FREQUENCY AND REASON FOR DRUGS RETURNED BACK TO PHARMACY

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Abstract:
Despite the veritable drug explosion since the 1950s, a large number of drugs is being dispensed with a significant amount of returned drugs. Little is known of the specific details of such returns. These could be contributing as a subset of wasted medications. Indigenously prepared case records form concerning details of drugs returned was prepared and administered to the drug sales persons at various local pharmacies, after a short briefing session. This study indicated that returned medicines were only a subset of the unused medications. The relevant reasons included death of the patient, wrong medication, change in medication, similar looking or sounding drugs.

Key words: Returned drugs, expired drugs, similar sounding/looking drugs, drug utilization, drug policy making, discarded drug disposal

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INTRODUCTION
There has been a veritable drug explosion over the past century. Wide varieties of drugs have hit the market leading to widespread dispensing of drugs. In fact it can also be inferred that there is wanton and indiscriminate use of drugs, globally. “Prescription drug misuse and abuse is an urgent and growing threat to nation and its citizens, [1]”. The literature survey initiated prior to the conduct of the study showed references for unused medications, wasted medications and very few references to returned medications. The financial burden of the returned medication on the pharmacist and on the national government would be considerable [2]. The World Health Organisation Guidelines for drug donations also state that sending medicines overseas that would not otherwise be used within the source country is unacceptable [7]. There is a definite need to address this seemingly small problem by formulating appropriate policies. With the view to clarifying and quantifying necessary data, we have undertaken this study as a pilot project.

Classification of wasted drugs
Drugs are wasted due to many reasons, commonly:
1. Unused drugs: A drug which is purchased, after prescription or not, but which is not taken by the patient [3] due to the following causes-
   i. Disease and symptoms cleared
   ii. Change of drugs
   iii. Unnecessary drugs
   iv. Wrong drugs
      a) Similar sounding
      b) Similar looking
      c) Spelling errors
2. Discarded drugs: These are the drugs that cannot be taken by the patient which may be due to-
   i. Expired shelf life of drug
   ii. Contaminated/damaged drug
3. Returned drugs: Dispensed to patients but not taken and return back to pharmacist due to the following reasons-
   a) Death of patient.
   b) Wrong medication.
   c) Subsidence of symptoms.
   d) Improperly compounded drug or dispensing error [4].
   e) Improperly stored drugs
   f) Expensive drugs [5].
4. Recalled drugs: Drugs that have to be recalled for regulatory reasons.

MATERIALS AND METHODS
Case record forms were indigenously prepared to record all the possible aspects relevant to the return of the drugs. Such case records were given to pharmacy sales persons in our locality. A briefing session was conducted before enlisting their cooperation. These case record forms were collected at regular intervals up to a period of 4 months and 10 days. Relevant statistical tools were employed for interpretation of the results.

DISCUSSION
The total numbers of returned drugs were 340. An approximation of the total number of drugs dispensed by the pharmacy is calculated so as to have a comparator to quantify the drugs returned. The total number of drugs dispensed was approximated to be 3448 (vide figure 1). The drugs returned mainly comprised, cardiovascular drugs [8], GIT drugs, antibiotics, nutritional supplements, painkillers etc. This is the direct reflection of the commonest group of drugs being prescribed. ACE inhibitors, B blockers diuretics, CCB, and nitrates have often come back to the pharmacies for varied reasons. Nutritional supplements have also been returned which is indeed surprising. It was noted that iron preparation have often been returned and exchanged for other formulations of the same. As the study was conducted in urban area this large number could be misleading and requires to be extrapolated with the drugs dispensed in an entire locality.

An interpretation of the reasons described for return of drug by patient/ patient party is an indication of Rational Drug Use. The commonest returnee was for ‘change of dose’ eg. Single strength/ double strength, 400 mg / 800mg. The next common reason was ‘discontinuation of medication upon doctor’s advice’ [10]. This may be attributed to development of resistance, ineffective treatment, ADR, drug interactions.. ‘Changed medications’ is also an entity that is encountered on return of drugs due to ineffective therapy, resistant development, ADR, drug interaction and contraindication [17]. To a smaller extent similar sounding drugs and fallout similar spelling drugs also contributed to return of drugs eg. Astenelol/Astelong, betamethasone/beclomethasone [6]. Often times route of the drug administration would be changed during therapy which could lead to return of drugs eg. Amoxiclav injection followed by Amoxiclav tablet. Due to the humanitarian grounds, pharmacist has been known to allow for return of their drugs within a limited period and upon presentation of the bill. Often the patient’s relative can exchange for other common items. Pharmacist do not refund patient/ bistander but allow for exchange in kind (toothpaste, sanitary napkins, multivitamins, skin creams). During busy hours pharmacist themselves has alluded to similar looking tablets and similar...
looking bottles have been given to patients, mistakenly. Drugs would be considered “wrong” if they fell into any of these categories: similar looking drugs, similar sounding drugs, wrong route and wrong dose. Legend drugs- it requires prescription of a registered medical practitioner. Antihypertensive and antibiotics while OTC drugs- It does not require prescription like aspirin, antihistaminic and antacids

Often in studies in the US, it was noted that the community returned the following category of drugs-

• Controlled substances are drugs that are regulated by state and federal laws that aim to control the danger of addiction, abuse, physical and mental harm, the trafficking by illegal means, and the dangers from actions of those who have used the substances. These are the drugs that are illegal for sale or use, but may be dispensed under a physician’s prescription. Federal Schedules for Controlled Substances are as follows-

  ❖ Schedule 1: Marijuana crack, Cocaine
  ❖ Schedule 2: Morphine, codeine, methadone, fentanyl, dextroamphetamine etc
  ❖ Schedule 3: Combinations of codeine with aspirin or acetaminophen
  ❖ Schedule 4: Benzodiazepines, phenobarbital, propoxyphene, certain sedative drugs
  ❖ Schedule 5: Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone; for example Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams [12].

Some countries have a returned drugs policy where the Pharmacist and Medicare accept returned drug with reimbursement [13]. The pharmacists usually are not allowed to accept returned drug products and biological, once it has gone out their possession. This could be a dangerous practice and should not be considered as unused portion of drugs. This is because the assurance quality, purity and identity of the article is lost and cannot be vouched for. It is forbidden to take back drugs in the interest of public health. This debate has been on for a long time now.

Disposing of unwanted and unused drugs into the garbage can or flushing down the toilet can lead to even worse consequences to public health and environment [14]. Some countries have police station, involved in such “take-back” [15] and “mail-back” events [16] which are organized under the scrutiny of drug enforcement agency, so as to prevent stealing and pilferage. Unusable drugs are sent to reverse distribution where some may be declared as waste but the rest could reach the needy patient. In a similar way, there is a need for recycling of expensive medicines which are returned in good condition with resistant packaging, including bar code identification of manufacturer, date of manufacture, expiration date, medication name, and dosage [18]. The data indicate that approximately one-quarter of returned medicines is in a condition potentially suitable for re-use with almost two-fifths of these being essential medicines as defined by WHO [9]. Thus despite the low frequency of drugs being returned it would be worthwhile to analyse and put forth remedial measures to curve the same. In fact, policies may be formulated that would lead to minimal and essential drug dispensing.

CONCLUSION

This study indication that returned medicines were only a subset of the unused medications. The relevant reasons included death of the patient, wrong medication, change in medication, look- alike sound-alike (LASA)[11].

Take home message: It is easy to get a thousand prescriptions but hard to get one single remedy. – Chinese proverb

Limitations of the study

This study has many limitations as it was undertaken in a small span of times (45 days) and used only two of the private pharmacies in the town. This was undertaken to probe the impact and frequency of return of drugs. It would be considered as a pilot project and at a later date would be expanded to encompass all aspects from total number of drugs, quality and quantity of drugs that are wasted or returned. This endeavour requires man power and funding which we now lack.

REFERENCES


12. www.fda.gov/regulatoryinformation/legislation (Controlled Substances Act Title 21 - Food And Drugs Chapter 13 - Drug Abuse Prevention And Control Subchapter I - Control And Enforcement)


**Fig 1: The Total Number of Drugs Dispensed Was Approximated To Be 3448**
Fig 2: A Graphical Representation of ACE Inhibitors, B Blockers, Diuretics, CCB, and Nitrates Have Often Come Back To the Pharmacies for Varied Reasons