreover, 8 (38.1%) have an experience of 11–15 years, and 7 (33.3%) have an experience of 16–22 years. The distribution of Study Participants by Gender (GDP), the study shows that (47.6%) of study participants were males and (52.4%) were females.

**Effectiveness of the SLEP as Perceived by the Staff in the General Directorate of Pharmacy**

Table (2) presents the total evaluation of SLEP as perceived by the staff in the GDP, SLEP is a joint program of the US Department of Defense (DOD) and the Food and Drug Administration (FDA) that aims to reduce the cost to the military of maintaining stockpiles of certain pharmaceuticals by researching the expiration of drugs. It tests medications for safety and stability for extended periods in controlled storage conditions. In many cases, medications tested were found to be effective for years past their printed expiry dates; a 2006 study by the Journal of Pharmaceutical Sciences found that two-thirds of 122 medications tested through SLEP remained effective for a mean of a minimum of four additional years. In 2016, the DoD reported that the program had helped save the

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

**Table** (1): Distribution of Study Participants by Sociodemographic Characteristics

| Variable | Frequency "n" | Percent % |
|---|---|---|
| Age | | |
| 30 – 39 years | 9 | 42.9 |
| 40 – 47 years | 12 | 57.1 |
| Total | 21 | 100.0 |
| Mean age = 39.571 SD = ± 4.863 years | | |
| Qualification | | |
| Bachelor degree | 12 | 57.1 |
| Master degree | 9 | 42.9 |
| Total | 21 | 100.0 |
| Job title | | |
| Subordinate (pharmacist) | 8 | 38.1 |
| Head of the department | 11 | 52.4 |
| Director of Directorate | 2 | 9.5 |
| Total | 21 | 100.0 |
| Years of experience | | |
| 5 – 10 years | 6 | 28.6 |
| 11 – 15 years | 8 | 38.1 |
| 16 – 22 years | 7 | 33.3 |
| Total | 21 | 100.0 |
| Mean experience = 13.238 SD = ± 5.146 years | | |

department $2.1 billion on replacing stockpiled medications. ( Lyon et al., 2006). The overall mean score was 4.124 and the weighted percentage was 82.4%, which indicated that the staff who are working in the GDP evaluated the SLEP as highly effective.

**Table** (2): Evaluation of the Effectiveness of the SLEP as Perceived by the Staff in the GDP

| Items | | Mean | SD (±) | Weighted % | Rank |
|---|---|---|---|---|---|
| 1 | Follow up the quantity of stock for the items whose shelf-life can be extended in the central drug stores | 4.164 | 0.341 | 83.2 | 2 |
| 2 | Mechanisms of receiving items and the storage conditions in the CDS | 4.152 | 0.426 | 83.0 | 3 |
| 3 | The quality of the items whose shelf life is extended in the CDS and the availability of alternatives | 4.064 | 0.500 | 81.2 | 5 |
| 4 | Scientific sources and studies of the SLEP | 4.067 | 0.499 | 81.3 | 4 |
| 5 | Labeling of the extended drugs | 4.285 | 0.488 | 85.7 | 1 |
| 6 | The impact of the SLEP on the shortage of drugs in the MOH | 4.010 | 0.515 | 80.2 | 6 |
| Total | | 4.124 | 0.369 | 82.4 | |

The results show that the highest score was in the domain “Labeling of the extended drugs” with a mean score of 4.285 and weighted percentage of 85.7%, followed by “Follow up the quantity of stock

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

for the items that shelf-life can be extended in the CDS" with mean score 4.164 and weighted percentage 83.2%. The lowest score was in "The impact of the SLEP on the shortage of drugs in the MOH" with a mean score of 4.010 and a weighted percentage of 80.2%.

**Follow up on the Quantity of Stock for the Items That Shelf Life Can be extended in CDS**

Table (3) shows that the weighted mean for follow-up of the quantity of stock for the items whose shelf life can be extended in the CDS was 83.2%, which indicated a high degree of follow-up for the extended drugs in the CDS.

According to the results, the highest score was in "Items are disbursed from the warehouse according to the FEFO" with a mean score of 4.666 and a weighted percentage of 93.3%, which means that participants strongly agreed on this item, these findings confirm with WHO stock control manual. Followed by three items with the same mean score of 4.476 and weighted percentage of 89.5% "There is a computerized system that enables good inventory control", "The quantities of items in stock and their financial value are monitored periodically" and "Lists of quantities of items required for purchase are prepared based on monthly consumption rates and shelf life of the item". The lowest score was in "The supply of items whose expiry date is less than three months is repeated in large quantities" with a mean score of 3.047 and weighted percentage of 60.9%, followed by "The supply of items whose expiry date is less than three months is repeated with high financial cost" with mean score 3.142 and weighted percentage 62.8%.

**Mechanisms of Receiving Items and the Storage Conditions in Central Drug Store**

Table (4) presents the responses of study participants about the mechanisms of receiving items and the storage conditions in the CDS. The results show that the total mean score was 4.152 and a weighted percentage of 83%, which indicated a high standard mechanism of receiving and storing drugs. According to the results, the highest score was in "There is an approved ministerial committee to receive the items in the warehouses" with a mean score of 4.619 and weighted percentage of 92.3%, followed by two items with the same mean score of 4.476 and weighted percentage 89.5%. "There is an approved mechanism for the Receipt Committee to receive items and inspect them upon receipt" and "The expiry date is confirmed upon receipt so that at least two-thirds of the stated expiration dates".

The lowest score was in "Check the suitability of the transport and storage conditions of the items

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

before receiving them" with a mean score of 3.761 and a weighted percentage of 75.2%, followed by an item with a mean score of 3.904 and a weighted percentage of 78%. "The temperature and humidity of all items are controlled according to the storage conditions blog on the products".

**Table (3):** Follow up the Quantity of Stock for the Items That Shelf Life Can be extended in CDS

| Items | | Mean | SD(±) | Weighted % | Rank |
|---|---|---|---|---|---|
| 1 | There is a computerized system that enables good inventory control | 4.476 | 0.601 | 89.5 | 2 |
| 2 | The quantities of items in stock and their financial value are monitored periodically | 4.381 | 0.497 | 87.6 | 3 |
| 3 | The expiration date of items in the store is periodically followed | 4.476 | 0.511 | 89.5 | 2 |
| 4 | Lists of quantities of items required for purchase are prepared based on monthly consumption rates and shelf life of the item | 4.476 | 0.511 | 89.5 | 2 |
| 5 | Items with an expiry date of less than three months are quantified periodically in terms of quantity and financial value | 4.238 | 0.624 | 84.7 | 4 |
| 6 | Periodic reports are issued for items with an expiry date of less than three months | 4.238 | 0.624 | 84.7 | 4 |
| 7 | The quantity is evaluated for the items in which the shelf life will be extended | 4.381 | 0.497 | 87.6 | 3 |
| 8 | The financial cost of the items in which the shelf life will be extended is evaluated | 4.238 | 0.538 | 84.7 | 4 |
| 9 | Items are disbursed from the warehouse according to the FEFO | 4.666 | 0.483 | 93.3 | 1 |
| 10 | Contact with the competent authorities of SLEP for items to be extended before enough time of expiration | 4.238 | 0.624 | 84.7 | 4 |
| 11 | The supply of items whose expiry date is less than three months is repeated in large quantities | 3.047 | 1.071 | 60.9 | 7 |
| 12 | The supply of items whose expiry date is less than three months is repeated with high financial cost | 3.142 | 1.062 | 62.8 | 6 |
| 13 | There is a report showing the justification for the expiration of the item before the shelf life can be extended | 4.142 | 0.792 | 82.8 | 5 |
| Total | | 4.164 | 0.341 | 83.2 | |

## The Quality of the Items Who's Shelf Life Is Extended in the Central Drug Store and the Availability of Alternatives

Table (5) presents the responses of study participants about the quality of the items whose shelf life is extended in the CDS and the availability of alternatives. The total mean score was 4.064 and the weighted percentage was 81.2%.

The results showed that the highest score was in two items "Items whose shelf life is extended have insufficient valid stock" and "Items whose shelf life is extended are difficult to provide in a short time" with the same mean score of 4.285 and weighted percentage 85.7% which means that participants

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

strongly agreed on these items.

**Table (4):** Mechanisms of Receiving Items and the Storage Conditions in CDS

| Items | | Mean | SD (±) | Weighted % | Rank |
|---|---|---|---|---|---|
| 1 | There is an approved ministerial committee to receive the items in the warehouses | 4.619 | 0.497 | 92.3 | 1 |
| 2 | There is an approved mechanism for the Receipt Committee to receive items and inspect them upon receipt | 4.476 | 0.601 | 89.5 | 2 |
| 3 | The expiry date is confirmed upon receipt so that at least two-thirds of the stated expiration date | 4.476 | 0.511 | 89.5 | 2 |
| 4 | Items that do not meet the specifications stated in the supply orders shall be rejected | 4.095 | 0.538 | 81.9 | 4 |
| 5 | Check the suitability of the transport and storage conditions of the items before receiving them | 3.761 | 0.768 | 75.2 | 8 |
| 6 | Separate items that do not meet the specifications and expired items in a place isolated from the rest of the items | 3.952 | 0.740 | 79.0 | 6 |
| 7 | Good storage specifications are followed when storing received items | 4.000 | 0.632 | 80.0 | 5 |
| 8 | The temperature and humidity of all items are controlled according to the storage conditions blog on the products | 3.904 | 0.830 | 78.0 | 7 |
| 9 | The competent authority shall ensure the storage conditions of the items to be extended in the central drug stores | 3.952 | 0.973 | 79.0 | 6 |
| 10 | The competent authority shall limit the number of items to be extended and inspect the shelf life before deciding to extend it | 4.285 | 0.462 | 85.7 | 3 |
| Total | | 4.152 | 0.426 | 83.0 | |

**Table** (5): The Quality of the Items whose Shelf Life is extended in the CDS and the Availability of Alternatives

| Items | | Mean | SD (±) | Weighted % | Rank |
|---|---|---|---|---|---|
| 1 | There is an accredited committee to study the items to be extended | 4.238 | 0.830 | 84.7 | 2 |
| 2 | There is an approved manual and procedures for studying the items for which the shelf life is extended | 4.047 | 0.864 | 80.9 | 4 |
| 3 | The items for which the shelf life is extended are items of basic services such as (surgery, emergency, etc.). | 4.238 | 0.624 | 84.7 | 2 |
| 4 | Items for which the shelf life is extended are items of high financial value | 4.095 | 0.624 | 81.9 | 3 |
| 5 | Items whose shelf life is extended have insufficient valid stock | 4.285 | 0.560 | 85.7 | 1 |
| 6 | Items whose shelf life is extended do not have a valid alternative stock | 4.238 | 0.624 | 84.7 | 2 |
| 7 | Items whose shelf life is extended are difficult to provide in a short time | 4.285 | 0.717 | 85.7 | 1 |
| 8 | Items for which the shelf life is extended are items that are available in large quantities stock above the monthly consumption | 3.619 | 1.203 | 72.3 | 7 |
| 9 | Items for which the shelf life is extended are items used only within the hospital departments | 3.952 | 0.920 | 79.0 | 5 |
| 10 | Items whose shelf life is extended cannot be funded | 4.047 | 0.804 | 80.9 | 4 |
| 11 | Items whose shelf life is extended are items originating from irregular donations | 3.666 | 0.730 | 73.3 | 6 |
| Total | | 4.064 | 0.500 | 81.2 | |

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

**Scientific Sources and Studies of the Shelf Life Extension Program**

Table (6) shows that the weighted mean for scientific sources and studies of the SLEP was 81.3%, and the mean score was 4.067 which means that participants highly agreed on scientific sources and studies of the SLEP.

According to the results, the highest score was in "Select the items to be extended based on the possibility of analysis in laboratories accredited by the MOH" with a mean score of 4.381 and a weighted percentage of 87.6%, which means that participants strongly agreed on this item, followed by four items with the same mean score 4.190 and weighted percentage 83.8% "The committee shall study the items to be extended each item separately", "There are standard operating procedures adopted for the shelf life extension mechanism in the MOH", "The inability to analyze some items included in the program is one of the most important obstacles that prevent the extension of the shelf life of the items" and " The stability of the items for which the shelf life is extended is studied according to the approved scientific references"

The study conducted by (MOH, 2015) mentions the main steps in SLEP of stability studies, method of analysis, and previous reports and studies about items to be extended.

In another direction, there is a study conducted by (Khan SR, et al. J Pharm Sci. 2014) that the program also provides the FDA's Center for Drug Evaluation and Research with significant scientific understanding and pharmaceutical resources. As a result of this unique resource, numerous regulatory research opportunities to improve public health present themselves from this distinctive scientific database, which includes examples of products' shelf life, their long-term stability issues, and various physical and chemical tests to identify such failures.

The lowest score was in "Scientific studies and information about the application mechanisms of extending the shelf life of drugs are available locally" with a mean score of 3.619 and a weighted percentage of 72.3% which means that participants moderately agreed about this item. The head of DCD explained that the SLEP is a new program applied locally and faces many challenges in conveying information about the program.

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

**Table (6):** Scientific Sources and Studies of the SLEP

| Items | | Mean | SD (±) | Weighted % | Rank |
|---|---|---|---|---|---|
| 1 | There is a scientific committee to provide studies and information about the mechanisms of applying the SLEP | 4.095 | 0.889 | 81.9 | 4 |
| 2 | Scientific studies and information about the application mechanisms of extending the shelf life of drugs are available globally and regionally | 4.047 | 0.804 | 80.9 | 5 |
| 3 | Scientific studies and information about the application mechanisms of extending the shelf life of drugs are available locally | 3.619 | 1.116 | 72.3 | 8 |
| 4 | Relying on scientific studies and documented information related to the mechanisms of applying the extension of shelf life | 3.952 | 0.740 | 79.0 | 6 |
| 5 | The committee shall study the items to be extended each item separately | 4.190 | 0.511 | 83.8 | 2 |
| 6 | There are standard operating procedures adopted for the shelf life extension mechanism in the MOH | 4.190 | 0.601 | 83.8 | 2 |
| 7 | Select the items to be extended based on the possibility of analysis in laboratories accredited by the MOH | 4.381 | 0.589 | 87.6 | 1 |
| 8 | The inability to analyze some items included in the program is one of the most important obstacles that prevent the extension of the shelf life of the items | 4.190 | 0.813 | 83.8 | 2 |
| 9 | Previous studies on shelf life extension are examined for each item | 4.142 | 0.792 | 82.8 | 3 |
| 10 | The stability of the items for which the shelf life is extended is studied according to the approved scientific references | 4.190 | 0.601 | 83.8 | 2 |
| 11 | Items with a narrow therapeutic index are excluded | 4.095 | 0.700 | 81.9 | 4 |
| 12 | Taking account the extension of the shelf life the source varieties of drugs and names of manufacturers | 3.714 | 1.007 | 74.2 | 7 |
| Total | | 4.067 | 0.499 | 81.3 | |

## Labeling of the Extended Drugs

Table (7) presents the responses of study participants about the labeling of the extended drugs. The results showed that the highest score was in “Labels are placed in such a way that the new expiration date can be easily seen” with a mean score of 4.571 and a weighted percentage of 91.4%, followed by “The establishment of the label of each item is a prerequisite to allowing it to be spent inside the Ministry's facilities” with mean score 4.523 and weighted percentage 90.4%.

These results are very close to the U.S. DOD in cooperation with the FDA regarding SLEP. Relabeling products granted an expiration date extension must be relabeled according to (CGMPs) and other FDA regulations (Leissa B. et, al.2010).

The lowest score was in “The cost of the labeling is studied for the items whose shelf life is extended” with a mean score of 3.428 and a weighted percentage of 68.5%.

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

The head of DCD explains that the cost of relabeling is simple and insignificant. It does not constitute an obstacle in the application of SLEP.

Table (7): Labeling of the Extended Drugs

| Items | | Mean | SD ( ±) | Weighted % | Rank |
|---|---|---|---|---|---|
| 1 | The cost of the labeling is studied for the items whose shelf life is extended | 3.428 | 1.164 | 68.5 | 5 |
| 2 | The establishment of the label of each item is a prerequisite to allow it to be spent inside the Ministry's facilities | 4.523 | 0.511 | 90.4 | 2 |
| 3 | Labels are placed in such a way that the new expiration date can be easily seen | 4.571 | 0.507 | 91.4 | 1 |
| 4 | The new label completely covers the previous expired date | 4.428 | 0.676 | 88.5 | 4 |
| 5 | The labels are positioned to include the new date and batch number | 4.476 | 0.601 | 89.5 | 3 |
| Total | | 4.285 | 0.488 | 85.7 | |

**The Impact of the Shelf Life Extension Program on the Shortage of Drugs in the Ministry of Health**

Table (8) presents the responses of study participants about the impact of the SLEP on the shortage of drugs in the MOH. The results showed that the highest score was in “Extending the shelf life of the items has contributed to reducing patients 'suffering of drugs shortage” with a mean score of 4.190 and weighted percentage of 83.8%, followed by “Extending the shelf life of the items provide emergency items to the Ministry's facilities” with mean score 4.142 and weighted percentage 82.8%.

These findings along with the memorandum of emergency extension for the expiration of selected field medications in California in 2013, review the process of SLEP for County EMS authorization to extend the expiration date for medications used to treat life-threatening field conditions. Extension of expiration for specific medications has become necessary because of persistent national pharmaceutical shortages (California EMS, 2013).

The justification for extending the expiration of specific medications is that treatment of a life-threatening condition with a medication that is available beyond shelf-life expiration is preferred over no treatment (Utah Bureau of EMS, 2013).

The head of CDS explains that this is long-standing with what the Israeli Ministry of Health has done to extend the shelf life of an anti-scorpion as an emergency item due to the unavailability of the item in the local markets and unavailability in its stockpile. The extension process is an appropriate solution as an emergency measure and as a response to provide a life-saving item that is not available in the local market.

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

The lowest score was in "Extending the shelf life of the items the therapeutic protocols in the Ministry's facilities did not stop" with a mean score of 3.714 and a weighted percentage of 74.2%.

The head of CDS explained that the number of extended items does not rise to a significant continuation of treatment protocols, as it contributed to a partial solution to the drug shortage crisis and the continuation of a therapeutic protocol consisting of several items and the continuation of the therapeutic service. SLEP has a role in the emergency service and treatment protocols related to emergencies.

**Table (8):** The Impact of the SLEP on the Shortage of Drugs in the MOH

| Items | | Mean | SD (±) | Weighted % | Rank |
|---|---|---|---|---|---|
| 1 | Extending the shelf life of the items has contributed to reducing patients 'suffering from drug shortage | 4.190 | 0.980 | 83.8 | 1 |
| 2 | Extending the shelf life of items keeps the quality of service provided to the patient | 4.000 | 0.948 | 80.0 | 4 |
| 3 | Extending the shelf life of the items reduces the financial cost to the patient | 4.000 | 0.774 | 80.0 | 4 |
| 4 | Extending the shelf life of the items provides emergency items to the Ministry's facilities | 4.142 | 0.478 | 82.8 | 2 |
| 5 | Extending the shelf life of the items contributes to the continued provision of therapeutic service to patients in the Ministry's facilities | 4.095 | 0.436 | 81.9 | 3 |
| 6 | Extending the shelf life of the items leads to the benefit of irregular donations in the ministry | 3.952 | 0.669 | 79.0 | 5 |
| 7 | Extending the shelf life of the items prevents the therapeutic protocols in the Ministry's facilities to stop | 3.714 | 0.717 | 74.2 | 6 |
| 8 | Extending the shelf life of the items reduces the damage to many items necessary for patients | 4.000 | 0.547 | 80.0 | 4 |
| 9 | Extending the shelf life of the items contributes to reducing the financial cost needed to provide these drugs to the ministry | 4.000 | 0.547 | 80.0 | 4 |
| Total | | 4.010 | 0.515 | 80.2 | |

**Inferential Results**

According to the Mann-Whitney test male staff obtained statistically significant higher scores in the following domains: "Follow up the quantity of stock for the items that shelf-life can be extended in the CDS" (P= 0.019), "Mechanisms of receiving items and the storage conditions in central drug stores" (P= 0.026), "Scientific sources and studies of the SLEP" (P= 0.016), "Labeling of the extended drugs" (P= 0.000), and overall score (P= 0.020). This result means that male staff expressed significantly higher evaluation of the effectiveness of the SLEP compared to female staff. The results are expected to be related to the larger number of male staff that working in the DCD and in managing the SLEP, for example, the SLEP committee consist of three male versus one female, and in the CDS the majority of heads of departments are male (MOH, 2019).

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

## Discussion

### Socio-Demographic Characteristics of the Study Participants

The majority of participants in the age group of 40–47 of 12 (57.1%) and 9 (42.9%) were aged 30–39 years, the mean age was 39.571±4.863 years so this is proportional to the rate of employment after the Palestinian division from 2007 to 2019 (MOH, 2019). Moreover, 8 (38.1%) have an experience of 11–15 years, and 7 (33.3%) have an experience of 16–22 years the same as above this is proportional to the rate of employment after the Palestinian division from 2007 to 2019 (MOH, 2019).

Effectiveness of the SLEP as Perceived by the Staff in the General Directorate of Pharmacy

The results are consistent with those mentioned above about the labeling of extended drugs. The relabeling does not constitute an obstacle in the application of SLEP, and this is confirmed by the head of CDS added that the labeling illustrates the extended item to prevent any misuse of the items.

The lowest score was justified by the head of CDS explaining the situation, assuring that the drug shortage is significant and the SLEP helps partially cover the shortage is so large that the SLEP covers the shortage, as it is a limited part of the solution. Therefore, the MOH needs larger practical plans to eliminate the shortage and does not depend on it mainly. He added that the SLEP was one of the solutions to the drug shortage crisis in intermittent periods of siege and aggressive attacks from the Israeli army.

### Follow up on the Quantity of Stock for the Items That Shelf Life Can be extended in CDS

Participants strongly agreed that “Items are disbursed from the warehouse according to the FEFO” this item, These findings confirm with WHO stock control manual. Followed by three items with the same score this is consistent with the mission of the storekeeper to specify the number of items required for purchase based on monthly consumption rates and shelf life of the items, another mission is to prepare monthly reports about items of near expiration to take the necessary measures to deal with them according to the system, provided that there is sufficient time to deal with the available quantities before their expiry date (MOH, 2013).

participants weakly agreed on “The supply of items whose expiry date is less than three months is repeated in large quantities”. The head of CDS explains that the basis of SLE depends on the availability of the items ( purchase, supply, alternatives) and the urgent need of the hospital for the

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

items. So the SLE does not depend on the high quantities of the items or the high financial cost of them.

**Mechanisms of Receiving Items and the Storage Conditions in Central Drug Store**

The findings stand with what is mentioned in the stored procedures manual (MOH, 2013b).

While the lowest score was consistent with the head of CDS explaining that the items who are the transport conditions controlled those that are supplied by international organizations such as WHO or ICRC, but the transport and storage conditions for those that are supplied from donations or MOH purchase meant does not control, There is no requirement for supplier companies to follow the transport and storage conditions

The head of CDS mentions that the CDS suffering from a shortage of means for monitoring the storage and transport conditions of humidity and temperature in different departments. This is consistent with the Gaza situation report (WHO, 2006); the purchased drugs of uninsured storage conditions during transport badly affect quality assurance.

**The Quality of the Items Who's Shelf Life Is Extended in the Central Drug Store and the Availability of Alternatives**

The total score indicated the causes of SLE of drugs. The findings were reinforced by the head of DCD for the reasons that prompted us to implement the SLEP at a time of drug shortage crisis and according to the GDP annual report, at the end of the year 2012, the shortage percent reached 33.5% from the Essential Drug List (EDL) drugs stock, so we did not have many choices to deal with drug shortage just by taking right practical steps, thus improving the stock.

The head of CDS explained the situation, and he assured that in general, the store would keep 6 months of drugs needed for an ideal strategic stock, but in reality, the stock at the Gaza CDS has at most one month, some less and some stocked out. But in reality, the CDS suffered from a severe chronic drug shortage for several years as a result of the continuous siege that caused the drug shortage, these situations forced the MOH to respond to the continuous shortage using the SLEP as an alternative solution. (MOH, 2019). There are four strategic objectives for the interagency document for good pharmaceutical procurement issued by WHO, UNICEF, UNFPA, and the World Bank (WHO, 2001):

- Procure the most cost-effective drugs in the right quantities.
- Prequalify reliable suppliers of high-quality products.
- Ensure timely delivery.

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

- Achieve the lowest possible total cost.

The head of CDS explained that according to the CDS in the GS, the procurement is not done systematically or periodically, this is consistent with WHO that the procurement is done according to the requirements from clinics and hospitals of the WB and the GS that have been consolidated by their respective CDS (WHO, 2006). The main issue faced regarding procurement is the high price of medicines that may reach up to eight times the international price, this is due to the Paris Agreement with Israel, which confines medicines' procurement from companies that are registered in Israel, this leads to a shortage of a real competition and high market entry barriers for international companies per-bidders (WHO, 2010). Another issue is the delaying of delivery by some suppliers (WHO, 2006). These findings were contradicted by the SLEP administered by the U.S. DOD in cooperation with the U.S. FDA as emergency procedures of the federal SLEP that extend the expiration dates on qualifying drugs and other materials in federal stockpiles. The purpose of SLEP is to defer replacement costs of stockpiled drugs by extending their useful life (U.S. Army., 2012).

The lowest score was compatible with what was mentioned in Table (2) and with the head of CDS that the SLE does not depend on the high quantities of the items or the high financial cost of them.

A significant part of the medicines are provided through donations (MOH and United States Agency for International Development-USAID, 2008), Some of the donated items are not needed or are already in inadequate supply or are expired and have not been quality assured. The management of these unneeded donations added to the burden on the MOH (WHO, 2011).

So the head of CDS indicated that items of medicines and medical supplies received from donations to the GS through the Rafah crossing are not coordinated with the MOH according to the real needs, The MOH works hard to coordinate the donations and there is no intention to reuse it according the SLEP. The head of CDS added that there is a committee to evaluate and maximize the benefit from donations for optimal use within a specific mechanism that does not depend on extending the shelf life for it (MOH, 2019), but the SLEP is not a priority to take advantage of the donations. The head of CDS assured that the criterion of the SLEP is the drug shortage and the urgent need in the absence of alternatives and benefiting from donations if it is an urgent need for use according to the donation evaluation committee.

The head of DCD explains that in the year 2013, the CDS in Gaza had received drugs in value of 23.7 million United States dollars from three main sources: donations which represented the largest

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

proportion of supply (55.8%), Gaza MOH procurements (22.3%), and Ramallah CDS (21.9%), but this is still not enough for the average annual needs of drugs that reach around 35 million United States dollars (MOH, 2014). The continuous shortage of emergency drugs and the high value of donations of near expiration forced the MOH to manage the problem, by applying the SLEP. Therefore, justifications for the application of the SLEP can be summarized according to the results as insufficient valid stock of the urgent emergency extended items that cannot be provided in a short time.

**Scientific Sources and Studies of the Shelf Life Extension Program**

The study conducted by (MOH, 2015) mentions the main steps in SLEP of stability studies, method of analysis, and previous reports and studies about items to be extended.

On the other direction, there is a study conducted by (Khan SR, et al. J Pharm Sci. 2014) that the program also provides the FDA's Center for Drug Evaluation and Research with significant scientific understanding and pharmaceutical resources. As a result of this unique resource, numerous regulatory research opportunities to improve public health present themselves from this distinctive scientific database, which includes examples of products' shelf life, their long-term stability issues, and various physical and chemical tests to identify such failures. The lowest score was in “Scientific studies and information about the application mechanisms of extending the shelf life of drugs are available locally” with a mean score of 3.619 and a weighted percentage of 72.3% which means that participants moderately agreed about this item. The head of DCD explained that the SLEP is a new program applied locally and faces many challenges in conveying information about the program.

**Labeling of the Extended Drugs**

The results are very close to the U.S. DOD in cooperation with the FDA regarding SLEP. Relabeling products granted an expiration date extension must be relabeled according to (CGMPs) and other FDA regulations (Leissa B. et, al.2010). The lowest score was in “The cost of the labeling is studied for the items whose shelf life is extended” with a mean score of 3.428 and a weighted percentage of 68.5%.

The head of DCD explains that the cost of relabeling is simple and insignificant. It does not constitute an obstacle in the application of SLEP.

**The Impact of the Shelf Life Extension Program on the Shortage of Drugs in the Ministry of Health**

ISSN:2523-0522
Volume 7: issue 1 , October 2023
ISRAA UNIVERSITY JOURNAL OF APPLIED SCIENCE (IUJAS)

The findings along with the memorandum of emergency extension for the expiration of selected field medications in California in 2013, review the process of SLEP for County EMS authorization to extend the expiration date for medications used to treat life-threatening field conditions. Extension of expiration for specific medications has become necessary because of persistent national pharmaceutical shortages (California EMS, 2013).

The justification for extending the expiration of specific medications is that treatment of a life-threatening condition with a medication that is available beyond shelf-life expiration is preferred over no treatment (Utah Bureau of EMS, 2013).

The head of CDS explained that this is long-standing with what the Israeli Ministry of Health has done to extend the shelf life of an anti-scorpion as an emergency item due to the unavailability of the item in the local markets and unavailability in its stockpile. The extension process is an appropriate solution as an emergency measure and as a response to provide a life-saving item that is not available in the local market lowest score was in "Extending the shelf life of the items the therapeutic protocols in the Ministry's facilities did not stop" with mean score 3.714 and weighted percentage 74.2%.

The head of CDS explained that the number of extended items does not rise to a significant continuation of treatment protocols, as it contributed to a partial solution to the drug shortage crisis and the continuation of a therapeutic protocol consisting of several items and the continuation of the therapeutic service. SLEP has a role in the emergency service and treatment protocols related to emergencies.

**Limitation of the Study**

1. Lack of many previous studies to cover all variables.
2. Inability to cover all governmental hospitals.
3. Inability to cover all HCPs in the hospitals due to time and effort limits.

**Conclusion & Recommendations**

The average score for the assessment of the effectiveness of the SLEP by staff of GDP was found to be 82.4%. This means that the effectiveness of the SLEP by the staff of GDP is of high-level evaluation. This can be attributed to the proper practical steps taken by the GDP regarding the procedures and the principles for dealing with the extended items. It is recommended that the GDP establish regulations and plans in emergencies for efficient management of the CDS stockpiles through the SLEP

to reduce waste associated with frequent replacement of stocks, enabling the maximum benefit of the expired drugs, and generalize these plans for all health workers. A system of monitoring the side effects of the extended drugs to increase the concern about the efficacy and safety of the extended items for the HCPs and the patients should be also established by MOH.

**The Authors' contributions**

Heba Al Basha was the researcher and the main author of the study.
Yousef Aljeesh was the main supervisor and contributed to setting the goals and the population of the study.
Shereen Ayoub was the second supervisor and contributed to setting the questionnaire and editing the result. Nahed Hegazy was an external expert and audited the study.

**Acknowledgment**

I would like to express my deepest gratitude to my advisor, Prof. Yousef Al-Jeesh and Dr. Shereen Ayoub. My appreciation is also extended to the Islamic University of Gaza for its assistance in completing this study. Also, I would like to express my deep appreciation to Dr. Zeyad Abu Hean and Dr. Nizam El-Ashqar for their valuable efforts in teaching us. I would also like to thank the Ministry of Health, especially Dr. Ayman Kordea and Dr. Zakari Abu Qamar for their excellent guidance. Special thanks and gratitude are extended to my friends and colleagues.

**References**

Bajaj, S., Singla, D., & Sakhuja, N. (2012). Stability testing of pharmaceutical products. J App Pharm Sci, 2(3), 129-138.

California (Orange Country) EMS, "Emergency Extension for Expiration of Selected Field Medications." Available at www.astho.org/Programs/Preparedness/Coping-With-Drug-Shortages/Orange-County-California-Drug-Shortage-Advisory/. Accessed 1/22/2013.

Capen, R., Christopher, D., Forenzo, P., Ireland, C., Liu, O., Lyapustina, S., ... & Schwenke, J. (2012). On the shelf life of pharmaceutical products. AAPS PharmSciTech, 13(3), 911-918.
FDA (2019), Web Site,
http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411446.htm [accessed 23 June 2019].

Khan, S.R., Kona, R., Faustino, P.J., Gupta, A., Taylor, J.S., Porter, D.A., et al. (2014) United States Food and Drug Administration and Department of Defense Shelf-Life Extension Program of Pharmaceutical Products: Progress and Promise. Journal of Pharmaceutical Sciences, 103, 1331-1336.

Kiron. S.S., Shirwaikar A., Saritha M., Influence of Storage Conditions on The Shelf Life of Cephalexin

Tablets Stored in Hospital And Community Pharmacies in Different Parts of Kerala. (2014). World Journal of Pharmaceutical Research; Volume 3, Issue 2, 2753-2759
Kopp S., (2011) Policy On Oseltamivir Shelf Life Expiry Draft For Comments. Medicines Quality Assurance Programme, World Health Organization.

Leissa B.et al, (2010). Food and Drug Administration. "Shelf Life Extension Program" presentation at Federal, State, and Local Public Health Preparedness meeting. Baltimore, Maryland. December 14-15, 2010.

Lyon, R. C., Taylor, J. S., Porter, D. A., Prasanna, H. R., & Hussain, A. S. (2006). Stability profiles of drug products extended beyond labeled expiration dates. Journal of Pharmaceutical Sciences, 95(7), 1549-1560.

MOH (2011). Legal Affairs - the era of the Palestinian National Authority -the Council of Ministers Decree No. 162 of 2006 for the Pharmacy Practice Ordinance.Retrieved Nov.22, 2014 from http://www.moh.gov.ps/portal/162-2006/.

MOH (2012). Annual Report of Pharmacy - Gaza Strip 2011. Palestinian Health Information Center-Gaza

MOH (2013a). Annual Report 2013. General Directorate of Pharmacy. Gaza Strip. Palestine

MOH (2013b). Stored procedures manual 2013. General Directorate of Pharmacy. Gaza Strip. Palestine

MOH (2014). Annual Report 2014. General Directorate of Pharmacy. Gaza Strip. Palestine

MOH (2015). Annual Report 2015. General Directorate of Pharmacy. Gaza Strip. Palestine

MOH (2016). Annual Report 2016. General Directorate of Pharmacy. Gaza Strip.

MOH (2017a). Annual Report 2017. General Directorate of Pharmacy. Gaza Strip. Palestine

MOH (2017b). Health Status Indicators in the Gaza Strip. Palestinian Health Information Center- Gaza

MOH (2017c). Health Sector Strategic Plan: Gaza Governorates 2014-2018

MOH (2018a). Annual Report of Pharmacy - Gaza Strip 2018. Palestinian Health Information Center-Gaza

MOH (2018b). Annual Report 2018. General Directorate of Pharmacy. Gaza Strip. Palestine

MOH (2019). Annual Report 2019. General Directorate of Pharmacy.

MOH and United States Agency for International Development-USAID, 2008Gaza Strip. Palestine U.S. Army. Shelf Life Extension Program website. Accessed January 31, 2012.

Utah Department of Health, Division of Family Health and Preparedness, "Utah EMS Medication Shortage Procedure: For Emergency Medication Use Up to Six Months Beyond Labeled Expiration Date" Available at www.health.utah.gov/ems/rulereg/medication_shortage_policy.pdf. Accessed 1/17/2013.

WHO (2001). How to Develop and Implement a National Drug Policy (Second edition). WHO Publications. Retrieved April 8, 2013, from: http://apps.who.int/medicinedocs/en/d/Js2283e/5.4.2.html

WHO (2006). Health Systems Profile- Palestine. Regional Health Systems Observatory- EMRO WHO Regional Office for the Eastern Mediterranean

WHO (2010). Country Cooperation Strategy for WHO and the Occupied Palestinian Territory 2009–2013-Occupied Palestinian Territory. Document EM/ARD/041/E/01.11.Retrieved April 3, 2013 from: http://www.who.int/countryfocus/cooperation_strategy/ccs_pls_en.pdf

WHO (2011). Drug shortages in Gaza: Background Note to the HC. 3 February, 2011. Retrieved April 15, 2012, from http://issuu.com/who-opt/docs/backgroundnote-drugs