

What's in your sample closet? A cross-sectional study to quantify the number of expired samples and to evaluate novelty and usefulness of sample closet medications.

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Background

Sample medications are commonly distributed in U.S., dispensed in 20% of office encounters.

- Sample medications are more frequently used by wealthy and insured.
- Use of sample medications associated with decreased medication counseling.
- Presence of sample medications alter physician prescribing practices.
- Use of sample medications Increase out of pocket cost for the patient.
- Time is required to maintain sample closets.
- Newly approved medications are commonly marketed as sample medications. Most new medications are not novel or useful.

No prior study has inventoried drug sample closets and examined the novelty and usefulness of their contents.



Figure 1: Examples of poorly organized and well organized sample closets.

Objective/Hypothesis

To quantify the number of expired sample closet medications and to analyze the medications most commonly found for their novelty and usefulness. We hypothesize that the medications found in local sample closets will often be expired and will not be novel or useful.

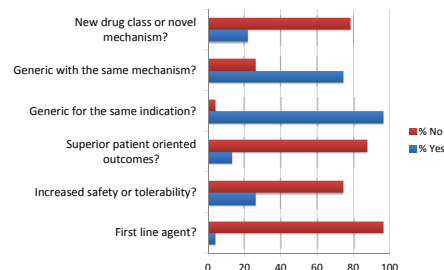


Figure 3: Analysis of novelty and usefulness of drug samples based on 6 designated questions.

Trade Name	Generic name	Date Initially FDA Approved	# Sites containing sample	Indications	Most Common Initial Dose	Cost of 30 day supply
Bystolic	nebivolol	2007	9	Hypertension	5mg daily	\$68 / 30 tabs
Crestor	rosuvastatin	2003	9	Hyperlipidemia	10mg daily	\$157 / 30 tabs
Januvia	sitagliptin	2006	9	Type 2 Diabetes	100mg daily	\$244 / 30 tabs
Micardis	telmisartan	1998	9	Hypertension	40mg daily	\$124 / 30 tabs
Toviaz	fesoterodine	2008	9	Overactive Bladder	4mg daily	\$159 / 30 tabs
Avodart	dutasteride	2001	8	Benign Prostate Hyperplasia	0.5mg daily	\$129 / 30 tabs
Cymbalta	duloxetine	2004	8	Depression, Anxiety	60mg daily	\$183 / 30 caps
Diovan	valsartan	2001	8	Hypertension	80mg daily	\$97 / 30 tabs
Lipitor	atorvastatin	1996	8	Hyperlipidemia	20mg daily	\$183 / 30 tabs
Lovaza	omega-3-acid ethyl esters	2004	8	Hypertriglyceridemia	4gm daily	\$190 / 120 1gm caps
Pristiq	desvenlafaxine	2008	8	Depression	50mg daily	\$153 / 30 tabs
Seroquel	quetiapine	1997	8	Schizophrenia, Bipolar Disorder	200mg BID	\$749 / 60 tabs
Actos	pioglitazone	1999	7	Type 2 Diabetes	30mg daily	
Amitiza	lubiprostone	2006	7	Chronic idiopathic constipation	24mcg BID	\$272 / 60 caps
Celebrex	celecoxib	1998	7	Joint Pain	100mg BID	\$176 / 60 caps
Enablex	Darifenacin	2004	7	Overactive Bladder	7.5mg daily	\$167 / 30 tabs
Levitra	ardenafil	2003	7	Erectile Dysfunction	10mg	\$21 / tab
Maxalt	rizatriptan	1998	7	Migraine Headache	5mg	\$32 / tab
Savella	milnacipran	2009	7	Fibromyalgia	50mg BID	\$146 / 60 tabs
Spiriva	tiotropium	2004	7	COPD	1capsule (18mcg) daily	\$289 / 30 caps
Synthroid	levothyroxine	2002	7	Hypothyroidism	100mcg daily	\$21 / 30 tabs
Trilipix	fenofibric acid	2008	7	Hyperlipidemia, hypertriglyceridemia	45mg daily	\$54 / 30 caps
Vytorin	ezetimibe and simvastatin	2004	7	Hyperlipidemia	10/20mg daily	\$148 / 30 tabs

Figure 2: Characteristics and cost of the most commonly found medications in sample closets.

Methods

We inventoried 10 sample closets in primary care clinics participating in the University of Arizona College of Medicine Phoenix longitudinal clinical experience program, quantifying the number of expired medications and analyzing the 23 medications found in seven or more closets. To assess novelty, we determined if the sample medication: had a new mechanism of action, had a generic on market with same mechanism of action, and had a generic medication on market for the same indication. To assess usefulness, we determined if the sample medication had improved patient oriented outcomes, safety, and tolerability. We searched evidence based guidelines to determine if the medication was a first line agent. We noted the cost of a one-month supply for the typical starting dose of each sample medication.

Results

See Figures 2-4.

- 12,581 drug packages and boxes inventoried
- 14% of were expired
- 96% (n=22) had a generic medication on the market for the same indication and 74% (n=17) with the same mechanism
- 3 medications (13%) had evidence of superior patient oriented outcomes and 6 medications (26%) demonstrated superior safety and tolerability
- 1 medication (4%) was recommended as first line
- \$178 = mean cost for a one month supply of a typical starting dose

	Mean	Median	Range	Total for 10 closets
Number of sample boxes/packages in closet	1,258	1,114	83-2,850	12,581
Number of expired boxes/packages in closet	170	96	0-796	1,698
Expired boxes/packages as % of total	10.4%	8.4%	0-28%	13.5%

Figure 4: Inventory results demonstrating presence of expired drug samples in most closets.

Discussion

We found that the medications most commonly found in drug sample closets are frequently expired, are rarely novel or useful, and are expensive.

Thirteen and a half percent of sample closet medications were expired, which extrapolates to an estimated \$2.2 billion of wasted samples in the United States annually.

Only 5 of the 23 medications are the first in a new class of medications and superior safety or tolerability data existed for only 26% of the sample close drugs, making 74% of the drugs "me too" drugs. Twenty-six percent may actually overstate the incremental benefit of the sampled medication since the incremental improvement in tolerability or safety often existed only in a limited number of industry-funded studies.

Ninety-six percent of medications found most commonly in sample closets are not first-line agents. Several medications are listed among guideline options, but often a generic is also listed as an option in the guidelines.

Sample closet medications are expensive. Non adherence is common when the cost to the patient is high; this has the potential to increase morbidity.

Sample closet medications commonly are no safer, are neither novel nor more effective than existing generics, and are often expired. Sample closet medications increase the cost both to the patient and society. The time has come to re-examine the use of sample closets.

Future Directions

- Expansion of study to urban and rural settings in US and across specialties to determine if our results can be generalized.
- Correlating drug sample inventories with office maintenance logs to determine number of medications that go to waste.
- Repeating drug inventories at regular intervals to track novelty and usefulness changes with new drugs on the market.