Chapter 2
History of Drug Safety and Technology for Drug Safety

2.1 History of Drug Safety

It is reported that the term primum non nocere (first, do no harm) is attributed by some historians to Galen and was introduced to American and British medical culture by Worthington Hooker in 1847 [1, 2]. Dr. Harvey Cushing, a pioneer in surgery and neurosurgery, published detailed descriptions of harm caused to his patients secondary to his own performance at the beginning of the twentieth century [2, 3]. However, it is believed that drug related problems had a very long history since the ancient's times [4] and literature reported that during the Greek period "a court physician called Glaucos, who took care of a mad man named Hephaestus. According to Arries, Glaucos prescribed him a wrong medication, and Hephaestus died" [5, 6]. Adverse drug reactions have been reported for more than 2000 years [7, 8]. Here some examples of drug safety incidence [4, 8]:

2.1.1 Chloroform Related Problems (1848)

In England in 1848, a young girl died after using chloroform in a purpose of removing an infected toenail. Arrhythmia or pulmonary aspiration were reported as the potential adverse drug reactions [9].

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2.1.2 Salvarsan Related Problems (1915)

Toxicity due to impurities was reported as adverse effect of salvarsan use in 1915 [10].

2.1.3 Sulfonamide Related Problems (1937)

In USA 1937, sulfonamide related death was reported for 107 patients. Diethyl glycol solvent in the sulfonamide elixir was reported as the cause of death (Routledge, P., 1998); Sulfonamide manufactories reported that there were not aware about its toxicity [9].

2.1.4 Diododiethyl Tin (1954)

Cerebral oedema was reported as adverse effect of diododiethyl tin use in 1954 [10].

2.1.5 Thalidomide Related Problems 1961

Congenital malformation among babies was reported as drug related problems of thalidomide in 1961 by Dr. McBride from Australia and wrote a letter to the Lancet Journal editor about the association between babies' congenital malformation and thalidomide. He mentioned that the incidence of thalidomide related problem congenital malformation increased up to 20% for those taking thalidomide during their pregnancy. This letter was the corner stone and the basics for developing the adverse drug reactions reporting systems later on [11, 12].

2.1.6 Chloramphenicol (1966)

Blood dyscrasias was reported as adverse effect of chloramphenicol use in 1966 [10].

2.1.7 Clioquinol (1975)

Subacute myelo-optic neuropathy was reported as adverse effect of clioquinol use in 1975 [10].

2.1.8 Practolol (1977)

Oculomucocutaneous syndrome was reported as adverse effect of practolol use in [10].

2.1.9 Benoxaprofen (1982)

Liver damage was reported as adverse effect of benoxaprofen use in 1982 [10].

2.1.10 Indoprofen (1984)

Gastrointestinal bleeding and perforation were reported as adverse effects of indoprofen use in 1984 [10].

2.1.11 Spironolactone (1988)

Animal carcinomas was reported as adverse effects of spironolactone use in 1988 [10].

2.1.12 Tacrolimus (1995)

Cardiomyopathy was reported as adverse effects of tacrolimus use in 1995 [13].

2.1.13 Cisapride (2000)

QT interval prolongation was reported as adverse effects of cisapride use in 2000 [10].

2.1.14 Rofecoxib (2004)

QT interval prolongation was reported as adverse effects of rofecoxib use in [10].

2.1.15 Rosiglitazone (2010)

Cardiovascular diseases were reported as adverse effects of rosiglitazone use in 2010 [10].

2.2 History of Technology for Drug Safety

The use of technology in drug safety research, education, and practice has a long and fascinating history. The history of drug safety has been characterized by a continual evolution of new tools and techniques for improving the safety and efficacy of medications. The use of technology has played a significant role in this evolution, from the development of computerized drug databases in the 1960s and 1970s to the use of artificial intelligence and machine learning in the 2020s. Technology has enabled the collection, analysis, and management of vast amounts of data, improving the speed and accuracy of drug safety surveillance. It has also facilitated patient engagement, collaboration, and regulatory compliance, which are essential components of drug safety. The integration of technology in drug safety research has also enabled the use of real-time monitoring, big data analysis, predictive analytics, digital biomarkers, and blockchain technology, all of which have contributed to the improvement of drug safety. In conclusion, the history of drug safety technology has been one of the constant innovation and advancement, enabling researchers, healthcare providers, and patients to identify potential safety concerns earlier and more accurately, leading to improved patient outcomes. Here are some key milestones [14–16]:

1. 1960s–1970s: The first computerized drug databases were developed, providing researchers with an efficient means of collecting and analyzing data on drug safety.
2. 1980s: Electronic health records (EHRs) began to be used in clinical practice, providing a way for healthcare providers to record patient data and medication histories electronically.
3. 1990s: The FDA launched the Adverse Event Reporting System (AERS), an electronic database that collects reports of adverse events associated with drugs and other medical products.
4. Late 1990s: The development of pharmacovigilance systems, which track the safety of drugs after they have been approved and are on the market, became more widespread.
5. Early 2000s: The use of electronic prescribing systems became more common, providing healthcare providers with a safer and more efficient means of prescribing medications.
6. Mid-2000s: The rise of social media and the internet enabled patients to report adverse drug events directly, leading to the development of new approaches to drug safety surveillance.

7. 2010s: The use of mobile health technologies, such as smartphone apps and wearable devices, became more widespread, providing patients with new ways to monitor their medications and report adverse events.
8. 2020s: The use of artificial intelligence and machine learning for drug safety surveillance is becoming more prevalent, providing new ways to identify potential safety signals and adverse events.

In summary, the history of technology for drug safety is characterized by a continual evolution of new tools and techniques for collecting, analyzing, and reporting data on drug safety. These advances have enabled researchers, healthcare providers, and patients to identify potential safety concerns earlier and more accurately, leading to improved patient outcomes.

2.3 Conclusion

This chapter has discussed the history of drug safety and technology for drug safety. The history of drug safety has been characterized by a continual evolution of new tools and techniques for improving the safety and efficacy of medications. The use of technology has played a significant role in this evolution, from the development of computerized drug databases in the 1960s and 1970s to the use of artificial intelligence and machine learning in the 2020s. Technology has enabled the collection, analysis, and management of vast amounts of data, improving the speed and accuracy of drug safety surveillance. It has also facilitated patient engagement, collaboration, and regulatory compliance, which are essential components of drug safety. The integration of technology in drug safety research has also enabled the use of real-time monitoring, big data analysis, predictive analytics, digital biomarkers, and blockchain technology, all of which have contributed to the improvement of drug safety. In conclusion, the history of drug safety technology has been one of the constant innovation and advancement, enabling researchers, healthcare providers, and patients to identify potential safety concerns earlier and more accurately, leading to improved patient outcomes.

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