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Review Article

A Review article of pharmacovigilance and studies of clinical research for health care

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ABSTRACT

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug- related problems, is intrinsically linked to effective information management. The pivotal role of information in pharmacovigilance encompassing data collection, analysis, and dissemination for optimal patient safety. The foundation of pharmacovigilance lies in robust information system that facilitate the collection of adverse event reports from healthcare professionals, patients, and other stakeholder. The evolution of data sources, emphasizing the integration of electronic health records, wearable devices and real world evidence to enhance the depth and breadth of information available for analysis. Innovative technologies, including artificial intelligence and machine learning, are transforming pharmacovigilance by automating signal detection and predictive modeling. How those tools are utilized to sift through vast datasets, identifying potential safety concerns and aiding regulatory decision-making. Furthermore, the abstract delves into the importance of structured information sharing between regulatory agencies, pharmaceutical companies, healthcare providers. Timely transparent communication of safety information ensure a proactive response to emerging risk and enable the development of effective risk management strategies.

The continues evaluation of information management strategies to adapt to the complexities of modern healthcare and pharmaceutical innovation. In essence, this abstract illuminates the symbiotic relationship between pharmacovigilance and information management, showcasing how the effective utilization of diverse and high quality data is fundamental to advancing drug safety practices and safeguarding public health.

1. Introduction

The historical development of word " pharmacovigilance" includes the Greek word phannacon= drug or medicinal substance and the Latin word Vigilare = 'to keep watch'.

Absolutely, pharmacovigilance is indeed a critical aspect of the entire drug development process. It involves the constant monitoring, assessment, and understanding of potential adverse effects or any issues related to medications. This helps ensure patient safety by evaluating this risks and benefits associated with specific drugs. With the aid of information technology, pharmacovigilance has significantly improved, allowing for more efficient monitoring and enhancing clinical safety practices. It's a pivotal part of ensuring the safety, efficacy and cost-effectiveness of medications throughout their lifecycle from discovery to post- marketing surveillance.[1]

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1.1. History

Certainly, let's delve into more detail on the key points in the history of pharmacovigilance

1. ***Thalidomide Tragedy (1950s-1960s) :*** Thalidomide, originally prescribed as a sedative and antiemetic, caused severe birth defects in thousands of infants. This catastrophe underscored the necessity for systemic monitoring of drug safety. The aftermath led to increased awareness of the potential harm drugs could cause ,especially during pregnancy.
2. **Formation of WHO Program(1968):** In response to the thalidomide incident, WHO established the international Drug Monitoring Program in 1968. This program laid the foundation for a global network of pharmacovigilance centers, fostering collaboration in collecting and analyzing data on adverse drug reactions (ADRs).
3. **FDA and AERS (1970s):** The FDA initiated the Adverse Event reporting system (AERS) in 1970s. AERS become a pivotal tool for collecting, managing, and analyzing data on adverse events associated with drugs, enabling the FDA to monitor and regulate drug safety in united states.
4. **ICH Guidelines (1990s):** The international conference on harmonization (ICH) played a crucial role in standardizing pharmacovigilance practices globally. ICH guidelines, such as E2B, provided a harmonized framework for the collection and exchange of safety data, fostering international cooperation among regulatory authorities.
5. **EU Pharmacovigilance system (2005):** The European Union introduced a comprehensive pharmacovigilance system, strengthening the monitoring and supervision of medicinal products. The European medicinal agency (EMA) played a central role in coordinating safety assessments and risk management strategies.
6. **Periodic safety update reports (PSURs):** PSURs become a standard requirement for marketing authorization holders. These reports involve the regular submission of safety data to regulatory authorities, ensuring continuous evaluation of a drugs safety profile throughout its lifecycle.
7. **Digital Era and Signal Detection (21^{st} century):** Technological advancement in the 21^{st} century facilitated the integration of big data and digital platforms in pharmacovigilance. Automated signal detection system, utilizing algorithms and data mining techniques, enhanced the efficiency of identifying potential safety concerns from large datasets.
8. **Global collaboration (present):** Modern pharmacovigilance emphasizes global collaboration. Initiatives like WHO global individual case safety Reports (ICSRs) platform facilitate standardized reporting and information exchange across countries. This collaborative approach involves regulatory agencies, pharmaceutical companies, healthcare professionals, and patients in monitoring and ensuring the safety of medicinal products.[2]

2. Objective

1. **Monitoring Adverse Effects**: Continues surveillance to detect and evaluate adverse drug reactions (ADRs) that arise during the use of medications.
2. **Assessment Of Risk and Benefits :** Analyzing the risk-to- benefit ratio of drugs to ensure that the therapeutic benefits outweigh potential risks or adverse effects.
3. **Data Collection and Analysis:** Systematically gathering and analyzing information on medication safety, including reports from healthcare providers, patients, and clinical trials.
4. **Risk Management and Mitigation:** Developing strategies to manage and minimize risks associated with medications, such as updating labeling ,implementing risk minimization plans, or even withdrawing drugs from the market if necessary.
5. **Promoting Safe Use of Medications:** Educating healthcare professionals and patients about the safe and effective use of medications, including appropriate dosing, administration ,and monitoring.
6. **Communication and Information Dissemination :** Facilitating the dissemination of safety information to healthcare providers regulatory agencies, and the public to ensure informed decisions-making about medication use.
7. **Regulatory Compliance:** Ensuring compliance with regulatory requirements related to drug safety monitoring and reporting.
8. **Post Marketing surveillance:-** monitoring the safety of medications after they are approved and made available in the market to identify rare or long- term adverse effects that might not have been evident during clinical trials. It's about promoting, learning, training and clear communication about drug safety to healthcare professionals and the public. It involves recognizing medication- related issues and effectively sharing that information in a way that's easy to understand.[1]

2.1. Scope

Enhance safety measures and regulatory oversight for these specific healthcare products.[1]

2.2. Constituted pharmacovigilance program of India

The Pharmacovigilance Program of India (PvPl) is deeply rooted in the legal framework provided by the Drugs

and Cosmetics Act of 1940 and subsequent Drugs and Cosmetics rule of 1945. This Regulatory structure places the program under the jurisdiction of the Central Drugs Standard Control Organization (CDSCO), which is India's apex regulatory body for pharmaceutical and medical devices.

PvPI has several key objectives, with a primary focus on monitoring adverse drug reactions (ADRs) to ensure patient safety. The National Coordinating Centre (NCC) serves as the central coordinating body, responsible for overseeing the program's functioning. It plays a pivotal role in receiving ADR reports from diverse sources ,including healthcare professionals, consumers, and pharmaceutical companies.

To facilitate efficient data collection and analysis, Regional Adverse Drug Reaction Monitoring Centre's (AMCs) are strategically located across the country. These AMCs act as regional hubs, processing ADR reports and forwarding relevant information to the NCC. The reporting mechanism are designed to be accessible to various stakeholders, including an online platform established by the CDSCO, making it user- friendly for healthcare professionals and the public a like.

Signal detection and analysis form a critical component of P PI's activities. Systematic evaluation, incorporating both statistical and clinical assessments, is employed to identify potential safety signals associated with pharmaceutical products. This rigorous approach ensures that emerging risks are promptly recognized and addressed.

PvPI also emphasizes communication and dissemination of safety information. Regular newsletters, safety alerts, and educational programs are employed to raise awareness among healthcare professionals and the broader public. This proactive public. This proactive approach contributes to informed decisions-making and supports a culture of safety within the healthcare community.

In addition to its domestic efforts, PvPI collaborates with international pharmacovigilance networks. This collaboration enables the sharing of information and best practices, contributing to global drug safety initiatives.

Capacity building is integral to PvPI's strategy, with training programs and workshops aimed at enhancing awareness and reporting capabilities among healthcare professionals. This proactive stance further strengthens the pharmacovigilance infrastructure in India.[3]

3. Objective

1. To produce a public- wide system for patient safety reporting.
2. To identify and dissect new signal from the report cases.
3. To dissect the benefit- threat rate of retailed specifics.
4. To induce substantiation grounded information on safety of drugs.
5. To support nonsupervisory agency in the decision-making process on use of specifics to promote rational use of drug.[3]

Table 1:

ADRMonitoring Centre	State
Department of pharmacology, All India Institute of Medical Science	New Delhi
Department of pharmacology, PGIMER	Chandigarh
Department of pharmacology, R.G.Kar Medical College	Kolkata
Department of Clinical Pharmacology, Lady Hardinge Medical College	Kolkata
Department of Clinical Pharmacy, JSS Medical College Hospital	Karnataka
Institute of pharmacology, Madras Medical College	Chennai
Department of pharmacology, SAIMS Medical College	Indore -Ujjain

3.1. Functions

1. **Identify**: Identifying adverse drug reactions (ADRs) involves recognizing unexpected, harmful effects of drugs. Causality assessment determines the relationship between a drug and suspected reaction, often using tools like the WHO causality assessment criteria.
2. **Documentation**: Documentation of ADRs include recording essential details like patient information, drug details, reaction description, and relevant medical history. Accurate documentation aids in comprehensive analysis
3. **Report**: Reporting serious ADRs to pharmacovigilance centers of ADR regulating authorities is crucial. This involves submitting detailed reports that contribute to the ongoing monitoring and evaluation of drug safety.[4]

4. Clinical Research

4.1. History

Clinical research encompasses a multifaceted approach to advancing medical understanding and improving patient outcomes. In the initial phases, preclinical research involves experiments in laboratories to explore the safety and potential efficacy of interventions. This stage often includes testing on cell cultures ,animals models ,or utilizing computer simulations to gather preliminary data. Once promising results are obtained, researchers meticulously craft protocol detailing study objectives, inclusions/ exclusion criteria, and robust methodologies. The ethical foundation of clinical research is upheld through obtaining informed consent from participants,

Table 2:

Phases	Objective	Participants	Dose	Duration	End point	Activities	Sample Size	Regulatory Approval
Phase	To explore drug behavior in human. Asses basic properties like (ADME).	Very small group (10-15 healthy volunteers)	Receive very low dose	Short duration (typically days)	Before starting phase 0 trials targeting a diseases progression, a validated test to accurately measure that progression must be in a place (PD end point).	Involve micro dosing where sub therapeutic dose are administered	Phase 0 studies are typically small-scale, involving fewer than 15 participants, and the the drug is administered for a brief duration.	Phase 0 trials do not require FDA approval and are not formal phase of drugs development. They are exploratory in nature
Phase 1	Determine safety, dosage range and potential side effects. Understand drug metabolism and pharmacokinetics.	Small group (22-100 healthy volunteers or individuals with the target conditions).	Focusing on small group to assess treatments safety profile.	Several months	Phase 1 studies aim to identify side effects, set safe dosages detect organ -related harm through lab test and pin point limiting toxicities.	Administered escalating doses to establish a safe dosage range. Monitor for adverse effect, pharmacokinetics, pharmacodynamics	In the context of phase l trial, the sample size typically involve fewer than 20 subjects.	Requires regulatory approval, and data collected is submitted to regulatory authorities.
Phase 2	Phase 2 trials further evaluate safety and begin to assess the drug's effectiveness.	Individuals with the condition the drug is intended to treat.	Administered at or near the anticipated therapeutic dose.	Phase 2 trials may last several months to 2 years	Evaluate efficacy and side effects. Continue to monitor safety.	Assess treatment safety and effectiveness and in more people for a specific condition, gathering, data before larger phase 3 trials.	Involve smaller group, usually less than 50 patients.	Approval from agencies like FDA or EMA.

Continued on next page

Table 2 continued

Phase 3	Phase 3 trials confirm effectiveness, monitor side effects and compare the new treatment to standard treatments.	Large groups of patients with the condition the drug is intended to treat.	Similar to phase 2 administered at or near the anticipated therapeutic dose.	Phase 3 trials can large several years.	Assess efficacy, monitor side effects, and overall benefits vs. risks. gather additional information about safety.	Test treatment on large groups to confirm effectiveness watch for side effects, compare to standard treatments.	Involves 100s to 1000s of participants	Phase 3 trials are big tests for treatment. They check safety, effectiveness and side effects.
Phase 4	Phase 4 trials occur after a drug has been approve and is on the market. They aim to gather additional information on long- term risk, benefits, optimal use.	Can involve a large number of patients, millions.	Reflects real world use.	Phase 4 trials can continue indefinitely, as they monitor the drug in real-world settings.	Evaluate long-term safety and effectiveness. May identify rare or long -term side effects.	Phase 4 trials occur post-approval. They assess safety, efficacy, new uses in diverse populations.	Can be very large due to real-world	Conducted after regulatory approval. Keep in mind that these are general outlines, and specifics can vary depending on the type of treatment and condition being studied.

who are provided with comprehensive information about the study's purpose, potential risks, and benefits. Regulatory approval from ethics Committees and relevant authorities is a critical step, ensuring that the research adheres to ethical standards and complies with established regulations.

Clinical trials progress through distinct phases, with phase I focusing on safety, Phase II expanding to a larger cohort to further assess safety and efficacy, and phase III involving large- scale trials comparing interventions to existing standards of care. The randomized controlled trial (RCT) design is often employed in these phases to enhance the reliability of results by randomly assigning participants to intervention or control groups.

Throughout the research process, data collection is rigorous, employing a variety of methods such as clinical examinations, laboratory tests, patient-reported outcomes. Independent monitoring Committees oversee the study's progress and safety, ensuring transparency and adherence to protocols. Statistical analysis of the collected data is crucial for drawing meaningful conclusions about the intervention's effectiveness and safety.

Positive outcomes from clinical research may lead to regulatory approvals for the intervention, marking a significant milestone in medical innovation. Dissemination of findings through publications in scientific journals contributes to the global knowledge base, fostering collaboration and further research. Post-marketing surveillance becomes imperative to continuously monitor the intervention's real- world safety and effectiveness once it is available to the broader population. In essence, clinical research is a dynamic and evolving process that bridges the gap between scientific discovery and tangible improvements in Healthcare practices.

Phases of clinical trials as given in below table:

5. Drug Controller General of India

The Drug Controller General of India (DCGI) is the regulatory authority in India responsible for the approval of Pharmaceuticals including drugs and medical devices. Its role in pharmacovigilance involves monitoring and assessing the safety of drugs post- marketing. It ensures that pharmaceutical companies comply with safety regulations and investigates adverse drug reactions reported by healthcare professionals and consumers.

The history of DCGI traces back to the formulation of the Central Drugs Standard Control Organization (CDSCO) in 1940. Over the years, CDSCO evolved, and in 1961, the Drugs and Cosmetics Act was enacted ,empowering the organization to regulate the import ,manufacture distribution, and sale of drug.

The pharmacovigilance Program of India (PvPI) was established in 2010 under the aegis of CDSCO and DCGI .PvPI aims to collect, monitor, analyze adverse drug reactions (ADRs) to enhance drug safety in India. It collaborates with the world Health Organization (WHO) to contribute ADR data to the global database.

DCGI's involvement in pharmacovigilance signifies India's signifies India's commitment to ensuring the safety and efficacy of Pharmaceuticals, emphasizing continual monitoring and evaluation even after a drug is in the market

5.1. Function of DCGI

The Drug Controller General of India (DCGI) plays a crucial role in pharmacovigilance by overseeing various aspects of drug regulation, safety, and surveillance.

1. **Regulatory Approval:** DCGI is responsible for granting approval for new drugs, ensuring they meet safety, efficacy, and quality standards before they enter the Indian market. This involves evaluating clinical trial data submitted by pharmaceutical companies.
2. **Clinical Trial Oversight:** DCGI regulates and monitors clinical trials conducted in India ensure ethical practices Patient safety, and adherence to regulatory protocols.
3. **WPost Marketing Surveillance:** After a drug is approved and available in the market, DCGI continues monitoring it for any adverse effects or safety concerns reported through pharmacovigilance systems. This involves analyzing and assessing adverse event reports submitted by healthcare professionals, patients, and pharmaceutical companies.
4. **Quality Control:** DCGI ensures that drugs in the market comply with established quality standards by inspecting manufacturing facilities, reviewing production processes, and regulating the import of Pharmaceuticals.
5. **Enforcement of regulations:** DCGI enforces regulations and guidelines related to drug manufacturing, labeling, distribution, and marketing to maintain public safety standards.

Overall, DCGI's functions in pharmacovigilance are centered around safeguarding public health by regulating the entire lifecycle of pharmaceutical products, from approval to post- marketing surveillance, ensuring their safety, efficacy, and quality.

6. Central Drugs Standard Control Organization(CDSCO)

The Central Drugs Standard Control Organization (CDSCO) in India, overseen by the Directorate General of health services, ministry of health and family welfare, regulates and controls the manufacture, distribution, and sale of drugs and Cosmetics. It functions through various collaborations and authorities such as the Drug Technical Advisory Board, Drugs Consultative Committee, and Central Drug Laboratories.

CDSCO manages approval processes for new medicines, conducts clinical trials, establishes prescription regulations, monitors Drug efficacy and maintenance uniformity in administering the Drugs and Cosmetics Act. Additionally, it collaborates with State Drug Control Organizations to ensure proper regulation and supervision at the state level, including authorizing drug testing facilities, regulating drug production and marketing, and overseeing the manufacturing process of drug within the state.

This comprehensive regulatory structure, established under the 1940 Drug and Cosmetics Act and 1945 Drug and Cosmetics Act 1945 rules, involves both Central and state agencies working together to maintain the quality and safety of Pharmaceuticals in India if you require assistance navigating the approval process from CDSCO ,eStartIndia offers free expert advice and Consultancy services.[5]

7. Functions Of CDSCO

The Central Drugs Standard Control Organization (CDSCO) in India plays a pivotal role in regulating the safety, efficacy, and quality of drugs, Cosmetics, medical devices and biological products. It's responsible for:[6]

1. **Regulatory Oversight:** CDSCO oversees the approval, licensing, and regulation of Pharmaceuticals, medical devices, and Cosmetics in India.
2. **Drug Approval:** It evaluates and approves new drugs and formulations, ensuring they meet safety and efficacy standards before they enter the market.
3. **QualityControl:** CDSCO enforces quality control measures to maintain the standard of Pharmaceuticals, ensuring they comply with set regulations.
4. **Clinical Trials:** It monitors and regulates Clinical trials conducted in India, ensuring ethical practices and patients safety.
5. **Post Marketing surveillance:** CDSCO monitors drugs and medical devices in the market, ensuring they continue to meet safety and quality standards after approval.
6. **Licensing and Inspection:** It grants license to manufacture, importers, and distributors of drugs and medical devices and conducts inspections to ensure compliance with regulations.
7. **Policy Formulation:** CDSCO develops policies and guidelines for the pharmaceutical industry to ensure the safe and effective use of drugs and medical devices.

Overall, CDSCO functions to safeguard public health by regulating the quality, safety, and efficacy of healthcare products in India.[5,7]

8. Abbreviated New Drug Application

The Abbreviated New Drug Application (ANDA) is submission to the FDA for the approval of generic drugs. It allows a manufacturer to produce a generic version of an already FDA- approved drug once it's patent or exclusivity period expires. An ANDA demonstrates that the generic drug is bioequivalent to the brand- name drug, ensuring it has the same active ingredient, strength, dosage form, route of administration, and performance characteristics. This application doesn't require extensive clinical trials but necessitates proving the drug's safety, efficacy, and quality through various studies, including bioavailability.[8]

8.1. Functions of ANDA

The Abbreviated New Drug Application (ANDA) plays a crucial role in pharmacovigilance by ensuring the safety and efficacy of generic drugs.[9]

1. **Regulatory submission:** AANDA is submitted to regulatory authorities (e.g. FDA in the United States) to seek approval for marketing a generic version of an already approved reference drugs. This involves comparative studies to establish similar pharmacokinetic parameters.
2. **Pharmacovigilance Data:** Submission includes pharmacovigilance data, addressing the safety and adverse reactions associated with the generic drug. This involves reporting any adverse events observed during clinical trials or post- marketing surveillance.
3. **Post- Marketing surveillance:** Once approved, post- marketing surveillance continues to monitor the generic drug's safety and efficacy. Pharmacovigilance activities involve collecting, analyzing, and evaluating adverse drug reactions (ADRs) and other safety-related information.
4. **Safety Reporting Obligations:** ANDA holders have obligations to promptly report any new safety information to regulatory authorities. This includes updates on known risks, emerging safety concerns, and any changes in the benefits-risks profile.
5. **Risk Management plans (RMP):** If necessary, an ANDA may include a risk management plan to outline strategies for identifying, characterizing, preventing and minimizing risks associated with the generic drug.
6. **Analysis:** Continues monitoring for potential safety signal involves the Analysis of various data sources, such as spontaneous reports, literature, and clinical studies.
7. **Agencies:** ANDA holders collaborate with regulatory agencies to address safety concerns and implement any necessary changes to the drug's labeling or prescribing information.
8. **Reports:** Submission of PSURs is required to provide of the generic drug at defined intervals.
9. **Recall and Market Withdrawal:** If serious safety concerns arise, the ANDA holder may need to initiate drug recalls or market Withdrawals in collaboration

with regulatory authorities.[8]

9. New Drug Application(NDA)

The new drug application (NDA) process is a pivotal and multifaceted stage in bringing a new pharmaceutical product to market in the United States. It begin with extensive preclinical testing, encompassing laboratory experiments and animal studies, aimed at understanding the drugs safety profile and potential efficacy. Following successful preclinical outcomes, the sponsor file an Investigation New Drugs(IND) application with the FDA, providing detailed data from preclinical studies and proposing protocol for clinical trials.

Clinical trials, conducted in phases I-III, involve human subjects to assess various aspects of the drug, including safety, optimal dosage, and effectiveness. These trials are conducted under strict ethical and regulatory guidelines to ensure the well-being of participants and the reliability of the collected data.

The NDA itself is a comprehensive document that serves as a compilation of all relevant information accumulated throughout the drug development process. This includes detailed analyses of preclinical and clinical trial data, information about the drug's chemical composition, manufacturing processes, requiring collaboration between scientists, clinicians, and regulatory experts.

Upon submission, the FDA conducts an exhaustive review process. This involves assessment by different divisions within the FDA, each focusing on specific aspects of the NDA, such as pharmacology, statistics, and manufacturing. The FDA may also convene an advisory committee of external experts to obtain additional perspective.

The final FDA decision is based on the collective evaluation of the submitted data. If the submitted data. If the data NDA is approved, the drug can be marketed in the United state marking in the culmination of an extensive and often years-long development and regulatory journey. Post- approval, the pharmaceutical company continues to monitor the drugs safety and effectiveness through post-market surveillance, ensuring ongoing compliance with regulatory standards and addressing any emerging concerns. This rigorous and intricate process is fundamental to safeguarding public health by ensuring that new drugs meet the highest standards of safety and efficacy before becoming widely available.[5]

10. Functions of New Drug Application

1. **Data Compilation :-** Gather comprehensive data on a new drug, including preclinical and clinical studies
2. **Regulatory Submission:**-Formal request for approval to market the drug, submitted to regulatory agencies.
3. **Through Review:-** Regulatory authorities evaluate safety, efficacy, and manufacturing details.
4. **Decision Making:-** Authorities decide to either approve or reject the New Drug Application (NDA).
5. **Labeling Approval:-** Includes proposed drug labeling, providing usage guidance upon approval
6. **Post- Marketing Surveillance:-** Ongoing monitoring of the drug's safety and effectiveness after approval.
7. **GMP Adherence:-** Approval signifies adherence to good manufacturing Practices for consistent product quality.
8. **Public Health Protection:-** Ensures only safe and effective drugs reach the market, minimizing risks.
9. **Innovation Facilitation:-** Provides a pathway for innovative drugs to address medical needs and reach patients.[5]

11. Conclusion

In conclusion, pharmacovigilance plays a crucial role in ensuring the safety of pharmaceuticals by monitoring, assessing, and preventing adverse effects. Continuous vigilance and robust reporting systems are essential for identifying and managing potential risks associated with medications, ultimately contributing to public health and patient well-being. As the pharmaceutical landscape evolves, ongoing advancement in pharmacovigilance practices will be pivotal in maintaining the balance between therapeutic benefits and safety consideration. It systematically monitoring and assessing adverse drug reactions, healthcare professionals and regulatory bodies can enhance patient safety and contribute to the continuous improvement of drug therapies. However, challenge such as underreporting and data quality issues persist, emphasizing the need for ongoing efforts to strengthen pharmacovigilance systems globally. As we. Move forward, collaboration between healthcare professionals, regulatory agencies, and the pharmaceutical industry remains essential for fostering a robust and proactive pharmacovigilance framework.

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13. Conflict of Interest

None.

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