EDITORIAL

Reporting of Adverse Drug Reactions

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Adverse Drug Reactions (ADR's) are unintended and sometimes noxious events associated with the use of a therapeutic good (medicine, vaccine or medical device). The occurrence of an ADR does not necessarily mean the therapeutic good is faulty. These events include side effects to medicines and vaccines. For medical devices, an ADR could be an incident that has caused, or could cause (including 'near misses'), harm to patients, caregivers, health professionals or others. It is notable that adverse events are not always caused by the therapeutic goods themselves but due to incorrect user interaction or two well-functioning devices that do not operate as intended when used in combination.

A serious ADR is a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening, results in death; or any combination of these. On the other hand, a medical device incident means an incident due to its failure or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur.

In practice, the causal relationship between the therapeutic good and serious ADR's is anchored on intelligible suspicion; one must never wait to be certain! Hospitals, principally Pharmacists and Medical Practitioners, are required to report serious ADR's regardless of whether they are expected or unexpected. In the current edition of the PJK, it is noted that up to 46% of patients in selected hospitals in Kirinyaga reported suspected ADR's yet over 73% of all patients were not aware of the Patient Alert Cards. It is therefore safer to assume that most patients seen in our healthcare facilities may not know that they should report drug related adverse events even on suspicion.

Some ADR's may not be serious yet still very important. Fair medical and scientific judgement should therefore be exercised in deciding whether they should be reported. It is particularly important to report ADR's that may not be serious but stand to jeopardize the patient or may require intervention to prevent one of the outcomes listed in the above definition. Reactions like allergic bronchospasm, blood dyscrasia, non-emergency convulsions, and development of drug dependency or drug abuse are all important enough to be reported.

The Pharmacy and Poisons Board (PPB) depends on our collective professional, scientific and clinical expertise in decision making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines, medical devices and other therapeutic goods. While individual reports may be insufficient in determining whether a therapeutic good caused an ADR, the more reports are filed the more it helps to clearly build the safety profile of a product and to assist with the PPB's National Pharmacovigilance System. In particular, the National Pharmacovigilance System needs the following information:

- all suspected adverse events to new therapeutic goods
- all suspected medicine and/or vaccine interactions
- unexpected adverse events (those adverse events that do not appear in the Product Information, Consumer Medicine Information and/or product labelling)
- serious adverse events (as defined above in paragraph 2 of this article)

Reporters should provide as much detail as possible, with the minimum being contact details for the reporter; patient identifier (like initials, date of birth or age, but not full name); product details; and details of the suspected ADR. Reports can be easily made through the link https://pv.pharmacyboardkenya.org/ which has the requisite tools.

Providing detailed information reduces the need for follow up by the PPB. However, it is important not to delay reporting an adverse event because some information is not available. For the peace of mind, it is noteworthy that "submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event", and that PPB keeps as confidential any information identifying the reporter or patient.

Bibliography

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