Pharmaceutical Management Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
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This issue's theme:

Childs Play

Wouldn't it be nice if everything was fun all the time? Sadly, it isn't, or as my old boss used to say, "If it was fun, they'd call it play. It isn't, so they call it work." Admittedly, he was kind of a grump, and in these enlightened times, most managers try to keep work engaging and at least a little fun. In this issue of INSIDE PMB, we use children's games to bring you the latest news.

- Ever wondered what to do to report an error involving PMB-distributed investigational agents? See below.
- Red Rover, Red Rover, send your ordering designee right over! That's right, the manual ordering team is facing off with the OAOP team, and we're hoping the OAOP team wins. What's OAOP? See page 2.
- When an error occurs, it's do-not-pass-go, do-not-collect-$200! Page three presents some tips to prevent several kinds or errors.
- Our patient page (page 4) includes a patient wallet card to ensure that when patients visit emergency departments (or new health care providers) they have critical information.

INSIDE PMB

May 2011

Marco! Polo!

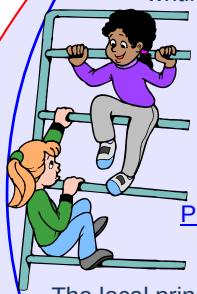
Every adult at the pool cringes when they hear the first kid call, "Let's play Marco Polo!" Any semblance of peace evaporates as a waterlogged kid calls, "Marco!" and screaming friends respond, "Polo!" endlessly.

There's a similar situation that arises here at PMB. Here's how it goes: Someone at a site sends in a request for something–it might be via pmbafterhours@mail.nih.gov or it might be on a Clinical Drug Request. Marco! We answer, usually within hours. Polo! Then someone else from the site sends the same question or request! Marco. And we answer again, and explain that someone else had already made the request. Polo! And sometimes, someone else asks the same question again. MARCO and POLO with a big eye roll here!

Many sites use a central e-mail address to save everyone's time. If that's not possible at your site, be sure to copy others who need to be in the know. We will always "reply all."

Error Reporting: A Group Activity

When you identify an error involving CTEP-supplied investigational agent, don't monkey around. Notify the Pharmaceutical Management Branch (PMB) as soon as possible afterward. Do it in writing or by e-mail. Using regular mail, send your report to:



Chief, Pharmaceutical Management Branch/CTEP
6130 Executive Boulevard
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Using e-mail, send your report to either PMBAfterHours@mail.nih.gov or hallch@mail.nih.gov.

The local principal investigator (PI) identified on PMB's shipping documents is ultimately responsible for all aspects of the protocol. Other staff members may develop and collate medication error reports and copy the PI in the final e-mail report that you send to PMB. This provides adequate documentation of the local PI's involvement in the process. PMB has an FAQ on this topic that tells you what to include in your report. Find it and many others that are very helpful here:

http://ctep.cancer.gov/branches/pmb/faq.htm

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Cancer Institute

INSIDE PMB
May 2011

On-line Ordering: Stop Playing Hide-and-Seek!

Since we made our new Online Agent Order Processing (OAOP) application available to ordering designees in November 2010, we've seen a steady increase in the number of players using this function. Currently, a third of our orders come over the Internet. If you're still on the sidelines watching or waiting, please know that this application replicates and improves the rapidly-becoming-obsolete manual process. All PMB customers who order investigational agent can now find this application at https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jspx. Very shortly, on-line ordering will replace the fill-out-the-form-and fax-it-and-hope-it-goes-through process for most sites. OAOP is full of e-mail notifications and self check-out options!

OAOP is like a game of Mother-May-I? The first time you use it will be the hardest. You ask for permission to do things by clicking on buttons, boxes and drop-down tables. If you ask, "Mother, may I order bevacizumab for Dr. Jumpinski on Protocol PLAY-0123?" and Dr. Jumpinski isn't registered on that protocol, the system will tell you gently, "No, you may not." The Box on this page gives an example of how using OAOP can save time when you unknowingly have an invalid courier account.

Get in the Game! It's simple once you do a few things:

If you don't have one, establish a CTEP Identity and Access Management (IAM) account.

- Access IAM from the PMB page on the CTEP web site http://ctep.cancer.gov/branches/pmb/associate_registration.htm or directly via the URL https://eapps-ctep.nci.nih.gov/iam/.
- An "active" account status requires an initial registration and annual re-registration, both of which can be completed online using IAM. You'll receive a "Re-registration Notification" email from "CTEP Identity and Access Management" 14 days in advance to let you know it's time to re-register.
- A "current" password requires you to change your alpha-numeric-and-special-character laden password every 60 days (yeah … we love that, too). OAOP will alert you if you try to login with an expired password, and will allow you to change your password.

To use OAOP, you must produce documentation that you are either the shipping designee (box 11) or an ordering designee (box 12) on the most recent Supplemental Investigator Data Form on file with PMB for each investigator for whom you want to order investigational agent.

- This is the same as the current requirement designating who can sign the Clinical Drug Request for a given investigator.
- For assistance with updating the shipping and ordering designees on an investigator's Supplemental Investigator Data Form, contact the PMB Registration Help Desk PMBRegPend@ctep.nci.nih.gov.

Invalid Account Numbers: Baby Steps?

Often, sites need agents more quickly than PMB's standard (and free) shipping will deliver them. When that's the case, you must provide a courier account number that we'll use to pay for the shipping. Lately, we've seen an upswing in the number of invalid account numbers provided by ordering sites.

If you order manually, we have to call or e-mail your site to let you know there's a problem. Then you have to investigate and call us back. PMB is Mother, and the answer to "Mother may I?" is, "Nope, not on this account number." It's baby steps to the desired outcome as we trade calls and e-mails.

If you use OAOP, the system is Mother, and it will check that the FedEx account number you provide is correct as you enter your order!* It's better than baby steps–it's even better than Giant Steps! It's jumping Jack steps or karate steps!

*At this time, it does not check UPS numbers.

If you decide to brave the new world of online agent ordering,

please let us know if you have questions or comments and, perhaps most importantly, if you encounter glitches.

And add the web link https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jspx to your favorite places or desktop!

OAOP Game of the States

Here's a guessing game for you: Where do you think the heaviest OAOP users are located? Are they in the big cities, on the coasts, or out in the country?

PMB thanks pharmacy staff at

- Memorial Sloan Kettering in New York City
- the University of Chicago in Chicago, Illinois; and
- the Mayo Clinic in Rochester, Minnesota

for their willingness to use OAOP. They are our heaviest system users–they are also very large institutions in all fairness!

Why aren't you using OAOP?

Whisper in our ears. Please.

E-mail pmbafterhours@mail.nih.gov

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INSIDE PMB
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Chalk it up to Experience…

Temsirolimus (Torisel) is a chemotherapeutic agent manufactured by Wyeth Pharmaceuticals. The agent is used in many NCI-sponsored investigational studies. An IV admixture error occurred at a site using PMB-supplied temsirolimus; after careful review, we determined that PMB's pharmaceutical information was not a reason for error. The error was caused by faulty computer programming. Here's a reminder for all of us how such an error could occur:

Temsirolimus's drug concentration hop scotches all over the place! At the start, the drug vial contains (and is labeled as) 25 mg/mL. Since it contains 1.2 mL with the overfill, it has 30 mg in actuality. The diluent vial contains 1.8 mL of vehicle. When you add the diluent to the vial containing active drug, it yields a volume of 3 mL at a final concentration of 10 mg/mL. Remember that the vial is still labeled with a concentration of 25 mg/mL although the concentration is now 10 mg/mL! You'll under-dose patients if you use (or you program your computer to use) 25 mg/mL as the agent concentration instead of 10 mg/mL. The Department of Veterans Affairs Medication Advisory Panel and Center for Medication Safety have made for following recommendations:

1. When preparing temsirolimus injection, be aware temsirolimus concentrations differ *before* and *after* dilution.
2. Keep the package insert with the full dilution instructions with the vials of both temsirolimus and its diluent, since no instructions appear on the vials themselves.
3. Create a warning system to notify staff that the temsirolimus concentration changes as you progress through dilutions! Consider using computer alerts during the ordering/verifying process and/or warning stickers on packaging.

Clinicians who don't adhere strictly to PMB or package insert admixture instructions increase the risk of mixing error.

E-Z Bake Ovens and Obsolescence

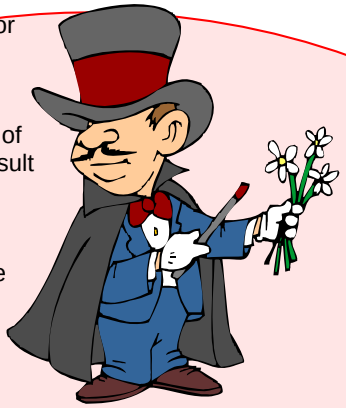
Since 1963, many aspiring chefs have started their careers with E-Z Bake Ovens. With federal legislation removing 100-watt incandescent light bulbs from the marketplace this year, those of us who've saved our personal E-Z Bake Ovens for our grandchildren may find ourselves unable to supply the heat needed to make those awful little cakes! (Don't fret! The new improved E-Z Bake Ultimate uses a heating element and lets kids make cakes, pizzas and batches of cookies!)

Speaking of batches, please make the following batches obsolete in your medication preparation areas and counseling practices:

- Please don't make batches of medication for patients on blinded studies. Make each patient's dose individually. We note that errors happen more often when clinicians line up all the blinded doses and prepare them like they're doing factory work.
- Please don't batch your entries on the Drug Accountability Record Form (DARF). As you use the agent, record the pertinent data. Sites that jot down what they used and when on little sheets of paper, note cards, the backs of hands, or cupcake papers often lose track of where their agent went.
- Please counsel patients on how to use medication diaries if they are included in the protocol. Tell them not to batch entries, instead recording doses as they take them.

Amendment Request: No Smoke 'N' Mirrors

PMB is amending trials using PMB-supplied lenalidomide. The amendment will address two major areas: trained counselors and package labeling.



We're not just pulling a rabbit out of our hats. The first change is a result of an FDA mandate that trained counselors document patient counseling with each month's supply. Each site needs to ensure that two trained health-care professionals have completed an on-line training program developed by Celgene.

The second is like changing nickels to dimes–we're transitioning from investigationally-labeled supply to commercially-labeled supply for investigational use. YAY! We're going to bottles of 100 across the board! Poof! Packages of 21,28, 63, or whatever will disappear.

Watch for the forthcoming amendment with more details. For questions contact Tali Johnson at tmjohnson@mail.nih.gov.

Do the Hokey Pokey

Novartis indicates that everolimus (Afinitor) 5 mg tablets are in short supply. This means that trials CALGB-80701 and 8603 will have to use 2.5 mg and 10 mg tablets to accommodate various dosing schedules. We sent an amendment request on April 15 to reflect the new strengths for the pharmaceutical section of the protocols. In the meantime, we ask that you order only what you need. It's like this: they put the 5 mg tabs in, they pulled the 5 mg tabs out, they'll put the 5 mg tabs back in…

We're doing the *shake it all about* dance here: Beware that all strengths of everolimus are packaged in boxes of blistercards, 7 tablets per card. Please flag the different tablet strengths to help differentiate between them.

After verifying the appropriate dose, counsel patients to ensure understanding. Unfortunately, PMB cannot guarantee that patients will receive the same strength each month during the shortage.

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Patient Page

In this age of medication reconciliation mandated by accrediting and certifying agencies, one of the biggest issues health care facilities face is getting a complete and accurate list of medications from patients. This can literally turn into a game of Hang Man in the emergency department as patients describe their medications as, "a blue pill for pressure, a white oval pill for blood sugar, something for cholesterol ..and I'm on a study for my cancer." Staff can try to figure out the FDA-approved medications by calling pharmacies and using pictures, but have little to go on for the investigational agent. Two ways to improve the chances of accurate drug lists are to encourage patients to always bring their medications with them in a bag, and to use a wallet medication card. The one we present below is a standard format used by many facilities across the nation annotated with clinical trial information. Although this patient information page is usually designed for you to give it to patients during counseling, we urge you to find the original of this form on our web site at http://ctep.cancer.gov/branches/pmb/faq.htm. The form there is full size and will be easier to use. More complete directions are included also.

Date of Most Recent Adult Immunizations:	Other Important Information:	Doctors:
Pneumonia:	*I am participating on a clinical trial to treat my _____ cancer. The trial number is _____, and I am taking the investigational drug _____.*	Name:
Tetanus:		Phone:
Hepatitis:	INVESTIGATIONAL DRUG STUDY CONTACTS	Name:
Flu:	**Doctor:**	Phone:
What medications should I include?	Name:	Name:
Prescription medicines	Phone:	Phone:
Over-The-Counter medicines	Study Nurse:	**Pharmacies:**
Vitamins	Name:	Name:
Herbal remedies	Phone:	Phone:
Nutrition pills	**Pharmacy:**	Name:
Respiratory therapy medicines (such as inhalers)	Name:	Phone:
Blood factors (such as Factor VIII)	Phone:	Name:
IV solutions		Phone:
IV nutrition		
Investigational or experimental drug		

Wallet Medication Card

Name:

Address:

(TIP: Use a return address label)

Phone:

Emergency Contact Name:

Emergency Contact Phone:

Allergies:

Fold here first *Fold here first*

Start date	Drug Name & (Strength)	Dose (pills, units, puffs, drops)	When do you take it? How many times a day? Morning & night? After meals?	Reason Why do you take it?	Start date	Drug Name & (Strength)	Dose (pills, units, puffs, drops)	When do you take it? How many times a day? Morning & night? After meals?	Reason Why do you take it?
1/1/06	Medicine (40 mg) **(Example)**	2 pills	Once a day with dinner	Heart					

Modified with permission based on the Wallet Medication Card developed by The Connecticut Department of Public Health with partners including the Connecticut Hospital Association (CHA), the CHREF Patient Safety Organization, Qualidigm, and the Qualidigm.

Find PMB's Frequently Asked Questions at http://ctep.cancer.gov/branches/pmb/faq.htm.

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