Jurnal Surya Medika (JSM)

http://journal.umpalangkaraya.ac.id/index.php/jsm

Literature Review of Practice Evaluation of Good Drug Distribution Methods at Public and Private Sector Pharmaceutical Distribution Facilities in Indonesia

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Abstrak

To ensure that the quality of pharmaceutical products is maintained throughout the distribution chain, it is necessary to implement Good Distribution Practices at distribution facilities that distribute pharmaceutical products. This literature review explores the evaluation of Good Drug Distribution (GDP) or CDOB guideline practices in pharmaceutical product distribution facilities engaged in the public and private sectors in Indonesia. The literature review method used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol. Articles were searched using the Google Scholar database and restricted to those related to GDP published from 2018 to 2022. The literature was reviewed using questions to assess studies organized by Population, Exposure, and Outcome (PEO) criteria. Articles obtained were then identified, screened, eligibility, then selected based on inclusion and exclusion criteria resulting in 19 pieces that will be extracted data. Of the 19 articles, the study was conducted in several pharmaceutical distribution facilities such as the Health Office, Puskesmas, Hospitals, Pharmacies, and Pharmaceutical Wholesalers spread across Indonesia. All articles used descriptive methods to show the conformity of implementing Good Distribution Practices guidelines. Some studies still do not use the latest regulation, namely the Food and Drug Administration Regulation Number 6 of 2020 concerning Amendments to BPOM Regulation Number 9 of 2019 concerning Technical Guidelines for Good Distribution Methods. The suggestions that can be made include the need for studies related to the evaluation of Good Distribution Practices of pharmaceutical distribution facilities in the public or government sector and studies on distribution facilities in Eastern Indonesia.

Kata Kunci:
GDP
Pharmaceutical Products
Distribution Facilities

Keywords:
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Abstract

To ensure that the quality of pharmaceutical products is maintained throughout the distribution chain, it is necessary to implement Good Distribution Practices at distribution facilities that distribute pharmaceutical products. This literature review explores the evaluation of Good Drug Distribution (GDP) or CDOB guideline practices in pharmaceutical product distribution facilities engaged in the public and private sectors in Indonesia. The literature review method used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol. Articles were searched using the Google Scholar database and restricted to those related to GDP published from 2018 to 2022. The literature was reviewed using questions to assess studies organized by Population, Exposure, and Outcome (PEO) criteria. Articles obtained were then identified, screened, eligibility, then selected based on inclusion and exclusion criteria resulting in 19 pieces that will be extracted data. Of the 19 articles, the study was conducted in several pharmaceutical distribution facilities such as the Health Office, Puskesmas, Hospitals, Pharmacies, and Pharmaceutical Wholesalers spread across Indonesia. All articles used descriptive methods to show the conformity of implementing Good Distribution Practices guidelines. Some studies still do not use the latest regulation, namely the Food and Drug Administration Regulation Number 6 of 2020 concerning Amendments to BPOM Regulation Number 9 of 2019 concerning Technical Guidelines for Good Distribution Methods. The suggestions that can be made include the need for studies related to the evaluation of Good Distribution Practices of pharmaceutical distribution facilities in the public or government sector and studies on distribution facilities in Eastern Indonesia.

 DOI: https://doi.org/10.33084/jsm.v10i1.4851

INTRODUCTION

Distribution is an important activity in the management of pharmaceutical product supply-chain management (1). This activity cannot be separated from the role of distribution facilities and the government, especially in Indonesia. The principles in this distribution activity must refer to aspects of the Good Manufacturing Process (GMP) or the Good Drug Distribution Practice (GDP) is called CDOB in Indonesia to ensure the quality of pharmaceutical products (2). The aim of consistently implementing CDOB is to secure the drug distribution channel from the rampant circulation of illegal drugs including counterfeit drugs, minimize the distribution of drugs to illegal facilities, other distribution irregularities and misuse of drugs by the public. In supply chain management, all activities and decisions must be coordinated and involve all stakeholders to ensure that all pharmaceutical products are safe until they reach consumers, distributed in the right amount, to the right location and at the right time. In terms of supporting the implementation of this activity, it cannot be separated from the role of the government, especially the Directorate of Drug Distribution and Service Supervision and the POM Center.

Based on the 2020 and 2021 annual reports of the Indonesian Food and Drug Agency, the Directorate of Monitoring the Distribution and Service of Narcotic Drugs, Psychotropic Substances and Precursors, the results of examinations from all major centers and POM workshops, a total of 373 Pharmaceutical Wholesaler or PBFs were found to Not Meet the Conditions (3,4) . As for the supervision of pharmaceutical service facilities such as pharmacies, pharmaceutical installations of health offices and hospitals, a total of 1,372 pharmacies, 122 health centers, 15 government hospitals and 43 private hospitals did not meet the provisions.4. Inspection of distribution facilities is also carried out at Provincial / Regency / City pharmaceutical installations related to the management of cold chain products. In the inspection, 233 IFPs were found to Not Meet the Conditions (3). In these results, not all distribution facilities are said to have met the provisions, it is feared that this will result in problems in drug distribution activities, for example, such as the high burden of disease and costs for the community. The implementation of good distribution practices should be one of the most important aspects to ensure the safe circulation and administration of drugs (5). The distribution chains available from the central, provincial, and local levels in both the public and private sectors have the potential to ensure the quality of medicines. This literature review aims to explore the evaluation of good drug distribution practices in pharmaceutical product distribution facilities operating in the public and private sectors in Indonesia.

METHODOLOGY

The method used in the research is descriptive research with a scoping review method. The literature and reference articles used relate to the evaluation of Good Drug Distribution Practices (CDOB) in drug distribution facilities engaged in the public and private sectors. This literature review uses the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) method (6). PRISMA stages consist of identification, screening, eligibility, inclusion and exclusion criteria, article mapping and summarizing results. The literature review was conducted using questions to assess the studies based on Population, Exposure and Outcome (PEO) criteria (7). This questionnaire was used to determine inclusion and exclusion criteria, describe the research problem and search for keywords.

Table I. PEO Framework

Framework	Scope
Population	Means of distribution of pharmaceutical
Exposure	Compliance with GDP guidelines
Outcome	Implementation of GDP practices

The article search was conducted using the Google Scholar database. Data was retrieved from January 12, 2023 to January 14, 2023 with the limitation of article publications from 2017 to 2022. The keywords used were evaluation OR implementation; distribution OR CDOB; PBF OR pharmacy OR pharmaceutical installation OR drug distribution facility. The literature used will be reviewed based on inclusion and exclusion criteria according to the title or abstract of the topic under study.

Table II. Insclusion and exclusion criteria

Inclusion	Exclusion
Article in Indonesian	English article
Topics or themes relevant to research	Literature that includes review articles
Research conducted in the public and private sectors	Not published through Google Scholar
Published between 2018-2022	

Data extraction was performed on articles that met the inclusion criteria. The data in the articles were then summarized in a list form grouped by article title, author, year, method results and conclusions. After obtaining the extracted data, it was then combined descriptively to provide an overview of good drug distribution practices in various distribution channels in the public and private sectors.

RESULTS AND DISCUSSION

Literature Review Studies

The results of the literature search using the Google Scholar database obtained 100 literatures. Consisting of 75 journals, 10 theses, 15 literature reviews. Literature screening resulted in 40 literatures with relevant titles and abstracts. Then identified based on the inclusion and exclusion criteria resulted in 19 literatures. Then the 19 literatures will be extracted. The flowchart used refers to the PRISMA 2020 template which has been modified based on recent studies (8).

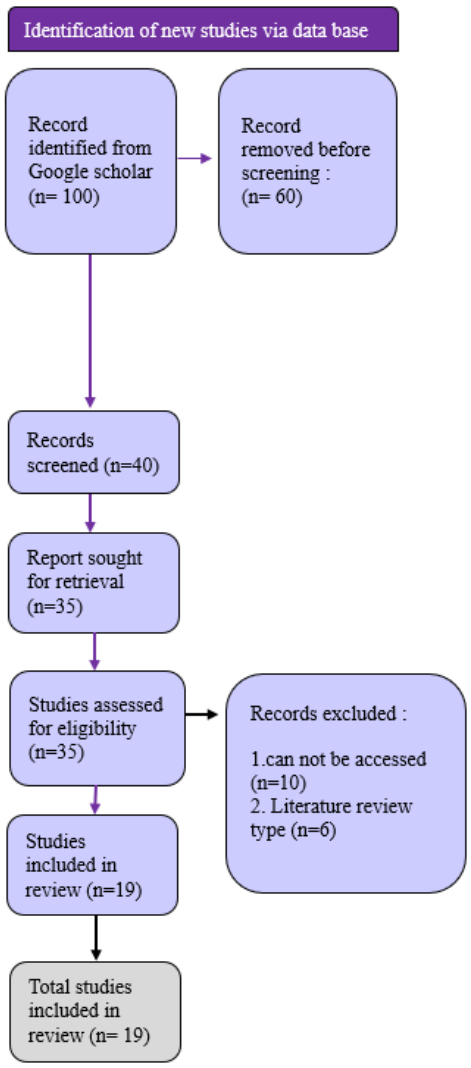

Figure 1. Flow of Literature Identification

From the literature that has been included in the scoping review, there is 1 literature published in 2018, 2 literatures published in 2019, 4 literatures published in 2020, 3 literatures published in 2021, and 9 literature published in 2022. Based on the included literature, there were pharmaceutical wholesalers in the BUMN sector (n = 1), private pharmaceutical wholesalers, pharmacies (n = 2), private hospitals (n = 1), government-owned hospitals (n = 2), health offices and health centers (n = 3). The overall study used a descriptive observational research design in the form of

checklist forms, questionnaires, interviews, and direct observation.

Pharmacy Installation of Health Office and Health Center

Based on the study that discussed CDOB at the Health Office and Puskesmas installations, the results showed that the suitability of the cold chain distribution system, especially vaccines from the Health Office to the Salatiga city Puskesmas based on the 2020 CDOB guidelines, was in the good category with a percentage of 72.72% and 84.21%(9) . Meanwhile, the evaluation study of the implementation of CDOB from the pharmaceutical warehouse of the Health Office to the UPT Puskesmas of Bengkalis Regency in 2022, the results showed that the implementation of CDOB in the pharmaceutical warehouse has not been in accordance with operations. In the projection of drug needs, it is not sufficient because there are still drug vacancies and there are drugs that have expired (10). The study of the implementation of vaccine storage was also carried out at the Mataram city health center. The results of the evaluation of the suitability of storing the Covid-19 vaccine at the Mataram city health center with CDOB in 2020 showed that the average percentage of 4 health centers obtained unfavorable assessment criteria, namely 54% only (11).

Hospital

Based on the evaluation study of CDOB practices in hospitals, the evaluation of cold medicine storage in one private hospital installation in Bandung city shows that it meets the requirements according to CDOB in 2019. From the assessment of acceptance indicators, storage operations and storage temperature, the parameter values obtained are more than 70% (12). From the government hospital sector, there is an evaluation study of the storage of the Covid-19 vaccine at the Madani Regional Hospital, Pekanbaru City, which shows that overall, the storage of the covid 19 vaccine is not in accordance with CDOB regulations in 2020. The percentage results from the checklist sheet, the aspect of personnel and training obtained 33.33% (not good), the aspect of the building 75% (good), the aspect of building facilities 50% (quite good), the operational aspect of storage 84.6% (very good), the aspect of storage maintenance 30.76% (not good) and the aspect of qualification, calibration, and validation 33.33% (not good) (13). Another study related to CDOB evaluation was also conducted at Sungai Bangkong Pontianak Mental Hospital, which is a public hospital owned by the government of West Kalimantan Province. The results showed that the Bangkong River Mental Hospital in the aspect of storage and distribution of narcotic and psychotropic drugs produced a good percentage with a value of 94.743% (14).

Pharmacy Drugstore

CDOB evaluation studies were also conducted at Kawijaya Pharmacy, Pamulang, South Tangerang with research using observation sheets by assessing several aspects such as aspects of the suitability of the number of drugs with stock cards, aspects of the warehouse arrangement system, aspects of expired or damaged drugs, aspects of dead drug stocks, aspects of drug availability levels (15). Another study on CDOB evaluation was also conducted at a pharmacy in Cikupa sub-district, Tangerang. Based on the 2012 CDOB technical guidelines, pharmacies in the Cikupa area obtained a percentage value of CDOB aspects including aspects of facility profiles, aspects of buildings and equipment, aspects of procurement, aspects of receiving and storage, and aspects of handling returned and expired products above 70%, while the distribution and destruction aspects were still below 70% (16).

Pharmaceutical Wholesaler (PBF)

There are 10 studies on the evaluation of CDOB practices spread across several regions in Indonesia. Many studies were conducted in private sector PBFs, and one study was conducted in a state-owned PBF. There were also some studies that did not mention the identity of PBFs in a region, for example in Central

Jakarta, Bandung, Jambi, Banjarmasin, and Bali. Almost all studies used descriptive research with direct observation methods, checklist forms, questionnaires, or interviews. There was 1 study using a quantitative approach with the CIPP (Context, Input, Process, Product) approach method. Data extraction based on research instruments and results are listed in Table 3.

Table III. Data extraction: research instruments and results

Author (year)	Research instruments	Results
Meilyanie Wijaya Adek Chan (2018)	Checklist	Not in accordance with CDOB technical guidelines in 2012. Aspects that are not yet compliate are storage building space and the OHS system (17)
Baharuddin Yusuf, Christina Avanti (2019)	Questionnaires and interviews	26 PBF (86.7%) have implemented more than 80% of CDOB aspects. 3 PBF (10%) apply 65%-80% of CDOB aspects and 1 PBF (3.3%) implemented 50%-64% of CDOB aspects (18)
Ayu Sutrisna Dewi (2019)	Observation with checklist forms and interviews	Aspects of CDOB that are not effectively implemented include aspects of quality management (56%), organization, management and personnel (68%), buildings and equipment (78%), operations (55%), self-inspection (57%), complaints, drugs returns, suspected counterfeits and recalls (45%), transportation (26%), distribution facilities under contract (25%), documentation (40%), and aspects of drug quality assurance (79%) (19)
Magdalena Wahyu Kristanti, Zelika Mega Ramadhania (2020)	Direct observation and interviews	The results of research on the storage system of drugs, supplement, and retail cosmetics in one warehouse PBF in Central Jakarta showed that some of the storage systems that used by the PBF is not in accordance with CDOB (20).
Taufiq Hidayat, Wan Syurya Tri Dharma (2020)	Questionnaires and interviews	The results showed that the application of the CDOB aspect in PBF A (1.84%) and PBF B (0.69%) had not meet the requirements. Meanwhile, the application of the CDAKB aspect at PBF A (0.45%) and PBF B (0.21%) not meet the requirements (21).
Dina Sembiring, Nasrul Wathoni (2021)	Direct observation, checklist and interview	The implementation at this PBF is in accordance with CDOB (22).
Armini Hadriyati, Mukhlis Sanuddin, Deva Ananda (2021)	Direct observation, questionnaires and interviews	The redults of the PBF research are very good category (100%) in implementing CDOB (23).
Novena Zuama, Armini Hadriyati, Deny Sutrisno (2021)	Direct observation, checklist form and interview	The results of the study showed that the percentage of CDOB implementation in one PBF in Jambi City was 96.87% very good. This is based on the CDOB implementation criteria table CDOB if the acquisition score reaches 81%-100%, it is included in the very good category (24).
Fanny SD Saputri, Iyan Sopyan (2022)	Direct observation, checklist form and interview	The results showed that the CDOB aspect of the storage building and equipment in one of the Pharmaceutical Wholesalers in Bandung Cityhad met the requirements (100%) (25).
Oke Juwita Lintogareng, Widya Astuti Lolo, Gerrald E. Rundengan (2022)	Direct observation and interviews	The results of the study related to the nine aspects of CDOB show that PBF has implemented it well (26).
Trya Sukmawati, Armini Hadriyati, Medi Andriani (2022)	Direct observation and interviews	PBF in Jambi is in accordance with BPOM regulations in 2020, namely 73.95% which is categorized as good (27).

From the results of data extraction, there are several studies that use only 1 research instrument, for example using a checklist only, while other studies use a combination of research instruments such as direct observation, checklist forms to interviews. There is 1 study that still uses the 2012 CDOB technical guidelines and another study that uses the latest 2020 CDOB technical guidelines. Several studies present the percentage results for each CDOB aspect, there are also those that present the percentage results for all CDOB aspects of a PBF.

Scoping Review Limitations

This study uses the PRISMA scoping review method with a systematic search using keywords to obtain articles that match the criteria. The scope of this study only focuses on the Indonesian region, so Google Scholar is used as a database to make it easier to find articles in Indonesian.

CONCLUSION

Studies related to the evaluation of Good Distribution Practices or CDOB found were descriptive in nature, showing the level of conformity of CDOB implementation to predetermined guidelines. From the results of data extraction, the studies were conducted at pharmaceutical installations of health offices, health centers, hospitals, pharmacies and PBFs spread across Indonesia. Some studies still do not use the latest regulation, namely the Food and Drug Administration Regulation Number 6 of 2020 concerning Amendments to BPOM Regulation Number 9 of 2019 concerning Technical Guidelines for Good Distribution Methods, besides that there are still several studies using just one (1) distribution facility as a research sample. The suggestions that can be made include the need to conduct studies related to the evaluation of CDOB practices for pharmaceutical distribution facilities in the public or government sector and studies on distribution facilities in Eastern Indonesia.

ACKNOWLEDGMENT

The Master of Pharmacy Management study program at Gadjah Mada University which has facilitated this research.

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