

Letter to the Editor

Drug expiry debate: the myth and the reality

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Introduction

There is so much wastage of drugs as they are not used in time. Medications are expensive, and in the Asian and African continents, where many have the problem of affordability the debate is to see if the medication could be used even after the expiry date without losing the efficacy. Most of drug expiration dates information is from the study conducted by the Food and Drug Administration at the request of the military. With a large and expensive stockpile of drugs, the military faced tossing out and replacing its drugs every few years. What they found from the study is 90% of more than 100 drugs, both prescription and over-the-counter, were perfectly good to use even 15 years after the expiration date.

Hence, the expiration date doesn't really indicate a point at which the medication is no longer effective or has become unsafe to use.

What does an expiration date mean?

The expiration date is the final day that the manufacturer guarantees the full potency and safety of a medication. Drug expiration dates exist on most medication labels, including prescription, over-the-counter (OTC) and dietary (herbal) supplements.

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Proper storage of medications may help to extend their potency. The bathroom and medicine cabinet are not ideal places to store medications due to heat and humidity. Similarly, medications should not be left in a hot car. Medications remain most stable in dry, cool spaces away from light. Keep the prescription bottle caps tightly closed and always keep medications out of reach of children and pets.

Expiry date

The 2015 commentary in Mayo Clinic Proceedings, "Extending Shelf Life Just Makes Sense," suggested that drug makers could be required to set a preliminary expiration date and then update it after long-term testing. An independent organization could also do testing similar to that done by the FDA extension program or data from the extension program could be applied to properly stored medications¹

The United States' Center for Drug Evaluation and Research officially recommends that drugs past their expiration date be disposed. It has been argued that this practice is wasteful, since consumers and medical facilities are encouraged to purchase fresh medication to replace their expired products, also resulting in additional profits for pharmaceutical firms.

According to the Food and Drug Administration (FDA) study gets to the heart of medicine expiration and safety. Updated: August 13, 2017, it turns out that the expiration date on a drug does stand for something, but prob-

ably not what you think it does. Since a law was passed in 1979, drug manufacturers are required to stamp an expiration date on their products. This is the date at which the manufacturer can still guarantee the full potency and safety of the drug.

Medical authorities state that expired medicine is safe to take, even those that expired years ago. It's true the effectiveness of a drug may decrease over time, but much of the original potency still remains even a decade after the expiration date. Excluding nitroglycerin, insulin, and liquid antibiotics, most medications are as long-lasting as the ones tested by the military. Placing a medication in a cool place, such as a refrigerator, will help a drug remain potent for many years.

Solid dosage forms, such as tablets and capsules, appear to be most stable past their expiration date. Drugs that exist in solution or as a reconstituted suspension, and that require refrigeration (such as amoxicillin suspension), may not have the required potency if used when outdated. Loss of potency can be a major health concern, especially when treating an infection with an antibiotic. In addition, antibiotic resistance may occur with sub-potent medications. Drugs that exist in solution, especially injectable drugs, should be discarded if the product forms a precipitant or looks cloudy or discolored.

A study by Khanchandani on efficacy, safety concern and disposal practices followed for expired drug preparations among medical personnel, found that 89.39% had knowledge that expiry date depends on both manufacturing and storing condition. Ninety one percent subject responded correctly that the drug should be best stored in cool dry and dark places. During the study they found out that majority consider expired drug use is not safe but 89.39% subject were aware about not using insulin, liquid antibiotic, nitroglycerin after expiry. The testing conducted by the US FDA ultimately covered more than 100 drugs prescription and OTC drugs. The result showed that about 90% were safe and effective as long as 15 years past their original expiration date. Loel Dawis, expiration date chief said that with a handful of exception notably nitroglycerin, Insulin and Liquid antibiotic most drugs are probably as durable as the agency tested.⁴

A study done by Simons on outdated EpiPen and EpiPen Jr auto injectors: past their prime, noted that, drugs dif-

fer in terms of their forms, dosage, and stability. Usually, drugs in liquid forms (e.g. solutions and suspensions) are not as stable as those in the solid forms (e.g. tablets and capsules). It has been reported that bioavailability of EpiPen® (epinephrine auto-injectors) were reduced when administered between 1 to 90 months after the labelled expiration date compared with those that were not yet expired⁵

Potency and efficacy

Medication's potency gradually decreases starting from the moment of its manufacture. This process is not in any way spontaneous after the expiry date.

Expired drugs have not necessarily lost their potency and efficacy. The expiration date is only an assurance that the labeled potency will last at least until that date. Ongoing research shows that stored under optimal conditions, many drugs retain 90% of their potency for at least five years after the labeled expiration date, and sometimes longer. Even 10 years after the expiration date many pharmaceuticals retain a significant amount of their original potency.²

Solid dosage forms, such as tablets and capsules, are most stable past their expiration date. Drugs that exist in solution or as a reconstituted suspension may not have the required potency if used when outdated.

The best evidence of acceptable potency of the medications beyond their expiration date is provided by the Shelf Life Extension Program (SLEP) undertaken by the FDA for the Department of Defense. The aim of the SLEP program was to reduce medication costs for the military. SLEP has found that 88% of 122 different drugs stored under ideal conditions should have their expiration dates extended more than 1 year, with an average extension of 66 months, and a maximum extension of 278 months.³ Certain medications have a narrow therapeutic index and little decreases in the pharmacological activity can result in serious consequences for patients. Monoclonal antibodies should be included in this group. These drugs should not be used beyond the expiry date.

Conclusion

The 2015 commentary in Mayo Clinic Proceedings, "Extending Shelf Life Just Makes Sense," suggested that drug makers could be required to set a preliminary expiration date and then update it after long-term testing. Even

though the literature denotes western circumstances, we can take a leaf or two to modify to work around it, so that it will be beneficial to the African continent, especially more so in the peripheral outreach health centers in Africa where availability and storage of medicines are a challenge.

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