

Pancreatic Cancer™

U P D A T E

Conversations with Oncology Investigators
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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Pancreatic Cancer™

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OVERVIEW OF ACTIVITY

Pancreatic cancer is the fourth most common cause of cancer-related death among men and women in the United States. The overwhelming majority of pancreatic cancers (approximately 90%) are ductal adenocarcinomas. Unfortunately, many patients diagnosed with pancreatic adenocarcinoma (PAD) do not exhibit disease-specific symptoms until the cancer has reached an advanced stage, and for all stages of PAD the combined 1-year survival rate for patients who do not receive surgery is approximately 29% and the 5-year rate is just 7%. Published clinical trial results have led to the emergence of new therapeutic targets and regimens, and the poor clinical course for many patients with progressive PAD mandates the investigation of even more new approaches. In order to offer optimal patient care — including the option of clinical trial participation — the practicing medical oncologist must be well informed of these advances. To bridge the gap between research and patient care, *Pancreatic Cancer Update* presents one-on-one discussions with leading gastrointestinal oncology investigators. By providing access to the latest scientific developments and the perspectives of experts in the field, this CME activity assists medical oncologists with the formulation of up-to-date management strategies.

LEARNING OBJECTIVES

- Develop an evidence-based strategy for the treatment of resectable or borderline resectable PAD, exploring the roles of neoadjuvant and adjuvant chemotherapy and/or radiation therapy.
- Consider patient age, performance status and other clinical and logistic factors in the selection of systemic therapy for locally advanced or metastatic PAD.
- Design and implement a plan of care to recognize and manage side effects and toxicities associated with the use of approved systemic regimens for patients with locally advanced or metastatic PAD to support quality of life and continuation of therapy.
- Appreciate the efficacy and tolerability profile of nanoliposomal irinotecan for treatment-refractory metastatic PAD, and optimally incorporate this agent into patient-care algorithms.
- Review the potential impact of early palliative care, pain management and end-of-life planning on clinical outcomes for patients with advanced pancreatic cancer, and integrate this information, as applicable, into routine practice.

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Interview with Andrew H Ko, MD

Tracks 1-23

- Track 1** **Case:** A 45-year-old woman with borderline resectable adenocarcinoma of the pancreas attains an excellent response to neoadjuvant FOLFIRINOX
- Track 2** Role of genetic counseling and molecular profiling for patients with pancreatic cancer
- Track 3** Effects of mutational load and PD-L1 expression on response to immunotherapy
- Track 4** Pathophysiology of pancreatic cancer
- Track 5** Radiographic criteria for defining resectable versus borderline resectable disease and implications for therapy
- Track 6** Response and tolerability with neoadjuvant FOLFIRINOX
- Track 7** Ongoing Phase II SWOG-S1505 trial of perioperative modified FOLFIRINOX (mFOLFIRINOX) versus gemcitabine/*nab* paclitaxel for resectable adenocarcinoma of the pancreas
- Track 8** Efficacy of neoadjuvant chemotherapy for patients with resectable pancreatic cancer
- Track 9** **Case:** A 78-year-old man with resected pancreatic cancer treated with adjuvant single-agent gemcitabine
- Track 10** Risk of recurrence for patients with resectable pancreatic cancer
- Track 11** Results from the Phase III PRODIGE 24/CCTG PA.6 trial evaluating adjuvant mFOLFIRINOX versus gemcitabine for patients with resected pancreatic ductal adenocarcinoma
- Track 12** Risks and benefits with *nab* paclitaxel/gemcitabine and FOLFIRINOX as adjuvant therapy
- Track 13** **Case:** A 70-year-old man with metastatic adenocarcinoma of the pancreas develops severe peripheral neuropathy with gemcitabine/*nab* paclitaxel as first-line therapy
- Track 14** Peripheral neuropathy associated with *nab* paclitaxel
- Track 15** Approach to first-line therapy for metastatic pancreatic cancer
- Track 16** Combination immunotherapeutic approaches under investigation for advanced pancreatic cancer
- Track 17** Efficacy and tolerability of the pegylated recombinant human hyaluronidase enzyme PEGPH20 in patients with advanced pancreatic cancer
- Track 18** Therapeutic options for patients with metastatic pancreatic cancer and disease progression on gemcitabine/*nab* paclitaxel
- Track 19** NAPOLI-1: Results of a Phase III trial of nanoliposomal irinotecan (nal-IRI) and 5-FU/leucovorin (LV) for metastatic pancreatic cancer after gemcitabine-based therapy
- Track 20** Palliative care for patients with metastatic pancreatic cancer
- Track 21** **Case:** A 54-year-old woman with locally advanced pancreatic cancer and refractory ascites
- Track 22** **Case:** A 53-year-old man of Ashkenazi Jewish descent with a strong family history of BRCA mutation-associated cancers presents with metastatic pancreatic cancer and is found to harbor a germline BRCA2 mutation
- Track 23** **Case:** A 62-year-old woman with pancreatic cancer and a solitary liver lesion receives FOLFIRINOX followed by stereotactic body radiation therapy

Interview with E Gabriela Chiorean, MD

Tracks 1-18

- Track 1** Biomarker-driven and molecular-targeted therapies for patients with adenocarcinoma of the pancreas
- Track 2** Rationale for the investigation of PEGPH20 in combination with pembrolizumab for previously treated hyaluronic acid (HA)-high metastatic pancreatic cancer
- Track 3** Tolerability and quality of life with PEGPH20 in combination with chemotherapy; mitigation of associated thromboembolic events

Interview with Dr Chiorean (continued)

- Track 4** Ongoing Phase II trial of PEGPH20 with pembrolizumab for previously treated HA-high metastatic pancreatic ductal adenocarcinoma
- Track 5** Testing for emerging biomarkers (eg, microsatellite instability) of response to immune checkpoint inhibitors in metastatic pancreatic cancer
- Track 6** Incidence of germline BRCA mutations and response to PARP inhibition
- Track 7** **Case:** A 55-year-old woman presents with back pain and dyspepsia and is diagnosed with borderline resectable adenocarcinoma of the pancreas
- Track 8** Risk of relapse with and without adjuvant chemotherapy for patients with lymph node involvement
- Track 9** Clinical experience with adjuvant FOLFIRINOX and gemcitabine/*nab* paclitaxel
- Track 10** Activity, tolerability and dosing of adjuvant FOLFIRINOX
- Track 11** Role of neoadjuvant chemotherapy in the treatment of resectable or borderline resectable adenocarcinoma of the pancreas
- Track 12** **Case:** A 69-year-old woman with metastatic pancreatic cancer receives nal-IRI/5-FU/LV after experiencing disease progression on gemcitabine/*nab* paclitaxel
- Track 13** Response and tolerability with FOLFIRINOX compared to gemcitabine/*nab* paclitaxel
- Track 14** Second-line therapy options for metastatic pancreatic cancer
- Track 15** SWOG-S1513: An ongoing Phase II trial evaluating FOLFIRI alone versus modified FOLFIRI with the PARP inhibitor veliparib as second-line therapy for metastatic pancreatic cancer
- Track 16** Investigation of CDK4/6 inhibition-based therapies for advanced pancreatic cancer
- Track 17** **Second opinion:** A 53-year-old man of Ashkenazi Jewish descent with a strong family history of BRCA mutation-associated cancers presents with metastatic pancreatic cancer and is found to harbor a germline BRCA2 mutation
- Track 18** Importance of palliative care in managing the symptoms of pancreatic cancer

Video Program

View the corresponding video interviews with (from left) Drs Ko and Chiorean by Dr Love at www.ResearchToPractice.com/PancreaticCancerUpdate119/Video



SELECT PUBLICATIONS

- Borzanci EH et al. **A phase II pilot trial of nivolumab + albumin bound paclitaxel + paricalcitol + cisplatin + gemcitabine (NAPPCG) in patients with previously untreated metastatic pancreatic ductal adenocarcinoma.** Gastrointestinal Cancers Symposium 2018;**Abstract 358.**
- Carnevale J, Ashworth A. **Assessing the significance of BRCA1 and BRCA2 mutations in pancreatic cancer.** *J Clin Oncol* 2015;33(28):3080-1.
- Chiorean EG et al. **Performance status dynamics during treatment with nab-paclitaxel plus gemcitabine versus gemcitabine alone for metastatic pancreatic cancer.** *Cancer Manag Res* 2018;10:1389-96.
- Chiorean EG et al. **Real-world comparative effectiveness of nab-paclitaxel plus gemcitabine (nab-P/G) vs FOLFIRINOX (FFX) in patients (pts) with advanced pancreatic cancer (aPC).** *Proc ESMO* 2018;**Abstract 724P.**
- Chiorean EG et al. **A phase II study of abemaciclib as a monotherapy and in combination with other agents in patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC).** *Proc ASCO* 2017;**Abstract TPS4150.**
- Chiorean EG et al. **Randomized phase II study of 2nd-line FOLFIRI versus modified FOLFIRI with PARP inhibitor ABT-888 (veliparib) (NSC-737664) in metastatic pancreatic cancer (mPC): SWOG S1513.** *Proc ASCO* 2017;**Abstract TPS4147.**
- Doherty GJ et al. **HALO-109-301: A phase III trial of PEGPH20 (with gemcitabine and nab-paclitaxel) in hyaluronic acid-high stage IV pancreatic cancer.** *Future Oncol* 2018;14(1):13-22.
- Goldstein D et al. **Nomogram for predicting overall survival (OS) in patients (pts) treated with nab-paclitaxel (nab-P) plus gemcitabine (Gem) or Gem alone for metastatic pancreatic cancer (MPC).** *Proc ASCO* 2017;**Abstract 4109.**
- Hingorani SR et al. **HALO 202: Randomized phase II study of PEGPH20 plus nab-paclitaxel/gemcitabine versus nab-paclitaxel/gemcitabine in patients with untreated, metastatic pancreatic ductal adenocarcinoma.** *J Clin Oncol* 2018;36(4):359-66.
- Neoptolemos JP et al. **Comparison of adjuvant gemcitabine and capecitabine with gemcitabine monotherapy in patients with resected pancreatic cancer (ESPAC-4): A multicentre, open-label, randomised, phase 3 trial.** *Lancet* 2017;389(10073):1011-24.
- Ouyang G et al. **Gemcitabine plus cisplatin versus gemcitabine alone in the treatment of pancreatic cancer: A meta-analysis.** *World J Surg Oncol* 2016;14:59.
- Picozzi VJ et al. **Initial gemcitabine/nab-paclitaxel (GA) followed by sequential (S) mFOLFIRINOX or alternating (A) mFOLFIRI in metastatic pancreatic cancer (mPC): The SEENA-1 study.** Gastrointestinal Cancers Symposium 2017;**Abstract 359.**
- Ramanathan RK et al. **A phase IB/II randomized study of mFOLFIRINOX (mFFOX) + pegylated recombinant human hyaluronidase (PEGPH20) versus mFFOX alone in patients with good performance status metastatic pancreatic adenocarcinoma (mPC): SWOG S1313 (NCT#01959139).** Gastrointestinal Cancers Symposium 2018;**Abstract 208.**
- Ramanathan RK et al. **Correlation between ferumoxytol uptake in tumor lesions by MRI and response to nanoliposomal irinotecan in patients with advanced solid tumors: A pilot study.** *Clin Cancer Res* 2017;23(14):3638-48.
- S1313, a phase IB/II randomized study of modified FOLFIRINOX + pegylated recombinant human hyaluronidase (PEGPH20) versus modified FOLFIRINOX alone in patients with good performance status metastatic pancreatic adenocarcinoma.** **NCT01959139**
- Sohal D et al. **SWOG S1505: A randomized phase II study of perioperative mFOLFIRINOX vs gemcitabine/nab-paclitaxel as therapy for resectable pancreatic adenocarcinoma.** *Proc ASCO* 2017;**Abstract TPS4152.**
- Sonbol MB et al. **Second-line treatment in patients with pancreatic ductal adenocarcinoma: A meta-analysis.** *Cancer* 2017;123(23):4680-6.
- Suker M et al. **FOLFIRINOX for locally advanced pancreatic cancer: A systematic review and patient-level meta-analysis.** *Lancet Oncol* 2016;17(6):801-10.
- Wang-Gillam A et al. **NAPOLI-1 phase 3 study of liposomal irinotecan in metastatic pancreatic cancer: Final overall survival analysis and characteristics of long-term survivors.** *Eur J Cancer* 2019;[Epub ahead of print].
- Zhen DB et al. **Biomarker-driven and molecularly targeted therapies for pancreatic adenocarcinoma.** *Semin Oncol* 2018;45(3):107-15.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. Pancreatic cancer cells tend to exhibit a _____ mutational burden.
 - a. High
 - b. Low
2. The ongoing Phase II SWOG-S1505 trial is evaluating perioperative mFOLFIRINOX versus _____ for patients with resectable adenocarcinoma of the pancreas.
 - a. Gemcitabine monotherapy
 - b. *Nab* paclitaxel monotherapy
 - c. Gemcitabine in combination with *nab* paclitaxel
3. The Phase III PREOPANC-1 study evaluating preoperative gemcitabine-based chemoradiation therapy versus immediate surgery for patients with resectable and borderline resectable pancreatic cancer demonstrated a survival benefit with preoperative chemoradiation therapy.
 - a. True
 - b. False
4. The Phase III PRODIGE 24/CCTG PA.6 trial evaluating adjuvant mFOLFIRINOX versus gemcitabine for patients with resected pancreatic ductal adenocarcinoma demonstrated a statistically significant improvement in _____ with mFOLFIRINOX.
 - a. Disease-free survival
 - b. Overall survival
 - c. Both a and b
 - d. Neither a nor b
5. PEGPH20 is _____.
 - a. An anti-PD-1/PD-L1 antibody
 - b. A MEK inhibitor
 - c. A PARP inhibitor
 - d. A pegylated formulation of a recombinant form of human hyaluronidase
6. PEGPH20 in combination with _____ has demonstrated encouraging activity and a tolerable safety profile for patients with metastatic pancreatic ductal adenocarcinoma.
 - a. FOLFIRINOX
 - b. Gemcitabine/*nab* paclitaxel
 - c. Both a and b
 - d. Neither a nor b
7. Common side effects that patients with advanced pancreatic cancer undergoing treatment with PEGPH20 may experience include _____.
 - a. Lower-extremity edema
 - b. Joint and/or muscle ache
 - c. Muscle spasms
 - d. Thromboembolism
 - e. All of the above
8. The ongoing Phase II SWOG-S1513 trial is evaluating FOLFIRI alone versus modified FOLFIRI with the PARP inhibitor veliparib as _____ for patients with metastatic pancreatic cancer.
 - a. First-line therapy
 - b. Second-line therapy
 - c. Late-line therapy
9. BRCA mutations occur in approximately _____ of patients with pancreatic cancer.
 - a. 0%
 - b. 5% to 10%
 - c. 30% to 40%
10. *Nal*-IRI is FDA approved _____ for patients with metastatic pancreatic cancer who have already received a gemcitabine-based regimen.
 - a. As monotherapy
 - b. In combination with 5-FU/LV

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Pancreatic Cancer Update — Volume 2, Issue 1

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 educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Choice and ongoing evaluation of gemcitabine/ <i>nab</i> paclitaxel or FOLFIRINOX as neoadjuvant therapy for locally advanced pancreatic cancer	4 3 2 1	4 3 2 1
Rationale for the investigation of PEGPH20 in combination with pembrolizumab for previously treated HA-high metastatic pancreatic ductal adenocarcinoma	4 3 2 1	4 3 2 1
PRODIGE 24/CCTG PA.6: Results of a Phase III trial evaluating adjuvant mFOLFIRINOX versus gemcitabine for resected pancreatic ductal adenocarcinoma	4 3 2 1	4 3 2 1
Activity and ongoing investigation of PARP inhibitors for patients with advanced pancreatic cancer and BRCA mutations	4 3 2 1	4 3 2 1

Practice Setting:

- Academic center/medical school Community cancer center/hospital Group practice
 Solo practice Government (eg, VA) Other (please specify).....

Approximately how many new patients with pancreatic cancer do you see per year? patients

Was the activity evidence based, fair, balanced and free from commercial bias?

- Yes No If no, please explain:

Please identify how you will change your practice as a result of completing this activity (select all that apply).

- This activity validated my current practice
 Create/revise protocols, policies and/or procedures
 Change the management and/or treatment of my patients
 Other (please explain):

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

.....

The content of this activity matched my current (or potential) scope of practice.

- Yes No If no, please explain:

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Develop an evidence-based strategy for the treatment of resectable or borderline resectable PAD, exploring the roles of neoadjuvant and adjuvant chemotherapy and/or radiation therapy..... 4 3 2 1 N/M N/A
- Consider patient age, performance status and other clinical and logistic factors in the selection of systemic therapy for locally advanced or metastatic PAD..... 4 3 2 1 N/M N/A
- Design and implement a plan of care to recognize and manage side effects and toxicities associated with the use of approved systemic regimens for patients with locally advanced or metastatic PAD to support quality of life and continuation of therapy..... 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Appreciate the efficacy and tolerability profile of nanoliposomal irinotecan for treatment-refractory metastatic PAD, and optimally incorporate this agent into patient-care algorithms. 4 3 2 1 N/M N/A
- Review the potential impact of early palliative care, pain management and end-of-life planning on clinical outcomes for patients with advanced pancreatic cancer, and integrate this information, as applicable, into routine practice. 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

Would you recommend this activity to a colleague?

Yes No

If no, please explain:

PART 2 — Please tell us about the faculty and editor for this educational activity

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal						
Faculty					Knowledge of subject matter					Effectiveness as an educator
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E Gabriela Chiorean, MD	4	3	2	1		4	3	2	1	
Editor					Knowledge of subject matter					Effectiveness as an educator
Neil Love, MD	4	3	2	1		4	3	2	1	

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