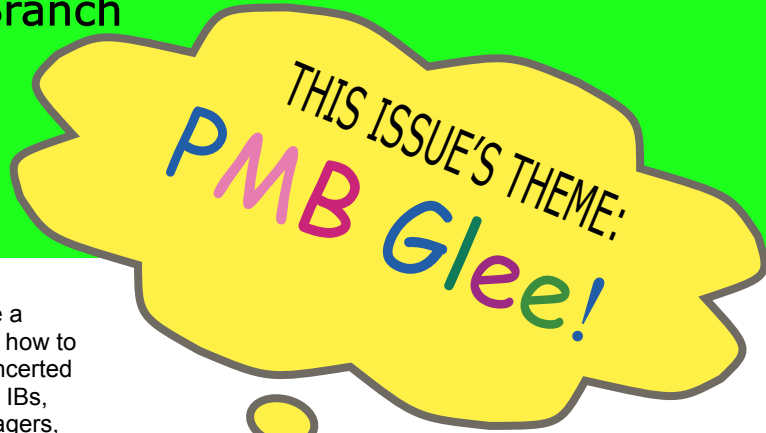


November 2011

INSIDE PMB

Pharmaceutical Management Branch

Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
6130 Executive Blvd * Suite 7149
Rockville, Maryland 20852
Phone: (301) 496-5725
Order fax: (301) 480-4612 * Other fax: (301) 402-0429



This issue's theme has a Glee! slant. We don't expect everyone to be a Glee! (ardent fan of the television show, Glee), but hopefully you know how to get your frolic on and break into song now and then. We've made a concerted effort to bring you quality programming. Watch for new stuff on OAOP, IBs, INDS, and BSA. Oh yeah, we also have an article on high school teenagers, written by one of our star performers. Enjoy the show!

BSA

IBs

INDS

OAOP

Pilot OAOP: Picked for Full Season

Many sites have taken advantage of Online Agent Ordering Processing (OAOP; located at <https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jsp>). If your site is not one of them, we strongly encourage you to begin using OAOP now. Soon, PMB's choral director will announce the deadline for sites to convert to OAOP for PMB-supplied agents. Don't be part of the Clinical Drug Request (CDR) rival network. Get on the OAOP bandwagon because the paper-based, faxed copy of the CDR form will be pulled off the air.

Like switching from VHS to DVD, OAOP has many user-friendly advantages, including order confirmation, shipment notification, and tracking information. OAOP guides users to select protocol-specific order elements and alerts users about incomplete requests, eliminating the many reasons that orders were placed on hold in the past. Sites can query previously submitted orders and use the built-in communication tools to correspond with PMB.



PMB has just two requirements for using OAOP to order investigational agents:

- **Create a CTEP IAM account and maintain an "active" account status and a "current" password**
 - IAM (Identity and Access Management) can be accessed from the CTEP web site http://ctep.cancer.gov/branches/pmb/agent_order_processing.htm, from the OAOP web site <https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jsp>, or directly via the URL <https://eapps-ctep.nci.nih.gov/iam/>.
 - An "Active" account status requires an initial registration as well as an annual renewal, both of which can be completed online using IAM. (Note ... 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 password every 60 days (yeah ... we love that one, too!) and follow the DHHS password requirements. OAOP will alert you when you try to login with an expired password and will allow you to change your password at that time.
 - For assistance with your IAM account, contact the CTEP Registration Help Desk <CTEPRegHelp@ctep.nci.nih.gov>.
- **Ask each investigator for whom you order investigational agents to identify you as either the shipping designee (box 11) or an ordering designee (box 12) on their most current Supplemental Investigator Data Form on file with PMB.**
 - This replicates the current paper-based requirement that identifies who can sign the CDR for a given investigator.
 - For assistance with updating shipping and ordering designees on an investigator's Supplemental Investigator Data Form, contact the PMB Registration Help Desk <PMBRegPend@ctep.nci.nih.gov>.

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

Missing an IB; Maybe it was a dress rehearsal?

Numerous reasons explain why your site may miss/skip an investigator's brochure (IB) version:

- PMB gets IBs from various sources. Some companies are good about sending them to the IB Coordinator or the responsible pharmacist. Others are not. Sometimes we miss a version or two, and since we don't know that the company has had an updated IB "go live," we don't know to ask for it. We do check periodically, but we may miss versions.
- PMB distributes IBs to investigators who have received a shipment of agent on all studies that are active (in a non-terminal status). If the protocol is open at a site but no one ordered agent, we don't send the IB.
- Sometimes, sites have an agent's IB for one protocol that goes into a terminal (complete) status—that's not a coveted timeslot when it comes to IB distribution. Then at some later time, they open a new study and get a later version of the agent's IB. They would not have received the interim versions.
- With IBs that are amended very soon after they are issued, we oftentimes don't receive the original (unamended) version. Those unamended versions might be considered just a dress rehearsal for the next one.
- And finally, PMB does not distribute anything other than the most current version of the IB. Similar to a theatrical performance, once it's over we can't bring it back to you.

To "reserve" your IB, contact IBcoordinator@mail.nih.gov

PMB: Top Holiday Billing!

Some important holidays are coming up in the next few months. Let us remind you of those important dates.

Veteran's Day is Friday, November 11 and PMB is closed.

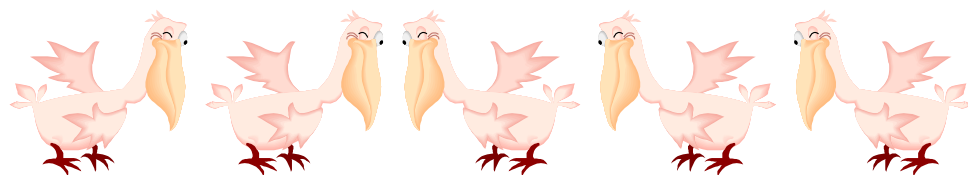
- For agents shipped at room temperature, the NCI Clinical Repository will ship as usual on Thursday.
- If you order on Thursday, November 10 for next day delivery, please confirm that you will be open on Friday.

Thanksgiving is Thursday, November 24 and PMB is closed.

- We are open on Friday.
- However, Tuesday, November 22, is the last day of the week to place orders for next day delivery.

Christmas and New Year's fall on Sundays this year.

- Monday December 26, and January 2 are the U.S. Government holidays and we will be closed.
- Please plan accordingly.



Bowing Out Gracefully

Not every agent can be a star at PMB! Here's a list of recent outcasts, otherwise known as agents that we are no longer developing.

Agents	NSC	CTEP-IND Status	Completed Date
SGN-30	731636	Withdrawn	11/2010
SB-715992 (ispinesib)	70273	Withdrawn	11/2010
XK469R	698215	Withdrawn	11/2010
GM-CSF (sargramostim)	613795	Withdrawn	2/2011
Ibritumomab tiuxetan (Zevalin)	710085	Withdrawn	4/2011
Rituximab	687451	Inactive	5/2011
Motexafin gadolinium	695238	Withdrawn	6/2011
CDDO	711193	Withdrawn	7/2011
Bryostatin	339555	Withdrawn	10/2011



Adieu... Adios... Ciao...

Curtain Time

As is true in life, all good things must come to an end, and we must bid CAPT Jeannette Wick, USPHS, a happy retirement. Jeannette was the person most responsible for creation and publication of PMB's newsletter, "INSIDE PMB." We will sorely miss her valuable contributions as editor of the newsletter and in PMB's day-to-day operations. Jeannette brought her unique perspective as she chose the newsletter theme, pulled topics together, and, in many cases, wrote or edited the articles. The newsletter was never too serious, and sometimes I cringed at the direction she selected or how close she walked the line. In the end she always had her way; far be it for me to deny freedom of the press. "INSIDE PMB" will continue to be published under the direction of Ravie Kem and Tali Johnson.

In addition to the newsletter, Jeannette initiated another institution called Rock Soup, a pot luck that we all enjoyed immensely. This tradition waxed and waned, as did our waistlines over the years, but it all started with Jeannette.

CAPT Wick has transitioned to the next phase in her life. She returns to whence she came on Long Island Sound, back with her family and friends. We will miss her, but not forget her. In the tradition of the Naval Services, we wish her Fair Winds and Following Seas, but certainly hope that the fair winds will blow her back this way from time to time. Jeannette, enjoy your retirement, you have earned it and thank you for all you have done.

-Skip Hall

BSA in Four-Part Harmony

Clinicians often use body surface area (BSA) to determine antineoplastic doses. Initially used to extrapolate human drugs doses from lab animal data, BSA dosing is now routine practice and believed to associate more closely with physiologic parameters than body weight alone.

Multiple formulas exist for BSA calculation, with DuBois & DuBois, Gehan & George, Haycock, and Mosteller making up the popular quartet. The Mosteller equation is an easy-to-remember derivation of Gehan & George (the square root of: the height times the weight, divided by 3600).

Ever wonder which equation sings melody in this four-part harmony? Verbraecken, et al calculated the BSA of 1868 normal weight, overweight, and obese adults using the Mosteller equation. After critical reviews, he wrote the Mosteller formula "deserves to be used as the first choice in clinical research and practice. It provides an accurate BSA calculation with ease of use and is applicable in normal-weight, overweight, and obese adults."

Speaking of weight, what change in weight should trigger BSA recalculation? There is no hard and fast musical score. Many institutional policies say to recalculate BSA when weight changes +/- 10%. A 10% change in weight would change a dose approximately 5%.

While the NCI does not have a policy on when to adjust a patient's BSA, it may be specified in the protocol. If not look to your institution, cooperative group or principal investigator. Your best bet is to be consistent with how you measure BSA and adjust doses--don't let the cheerleading squad bully you into changing your song and dance!

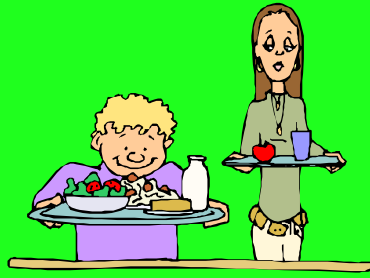


Attention P-M-Bleeks!

Be the first to send in a correct word find and win two dozen homemade chocolate chip cookies. Scan in the puzzle and send to PMBafterhours@mail.nih.gov. We'll announce the winner in February.

- BULLY
- CAST
- CHEERLEADER
- CHOREOGRAPHY
- CHORUS
- COMPETITION
- CONCERT
- GENRE
- GLEEK
- PRODUCER
- PROM QUEEN
- SCREENGRAB
- SOLOIST
- TRIBUTE
- VIEWER

T	A	M	F	E	C	R	O	U	T	X	S	B	G	R	Z	L	U
T	R	I	B	U	T	E	N	E	E	U	Q	M	O	R	P	K	H
B	J	P	I	T	N	D	N	O	I	T	I	T	E	P	M	O	C
U	S	C	N	O	B	P	G	L	E	E	K	Z	G	I	E	L	H
R	L	H	P	F	Y	V	E	F	A	M	M	T	D	G	Y	O	E
O	C	O	G	R	U	Y	N	N	S	P	B	U	L	L	Y	F	E
W	S	R	K	Y	O	M	R	L	P	R	B	C	P	V	Y	K	R
X	W	E	R	E	Z	D	E	T	H	X	W	H	M	T	J	B	L
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V	L	G	E	D	B	O	M	C	I	O	I	N	A	R	S	S	A
I	A	R	G	E	U	E	D	D	E	U	A	Q	I	H	I	F	D
E	K	A	R	R	M	I	L	L	H	R	M	L	G	Y	O	C	E
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E	M	H	B	O	C	H	O	R	U	S	A	E	I	W	O	I	N
R	T	Y	E	Y	A	Q	I	M	D	E	U	C	C	P	S	T	O
C	S	U	O	A	H	B	A	R	G	N	E	E	R	C	S	M	L
T	A	P	Z	U	K	R	Y	L	B	H	R	B	T	B	L	P	T
N	C	O	N	C	E	R	T	A	N	F	X	Y	C	W	K	J	G



Now that you're using OAOP

Problem: I can't find my cast of characters in the OAOP List of Values (LOVs).

Solutions: OAOP users should contact PMB at 301-496-5725 when they find...

Investigator Not listed: Designee is not listed as an authorized designee for the investigator.

Resolution: Ask the PMB Registration Help Desk <PMBRegPend@ctep.nci.nih.gov> to check the investigator's registration (IR). It could be as simple as the investigator completing an IDF or updating the site's PSD worksheet.

Protocol not displayed: Any combination of the following: investigator does not have group affiliation; investigator and/or institution are not listed as participants; site requires IRB approval; agent is not PMB-distributed
Resolution: Ask for PMB's Protocol Specialists.

Patient not listed: Patient is registered under or transferred to a different investigator. Initial/new patients will not display until the group has submitted an automated electronic order.

Resolution: Ask for PMB's Blinded Studies Coordinator.

Investigator Shipping Address is different: Any combination of the following: investigator moved to a new institution and did not update his/her IR; investigator submitted IR, but we either have not received it or updated it at this time; PSD is in the process of being updated; the site has one recognized investigator as the person to order all open label agents.

Resolution: Ask for PMB's Registration Team.

Top Ten: Cancer Concerns During the High School Years

Teenagers. Not children, but not adults. Teenagers don't want to be embarrassed, and everything embarrasses them. Here's a list of the Top Ten things that oncology practitioners should do for teenagers.

1. Recommend the quadrivalent human papillomavirus vaccine (HPV). A decline in immunization rates has experts worried. Successful immunization campaigns must reach almost all children. HPV4 is one of the newest vaccines given as a three shot series in children 9 or older. It prevents cervical precancers/cancers and genital warts in females and the likelihood of genital warts in males.
2. Talk about and watch for cutaneous malignancies. No Cheerio wants to be seen in that skimpy uniform in her "birth skin," so tanning is still remarkably popular among teenagers. Promote cautious sun exposure, and recommend sunscreens for daily use. Discourage visits to tanning salons!
3. Discourage smoking. Smoking is a pediatric disease-almost all smokers begin before their 18th birthday. Address second hand smoke exposure with parents who smoke also-no smoking in the house or car, please.
4. Understand confidentiality. There are no secrets at Lima High. Everyone seemed to know who Quinn's baby-daddy was (except Finn). Adolescents sometimes approach health care providers for information, and ask them not to tell his or her parents. All patients are entitled to confidentiality, but there are some limits for children. Always stress these are limits. Health care providers must tell parents if teenagers are suicidal, and may need to report birth control use depending on the state.
5. Teach testicular and breast self exam. Testicular germ cell cancer is the most common malignancy in teen males. Breast cancer is a common yet curable cancer in women if caught early. Teaching teens to take responsibility for their preventive health is something to sing about.
6. Hair loss. Baldness and Mohawks in teenagers are only awesome if they're on purpose. Counsel teens if chemotherapy will cause hair loss, and help them plan how they will handle it.
7. Make kids aware of dietary nitrates and the hazards of fat. Nitrates increase risk for thyroid cancer and bladder cancer. Meat, with its high fat content, should be consumed in moderation. The Glee chorus loves a trip to the restaurant Breadstix. That's just another opportunity added to all the others—footballs games, fundraisers, cafeteria—to have a hot dog, a hamburger, or meatball. Encourage the bottomless bowl of salad instead.
8. Adherence. Approximately one third of children and adolescents who have cancer are seriously or occasionally nonadherent. Adolescents are especially challenging: their nonadherence increases precipitously around 20 weeks after diagnosis. Why? Teenagers sometimes think they are indestructible or succumb to peer pressure. They don't want to do anything that sets them apart or causes side effects that alter their bodies. Cancer is a stigma. Be vigilant. Be compassionate.
9. Polycystic Ovary Syndrome (PCOS). Five to ten percent of women develop PCOS. Take it seriously, as it increases risk for endometrial cancer if menstrual cycles are irregular. Menstruating once every three months confers a normal risk of endometrial abnormalities or cancer. If menstruation occurs less often or not at all, consider hormonal therapy.
10. Talk about new primary cancers. Teenager cancer survivors are invincible—just ask them! Lightning never strikes twice in the same place, right? Wrong. Around 17% of cancer survivors develop another new cancer (as opposed to a recurrence), and kids are at highest risk. Keep reminding kids to choose healthy behaviors. When it comes to cancer, no one cheers and claps for an encore.

