

Sourcing, Compounding, & Administering TB Drugs

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Why Compounding Pharmacy?

- Practitioners asking for practical information
- Small Facilities may not have the infrastructure to meet the patients needs



Why Compounding Pharmacy?

Can help
with Rx
sourcing



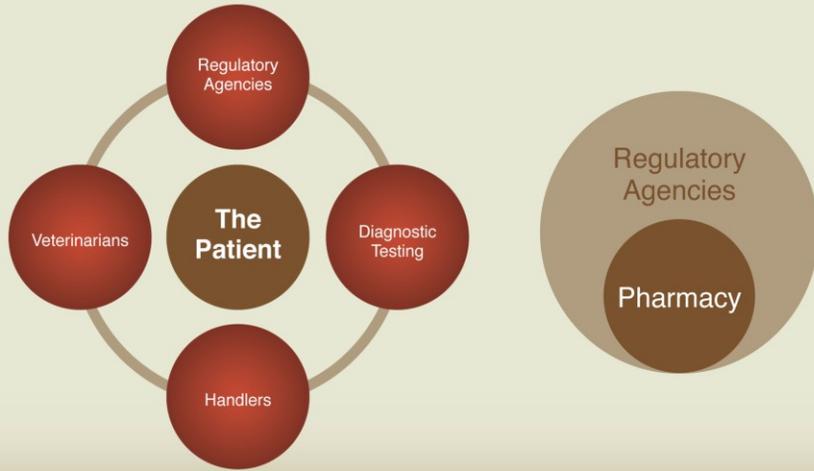
Have
compounding
equipment



Can
manipulate the
drug into a
patient suitable
dosage form



The Big Picture



Information That Helps The Pharmacist

- Name of Elephant
- Name of Drug(s)
- Initial dose of each drug
- Body weight of animal(s)



Information That Helps The Pharmacist (continued)

- Route of administration – Oral or Rectal
- What foods and flavors the patient likes
- What dosage form to try starting with – how you want it packaged
- Formulations that have been used
- Expected duration of treatment
- Sources of TB information/literature/web



Sourcing Large Drug Quantities

- Pharmacies have 4 avenues to obtain drugs
- Traditional Drug Wholesalers
- Compounding Suppliers
- Chemical and Raw Drug Companies
- Manufacturers



Traditional Drug Wholesalers- This is where 90+% of pharmacies in the country purchase their drugs. These are the commercially available meds that you and I get at a typical pharmacy.

Compounding Suppliers- They supply raw drugs and equipment basically most everything a small compounding pharmacy needs to make a typical prescription.

Chemical and Raw Drug Companies- These are companies that sell chemicals and raw drugs. Some of them sell to drug manufacturers, some of them sell to compounding suppliers, and tons of other manufacturers.

Drug Manufacturers- In the 10 years I have worked for this company we have purchased directly from the manufacturer a hand full of times and it was usually because it was a newly released chemo drug that the company wanted to control the chain of custody on. However many times they have programs in place for low income patients but I have never been successful in getting them to donate for veterinary use. By all means if you have an in with a drug company I would try any way you can to leverage it for donated drugs.

Commercial Product Availability

Drug	Availability 4/1/11
Isoniazid 300mg tab	43 Bottles
Rifampin 300mg cap	22 Bottles
PZA 500mg tab	17 Bottles
Ethambutol 400mg tab	98 Bottles



These totals are from McKesson who is the largest drug wholesaler in the country. This is their total inventory available to us w/i a reasonable time frame. In the past when we have sourced these drugs we purchased entire quantities from multiple warehouse's and wiped out all their stock. After doing this a few times we were told just because the inventory is available doesn't mean we are entitled to it. McKesson has min inventory commitments to hospitals and state health agencies and their official position is now that they will not deplete their inventory below min levels due to not being able to supply meds to treat a human patient and that poses "a public health risk". The last time we sourced Ethambutol commercially we bought almost everything from the top 3 wholesalers in the country.

API Availability

Many APIs are sourced from Chemical Companies and Compounding Suppliers

- The majority, if not all, of the of the primary TB drugs are made over seas and are imported from FDA registered facilities
- Customs can add delays to delivery



After a recent conversation with someone at Center for Veterinary Medicine @ FDA we were told that if we experience a delay in customs they will intervene to prevent an elephant from suffering. I wish we would have know this when we waited 12 weeks for our Ethambutol.

Relative Costs?

The cost of APIs are usually significantly cheaper than the commercially available product.
However this is not always true.



Cost of Commercial Products vs API (Bulk Chemicals)

Drug	Qty	API	Commercial Product
INH	1kg	\$1500-\$1600	\$350-\$1000
Rifampin	1kg	\$1000-\$3800	\$3500-\$5000
PZA	1kg	\$1300-\$2500	\$6000-\$7500
Ethambutol	1kg	\$1200-\$2500	\$4500-\$5500



This slide is pretty self explanatory but I want to point out that in the instance of INH the commercially available tablets are less expensive than the raw drug. These prices are effective as of 4/1/11. Please understand we are at the mercy of our suppliers and the quantities we order. Recently we leverage our buying power buy combining orders for multiple facilities buying 5kg is a lot more expensive than buying 100kg.

Routes of Administration

Oral vs. Rectal



Oral Administration

- The best levels of TB medications have achieved with:
- bolus dosing
- empty stomach
- elephants trained to accept a bite block



Rectal Administration

This is a G rated slide
No photographs please



Rectal Administration

- Adequate bowel evacuation
- Liquid administration placement via syringe/pump and tubing



Oral Administration

- Intake of medications over food –
or on the floor
- Absorption of medications with food
- Medication inactivation with foods
i.e. INH with glucose



FOOD

How much is too much?



Foods LONG List

- Coke
- Jello
- Bread
- Bananas
- Fruit juice
- Oats
- Barley
- Apples
- Corn
- Potatoes
- Broccoli



Foods Continued

- Chocolate
- Donuts
- Molasses
- Molasses balls
- Bread
- Icecream
- Pineapple
- Honey
- Popsicles
- Rice balls
- More.....



Flavors

- Anything sweet
- Marshmallow
- Mint
- Peppermint
- Tobacco
- List continues.....



Initial treatment attempts

- Molasses
- Gelatin block
- Flavors
 - Citrus



Wasted Medication

- If we prepare a drug in a dedicated flavor or dosage form and it can't be used then the facility has lost money



How we avoided wasted medications

- Provide a carrier agent that would neutralize the taste of the drug
- Utilize the smallest volume possible
- To be added not long before administration



Stability

- There is no long term data for stability of compounded medications



One Successful treatment vehicle

- Ethambutol – agents to block the taste and then incorporate flavors to match what the patient would ingest
- Complex combination of ingredients
Sweetening agents, flavors, bitter reducers
- Bitterness of Ethambutol modified



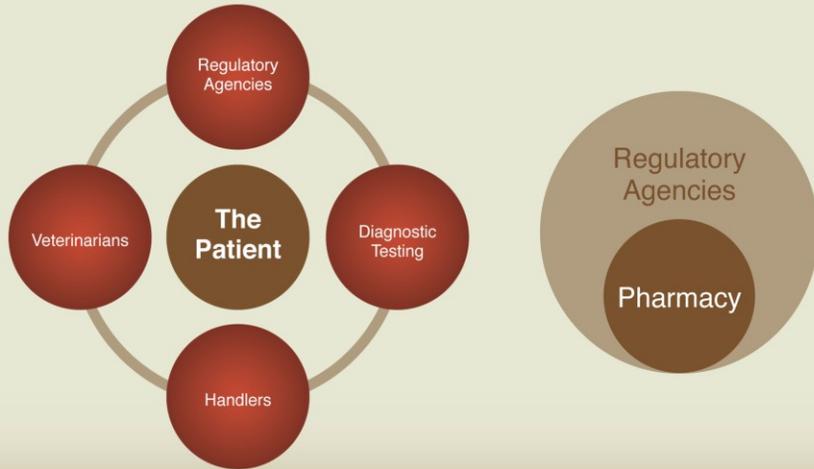
Down side to choosing dedicated flavor is if animal refuses it you are stuck with that dosage form

Palatability Modifying Attempts

- Patient Specific
- Many techniques may need to be employed



This is how we started





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