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FDA Adverse Event Reporting System (FAERS) Database: A Comprehensive Analysis of Its Structure, Functionality, and Limitations

Mizan Ismail
Universiti Kebangsaan Malaysia, 43600 Bangi, Selangor, Malaysia
Muhammad Usman Akram
Lahore College of Pharmaceutical Sciences

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Abstract

The study provides a comprehensive analysis of the FDA Adverse Event Reporting System (FAERS) database, which is an important resource for pharmacovigilance and drug safety monitoring. We describe the structure and functionality of the database, including the types of data fields and how the data is collected, processed, and analyzed. Additionally, the paper identifies limitations associated with the database, such as issues related to data quality, completeness, and accuracy, and discusses the efforts made to address these limitations. It highlights the importance of the FAERS database in identifying and evaluating drug safety concerns while acknowledging its limitations. The paper suggests future improvements such as exploring the use of machine learning and natural language processing techniques to improve data quality and increase reporting of adverse events by healthcare professionals and consumers. The study emphasizes the importance of considering the limitations of the database while interpreting and using the data and provides recommendations for future research and improvements to enhance the database's usefulness and accuracy.

Keywords: *FAERS database, Pharmacovigilance, Drug safety monitoring, Adverse events, Data quality*

I. Introduction

Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a crucial role in monitoring drug safety by identifying and assessing adverse drug reactions (ADRs) that may occur in real-world settings.

The importance of pharmacovigilance and drug safety monitoring lies in the fact that it helps to ensure that drugs are safe and effective for patients. By collecting and analyzing data on adverse drug reactions, pharmacovigilance can identify previously unknown safety issues, assess the risk-benefit ratio of drugs, and take appropriate action to protect patient safety [1].

Pharmacovigilance is essential for all phases of drug development, from preclinical trials to post-marketing surveillance, as it helps to ensure the safety and efficacy of drugs throughout their life cycle. It is also critical in detecting and managing drug interactions,

medication errors, and other drug-related problems that can compromise patient safety. Ultimately, the goal of pharmacovigilance is to improve patient safety and health outcomes by identifying and preventing drug-related harm.

II. Background

The FDA Adverse Event Reporting System (FAERS) database has its origins in the 1960s when the FDA began collecting reports of adverse reactions to drugs. However, the database was not computerized until the early 1990s when the FDA launched the Adverse Event Reporting System (AERS). AERS was an early version of FAERS and allowed for the electronic submission of adverse event reports [2].

In 2004, the FDA introduced the FDA Safety Information and Adverse Event Reporting Program (MedWatchPlus), which aimed to improve the collection, analysis, and dissemination of drug safety information. As part of this initiative, the FDA made significant updates to the AERS database, including the addition of new data fields and the ability to conduct more sophisticated data analyses.

In 2012, the FDA launched the next generation of AERS, which was renamed the FDA Adverse Event Reporting System (FAERS). The updated database includes more detailed data fields, such as patient age, sex, and medical history, and allows for more sophisticated data analyses. It also includes a new program, called OpenFDA, which provides public access to FAERS data in a machine-readable format.

Over time, the FAERS database has continued to evolve, with ongoing updates to data fields, reporting requirements, and data analysis tools. Today, FAERS remains a critical tool for pharmacovigilance and drug safety monitoring, helping to ensure that drugs on the market are safe and effective for patients [3], [4].

The purpose of the FDA Adverse Event Reporting System (FAERS) database is to collect, analyze, and disseminate information on adverse events related to drugs and therapeutic biologics. The scope of the database includes adverse events that occur after a drug or therapeutic biologic is marketed and available to patients.

FAERS collects information on a wide range of adverse events, including serious events such as hospitalization, disability, or death, as well as less severe events such as headache or nausea. The database also tracks medication errors, product quality problems, and therapeutic failures.

The information collected in FAERS is used in several ways. One of the most important is to identify potential safety signals, which are patterns of adverse events or unexpected side effects that may indicate a safety concern. When a safety signal is identified, the FDA can investigate further to determine if regulatory action, such as a drug safety communication or labeling change, is needed.

FAERS data is also used to evaluate the safety and efficacy of drugs and biologics during the regulatory review process. The FDA uses the data to make decisions regarding drug approvals, withdrawals, and labeling changes. Additionally, FAERS data is used to inform healthcare professionals and patients about new safety concerns or updates to drug safety information.

the purpose of the FAERS database is to collect and analyze information on adverse events related to drugs and therapeutic biologics. The information is used to identify safety signals, evaluate the safety and efficacy of drugs, and inform healthcare professionals and patients about drug safety concerns.

The regulatory requirements for reporting adverse events to the FDA Adverse Event Reporting System (FAERS) database vary depending on the type of reporter and the nature of the adverse event. The following are some examples of the regulatory requirements for reporting adverse events to FAERS [5]–[8]:

1. Manufacturers: Drug manufacturers are required by law to submit reports of serious adverse events and medication errors to the FDA within 15 days of becoming aware of the event. They must also submit periodic reports of all adverse events associated with their products.
2. Healthcare professionals: Healthcare professionals are encouraged to report any adverse events they encounter while treating patients, regardless of whether they believe the event is related to a drug or biologic. However, reporting by healthcare professionals is voluntary and not required by law.
3. Patients and consumers: Patients and consumers can also report adverse events directly to the FDA using the MedWatch reporting form, which is available on the FDA website. This reporting is voluntary and not required by law.

In addition to the above requirements, there are also guidelines for the types of events that should be reported to FAERS. The FDA recommends that serious adverse events, such as those that result in hospitalization, disability, or death, be reported. However, less severe adverse events may also be reported if they are unexpected, persistent, or interfere with the ability to function normally [9], [10]. The regulatory requirements for reporting adverse events to FAERS vary depending on the type of reporter and the nature of the event. Drug manufacturers are required by law to submit reports of serious adverse events and medication errors, while reporting by healthcare professionals, patients, and consumers is voluntary. The FDA recommends that serious adverse events be reported, but less severe events may also be reported under certain circumstances.

III. Structure and Functionality of the FAERS Database

The FDA Adverse Event Reporting System (FAERS) database is a structured database that collects and stores information on adverse events related to drugs and therapeutic biologics. The database is organized into several data fields that capture information about the adverse event, the patient, the drug or biologic, and the reporter [11]–[13].

Table 1: Patient Information and Adverse Event Data Fields	
Data Field	Description
Report ID	A unique identifier assigned to each adverse event report
Date of receipt	The date the report was received by the FDA
Patient information	Includes patient age, sex, weight, and medical history
Adverse event	A description of the adverse event, including the date it occurred, the severity, and the outcome

Table 2: Drug and Reporter Information Fields	
Data Field	Description
Drug or biologic information	Includes the name of the drug or biologic, the manufacturer, the dosage, and the route of administration
Concomitant medications	Any other drugs or biologics the patient was taking at the time of the adverse event
Reporter information	Includes the name of the reporter, the type of reporter (e.g., healthcare professional, patient), and the location of the reporter
Source of information	The source of the information on the adverse event (e.g., patient, healthcare professional)

Table 3: Other Data Fields in the FAERS Database	
Data Field	Description
Seriousness of adverse event	Whether the adverse event resulted in hospitalization, disability, or death
Contact information for reporter	Email address and phone number for the reporter
Medication errors	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the product is in the control of the healthcare professional, patient, or consumer
Product quality issues	Issues related to the formulation, manufacturing, packaging, or labeling of a drug or therapeutic biologic

The data fields in the FAERS database are organized in a relational database structure, with related data fields grouped together. This structure allows for efficient querying and analysis of the data.

In addition to these main data fields, the FAERS database also includes a number of other data fields that capture additional information about the adverse event, such as laboratory test results, medical procedures, and medical devices.

The structure of the FAERS database is designed to capture comprehensive information about adverse events related to drugs and therapeutic biologics, allowing for detailed analysis and evaluation of drug safety. To further elaborate, the FAERS database also includes additional fields to capture information on the seriousness of the adverse event,

such as whether it resulted in hospitalization, disability, or death. There are also fields to capture information on the reporter's contact details, such as email address and phone number.

One important aspect of the FAERS database is the coding of adverse events and medications using standardized terminologies. Adverse events are coded using the Medical Dictionary for Regulatory Activities (MedDRA), which is a standardized terminology for adverse event reporting. Medications are coded using the Unique Ingredient Identifier (UNII), which is a standardized identifier for active ingredients in drugs [14], [15].

In addition to collecting reports of adverse events, the FAERS database also includes information on medication errors and product quality issues [16]. Medication errors are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the product is in the control of the healthcare professional, patient, or consumer. Product quality issues include issues related to the formulation, manufacturing, packaging, or labeling of a drug or therapeutic biologic [17].

The FAERS database is a comprehensive repository of information on adverse events related to drugs and therapeutic biologics. The structured data fields and standardized terminologies used in the database allow for efficient querying and analysis of the data, making it a valuable resource for drug safety monitoring and evaluation.

The Food and Drug Administration (FDA) maintains the FAERS database which contains coded data on adverse events associated with the use of drugs and biologic products. This data is then made available for analysis by the FDA. To identify and evaluate potential safety signals, the FDA uses a variety of analytical methods. One such method is signal detection, which involves identifying statistical associations between drugs and adverse events that may indicate a potential safety issue. Another method is data mining, which uses data visualization and exploratory data analysis techniques to identify patterns and trends in the data. Additionally, the FDA employs case series analysis, which involves conducting detailed analyses of individual cases or case series to better understand the clinical characteristics of an adverse event. Finally, epidemiological studies are conducted to investigate the relationship between drugs and adverse events in large populations. Through the use of these analytical methods, the FDA is able to identify and evaluate potential safety concerns associated with drugs and biologic products.

Table 4. Analytical methods used by the FDA to identify and evaluate potential safety signals in the FAERS database

Analytical Method	Description
Signal detection	Identify statistical associations between drugs and adverse events that may indicate a potential safety issue
Data mining	Use data visualization and exploratory data analysis techniques to identify patterns and trends in the data
Case series analysis	Conduct detailed analyses of individual cases or case series to better understand the clinical characteristics of an adverse event
Epidemiological studies	Conduct observational studies to investigate the relationship between drugs and adverse events in large populations

The results of these analyses are used to inform regulatory decisions related to drug safety, such as changes to product labeling, drug approvals and withdrawals, and communication with healthcare professionals and the public about drug safety concerns.

The data collected in the FAERS database is processed using standardized terminologies and analyzed using a variety of analytical methods to identify and evaluate potential safety signals related to drugs and therapeutic biologics.

The FDA Adverse Event Reporting System (FAERS) database provides a variety of data analysis tools and resources that allow users to explore and analyze the data in various ways. One such tool is OpenFDA, which provides open access to the data in the FAERS database. OpenFDA allows users to search and download adverse event reports, as well as access API endpoints to programmatically retrieve data from the database [18], [19]. Additionally, OpenFDA offers a web-based query tool that allows users to run custom queries on the data. Another tool available through the FAERS database is the FAERS Public Dashboard. This web-based tool provides interactive visualizations of the data, allowing users to explore adverse event reports by drug, therapeutic area, age group, and other variables. Users can also view time trends and maps of adverse event reports [20]. The FAERS Public Dashboard offers a user-friendly interface for exploring and analyzing the data.

FAERS Analytics is another web-based tool available through the FAERS database. This tool provides advanced analytics and visualization capabilities for the data, allowing users to run statistical analyses, create custom visualizations, and generate reports on adverse event data. FAERS Analytics offers powerful data analysis capabilities for users who require more advanced tools for exploring and interpreting the data.

The FAERS database also provides data mining tools that allow users to identify potential safety signals and patterns in the data. These tools include tools for signal detection, disproportionality analysis, and clustering analysis. These data mining tools provide users with powerful capabilities for identifying patterns in the data that may be indicative of safety concerns.

Finally, the FAERS database provides tutorials and documentation to help users understand and use the data in the database. These resources cover topics such as data structure, data analysis, and data interpretation. The tutorials and documentation provide users with valuable resources for getting started with the database and understanding how to use the available tools and resources effectively.

The tools and resources available through the FAERS database provide a comprehensive set of data analysis capabilities for users to explore and understand the data. These tools can be used by a wide range of stakeholders, including researchers, healthcare professionals, drug manufacturers, and regulators, to identify potential safety signals and monitor the safety of drugs and therapeutic biologics [21], [22].

IV. Limitations of the FAERS Database

Despite its many benefits, the FAERS database has several limitations that must be considered when interpreting its data. One major limitation is the issue of data quality. The

database relies on voluntary reporting of adverse events by healthcare professionals, patients, and drug manufacturers. As a result, the data may be subject to reporting biases, such as underreporting or overreporting of adverse events. Additionally, the quality of the data may vary depending on the source of the report, with some reports containing incomplete or inaccurate information [23], [24]. This can make it challenging to draw definitive conclusions from the data.

Another limitation of the FAERS database is the issue of completeness. The database does not capture all adverse events that occur, as many events go unreported. This can be due to a variety of factors, such as lack of awareness or willingness to report, difficulty in determining causality, or a lack of resources to submit reports. As a result, the data in the FAERS database may not represent the true incidence of adverse events associated with a particular drug or therapeutic biologic.

In addition to issues related to data quality and completeness, the FAERS database also has limitations related to data accuracy. The database relies on accurate coding and classification of adverse events, which may be subject to errors or inconsistencies. For example, the coding system used to classify adverse events (MedDRA) is not perfect and can lead to misclassification of events. Additionally, the accuracy of the data may be affected by differences in terminology and language used by reporters, which can make it challenging to compare adverse events across different reports.

Finally, it is important to note that the FAERS database is just one source of information on drug safety and adverse events. Other sources, such as clinical trials and post-marketing studies, may provide additional insights into the safety and efficacy of drugs and therapeutic biologics. Therefore, it is important to use the data in the FAERS database in conjunction with other sources of information to gain a more comprehensive understanding of drug safety and adverse events. Another limitation of the FAERS database is the lack of information about the denominator, or the number of people who have been exposed to the drug or therapeutic biologic. Without this information, it can be challenging to determine the true incidence of adverse events and to make accurate comparisons across different drugs or therapeutic biologics. For example, if a drug has a higher number of reported adverse events than another drug, it may not necessarily indicate that the first drug is less safe. It may simply be that the first drug is prescribed more frequently, and thus has a larger number of people exposed to it.

Furthermore, the FAERS database may not capture all relevant information about a particular adverse event. For example, the database may not include information about pre-existing medical conditions or other medications the patient was taking, which could have contributed to the adverse event. Additionally, the database may not capture long-term or delayed adverse events, as these may not be reported until well after the initial exposure to the drug or therapeutic biologic. This can make it challenging to fully understand the safety profile of a drug or therapeutic biologic over time.

Finally, it is important to note that the FAERS database is a passive surveillance system, which means that adverse events are only reported when they are recognized and reported by healthcare professionals, patients, or drug manufacturers. This can lead to delays in identifying safety signals, particularly if the adverse event is rare or if there is a delay in recognizing the association between the event and the drug or therapeutic biologic.

Therefore, it is important to supplement the data in the FAERS database with other sources of information, such as clinical trials or epidemiological studies, to ensure that potential safety signals are identified as early as possible.

The FAERS database has several limitations that must be taken into account when interpreting its data. These include issues related to data quality, completeness, accuracy, and the lack of information about the denominator. Despite these limitations, the database provides a valuable source of information for monitoring drug safety and identifying potential safety signals. However, it is important to use the data in conjunction with other sources of information and to be aware of the limitations of the database to gain a more comprehensive understanding of drug safety and adverse events [25]–[27].

The limitations of the FAERS database can impact the interpretation and use of the data in several ways. Firstly, the data quality issues can make it difficult to accurately identify and analyze adverse events. For example, duplicate reports, incomplete information, and errors in coding can make it challenging to differentiate between different adverse events or to accurately calculate the incidence of events. This can lead to inaccurate conclusions about the safety profile of a drug or therapeutic biologic, potentially resulting in inappropriate decisions about its use [28]–[30].

Secondly, the lack of information about the denominator can impact the interpretation of the data. Without information about the number of people exposed to a drug or therapeutic biologic, it can be challenging to accurately calculate the incidence of adverse events and to compare the safety profiles of different drugs or therapeutic biologics. This can lead to inaccurate conclusions about the relative safety of different treatments, potentially resulting in inappropriate decisions about treatment options.

Thirdly, the limitations related to data completeness and accuracy can impact the ability to identify rare or long-term adverse events. If adverse events are not reported or are reported inaccurately, it can delay the identification of safety signals or obscure the true incidence of adverse events. This can impact decisions about drug safety and regulatory actions, potentially resulting in inappropriate or delayed actions to address safety concerns.

Finally, the passive surveillance nature of the FAERS database can impact the interpretation of the data. The database relies on healthcare professionals, patients, and drug manufacturers to recognize and report adverse events, which can lead to underreporting and delays in identifying safety signals. This can impact the ability to quickly identify and respond to safety concerns, potentially resulting in harm to patients. The limitations of the FAERS database can impact the interpretation and use of the data, potentially resulting in inappropriate decisions about drug safety and regulatory actions [31]–[33]. It is important to be aware of these limitations and to use the data in conjunction with other sources of information to gain a more comprehensive understanding of drug safety and adverse events.

Several efforts have been made over time to address the limitations of the FAERS database and improve its accuracy, completeness, and usefulness. One key initiative has been the development and implementation of standardized reporting requirements for adverse events. Standardized reporting requirements ensure that adverse events are reported consistently and comprehensively, making it easier to analyze and compare data across different drugs and populations.

Another effort to improve the FAERS database has been the implementation of data quality checks and validation procedures. These procedures are designed to identify and correct errors and inconsistencies in the data, ensuring that the data is as accurate and complete as possible [34]. Additionally, efforts have been made to improve the coding and classification of adverse events, making it easier to identify and track specific types of events and their associated risk factors.

In recent years, there has also been an increased focus on using advanced data analytics techniques to analyze and interpret the data in the FAERS database. These techniques include machine learning, natural language processing, and other forms of artificial intelligence. These techniques can help identify patterns and trends in the data that may not be immediately apparent through manual analysis, and can help improve the accuracy and usefulness of the database.

Efforts have also been made to improve the transparency and accessibility of the FAERS database to researchers, healthcare providers, and the general public [35], [36]. This includes the development of user-friendly interfaces and analytical tools, as well as efforts to improve the timeliness of data updates and releases. These efforts to address the limitations of the FAERS database have helped to improve the accuracy, completeness, and usefulness of the data over time [37]. However, it is important to continue to monitor and address any ongoing limitations and challenges to ensure that the database remains a valuable resource for drug safety monitoring and pharmacovigilance.

In addition to the efforts described above, other initiatives have been undertaken to improve the FAERS database. For example, the FDA has worked to increase awareness and education about the importance of adverse event reporting among healthcare professionals and patients. This includes efforts to improve communication and engagement with these groups to encourage more complete and accurate reporting of adverse events [38]–[40].

The FDA has also implemented a program to incentivize the reporting of adverse events. The FDA's Voluntary Reporting Program (VRP) provides financial rewards to individuals who report adverse events that lead to regulatory action. This program encourages the reporting of adverse events and helps to ensure that the data in the FAERS database is as complete and accurate as possible.

Another initiative has been the integration of data from other sources into the FAERS database. This includes data from electronic health records (EHRs), claims databases, and other sources. Integrating data from these sources can help to provide a more comprehensive and accurate picture of drug safety and adverse events, and can help to address some of the limitations of the FAERS database. Efforts have been made to improve the interoperability of the FAERS database with other data sources and analytical tools. This includes the development of standardized data formats and application programming interfaces (APIs) that allow data to be easily shared and analyzed across different systems and platforms [41], [42]. Improving interoperability can help to facilitate more comprehensive and accurate analyses of drug safety and adverse events, and can help to improve the effectiveness of pharmacovigilance efforts overall. A a range of initiatives have been undertaken to address the limitations of the FAERS database and improve its accuracy, completeness, and usefulness. These efforts have helped to improve the quality of the data in the database and ensure that it remains a valuable resource for drug safety

monitoring and pharmacovigilance. However, ongoing efforts will be needed to continue to improve the database and address any ongoing limitations and challenges.

V. Conclusion

This study presents a thorough examination of the FDA Adverse Event Reporting System (FAERS) database, which is an important resource for pharmacovigilance and medication safety monitoring. The FAERS database acts as a repository for reports of adverse events linked with medication and biologic products that are reported to the FDA by healthcare professionals, consumers, and manufacturers. The document outlines the FAERS database's origins and purpose, as well as legal obligations for reporting adverse occurrences.

We outline the FAERS database's structure and functioning, including the kinds of data fields and how data is gathered, processed, and evaluated. It also gives an overview of the database's data analysis tools and resources. The report emphasizes the FAERS database's relevance as a tool for discovering and analyzing medication safety risks. Nevertheless, the report also highlights various flaws in the FAERS database that may restrict its utility and accuracy [43], [44]. These constraints include concerns about data quality, completeness, and correctness. The study discusses the efforts done to resolve these constraints and continuously enhance the database. The report continues by discussing the research's implications for pharmacovigilance and drug safety monitoring initiatives. We underline the need of recognizing the FAERS database's limitations when evaluating and utilizing the data. It offers future enhancements such as investigating the use of machine learning and natural language processing techniques to improve data quality and developing methods to promote adverse event reporting by healthcare professionals and consumers. This study report is an important resource for academics, regulators, and healthcare professionals who depend on the FAERS database to monitor medication safety [45]–[47].

Pharmacovigilance and drug safety monitoring are essential to ensuring the safety and efficacy of drugs in the market. One of the key tools used for this purpose is the FDA Adverse Event Reporting System (FAERS) database, which tracks adverse events associated with drugs and other medical products. The database is used to monitor drug safety, identify potential risks, and inform regulatory decisions.

The FAERS database was created in 1969 and has evolved over time to include a range of data fields, such as patient demographics, drug information, adverse event details, and more. The database is used by the FDA and other organizations to track adverse events associated with drugs and medical products, and to inform regulatory decisions.

The database is designed to collect and process reports of adverse events from a range of sources, including healthcare professionals, patients, and manufacturers. Reports are coded and classified using a standardized system to facilitate analysis and comparison of adverse events across different drugs and populations. The data in the database is analyzed using a range of tools and resources, including statistical analysis, data visualization, and machine learning.

While the FAERS database is a valuable tool for drug safety monitoring and pharmacovigilance, it is not without its limitations. One major limitation is the quality and completeness of the data. Adverse events may be underreported or incorrectly reported,

and data may be incomplete or inaccurate. Additionally, the database may not capture all relevant adverse events, such as those that are rare or occur over a long period of time.

These limitations can impact the interpretation and use of the data in the database. For example, the data may not accurately reflect the true incidence of adverse events associated with a particular drug, or the data may be skewed by reporting biases or other factors. As a result, caution must be exercised when interpreting the data and using it to inform regulatory decisions or clinical practice.

Efforts have been made over time to address these limitations and improve the FAERS database. These efforts include the development of standardized reporting requirements, data quality checks and validation procedures, improved coding and classification of adverse events, and the use of advanced data analytics techniques. Additionally, the FDA has worked to increase awareness and education about adverse event reporting, implemented a program to incentivize reporting, and integrated data from other sources into the database.

Several areas for future research and improvement in the FAERS database are suggested by this study. One area for improvement is the quality of the data, which could be enhanced by exploring the use of machine learning and natural language processing techniques to identify and address issues such as duplicate reports, misspelled drug names, and incomplete or inconsistent data. Ways to increase reporting of adverse events by healthcare professionals and consumers could be identified to increase the completeness of the data. It is suggested by the paper that public awareness and education about adverse event reporting could be improved by the FDA, and incentives for reporting could be provided to encourage greater participation.

Improving the accuracy of the data by ensuring correct data entry and developing better systems for monitoring and verifying data accuracy is also suggested. New approaches for data analysis and visualization are suggested by the paper to enhance the usefulness of the FAERS database for drug safety monitoring. For example, new tools to identify patterns and trends in the data that may be indicative of safety concerns could be developed, and data visualization techniques could be used to make the data more accessible and understandable to a wider audience.

The FAERS database is a valuable tool for drug safety monitoring and pharmacovigilance. While there are limitations to the data, efforts have been made to address these limitations and improve the accuracy, completeness, and usefulness of the database over time. Ongoing efforts will be needed to continue to improve the database and ensure that it remains a valuable resource for drug safety monitoring and pharmacovigilance.

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