

BEST PRACTICES FOR SHORT-TERM HEALTHCARE MISSIONS	
Question: Under which (if any) conditions can expired/outdated medications be used in short-term healthcare missions?	
Participants in discussion	Background (perspective)
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Why is this important? This is an issue of trust, safety and perceptions.	

Biblical concepts involved

Deception

[Psalm 12:2](#)

Everyone lies to his neighbor; their flattering lips speak with **deception**.

[Psalm 38:12](#)

Those who seek my life set their traps, those who would harm me talk of my ruin; all day long they plot **deception**.

[Jeremiah 9:6](#)

You live in the midst of **deception**; in their deceit they refuse to acknowledge me," declares the LORD.

[Hosea 10:13](#)

But you have planted wickedness, you have reaped evil, you have eaten the fruit of **deception**. Because you have depended on your own strength and on your many warriors,

[2 Corinthians 4:2](#)

Rather, we have renounced secret and shameful ways; we do not use **deception**, nor do we distort the word of God. On the contrary, by setting forth the truth plainly we commend ourselves to every man's conscience in the sight of God.

Good gifts

[Matthew 7:11](#)

If you, then, though you are evil, know how to give **good gifts** to your children, how much more will your Father in heaven give **good gifts** to those who ask him!

Do unto others as you would have them do unto you

Luke 6:31

Do to **others** as you would have them do to you.

Healing and trust

Proverbs 13:17

A wicked messenger falls into trouble, but a **trustworthy** envoy brings **healing**.

Submission to authority

Rom 13:1 Everyone must submit himself to the governing authorities, for there is no authority except that which God has established. The authorities that exist have been established by God. 2 Consequently, he who rebels against the authority is rebelling against what God has instituted, and those who do so will bring judgment on themselves. NIV

What is the scientific evidence regarding the use of expired medications?

Pharmaceutical companies are required to certify that their medications are safe, stable and efficacious.

The expiration date on medication was required by law in the United States, in 1979. The law specifies only the date the manufacturer guarantees the full potency and safety of the drug. Numerous studies have confirmed that medications used prior to the expiration date are stable¹⁻⁵. Studies have also confirmed that expired drugs lose some of their potency over time⁶. However, there is no evidence that a drug will stop being effective after the expiration date.

Studies indicate that many drugs have excellent bioactivity beyond their expiration dates

There are widely held opinions that most medication expiration dates are overly conservative. The rationale for such opinions is often based on the perception that the pharmaceutical companies will make more money if the medication has a relatively short expiration date. According to this theory, a lot of good medication will be discarded thus making it imperative that additional medications are manufactured. By having a more rapid turn-over of medication, more product will be sold and profits will be higher.

The Department of Defense and FDA evaluated the shelf life of 96 different drugs that were stored in US military facilities. Their data showed that 84% of 1122 lots in their unopened original containers would be expected to remain stable for an average of 57 months after their original expiration date⁷. Lyon et al recently expanded upon their previous Department of Defense work by evaluating the stability of a large number of medications⁸. Their report summarizes the extended stability profiles for 122 different

drug products (3,005 different lots). Based on testing and stability assessment, 88% of the lots were extended at least 1 year beyond their original expiration date for an average extension of 66 months, but the additional stability period was highly variable. The authors concluded that many drug products, if properly stored, can be extended past the expiration date; yet, the stability and quality of extended drug products can only be assured by periodic testing and systematic evaluation of each lot.

A study by Stark et al showed that captopril, cefoxitin sodium powder for injection and theophylline tablets stored under both ambient and "stress" (40°C and 75% relative humidity) remained chemically and physically stable for 1.5-9 years beyond their expiration dates⁸. Scholtissek et al showed that amantadine and rimantidine are stable in ambient conditions for 25 years and are even stable after being boiled⁹. Studies have reported efficacy for eye-drops removed from laminated packaging, left in a light in room temperature for 6 weeks, oral medications including policosanol^{4,5}, diazepam rectal gel³.

Pharmacists are required to label prescription bottles with an expiration date

Retail pharmacists, in accordance with the standards of the US Pharmacopoeia (USP), label prescription bottles with a "beyond-use" date which is generally one year from the date the prescription is filled¹⁰. In a study of pharmacist responses, most pharmacists recommended discarding medications within 1-2 years of purchase¹¹.

Some physicians use expired medications in their offices

Bottles of ophthalmic drops were evaluated in a study by Wessels et al. In 18 offices, of 1,485 open bottles (mean 12.2) on average 19.8% (range 0% to 88%) were expired¹². Only one open bottle (out of 1,485 bottle) of ophthalmic drops grew a *Micrococcus* (0.07%). Wessels concluded that drops in ophthalmology offices may be expired, but are not contaminated.

Not all medications have prolonged stability

Frimpter et al reported that a reversible renal tubular injury could be caused by expired tetracycline¹³. Current forms of tetracycline have been reformulated so that they do not cause the reversible renal damage reported by Frimpter et al¹⁰.

Drugs in liquid forms may not be as stable, particularly when frozen¹⁰. Any injectibles that have become cloudy or discolored should be discarded. Intravenous solutions with dextrose which have yellowed due to caramelization should also be discarded. Storage in high humidity may interfere with the dissolution characteristics of some oral formulations¹⁰.

Epi-pens have been shown to lose their potency after their expiration date¹⁴.

Oral rehydration salt (ORS) packets suitable for cottage industry scale produced by the International Center for Diarrhoeal Disease Research, Bangladesh were found to be stable for a period of 8 months. Some of the contents in the ORS packets were found to have turned a light brown color but this did not affect stability¹⁵.

Problems with medications obtained in informal markets in third world countries

Medications acquired in-country may not be effective. In a recent study by Guadiano MC, et al the investigators analyzed thirty antimalarial tablet samples containing chloroquine, quinine, mefloquine, sulphadoxine and pyrimethamine obtained

in the informal markets in Congo, Angola and Burundi¹⁶. The medications were found to have different kinds of problems: a general problem concerning the packaging (loose tablets, packaging without producer name, producer Country and sometimes without expiration date). Some medications were found to have a low content of active substance (in one sample); different, non-declared, active substance (in one sample); sub-standard technological properties and very low dissolution profiles (in about 50% of samples).

Buyers need to be aware of the practice of "dumping" drugs in developing countries that do not sell or sell for different indications at home; labeling of products differently than in the US; permitting over the counter sales of drugs that a prescription only goods in the US; selling products whose stated expiration date has passed; and charging high prices and reaping excessive profits.

World Health Organization (WHO) Standards for Donated Drugs (Second Edition 1999) - Excerpts

1. No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.

- a. *Justification and explanation*

Patients return unused drugs to a pharmacy to ensure their safe disposal; the same applies to drug samples that have been received by health workers. In most countries it is not allowed to issue such drugs to other patients, because their quality cannot be guaranteed. For this reason returned drugs should not be donated either. In addition to quality issues, returned drugs are very difficult to manage at the receiving end because of broken packages and the small quantities involved.

2. After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year. An exception may be made for direct donations to specific health facilities, provided that: the responsible professional at the receiving end acknowledges that (s)he is aware of the shelf-life; and that the quantity and remaining shelf-life allow for proper administration prior to expiration. In all cases it is important that the date of arrival and the expiry dates of the drugs be communicated to the recipient well in advance.

- a. *Justification and explanation*

In many recipient countries, and especially under emergency situations, there are logistical problems. Very often the regular drug distribution system has limited possibilities for immediate distribution. Regular distribution through different storage levels (e.g. central store, provincial store, district hospital) may take six to nine months. This provision especially prevents the donation of drugs just before their expiry, as in most cases such drugs would only reach the patient after expiry. It is important that the recipient official responsible for acceptance of the donation is fully aware of the quantities of drugs being donated, as overstocking may lead to wastage. The argument that short-dated products can be donated in the case of acute emergencies, because they will be used rapidly, is incorrect. In emergency situations the systems for reception, storage and distribution of drugs are very often disrupted and overloaded, and many donated drugs tend to accumulate.

- Additional exception*

Besides the possible exception for direct donations mentioned above, an exception should be made for drugs with a total shelf-life of less than two years, in which case at least one-third of the shelf-life should remain.

Sender Perspective

Before

Senders may apply indirect pressure to team leaders/physician team members to take donations of medications or equipment. Often these conversations start with, “I have some _____. Can you use it in _____ (fill in the name of a developing country)...”. Early explanation of policies (specifically: “No junk for Jesus”) is needed to decrease this problem. There also may be a gap in understanding and expectations. Often 19th and early 20th century paternalistic perceptions of medical missions predominate in many churches.

Senders may balk at paying for medications which may be very expensive. When medications from the home country are purchased, the cost for medications is often borne by team members who are already bearing the cost of the transportation, food and housing...

Senders have an expectation that team leaders have demonstrated due diligence when dealing with all aspects of their healthcare mission trip. Most senders will expect that the healthcare mission team leaders will be knowledgeable about issues of what is legal and right. If this

During

During the trip, senders expect that the team leaders will use good judgment to avoid problems for the team and the church. Jesus is to be glorified in what is done.

After

If a team has unexpected problems with expired medications in the country (medications confiscated, group asked to leave country, then the church will hold the leader accountable for the problems.

Goer Perspective

Before

One of the significant problems for leaders and teams that are geared to providing clinical care in a remote region, is that of gaining sufficient supplies. Most of these teams have limited or no money from outside sources (personal communication Peter Yorgin, MD). Friends may offer medications and physicians may have samples donated by a pharmaceutical company that have not been used. Given the limited resources available to the team, the offer of free medications can be tempting. Once acquired, however, sorting and removing unnecessary packaging can be time consuming. If all expired medications are extracted from the pool of donated medications, there are questions as to how to dispose of the medications in a safe way such that the medications do not end-up in landfills or the sewer system. One major concern regarding donations is the storage conditions of the medications (Humidity and heat). Teams certainly should be culling medications with damaged packaging or unrecognizable/unlabeled medications.

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One of the major questions that a team leader will need to address is, “Is more (medications) better?”. What if we had no medications, nothing (except God, of course!).

During

When entering a country with expired medications the leader and team may experience anxiety about being caught with the medications. Therefore, some teams spread the risk by dividing the medications to all team members. Bribes have been used to ensure that expired medications can enter the country without customs problems. One of our teams was told to “pray” when going through customs with large boxes of expired medications (personal communication Peter Yorgin, MD). Often the team leader and the team members are left with a sense of guilt even if the medications are successfully brought into the country.

Patients do not receive culturally relevant informed consent regarding the expired medications they receive. How does one explain the use of expired medications in a contextualized appropriate way given the culture?

Often the remaining donated medications, which are not used during the “clinic”, are the ones that are rarely used in clinical practice in the United States; thus they pose a “dumping” problem when the team wants to leave the remaining medications in the host country.

After

Some team members will have long-term guilt and concern about the deception required to prescribed expired medications.

Recipient Perspective

Before

If there is knowledge that a short-term healthcare mission team is coming to a particular location, the people may have pre-conceived notions. There may be an assumption that there is a high correlation between medical missionaries and high efficacy healing. Basically stated, there are high expectations and a high level of inherent trust.

During

Most medications distributed to patients are not in their original container. At a minimum there should be the name of the medication written in the local language so that a physician could understand what was given. Secondly, the amount and frequency should be written in the local language. Someone should review the instructions with the patient and basic indications to seek a physicians help. It would be good if the drug expiration date was written on the form.

If an expired medication is administered, would the person understand issues related to the lack of efficacy? Any discussion like this could easily erode trust.

After

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If the recipient perceived that they are receiving something that is second-hand, then there is likely to be a sense of betrayal which can impede the ability of our partner to be effective in our sharing of the Gospel.

CONSENSUS STATEMENT

As followers of Christ, we represent what is good and right. Deception is not part of who we are, as it can quickly erode trust. Trust is at the crux of this issue. Do we trust God's ability to heal, when we have less?

BEST: DO NOT USE EXPIRED MEDICATIONS

BETTER: ONLY USE EXPIRED MEDICATIONS FOR OURSELVES AND OUR FAMILIES

GOOD: EXPIRED MEDICATIONS MAY BE USED AFTER ALL OF THE FOLLOWING CONDITIONS HAVE BEEN MET:

1. The patient's condition justifies accepting some risk
2. No other good options are available (use of non-expired medications)
3. Ministry partner is aware and concurs
4. Efficacy and stability of medication is likely to be good given storage conditions and condition of packaging
5. Contextualized consent obtained and witnessed
6. [Compliance with local government rules and regulations is confirmed](#)

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News related to this issue:

<http://www.dailynews-tsn.com/page.php?id=235>

Expired drugs destroyed in Kagera

Correspondent MEDDY MULISA in Bukoba
Sunday News; Sunday, April 02, 2006 @01:03

UNREGISTERED and **expired** drugs worth 30.7m/- have been destroyed by the Tanzania Food and Drugs Authority in Kagera Region, it has been disclosed.

The Authority's co-ordinator in Lake Zone, Mr Yonah Hebron, said the drugs were **confiscated** during an inspection carried out between February and last month in Bukoba Rural, Muleba, Bukoba Urban and Biharamulo districts.

He said in Biharamulo District drugs worth 28.3m/- were destroyed including those unregistered, which were worth 1.5m/- while in Muleba District unregistered drugs worth 16,200/- were destroyed.

Mr Hebron said drugs worth 2.4m/- were destroyed last Friday with the Bukoba regional hospital alone.

He said some of the drugs were issued to hospitals through donations as they were approaching expiry dates.

He said in some instances some of the drugs were in no use in the tropical countries .

The co-ordinator said some of the unregistered drugs were being sold by unscrupulous traders through black market and were hard to control.

Mr Hebron warned any person who contravenes the provisions of the Tanzania Food, Drugs and Cosmetics Act, 2003 relating to manufacture, importation on retail or wholesale of products regulated under the act, commits a criminal offence.

He said upon conviction such a person shall be liable to a fine ranging between 500,000/- and 5m/- or sent to jail up to two years, or both.