

Clinical Investigator and Nursing Perspectives on the Management of Common Cancers

FACULTY INTERVIEWS

Krista M Rubin, MS, RN, FNP-BC Keith T Flaherty, MD

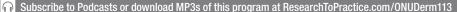
EDITOR

Neil Love, MD

DERMATOLOGIC ONCOLOGY EDITION







Oncology Nursing Update Dermatologic Oncology Edition

A Continuing Nursing Education Audio Series

OVERVIEW OF ACTIVITY

Taken together, melanoma and nonmelanoma skin cancers likely represent the most prevalent form of human cancer. Fortunately, the vast majority of skin cancers present as minimally invasive basal cell carcinoma and squamous cell cancer and, as such, are highly curable with local treatment alone. However, in rare instances these characteristically indolent lesions progress and necessitate systemic intervention with the support of limited randomized clinical evidence. In contrast, cancerous melanoma is the most aggressive form of skin cancer with a predilection toward distant metastases, even when identified in the early stages of the disease. Thus melanoma and nonmelanoma skin cancer are distinct entities, each posing unique challenges to the oncology nursing community. To provide oncology nurses with therapeutic strategies to address the disparate needs of these patients, the *Oncology Nursing Update* audio series employs one-on-one interviews with medical oncologists and nurses with expertise in the field. Upon completion of this CNE activity, oncology nurses should be able to formulate an up-to-date and more complete approach to the care of patients with melanoma and nonmelanoma skin cancers.

LEARNING OBJECTIVES

- Counsel patients considering adjuvant therapy after surgical removal of primary melanoma regarding the risks and potential benefits of high-dose versus pegylated interferon therapy.
- Discuss the benefits and risks associated with systemic therapies used in the evidence-based treatment
 of metastatic melanoma, including chemotherapeutic agents, standard and novel immunotherapeutic
 strategies and targeted biologic agents.
- Counsel patients regarding the risk of BRAF inhibitor-associated secondary nonmelanoma skin cancers, and assist patients in managing these and other side effects associated with this targeted approach.
- Develop a plan to identify and manage the side effects and toxicities associated with immunotherapeutic regimens, including high-dose interleukin-2 and ipilimumab, to support patient quality of life.
- Discuss the risks and benefits of hedgehog inhibitor therapy in patients with locally advanced or metastatic basal cell carcinoma.

ACCREDITATION STATEMENT

Research To Practice is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

CREDIT DESIGNATION STATEMENT

This educational activity for 1.5 contact hours is provided by Research To Practice during the period of December 2013 through December 2014.

HOW TO USE THIS CNE ACTIVITY

This is an audio CNE program. This booklet contains CNE information, including learning objectives, faculty disclosures, a Post-test and an Educational Assessment and Credit Form. The corresponding website **ResearchToPractice.com/ONUDerm113** also includes links to relevant abstracts and full-text articles.

The Post-test and Educational Assessment and Credit Form may be completed in this booklet and either mailed to Research To Practice, One Biscayne Tower, 2 South Biscayne Blvd, Suite 3600, Miami, FL 33131 or faxed to (800) 447-4310. They may also be completed online. A statement of credit will be issued only upon receipt of a completed Post-test with a score of 75% or better and a completed Educational Assessment and Credit Form. Your statement of credit will be mailed to you within 3 weeks or may be printed online.

This activity is supported by educational grants from Genentech BioOncology, Merck and Prometheus Laboratories Inc.

There is no implied or real endorsement of any product by RTP or the American Nurses Credentialing Center.

If you would like to discontinue your complimentary subscription to *Oncology Nursing Update*, please email us at **Info@ResearchToPractice.com**, call us at (800) 648-8654 or fax us at (305) 377-9998. Please include your full name and address, and we will remove you from the mailing list.



FACULTY AFFILIATIONS



Krista M Rubin, MS, RN, FNP-BC Nurse Practitioner Center for Melanoma Massachusetts General Hospital Cancer Center Boston, Massachusetts



Keith T Flaherty, MD
Director, Henri and Belinda Termeer
Center for Targeted Therapies
Massachusetts General Hospital
Cancer Center
Associate Professor
Harvard Medical School
Director of Developmental
Therapeutics
Boston, Massachusetts

EDITOR



Neil Love, MD Research To Practice Miami, Florida

CONTENT VALIDATION AND DISCLOSURES

Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-the-art education. We assess potential conflicts of interest with faculty, planners and managers of CNE activities. Real or apparent conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent physician reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations.

FACULTY — The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Ms Rubin** — Advisory Committee: Genentech BioOncology, Merck. **Dr Flaherty** — Advisory Committee: Boehringer Ingelheim Pharmaceuticals Inc, Eisai Inc, Millennium: The Takeda Oncology Company, Novartis Pharmaceuticals Corporation, Sanofi; Consulting Agreements: Genentech BioOncology, GlaxoSmithKline, Momenta Pharmaceuticals Inc, Otsuka Pharmaceutical Co Ltd, Roche Laboratories Inc; Contracted Research: Novartis Pharmaceuticals Corporation. Sanofi.

EDITOR — Dr Love is president and CEO of Research To Practice, which receives funds in the form of educational grants to develop CME/CNE activities from the following commercial interests: AbbVie Inc, Algeta US, Allos Therapeutics, Amgen Inc, ArQule Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, Biodesix Inc, Biogen Idec, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Daiichi Sankyo Inc, Dendreon Corporation, Eisai Inc, EMD Serono Inc, Exelixis Inc, Foundation Medicine Inc, Genentech BioOncology, Genomic Health Inc, Gilead Sciences Inc, Incyte Corporation, Lilly, Medivation Inc, Merck, Millennium: The Takeda Oncology Company, Mundipharma International Limited, Novartis Pharmaceuticals Corporation, Novocure, Onyx Pharmaceuticals Inc, Prometheus Laboratories Inc, Regeneron Pharmaceuticals, Sanofi, Seattle Genetics, Spectrum Pharmaceuticals Inc and Teva Oncology.

RESEARCH TO PRACTICE STAFF AND EXTERNAL REVIEWERS — The scientific staff and reviewers for Research To Practice have no real or apparent conflicts of interest to disclose.

This educational activity contains discussion of published and/or investigational uses of agents that are not indicated by the Food and Drug Administration. Research To Practice does not recommend the use of any agent outside of the labeled indications. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications and warnings. The opinions expressed are those of the presenters and are not to be construed as those of the publisher or grantors.

SELECT PUBLICATIONS

Ally M et al. Vismodegib as an adjuvant to surgery for basal cell carcinomas. Proc Am Acad Dermat 2012. No abstract available

Chang AL et al. Surgical excision after neoadjuvant therapy with vismodegib for a locally advanced basal cell carcinoma and resistant basal carcinomas in Gorlin syndrome. *JAMA Dermatol* 2013;149(5):639-41.

Chapman PB et al. Improved survival with vemurafenib in melanoma with BRAF V600E mutation. N Engl J Med 2011;364(26):2507-16.

Davies H et al. Mutations of the BRAF gene in human cancer. Nature 2002;417(6892):949-54.

Flaherty KT et al. Improved survival with MEK inhibition in BRAF-mutated melanoma. $N Engl \ J \ Med \ 2012a; 367(2):107-14.$

Flaherty KT et al. Combined BRAF and MEK inhibition in melanoma with BRAF V600 mutations. *N Engl J Med* 2012b;367(18):1694-703.

Hodi FS et al. Improved survival with ipilimum ab in patients with metastatic melanoma. $N \ Engl\ J \ Med\ 2010;363(8):711-23.$

Jang S, Atkins MB. Which drug, and when, for patients with BRAF-mutant melanoma? *Lancet Oncol* 2013;14(2):e60-9.

Sekulic A et al. Efficacy and safety of vismodegib in advanced basal-cell carcinoma. N Engl J Med 2012;366(23):2171-9.

Smalley KS, Sondak VK. **Melanoma** — An unlikely poster child for personalized cancer therapy. *N Engl J Med* 2010;363(9):876-8.

Von Hoff DD et al. Inhibition of the hedgehog pathway in advanced basal-cell carcinoma. N Engl J Med 2009;361(12):1164-72.

POST-TEST

Oncology Nursing Update Dermatologic Oncology Edition — Issue 2, 2013

QUESTIONS (PLEASE CIRCLE ANSWER):

- 1. Adjuvant treatment options for Stage III melanoma include which of the following?
 - a. Observation
 - b. High-dose interferon
 - c. Pegylated interferon
 - d. Clinical trial participation
 - e. All of the above
 - f. None of the above
- The most common side effect associated with ______ therapy is fatigue.
 - a. High-dose interferon
 - b. Pegylated interferon
 - c. Both a and b
 - d. Neither a nor b
- 3. Side effects of ipilimumab include diarrhea, liver function test abnormalities and endocrine dysfunction.
 - a. True
 - b. False
- is a hedgehog inhibitor used in the treatment of basal cell carcinoma.
 - a. Nivolumah
 - b. Lambrolizumah
 - c. Vismodegib
- 5. Vemurafenib and dabrafenib are _____ approved by the FDA for treatment of metastatic melanoma.
 - a. BRAF inhibitors
 - b. Immune-based therapies
 - c. MEK inhibitors

- 6. Data from a Phase I/II trial published by Flaherty and colleagues evaluating combined BRAF and MEK inhibition in patients with metastatic melanoma with BRAF V600 mutations recorded higher response rates and overall disease control with the combination than with dabrafenib monotherapy.
 - a. True
 - b. False
 - 7. Vismodegib is associated with a high incidence of taste changes and
 - a. Muscle cramps
 - b. Flulike symptoms
 - c. Memory loss
 - d. Secondary nonmelanoma skin cancers
 - e. All of the above
- 8. Common side effects associated with high-dose interleukin-2 therapy include
 - a. Hypotension
 - b. Low blood cell counts
 - c. Drug-induced sepsis
 - d. All of the above
 - e. None of the above

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this education	onal activity								
How would you characterize your level of knowledge on the following topics?									
4 = Excellent $3 = Good$ $2 = A$	dequate 1 =	1 = Suboptimal							
	BEFORE	AFTER							
Incidence, development and management of vemurafenib-associated secondary nonmelanoma skin cancers	4 3 2 1	4 3 2 1							
Differences in side effects, tolerability and duration of therapy with high-dose versus pegylated adjuvant interferon therapy	4 3 2 1	4 3 2 1							
Management of vismodegib-associated dysgeusia and muscle cramps	4 3 2 1	4 3 2 1							
Identifying risk factors associated with the development of metastatic basal cell carcinoma, including family history, germline mutations and immunocompromised patients	4 3 2 1	4 3 2 1							
Mechanism of action and dosing of ipilimumab in metastatic melanoma	4 3 2 1	4 3 2 1							
Has the activity unfairly influenced you toward a particular product or Yes No If yes, please describe what was presented:									
Will this activity help you improve patient care?									
☐ Yes ☐ No ☐ Not applicable									
If yes, how will it help you improve patient care?									
Did the activity meet your educational needs and expectations?									
☐ Yes ☐ No If no, please explain:									
Please respond to the following learning objectives (LOs) by circling the 4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO no									
As a result of this activity, I will be able to:	Diffiel N/A = N	и аррисаые							
Counsel patients considering adjuvant therapy after surgical removal of primary melanoma regarding the risks and potential benefits of high-do versus pegylated interferon therapy.		1 N/M N/A							
Discuss the benefits and risks associated with systemic therapies used in the evidence-based treatment of metastatic melanoma, including chemotherapeutic agents, standard and novel immunotherape strategies and targeted biologic agents	eutic 4 3 2	1 N/M N/A							
Counsel patients regarding the risk of BRAF inhibitor-associated second nonmelanoma skin cancers, and assist patients in managing these and other side effects associated with this targeted approach	dary								
Develop a plan to identify and manage the side effects and toxicities associated with immunotherapeutic regimens, including high-dose interleukin-2 and ipilimumab, to support patient quality of life		1 N/M N/A							

• Discuss the risks and benefits of hedgehog inhibitor therapy in patients

EDUCATIONAL ASSESSMENT	AND CR	EDIT	FOR	M (contin	ued)				
What other practice changes will y								-	
What additional information or trairelated topics?									
Additional comments about this ac	tivity:								
As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow- up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey. Yes, I am willing to participate in a follow-up survey. No, I am not willing to participate in a follow-up survey.									
PART 2 — Please tell us about	the faculty	and e	ditor	for this ed	ucational	activit	y		
4 = Excellent 3	= Good	= Good 2 = Adequate				1 = Suboptimal			
Faculty	Knowled	ge of	subje	ct matter	Effectiveness as an educator				
Krista M Rubin, MS, RN, FNP-BC	4	3	2	1	4	3	2	1	
Keith T Flaherty, MD	4	3	2	1	4	3	2	1	
Editor	Knowled	ge of	subje	ct matter	Effective	eness	as an	educator	
Neil Love, MD	4	3	2	1	4	3	2	1	
Please recommend additional facul	ty for future	activ	ities:						
Other comments about the faculty and editor for this activity:									
REQUEST FOR CREDIT $-$	Please prin	t clea	rly						
Name:				Special	ty:				
Professional Designation: MD D0 PharmD PA Other									
Street Address:					Box/Sı	uite:			
City, State, Zip:									
Telephone:		F	ах:						
Email:									
Ciamatura					Data				

The expiration date for this activity is December 2014. To obtain a certificate of completion and receive credit for this activity, please complete the Post-test, fill out the Educational Assessment and Credit Form and fax both to (800) 447-4310, or mail both to Research To Practice, One Biscayne Tower, 2 South Biscayne Boulevard, Suite 3600, Miami, FL 33131. You may also complete the Post-test and Educational Assessment online at www.ResearchToPractice.com/ONUDerm113/CNE.



Editor Neil Love, MD

Director, Clinical Content and CPD/CME Kathryn Ault Ziel, PhD

Scientific Director Richard Kaderman, PhD

Editorial Clayton Campbell

Marilyn Fernandez, PhD

Gloria Kelly, PhD Kemi Obajimi, PhD

Margaret Peng

Creative Manager Fernando Rendina

Graphic Designers Tamara Dabney

Silvana Izquierdo

Managing Editor Kirsten Miller

Senior Production Editor Aura Herrmann

Copy Editors Margo Harris

Rosemary Hulce
Pat Morrissev/Havlin

Alexis Oneca

Production Manager Tracy Potter

Audio Production Frank Cesarano

Web Master John Ribeiro

Faculty Relations Manager Lisa Suarez

Continuing Education Administrator for Nursing Karen Gabel Speroni, BSN, MHSA, PhD, RN

Contact Information Neil Love, MD

Research To Practice

One Biscavne Tower

2 South Biscayne Boulevard, Suite 3600

Miami, FL 33131 Fax: (305) 377-9998

Email: DrNeilLove@ResearchToPractice.com

For CME/CNE Information Email: CE@ResearchToPractice.com

Copyright © 2013 Research To Practice, All rights reserved.

The compact disc, Internet content and accompanying printed material are protected by copyright. No part of this program may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording or utilizing any information storage and retrieval system, without written permission from the copyright owner.

The opinions expressed are those of the presenters and are not to be construed as those of the publisher or grantors.

Participants have an implied responsibility to use the

newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management.

Any procedures, medications or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patients' conditions and possible contraindications or dangers in use, review of any applicable manufacturer's product information and comparison with recommendations of other authorities.



Copyright © 2013 Research To Practice.

This activity is supported by educational grants from Genentech BioOncology, Merck and Prometheus Laboratories Inc.

Research To Practice®

Sponsored by Research To Practice.

Last review date: December 2013 Release date: December 2013 Expiration date: December 2014 Contact hours: 1.5