



ORIGINAL RESEARCH PAPER

Healthcare

**UNDER REPORTING OF SUSPECTED ADRS
MAJOR PROBLEM IN PVPI : PRACTICAL ,
POSSIBLE AND CHEAP SOLUTION**

KEY WORDS:

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ABSTRACT

Aim : To find out practical solution for under reporting in PVPI with same existing manpower and same funding with help of existing health care system in India. **Methods:** Author is Pharmacology faculty in MCGM medical college and also has vast experience (11 years) of working with public health department and has practical knowledge of existing public health department and PVPI as well. Thus Author has given this practical, possible and cheap solution with his experience for under reporting of ADRs in PVPI. **Result :** If plan and methods given by Author are implemented properly, problem of under reporting of ADRs in PVPI can be solved and Suspected ADR reporting can be increased tremendously.

INTRODUCTION-

Adverse drug reactions (ADRs) have been reported to be among leading causes of morbidity and mortality [1-3]

The main function of spontaneous reporting is the early detection of signals of new, rare and serious aDRs [4]

It is also one of the cheapest methods of monitoring the safety of medicines as utilized by many drug regulatory agencies worldwide [5]

In many countries (including India) a pharmacovigilance system is operational; however, under-reporting is a major problem [6,7]

Among the top 20 countries enthusiastic about sending ICSR per million population between 2015 and 2020, India shares 2% of the total ICSRs in VigiBase. India is now being recognized as a hub of global clinical trials and clinical research studies. Hence, it is the need of the hour in India to have a dynamic PV network system with an efficient and prudent operation method. Nevertheless, in India, PV programs are at an early stage on par with other countries, and only because of underreporting of ADRs. However, in the future, PvPI may appear as a big dashboard for ADR reporting culture in India as it continuously works hard to improve patients and drug safety. [8]

Adverse drug reactions (ADRs) contribute significantly to patient morbidity, mortality and economic expenditure worldwide. Patients' quality of life can be significantly affected as a result of ADRs because they perceive their doctors to be abusive or hostile towards them [9]

These AMCs assist in collecting, evaluating, and submitting ADRs to the IPC. Complete the Suspected ADR Reporting Form (found at www.ipc.gov.in) and send it to the nearest AMC [9]

Under reporting of adverse reactions is a major cause of concern and a threat to the pharmacovigilance systems. [10]

As per available scientific literature, the major impediments to ADR reporting are inadequate knowledge and awareness among health professionals, clinicians' perceptions towards reporting, problems with establishing reporting systems in hospitals and insufficient training to recognize ADRs. [10]

Adverse drug reactions are unintended events that occur after exposure to a drug, biological product, or medical device, and they may result in morbidity and mortality. It is

critical to monitor the safety of drugs during the post-marketing phase to find long-term and rare ADRs, as well as ADRs in special populations and patients with co-morbidities that are not usually included during clinical trials. [11]

Review found that 24.8%–73.33% of healthcare professionals were unaware of the National Pharmacovigilance Center. [12]

The most frequently highlighted barriers to pharmacovigilance were a lack of awareness and knowledge regarding what, when, and to whom to report. [12]

Underreporting issues require immediate attention among healthcare professionals due to a lack of awareness and knowledge of pharmacovigilance and adverse drug reaction reporting [12]

The detection and reporting of ADRs are highly important in order to ensure the safety of drug use for patients and the public's health. Due to the increasing number of drugs on the market and insufficient safety data from premarketing phase trials, drug safety must be monitored on a regular basis [13,14].

Spontaneous reporting is the most frequently used strategy in PV and the most effective method for generating signals on new or uncommon ADRs [15,16].

This approach has the capability to offer a substantial amount of data at minimal expense [17].

It encourages the rapid detection of potential alarm signals associated with medication use through the early detection of new ADRs [18].

However, under-reporting is a serious flaw in the PV system, and it occurs for a variety of reasons, including lack of awareness about the ADR reporting system [19], lack of time [20]

According to the annual report shared by Upsala Monitoring Centre (UMC), a World Health Organisation (WHO) collaborating centre for international drug monitoring, India's ADR reporting (2 %) is less, compared to globally where major countries reporting percentages lie between 2 and 8 %; the United States of America (USA) reports ADRs up to 43 %.[1,2]

The ADR reporting rate is below 1% in India compared to the worldwide rate of 6%-10% A systematic review of the determinants of underreporting of ADRs identified the

following factors: ignorance, lack of interest, unavailability of reporting forms, lack of time, and not being sure whether the report will make any difference

ADR reporting rate is better with Govt. set up (around 75 % reporting). It is poor with Private set up (around 25 %). The highest reporting rate was observed in Govt. medical institute (74.4%) as compared to Non Govt medical institute (24.5%) [21]

Thus ADR monitoring is important task to ensure well being of mankind. but there is under reporting of ADRs in Pharmacovigilance programme of India (PVPI)

To increase the ADRs cases with same resources and same funding, following plan can be executed. This plan is formed by author as he has worked with MCGM as assistant medical officer, at health post, as Medical officer with peripheral hospital, as resident doctor with maternity home and as relieving medical officer with dispensary for many years before completing MD Pharmacology and working as assistant Professor with Medical College in Mumbai. Author has practical knowledge of health care system as well as PVPI. Thus such plan formed by him can be good, cheap, possible practical solution to under reporting in PVPI.

Practical, Possible And Cheap Solution-

PVPI has limited resources and limited manpower.

With limited resources and manpower reporting ADRs in PVPI can be improved significantly in following way. Lets consider Mumbai as a role model.

In Mumbai there are around 180 health posts. Each health post caters around 70-80 thousand populations. In one healthpost there are around 40- 50 private doctors treating patients. Assistant medical officer (AMO) has direct access to these doctors. Whats app group of such doctors can be formed and private doctors can be instructed to report their cases to on whats app group with filled " suspected ADR reporting form".

Each health post are provided with around 15-20 community health workers (CHVs). These CHVs are allotted certain are with certain population. CHVs can visit private doctors and collect filled " Suspected ADR reporting form " and hand over to Assistant medical officer (AMO) of health post. Visiting private practioners is one of the routine activities for CHVs. CHVs visits private medical practitioner (pmps) for collecting other data required by MCGM. Eg. Collecting data regarding mansoon related diseases , immunization coverage, deworming in pediatric population etc.

Collection of suspected ADR reporting form can collected during same visit.

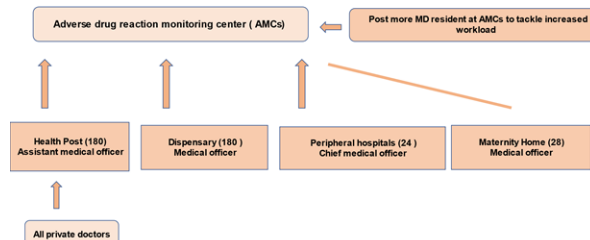
MCGM has 24 wards. Each ward contains around 7-8 health posts. AMO of health post can report these ADR cases to his respective ward to data entry operator (DEO) who works under Medical officer of health (MOH). From ward, ADR cases can be reported to neighboring adverse reaction monitoring center (AMCs).

Similarly each MCGM ward has around 7-8 dispensary. Medical officer (MO) is Incharge of Dispensary and is responsible for treating the patients visiting OPD. MO can report ADR cases to his respective ward to DEO. From ward, ADR cases can be reported to neighbouring AMCs.

MCGM has 28 maternity homes which caters maternal and child services. Medical officer is encharge of maternity home. Staff nurse and MO can report their ADR cases to nearby AMCs.

MCGM has 24 peripheral hospitals which caters secondary care to its population. Chief medical officer (CMO) is Incharge of peripheral hospital. All medical officers and staff nurse working in peripheral hospital can report their suspected ADR to nearby AMC through CMO.

With such tremendous reporting of Suspected ADRs, workload at AMCs will increase. This can be tackled by posting more MD Pharmacology residents of respective medical college to their AMCs. Also use of artificial intelligence can be done at AMCs to absorb extra workload.



Flow chart showing reporting of ADR to AMC in Municipal corporation of Greater Mumbai

This format of ADRs reporting can be applied for other major Municipal corporations in Maharashtra.

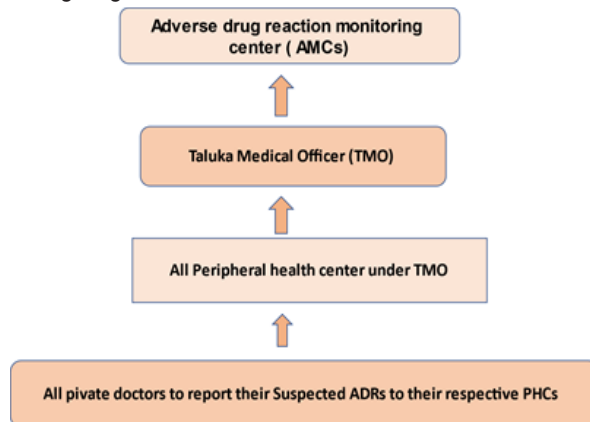
In State Government, Similar Pattern Can Be Used.

At Periphery, Peripheral health centers (PHCs) are back bone of health care system in India. Medical officer (MO) is Incharge of PHC. MO can form whats app group with private doctors and get ADRs reporting from them. He can get phone numbers of private doctors from ASHA (Accrediated social health activist) working with PHCs.

All Mos can report their cases to Taluka medical officer (TMO) office. From TMO office cases to can be reported to nearby AMC.

All secondary care hospitals can report can report their cases to nearby AMC.

Sensitization of all private corporate hospitals for reporting their ADR cases by govt. authority by periodic trainig or through regular circulars.



Flow chart showing reporting of ADR to AMC in peripheral health setting

This pattern of Suspected ADR reporting is for Maharashtra state.

Similar pattern can be applied to all other states with required modifications.

To apply this pattern of ADR cases reporting, coordination between health care set up and AMCs is required.

For this purpose there should be meeting conducted between Executive health officer (EHO) , Medical superintendent (MS) from MCGM, District health officer (DHO) from each district and senior officers from PVPI.

EHO will represent public health department. (All health posts and dispensary under him).

Medical superintendent will represent all peripheral hospitals.DHO will represent all PHCs in particular district under him . Subsequently training sessions of all health care professionals should be conducted.

With these efforts reporting of suspected ADR can be improved tremendously. Currently reporting of ADR cases are only 2 % compared to global reporting to Upssala monitoring center (Sweden).

Major problem of underreporting can be solved with existing health care system of India. No extra funding is needed to solve the problem of under reporting. Only thing is needed to achieve is coordination between different health care set up and AMCs and tremendous will power from existing health care system.

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