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Adverse Drug Reaction Reporting System in Pharmacovigilance

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Abstract: ***Pharmacovigilance is the process of the collection, detection, analysis, monitoring and prevention of various ADRs (adverse drug reactions) or AEs (adverse events) and any drug related issues and problems. After the thalidomide tragedy (1961) health professionals, doctors, nurses, clinicians, dentists, pharmacists, WHO (World Health organization) started International Drug Monitoring Program (1968) with the collaboration of WHO collaborating centre UMC (Uppsala Monitoring centre) to protect public health and safe use of the medicinal products and improving public health to decrease ADRs (adverse drug reactions) occurs from the interventions or pharmaceutical products. Pharmacovigilance aim is to care and safety of patient in relation to the medicinal use. The purpose of pharmacovigilance is to secure early detection. In 2010, there are 134 countries were the members of the WHO (World Health Organization) for International Drug Monitoring program. WHO establish various pharmacovigilance centers for the reporting of ADRs. The hospitals and pharmaceutical industries can reports ADRS (adverse drug reactions) to regional pharmacovigilance center or directly to the drug regulatory authority like USFDA (United States Food and DRUG Administration) in America, EMA (European Medicine Agency) in Europe, MHLW (Ministry of Health and Labour Welfare) in Japan, CDSCO (Central Drugs standard Control Organization) in India. The suspected unexpected serious adverse reactions can be reported within 7 calendar days and ADRs can be reported in 15-30 calendar days. The adverse drug reaction can also be reported online.***

Keywords: Pharmacovigilance, ADRs, WHO, USFDA

1. Introduction

Pharmacovigilance is the process collection, detection, monitoring, and analysis of ADRs/AEs that occurs from the medicines. The WHO started pharmacovigilance program in each country for the prevention of ADRs, safe use of medicines, decrease number of ADRs, promote public health, protection of public health. WHO (World Health organization) started International Drug Monitoring Program (1968) with the collaboration of WHO collaborating centre UMC (Uppsala Monitoring centre) to protect public health and safe use of the medicinal products and improving public health to decrease ADRs (adverse drug reactions) occurs from the interventions or pharmaceutical products. Pharmacovigilance aim is to care and safety of patient in relation to the medicinal use. The purpose of pharmacovigilance is to secure early detection. In 2010, there are 134 countries were the members of the WHO (World Health Organization) for International Drug Monitoring program. WHO establish various pharmacovigilance centers for the reporting of ADRs. The hospitals and pharmaceutical industries can reports ADRS (adverse drug reactions) to regional pharmacovigilance center or directly to the drug regulatory authority like USFDA (United States Food and DRUG Administration) in America, EMA (European Medicine Agency) in Europe, MHLW (Ministry of Health and Labour Welfare) in Japan, CDSCO (Central Drugs standard Control Organization) in India. The suspected unexpected serious adverse reactions can be reported within 7 calendar days and ADRs can be reported in 15-30 calendar days. The adverse drug reaction can also be reported online.

Origin of Pharmacovigilance

In 1937, diethyleneglycol (DEG) mistakenly used to solubalize Sulphanilamide which causes death of 107 peoples. In 1956 thalidomide launched in market. Thalidomide causes foetal abnormalities (sealed limbs) 20,000 cases are reported maximum in Germany.

Regulatory Authoroties

INDIA-CDSCO (Central Drug Standard Control Organization)
US- USFDA (United States Food and Drug Administration)
UK-MHRA (Medicinal healthcare Products Regulatory Authority
JAPAN-MHLW (Ministry of Health and Labor Welfare)
EUROPE-EMA (European Medicine Agency)

History of Pharmacovigilance

In 1962 USA revised law requiring to prove safety and efficacy before issuing marketing authorization. In 1963 British committee on safety of drug monitoring. In 1964 UK starts yellow card system. In1964-1965 national ADRs reporting system in UK, Australia, New Zealand, Canada, West Germany and Sweden. In 1978 WHO centre moved from Geneva to uppala. In January 2005 national pharmacovigilance centre established with the advisory of CDSCO (Central drug standard control organization), King Edward Medical College Mumbai, AIIMS (All India institute of medical sciences). In 2010 establishment of Pharmacovigilance Program in India (Ghaziabad).

Aims of Pharmacovigilance

1) To improve patient safety and care.
2) To improve public health.
3) Risk benefits assessment of the medicines.
4) To promote education and clinical training.
5) To promote rational and safe use of medicines.

Spontaneous Reporting System

India – 'SADRR' Form':
In India Reporting of ADR done by
1. Healthcare Professional
2. Consumer Reporting

3. Public Health Programme-PHP
4. Doctors
5. Nurses

The reports are recorded through ADR reporting form by ADR monitoring centre National Coordination Centre. Then the ADR reports are entered into the vigiflow software and reports re-checked for completeness. All the information of ADR converted into unique identification number. Assessment is performed and follow-up is done.

UK – 'Yellow Card', since 1964

The British committee started yellow card scheme for ADR reporting system in 1964 after thalidomide tragedy. Spontaneous reports of suspected adverse drug reactions. Acts as an early warning system to identify ADRs and risk factors. Overall 600,000 confidential reports have been received in UK. Doctors, dentists, pharmacists, coroners, nurses, midwifes, health visitors. Non-medical prescribers and now patients. MHRA can detect duplicate reports. It is voluntary for health professionals but pharmaceutical companies have legal obligations to report ADRs to the MHRA.

US – 'Med Watch' Form

- FDA 3500A -Mandatory Reporting
- FDA 3500B - Voluntary Reporting Form

In USA, Adverse Drug Reactions are reported according to the PMS Reporting of ADRs 21 CFR 314.80 to US Food and Drug Administration and FDA submit the Reports to the FDA Adverse Event Reporting System-FEARS. Reporting of ADR is done by the Healthcare Professionals (Physicians, Pharmacists, Nurses and Others), Consumers (Patients, Family Members, Lawyers and Other), Regulated industries, Facility Users. Healthcare professionals, consumers, pharmaceutical Industry and User facilities record the ADRs through either ADR form 3500A or ADR form 3500B and send these reports to FDA. Reporting is done online through Med Watch form. FDA sends ADRs report to FDA Adverse Event Reporting System. Reports are assessed by clinical reviewers in the (CDER) and (CBER). The records are maintained for 10 years.. The suspected unexpected serious adverse reactions can be reported within 7 calendar days and ADRs can be reported in 15-30 calendar days. The adverse drug reaction can also be reported online.

EMA- EUDRAVIGILANCE

In Europe the adverse drug reactions reported through Eudravigilance. It is an online reporting system for reporting ADRs. The doctors, nurses, pharmacists, healthcare professionals and patients can report ADRs.

JAPAN-(DPRS for ADRs)

In Japan adverse drugs reactions reported through DPRS (Direct Patient Reporting System) for ADRs. Patient can report ADRs online or offline.

2. Conclusion

Think less about the drug safety more about the patient safety. Think less about the regulating and automated data input: more about the useful information output. Mainly focus on the impact and consequences of decisions and non-decisions.

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