Improving Informed Consent for Palliative Chemotherapy

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B. Abstract

Background: Many patients with metastatic cancer receive chemotherapy, without expressing their understanding that cure is unlikely.

Objectives: Aim 1: To develop a suite of patient-centered videos and booklets to support informed consent (IC) for common palliative chemotherapy regimens. Aims 2 and 3: To determine if these IC tools improve patients' understanding of palliative chemotherapy risks and benefits, and reduce decisional conflict.

Methods: Aim 1: We partnered with patients, caregivers, and clinicians to develop a prototype chemotherapy IC video and companion booklet, which underwent acceptability testing by a national panel of 57 patient advocates and 25 oncologists. After iterative stakeholder-driven revisions, the prototype was extended to other chemotherapy regimens. Aim 2: In a randomized trial at 5 academic centers, patients with advanced colorectal or pancreatic cancers considering first- or second-line chemotherapy were randomized 1:1, stratified by line of treatment, to the usual IC process or to IC supplemented by access to the IC tools. Patients were surveyed at baseline, 2 weeks, and 3 months. Our primary outcome was the proportion of patients at 3 months who understood that chemotherapy was "not at all likely" to cure their cancer. Prespecified secondary outcomes were understanding of chemotherapy risks and treatment goal, decisional conflict, decisional regret, emotional distress, and satisfaction. Analyses used multiple imputation to account for missing data.

Results: Aim 1: Few oncologists (5 of 25, 20%) or advocates (10 of 22, 45%) were satisfied with standardly available IC materials. In contrast, most oncologists and advocates rated our intervention highly, with 89% to 96% agreeing that it would be useful and promote informed decisions. Inclusion of patient voices in developing the intervention was considered a key strength. Every oncologist indicated they would use the intervention regularly. Aim 2: For the study, 186 patients were randomized and completed at least 1 survey. Most participants indicated desire for maximal information about chemotherapy risks/benefits; however, 80% (59 of 64) had reviewed the IC booklet, but only 41% (30/66) had watched the IC video by 2 weeks. Accurate understanding of

the likelihood of cure was similar between intervention and control arms at 3 months (52.6%, 95% CI, 40.3-65.0 versus 55.5%, 95% CI, 45.1-66; p = 0.72). Very few patients in either arm (9% and10%; p = 0.80) reported that the goal of treatment was cure. Intervention patients were slightly more likely to have an accurate understanding of chemotherapy risks (56.0%, 95% CI, 44.3-67.7 versus 40.2%, 95% CI, 29.5-50.9; p = 0.05). Decisional conflict, decisional regret, satisfaction, prognostic understanding, and emotional distress did not differ by study arm.

Conclusions: Aim 1: Chemotherapy IC videos and booklets were highly acceptable to patient advocates and oncologists and were considered an improvement over existing resources. Aim 2: Our intervention did not impact patients' reported understanding of the likelihood of cure from chemotherapy, which was high before the intervention.

Limitations: Aim 1: We assessed acceptability among advocates, whose perspectives may differ from those of patients. Aim 2: Use of the intervention, particularly video, was poor despite ready access and patients' desire for maximal information. Structured intervention review might have yielded different results. Future interventions should consider the optimal timing and modes of information delivery.

C. Background

Choosing to pursue palliative chemotherapy is a complex decision for patients with incurable cancer. Patients must weigh the toxicities and benefits of chemotherapy against their priorities for what may be a very limited prognosis.[1] Over the past decade, it has become standard practice for oncologists to obtain informed consent (IC) from patients prior to initiating chemotherapy, whereby patients attest they understand core information and agree to treatment.[2,3] The goal of IC is to equip patients with the knowledge to make an informed decision, including the purpose of treatment (eg, cure versus palliate), benefits and risks, effects on prognosis as well as quality of life (QOL), and alternatives.[1,2]

Unfortunately, the chemotherapy IC process is failing to achieve its purpose, particularly in the palliative setting. Many patients lack the minimal understanding required for informed decision making, particularly about the purpose and likely magnitude of benefits from palliative chemotherapy.[4-10] Although most patients indicate a preference for detailed information about

their illness and an active role in their treatment decisions,[5-7] many harbor inaccurate and overly optimistic conceptions about potential benefits of palliative chemotherapy.[3,8,9,11] For example, they may think that treatment will cure their illness or extend their lives by many years, whereas several months is far more typical. We recently reported, from the CANCORS (Cancer Care Outcomes Research and Surveillance) survey of 1193 cancer patients receiving palliative chemotherapy, that 81% of colorectal cancer and 69% of lung cancer patients erroneously believed that chemotherapy might be curative.[12] These fundamental misconceptions are concerning for several reasons. First, they call into question the validity and integrity of the current IC process. Second, inaccurate understanding of these issues negatively impacts end-of-life (EOL) medical care. Overly optimistic expectations of chemotherapy drive the use of late-line, minimally effective chemotherapy,[8,9] and overoptimistic prognostic expectations are known to promote intensive and burdensome care near EOL.[12] If such patients harbor false beliefs that chemotherapy may cure their cancer, they are robbed of opportunities to make the most of their remaining time or to plan for care at EOL.

Failures in IC may relate in part to gaps in doctor–patient communication. Because patients look to oncologists for hope,[13] physicians may consciously or subconsciously magnify the benefits and suppress negative information about prognosis and the limitations of palliative chemotherapy.[10,14] Oncologists seek to establish therapeutic alliance with their patients, to convey hope, and to be well regarded by their patients. This may lead them to avoid explicitly discussing prognosis or survival benefits associated with chemotherapy or to downplay potentially distressing information. For example, an analysis of audio-recorded oncologic consultations found that only 30% of visits included any discussion of the likelihood or magnitude of benefit associated with chemotherapy.[15] This directly conflicts with surveys demonstrating that the vast majority of patients want frank and complete disclosure, including quantitative information about treatment benefits.[16,17] Finally, even if the likelihood of benefit is discussed, many patients are overwhelmed at the time of these conversations and may misinterpret or not remember key information.[5]

Unfortunately, resources available to support the chemotherapy IC process documents do little to improve patient understanding. Instead of providing balanced information about the

risks and likely benefits, consent documents have become increasingly focused on disclosing all possible side effects.[2] It is not surprising that cancer patients perceive IC documents as primarily serving to protect physicians against litigation, rather than being useful or patient-centered resources.[18] Other documents accompanying IC, such as chemotherapy information sheets, are similarly flawed by their technical language, risk emphasis, and focus on individual drugs. As a result, these documents do little to educate patients about the totality of the chemotherapy experience, nor do they help patients know what to expect in the future.

Despite an overwhelming number of cancer-related websites, information about prognosis and the magnitude of benefit from specific regimens is challenging to obtain.[19] Answers to questions such as, "What does this all mean for my future?" are exceedingly difficult to come by, which impedes patient-centered decision making.

We hypothesized that the chemotherapy IC moment is a strategic opportunity to enhance patients' understanding of their illness, prognosis, and likely risks/benefits of their cancer treatment options. Because IC documents and chemotherapy information sheets are often distributed to patients, these tangible resources represent an attractive target for intervention, which could be readily adopted within routine clinical practice. Providing patients with tangible supplementary information about their illness and treatment,[7,20-23] and encouraging questions,[24] has been shown to improve patients' understanding of these topics without increasing distress. Conceptually, this strategy is also attractive because it may help provide extra support to oncologists as they convey difficult information about the limitations of palliative chemotherapy. Moreover, access to high-quality patient-centered educational materials may reinforce difficult information conveyed during oncology office visits or fill in gaps in understanding.

In this study we sought to partner with patient and clinician stakeholders to develop a patient-centered multimedia intervention to support the IC process for common palliative chemotherapy regimens used to treat advanced gastrointestinal (GI) cancer. We specifically chose to focus on the most commonly administered chemotherapy regimens used to treat advanced colorectal cancer (CRC) and advanced pancreatic cancer, which are among the leading causes of cancer-related death in the United States. Most patients receive chemotherapy

treatment, yet median survival is only 2 to 2.5 years for advanced CRC and less than a year for advanced pancreatic cancer. Patients with these diseases have several treatment options, which differ in toxicity and, in some cases, efficacy.[25] These patients clearly face important decisions about their personal priorities in life, balancing treatment intensity with QOL, and planning for EOL care. These diseases represent an ideal model in which to test the efficacy of a patient-centered multimedia IC intervention, which if effective could be extended to other cancer types and scaled into routine practice.

D. Participation of Patients and Other Stakeholders in the Design and Conduct of Research and Disseminating of Findings

Design: We designed this study with patient input to answer 3 fundamental patient questions:

(1) Given my personal characteristics and preferences, what should I expect will happen to me when I receive (or choose not to receive) chemotherapy? Most patients with advanced cancer want to be maximally informed about their illness and therapy.[13,16,26,27] Direct conversations about poor prognosis and the lack of curative treatment for advanced CRC are challenging and occur infrequently; when they do occur, they are often misunderstood by patients.[6,15,28] The materials we've developed address these topics and discuss issues on the forefront of patients' minds, such as, "Can I keep working on this treatment?" or "How will oxaliplatin neuropathy affect my daily activities?"

(2) What are my options instead of this regimen, and what are the potential harms/benefits of those options? We reactively designed ach IC booklet/video to discuss a chemotherapy regimen and alternatives such as other regimens, clinical trials, and supportive care, along with the pros and cons of each.

(3) How can clinicians best convey information about the pros and cons of my cancer treatment options so that I can make the best decisions about my health care? Discussing the benefits of palliative chemotherapy is challenging because the magnitude of benefit is substantially less than what most patients expect. Although patients widely report wanting concrete information about these topics, research has repeatedly shown that clinicians rarely

disclose specifics about chemotherapy response rates or its impact on life expectancy. We hypothesized that tangible educational tools would support oncologists in this role and help patients obtain the information they want about treatment risks/benefits. We chose to create a suite of multimedia IC tools, including written booklets and complementary videos. This decision was predicated on the fact that people have different learning styles and preferences for information delivery. We thought written tools necessary because this is the prevailing mode of instructional chemotherapy tools. We selected video as a complementary media based on its ability to overcome literacy barriers, its ability to present patient voices, and the growing literature that supports the success of video decision aids in informing patients and impacting care choices about sensitive topics including advance directives.[22,57]

Conduct: Approach to stakeholder engagement: Our stakeholder engagement focused on central participants in the chemotherapy IC process[29]: patients, caregivers, oncology physicians, and nurses. First, we ensured that our multidisciplinary research team included the perspectives of patient advocacy (EF), medical oncology (ACE, DS, NJM), palliative care (ACE), oncology nursing (HC), and health services research (DS, JKW). This group met frequently and shared editorial control over the project. Next, we established core panels of patient/caregiver and clinician stakeholders to advise the team and assist throughout the development process. We created several other opportunities for stakeholder engagement: metastatic colorectal cancer (mCRC) patients and clinicians were filmed within the IC videos; patients contributed quotes to the IC booklets; clinicians and advocates were surveyed; and mCRC patients participated in qualitative interviews.

Patient/caregiver stakeholder panel: Our local patient/caregiver stakeholder panel included 4 mCRC patients and 2 cancer survivors who coidentified as caregivers, recruited from the Dana-Farber Cancer Institute (DFCI). An expert patient stakeholder panel included 4 patient advocates with leadership experience in national cancer research and advocacy organizations, such as the Colon Cancer Alliance. These panels were oriented to the project during separate kick-off calls. Subsequently, our lead patient advocate (EF) liaised with panel members for advice and feedback on various iterations of the intervention, using a flexible combination of email, circulation of draft documents, phone calls, and individual meetings. Local stakeholders

participated in 2 additional in-person group meetings (also attended by the core research team), during which they discussed the intervention at critical stages of development.

Clinician stakeholder panel: Our core clinician panel included 5 GI oncologists, 2 oncology nurses, 2 palliative care specialists, and an oncology social worker. Panel members advised the study team and critiqued iterative drafts of the intervention via email, circulation of draft documents, and individual discussions.

Stakeholder-driven revisions: We communicated results of acceptability testing to our core stakeholder panels and discussed them a second in-person patient stakeholder meeting. Stakeholders helped guide intervention revisions in response.[30]

Dissemination: To date, the primary source of dissemination has been through publication: 1 manuscript accepted, 1 American Society for Clinical Oncology (ASCO) abstract submitted, and 1 manuscript in preparation. Patient stakeholders have/are successfully coauthoring all 3 projects.

E. Methods Aim 1 Methods

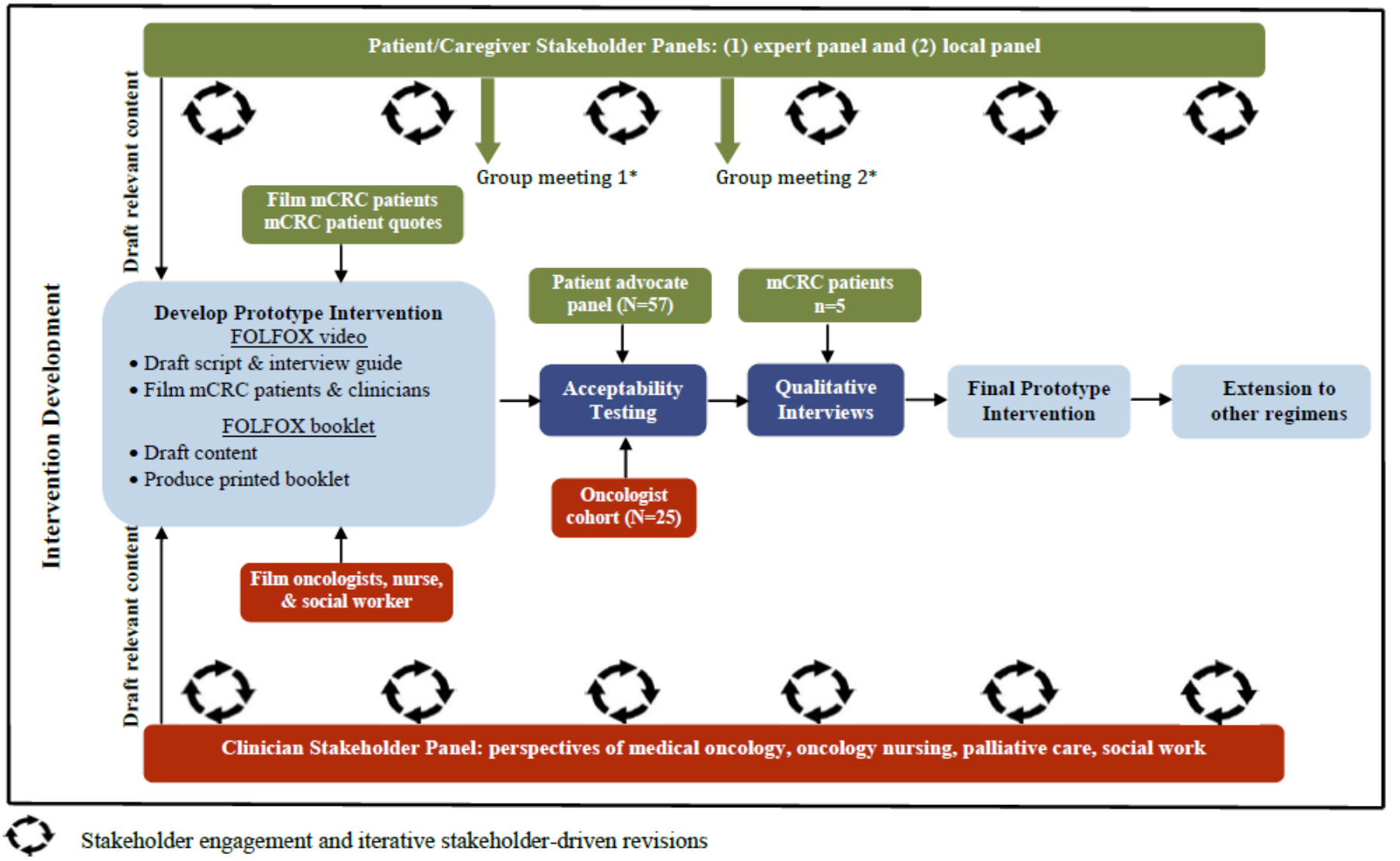
Overview of study processes:

Figure 1 presents a visual overview of the intervention development processes. Here we describe the development, critical evaluation, and refinement of our prototype intervention.

Content development phase:

The study team first reviewed the literature on FOLFOX+/–bev (folinic acid + fluorouracil + oxaliplatin +/– bevacizumab) and used this evidence base to draft the prototype IC booklet and scripted portions of the IC video. Content was broadly organized into chemotherapy purpose/benefits, infusion process, risks/side effects, impact of bevacizumab, coping and decision making, treatment alternatives, and life expectancy. We circulated all draft materials to our core stakeholder panels and iteratively revised the content prior to moving to the production phase.

Figure 1: . Intervention Development and Stakeholder Engagement



[a] Local stakeholder panel met in person with members of the study team to review and discuss the intervention at critical stages of development.
mCRC = metastatic colorectal cancer

Production phase:

For the prototype IC booklet, health communication specialists from the DFCI Health Communication Core edited the material to target a sixth- to eighth-grade reading level and to adhere to best health communication practices.[31] Graphics specialists then created a printed booklet using colors, fonts, call-out boxes, graphics, authentic patient photos, and quotes. A professional health videographer filmed several oncologists and an oncology nurse reading scripted material from a teleprompter and conveying similar information in an unscripted fashion. Next, several mCRC patients were filmed describing their experiences on FOLFOX +/– bev using an interview guide designed by patient stakeholders to touch on side effects, QOL, coping, and any benefits derived from treatment. We used no professional actors. Footage was edited professionally, with significant input from the stakeholders.

Critical evaluation:

Our prototype intervention underwent acceptability testing by (1) a national panel of patient advocates and (2) a cohort of oncology practitioners. After responsive stakeholder-driven revisions, we conducted qualitative interviews with mCRC patients. We obtained IRB approval, and written documentation of IC was waived.

All patient advocates who registered to attend the 2014 ASCO Annual Meeting in Chicago, Illinois, were invited by email to attend an on-site, interactive session. Of 323 advocates invited, 57 actively participated. Using an audience response system, advocates then rated their agreement with a series of items about the clarity of the intervention as well as its balance, tone, and utility (eg, “The booklet is well organized and easy to follow.”). Responses ranged from “strongly disagree” to “strongly agree” on a 5-point Likert scale.

Additional items assessed the importance of communicating chemotherapy benefits (eg, “Information about life expectancy is important to most cancer patients.”). Participants then assessed the prognosis sections of the booklet and video; we then asked whether they should be retained as core intervention components, made optional (opt-in approach), or removed. Advocates wrote open-ended critiques on a handout and directly in their IC booklets. Finally, JW moderated a 20-minute discussion focused on survey items with low acceptability and on optimal strategies to communicate prognostic information.

A convenience sample of 44 medical oncology physicians and midlevel providers from 10 US practices were invited by email to review the intervention online and complete an anonymous e-survey. A total of 25 practitioners from 9 sites participated (response rate = 57%). The survey first assessed satisfaction with chemotherapy educational materials used in their current practice. Similar to the advocate survey, practitioners then assessed acceptability of the intervention with a focus on clarity, accuracy, balance, and clinical utility. We asked practitioners whether the prognosis chapters should be retained in the intervention, removed, or made optional. Finally, they provided open-ended critiques of the IC video and booklet.

Analyses of acceptability testing:

Any survey items rated negatively (defined as disagree or strongly disagree) by more than 20% of either cohort were deemed unacceptable and revised. Pair-wise, chi-square tests determined participants' preferred approach to the prognosis sections (retain, make optional, or remove). We collated advocates' and oncologists' open-ended critiques, and common critical feedback prompted intervention revisions.

Qualitative interviews:

We conducted these interviews with our target population. Eligible patients aged 21 and older and had received palliative chemotherapy for mCRC. Exclusion criteria included inability to speak, understand, or read English; delirium or dementia; or inadequate stamina for the 60-minute interview. After participants reviewed the revised IC booklet and video, they were led through a semistructured series of questions to assess their understanding of the material and its acceptability, using standard qualitative interviewing techniques.[32] Interviews were audio-recorded, and notes were taken during and after. We examined feedback, and common critiques prompted refinements.[30]

Extension to other chemotherapy regimens: Once evaluation of the FOLFOX +/– bev educational materials was finished, the study team expanded the suite of chemotherapy IC materials to include other commonly used regimens for advanced GI cancers. First, the team developed educational materials for FOLFIRI +/– bev, another treatment often used when treating mCRC patients. Our core panel of stakeholders reviewed these new materials and provided their feedback in person and via written comments. The study team then began

expanding to create educational materials for pancreatic cancer. For those materials, we convened a stakeholder panel of patients/caregivers and clinicians with direct experience with pancreatic cancer and had them review the CRC intervention and give suggestions for adapting it to better suit the needs of pancreatic cancer patients, who have a much worse prognosis and therefore more intense needs. Our study team used their feedback to draft written materials (booklets and video scripts) for 3 common chemotherapy regimens used to treated advanced pancreatic cancer: FOLFIRINOX, gemcitabine + nab-paclitaxel, and gemcitabine. Once these drafts were developed, we convened another stakeholder meeting to get specific feedback on them. Additionally, we circulated draft documents to key stakeholders (including patients/caregivers/clinicians) for feedback on draft materials. The final prototype chemotherapy regimens represented our suite of IC tools, and instructions for accessing the individual informed consent videos and booklets can be found in Table 0.

Aims 2 and 3 Methods

Study overview:

We conducted a multicenter randomized clinical trial (RCT) in which patients with advanced CRC and pancreatic cancers making first- or second-line palliative chemotherapy decisions were randomized to the usual process of chemotherapy IC or to IC supplemented by our suite of IC videos and companion booklets. Survey assessments at 2 weeks and 3 months evaluated patient understanding and other metrics of the quality of informed decision making.

Study setting and participants:

Patients were enrolled at DFCI, Dana-Farber/Milford Regional Medical Center, Beth Israel Deaconess Medical Center, University of California San Francisco, Virginia Commonwealth University, and University of North Carolina at Chapel Hill. The protocol was approved by the IRBs of all participating sites. Patients with mCRC, locally advanced pancreatic cancer, or metastatic pancreatic cancer were eligible to participate if they were making a treatment decision regarding first- or second-line palliative chemotherapy, and if the treatment under consideration was represented within our suite of IC tools. Exclusion criteria included aged <21; inability to speak English, delirium or dementia, or a curative treatment intent (eg, receiving chemotherapy in preparation for a potentially curative surgery). Patients meeting these same

criteria were also eligible for participation if they were receiving first-line chemotherapy and were anticipated to make a second-line treatment decision in the future; however, these patients were not randomized until the time of the second-line treatment decision.

Table 0. Chemotherapy Regimens Represented in Our Suite of IC Tools, and Instructions for Accessing the Individual IC Videos and Booklets

Colorectal Cancer Chemotherapies	**www.chemovideo.org** User ID and Password[a]	**Pancreatic Cancer Chemotherapies**	**www.chemovideo.org** User ID and Password
FOLFOX +/– bevacizumab	FOLFOX	**Gemcitabine**	GEM
FOLFIRI +/– bevacizumab	FOLFIRI	**Gemcitabine + nab-paclitaxel**	GEMPLUS
		FOLFIRINOX	FOLFIRINOX

[a] UserID and password for each regimen are identical.

Table 1. Summary of Survey Assessments

Domain	Measures	Assessments		
		Baseline	Postdecision	Follow-up
Sociodemographics	Standard assessments	x		
Health literacy and numeracy	Stagliano[2] (2013), Lipkus[3] (2001)	x		
QOL	FACT-G[4]	x	x	x
Optimism	Life Orientation Test-Revised[5]	x		
Distress	Emotional Well-being Component of FACT-G	x	x	x
Communication and decision preferences	Control Preferences Scale[17]	x		
	Preferred Information for Chemotherapy Decision (for study)	x		
	Prognostic Communication Preferences, Meropol[6]	x		
Illness understanding	Developed for study	x		
Use of IC booklet and video	Self-report	x	x	x
Quality of IC				
Core understanding				
Chemotherapy bisks	Modified from Leighl et al[7]		x	
Chemotherapy Benefits	Adapted from CANCORS[8] (primary outcome)		x	x
Decision making				
Adequate information	Developed for study			
Decisional involvement	Modified Control Preferences Scale[17]		x	
Communication satisfaction	5 Items from Mazor's PACE scale		x	
Decisional conflict	Modified SURE Assessment[9]		x	
Satisfaction				
Doctor–patient relationship	Modified Human Connection Scale[10]			x
With study IC tools/standard IC	Developed for study		x	
With decision	Decisional Regret Scale[11]		x	x

Doctor–Patient Communication				
Patient-centered communication	Mazor's PACE scale[12]		x	x
Prognostic communication	Developed for study			x
Prognostic understanding	Adapted from CANCORS[8]			x
Advance care planning	Chart Abstraction (DNR) and Patient Report (Health Care Proxy)			x

Table 2. PICOTS

Population	Patients with mCRC or advanced pancreatic cancer making treatment decisions about palliative chemotherapy
Intervention	Palliative chemotherapy education and IC using the interventional materials developed by the study team: a regimen-specific booklet and video
Comparator	Palliative chemotherapy education and IC via usual care/standard approach
Outcomes	Primary Outcomes: (1) Understanding of prognosis and (2) decisional conflict Secondary Outcomes: (1) Core understanding required for IC; (2) understanding of RISKS; (3) understanding of BENEFITS; (4) achievement of decisional control preferences; (5) satisfaction with physician communication; (6) satisfaction with IC documents; (7) decisional regret; and (8) emotional distress
Timing	Participants surveyed at baseline, 2 weeks, and 3 months
Study setting	1 tertiary referral center, 4 major hospitals, and 1 community hospital

Study procedures and enrollment:

We identified potentially eligible patients by screening daily clinic schedules and by direct referrals from oncologists. Oncologists confirmed eligibility and granted permission to approach the patient for participation. Enrollment and study procedures differed, depending on whether (1) patients were currently making a palliative chemotherapy decision or (2) they were on first-line therapy and were anticipated to make a second-line chemotherapy decision in the future.

1. Patients currently making a palliative chemotherapy decision were approached by the study RA immediately after receiving a treatment recommendation and no later than 2 weeks after their first treatment. After signing consent and completing the baseline assessment, patients were randomized to usual care or to the intervention by a computer-generated 1:1

randomization, stratified by line of therapy. Because these patients were frequently too overwhelmed to complete all study procedures on the same day of an initial treatment consultation, these patients were permitted to enroll in the study and be randomized prior to completing their baseline assessment of sociodemographics. The baseline assessment was then conducted as soon as possible and prior to the next survey assessments.

2. Eligible patients who were receiving first-line chemotherapy were approached for participation at the time of a routine clinic visit, signed consent and completed the baseline assessment. When these patients were confronted with a second-line treatment decision (typically upon disease progression), they were then randomized to intervention or control.

Randomization and interventions:

Patients were randomized to usual care or to the intervention by a computer-generated 1:1 randomization, stratified by line of therapy. Neither patients, clinicians, nor investigators were blinded as to the randomization allocation. Patients in both study arms were given standard chemotherapy educational materials at the discretion of the treating oncologist. Patients randomized to the intervention were also given a copy of the appropriate investigational IC booklet(s). The web address, login, and password for online access for the corresponding IC video(s) were printed inside the booklet. RAs at all study sites offered patients the opportunity to review the IC video on a study iPad in a private location in the clinic; alternatively, patients could choose to access the video from their home computer or other device at any time (and as many times as they desired).

The IC booklets and videos were upfront about the noncurative potential of palliative chemotherapy; however, life expectancy statistics were included as optional segments within each of these tools. Patients were encouraged, but not required, to review the IC booklet and video. Patients did not receive any financial incentives for reviewing the intervention. We chose to give patients control over whether and when to review the intervention, rather than mandating a facilitated session to review the intervention, for several reasons. First, we designed the intervention to be simple to use and to require little to no orientation or facilitation. Second, patients who have been recently diagnosed and are preparing to start palliative chemotherapy are under tremendous emotional stress and have many other

competing time commitments, which would make an additional study visit overly burdensome to patients and infeasible. Third, given the sensitive information discussed, we felt it important to allow patients to review the information in the environment in which and with the people with whom they felt most comfortable. All patients were given the option to review the intervention in clinic (on study iPads) at the time of a scheduled clinic visit or another time of their choosing, but few chose to do so.

Assessments:

Participants were asked to complete 3 assessments: at baseline, at 2 weeks after their treatment decision/chemotherapy initiation (window 2-4 weeks), and at 3 months (window 8-16 weeks). Patients could complete survey assessments in their preferred method: administered by the study RA via phone or in clinic, at home via a secure online survey, or in clinic via pen and paper or tablet. We contacted patients up to 3 times for each survey before considering them as nonrespondents. Our study team created the surveys, with iterative revisions, based on feedback and review of patient stakeholders. We took most survey items from validated instruments, with additional items created for our specific study purposes. In appreciation of their participation, participants were given a $25 giftcard after the 3-month assessment.

Baseline survey:

The baseline survey assessed basic sociodemographic characteristics as well as decision-making and information preferences. Seven items assessed how much information patients wanted when making a chemotherapy decision about its risks and benefits, with response options on a 5-point Likert scale (ranging from “no information” to “as much as possible”). We assessed preference for patient-controlled, shared, or physician-controlled decision making using the Control Preferences Scale.[33] Five items from an instrument developed by Meropol et al assessed patients’ prognostic communication preferences.[8] Patients were asked how likely they thought chemotherapy was to cure their cancer.[4]

Postdecision survey:

We assessed patients at 2 weeks regarding the quality of informed decision making, satisfaction with the decision-making process, and use and satisfaction with educational

materials. To assess *understanding of treatment goal*, patients were asked, "According to your doctor, what is the goal of the chemotherapy?" They could choose any/all of the following response options: cure, control cancer growth, alleviate symptoms, prolong life, or other. Selecting either control cancer growth and/or alleviate symptoms, and/or prolong life were defined as accurate understanding; "to cure" was inaccurate. To determine *understanding of chemotherapy risks*, patients were asked to indicate the likelihood that they would experience specific side effects because of the chemotherapy under consideration, with separate items for nausea/vomiting, diarrhea, neuropathy, and hair loss.

Patients' responses were correlated to the known side effect profile of their chemotherapy regimen. For example, we considered patients receiving FOLFOX to have accurate understanding if they responded "somewhat/very likely" for nausea/vomiting and neuropathy, and if they responded "a little/not at all likely" for hair loss. We created similar algorithms for each of the other regimens. We assessed *achievement of preferred role in decision making* with the Control Preferences Scale[33]; patients indicate the role they played in their treatment decision, which is compared to their preferred role (assessed at baseline). We assessed *satisfaction with communication during treatment decision-making process* via 5 items from the Patient Assessment of Cancer Communication Experiences (PACE) scale.[34] We averaged scores ("does not apply" excluded), creating a score of 1 to 4, with 4 being the most satisfied. We assessed *decisional conflict* using a modified version of the SURE[35] 4 item-screening test, assessing (1) whether patients are sure of the best option, (2) whether they know the risks and benefits, (3) whether they are clear about which risks and benefits matter, and (4) whether they have sufficient support. Given our study's interest in patients' understanding of chemotherapy risks and benefits, we expanded items 2 and 3 into 4 separate items to assess risks and benefits individually, analogous to items from the original Decisional Conflict Scale.[33] We summed responses, resulting in a scale of 0 to 6, where 0 indicates maximum conflict.

Patients randomized to usual care rated their satisfaction with these materials on a scale of 1 to 10, where 10 is the most satisfied. Patients randomized to the intervention rated their satisfaction on a scale of 1 to 10 separately for the IC booklet and the IC video; We averaged these scores as a measure of global satisfaction with the IC tools. Patients also responded to an

additional 8 items about the tools' usefulness, with response options ranging from "strongly disagree" to "strongly agree" on a 5-point Likert scale. We assessed *emotional distress* via the 6 items of the emotional well-being subscale of the FACT-G QOL scale, with scores ranging from 0 to 24 (higher scores are more desirable).

Follow-up survey:

We surveyed patients again at 3 months to assess stability/change in understanding of chemotherapy benefits, prognostic understanding, satisfaction with clinician relationship and communications, and advance care planning. Patients were asked an item from the CANCORS study: "How likely do you think that chemotherapy is to cure your cancer?" Response options were "very likely," "somewhat likely," "a little likely," "not at all likely," and " don't know."[4] We defined accurate *expectations of chemotherapy benefits* (our primary study outcome) as a response of "not at all likely." Also from CanCORS, patients were asked how likely they thought chemotherapy was to control the growth of their cancer, with identical response options. We assessed understanding of treatment goals by asking patients, "According to your doctor, what is the goal of chemotherapy?" Response options were (1) "cure," (2) "shrink cancer," (3) "improve symptoms," (4) "prolong life," and (5) "other." We considered patient responses of options 2, 3, or 4 accurate. We considered all others inaccurate. Patients completed the validated 5-item *Decisional Regret* Scale,[36] with scores of 0 to 100 in which 100 indicates maximal regret. An additional 9 items from Mazor's PACE scale assessed *patient-centered communication.*[34]

We averaged responses, with scores ranging from 1 to 4, 4 being most satisfied. We assessed strength of the patient–physician relationship with 9 items from the Human Connection Scale. We assessed *prognostic understanding* by asking patients about their understanding of the prognosis of a typical patient with their condition (<1 year, 1-2 years, 2-3 years, 3-5 years, 5-10 years, >10 years) and their beliefs about their own prognosis. Patients were asked whether they had discussed EOL care preferences with their care team or health care proxy.

Primary and secondary study outcomes:

Our primary outcome was the proportion of patients at 3 months with accurate

expectation of palliative chemotherapy benefits. This is relevant as a primary outcome because it represents the most basic understanding needed for an informed treatment decision; moreover, it has been shown to predict improved EOL care outcomes.[58] Our original application proposed assessing this outcome at 4 months; however, we changed it to 3 months because we expanded eligibility to include poor prognosis pancreatic cancer patients, which could have increased excess missing data due to death or debility. The primary rationale for making the 3-month (rather than 2-week) time point our primary outcome was that it reflects sustained understanding rather than short-term recall. Prespecified secondary outcomes included understanding of treatment goals, understanding of chemotherapy risks, decisional conflict (aim 3 primary outcome), decisional regret, satisfaction with communication during the treatment decision-making process, emotional distress, and prognostic understanding.

Analysis plan and power calculation

We conducted all primary analyses according to the intention-to-treat principle; however, we also prespecified that outcomes would be explored according to intervention use. We analyzed differences in dichotomous and categorical outcomes using Fisher exact, chi-square, Wilcoxon, and ANOVA tests, as appropriate.

Reported *P* values were 2-sided and were considered significant if less than .05. As prespecified in our study protocol, our primary analysis for our primary and key secondary outcomes employed multiple imputation to mitigate potential bias associated with missing data. We performed multiple imputation according to a *missing at random* assumption, which postulates that the missingness of data is not completely random but may be partly accounted for by observed data. Using multivariate imputation by chained equations, we created 10 complete data sets. Imputation models included prespecified primary and secondary outcomes and patient baseline characteristics (age, gender, race, cancer type, and lines of therapy). We analyzed results for the prespecified primary and secondary outcomes and integrated them from the 10 imputed data sets using Rubin's rule.[59]

Our original study plan and contract with PCORI was to enroll 160 patients in this study. Due to concerns of inadequate power, project officer Dr. Ip requested that this sample size calculation be revised prior to opening the study. After communications between the study

team and Dr. Ip, we calculated that a total number of 194 patients (97 per treatment arm) were required for an 80% power to detect a 33% relative increase in our primary outcome, presuming a 40% rate of accurate expectations in the control arm, with a 2.5% 1-sided type 1 error. We extrapolated this assumed rate from CanCORs,[4] which demonstrated a 19% rate of accurate expectations in CRC patients and a 31% rate among lung cancer patients. Because we conducted the study at large urban academic cancer centers and included patients considering second-line therapy, we conservatively assumed that rates of accurate understanding would be approximately 40%. We raised our enrollment target to 250 when it became clear that attrition was higher than expected. The study closed to accrual with a total of 200 patients randomized. With mature data for all participants on the study, primary outcome data are available for a total of 144 patients.

F. Results

Aim 1 Results

Prototype intervention. The final prototype video and booklet can be found at www.chemovideo.org (logon and password: FOLFOX); both are summarized in Table 3.

The 21-minute video is narrated by 6 oncologists and 1 nurse. A social worker offers unscripted advice about coping and addresses the emotional impact of a new diagnosis. An optional hyperlink allows patients to watch an additional 2-minute segment about the impact of chemotherapy on prognosis. Unscripted interviews with 5 mCRC patients present their perspectives on treatment. The 22-page booklet serves as both a reference guide and an alternative resource, allowing patients to access information in their preferred format. Graphics reinforce key concepts, and photographs illustrate the treatment process. Patient-centeredness is augmented through authentic patient quotes, call-out boxes answering common questions, and a section on frequently asked questions (FAQs). Side effects are displayed in tabular format, with a column presenting self-management advice. Prognostic information is presented in 2 opposing pages, which are sealed and preceded by a cautionary explanation.

Table 3. Overview of Final Prototype IC Intervention for FOLFOX +/– Bev

Organization	Core Content	Distinguishing Features	
		IC Video	IC Booklet
Background	• Intervention purpose • Key definitions • Drug names & FOLFOX acronym • Major differences between FOLFOX +/– bev	• Narrated by an oncologist	• Introduction • Table of contents • "What is FOLFOX?"
Purpose and benefits	• Explicit disclosure that chemotherapy does not cure mCRC • 3 potential benefits: o Control cancer growth o Palliate symptoms o Prolong life	• Narrated by oncologists • Patients describe outcomes of treatment (eg, radiographic response, symptom improvement) • Includes experience of patient who derived no benefit	• Presents likelihood of response with o Text o Dot graphic • Two call-out boxes answering o "Will I benefit?" o "Can my disease be cured with surgery?"
Treatment administration	• Chemotherapy schedule • Typical infusion process • Information about ports	• Nurse narrates infusion process • Patient footage visually demonstrates o Port access o Chemotherapy infusion o Home infusion and pump disconnect • Patients share infusion experiences	• Visual of chemo cycle • Photo of port and chemo pump • Patient quotes about operating chemo pump
Side effects	• Focuses on toxicities that o Are common o Affect QOL o Are potentially dangerous • Minimizes attention to laboratory abnormalities and uncommon, minor toxicities	• Narrated by oncologists • Patients describe o Side effects o Impact on QOL o Management tips	• Qualitative overview "How will I feel?" • Side effects in tabular format: o In order of frequency o Paired with self-management advice ("What you can do about it") • Call-out box explaining neuropathy
Bevacizumab	• Impact on efficacy • Additional risks/toxicities • Reasons bevacizumab might be preferred	• Narrated by an oncologist	• Text
Coping/making a treatment decision	• Addresses emotional dimensions of a new treatment, resiliency of patients, and the personal nature of treatment decisions	• Social worker offers advice about coping • Patients share coping, sources of hope, ways to maintain normalcy	• Brief section on making a treatment decision • Patient quotes about coping interspersed
Opt-in section on prognosis	• Median survival with and without chemotherapy • 1-, 2-, and 5-year survival statistics	• Preamble allows patients to opt-in if they want prognostic info • 2-minute section narrated by oncologists	• 2 opposing pages, sealed • Preceded by a warning and opt-in • Text only (no dot graphics)
Treatment alternatives	• Clinical trials • Other chemotherapy regimens • Palliative care (adjunct or instead of chemo)	• Narrated by oncologists • Supplemented by patient voices	• Basic information on 3 options • Supplementary 2 pages compare and contrast other standard chemotherapy regimens
Frequently asked questions	Answers FAQs contributed by patient stakeholders	Absent	Present

Core stakeholder panels substantively shaped the intervention. Video modifications prompted by patient stakeholders include filming a social worker who discusses coping, emphasizing patients' resilience, and eliminating unnecessarily "scary" side effect descriptions. Patients strongly supported our decision to film authentic patients and clinicians rather than actors; however, clinicians were considered "stiff" on camera. In response we refilmed clinicians and worked with patients to select the most acceptable footage. With respect to the booklet, patients rephrased sensitive passages, added a segment about decision making, and populated FAQs. At the patients' suggestion we added phonetic pronunciations, augmented patient photographs, and solicited quotes about coping and symptom management from patient members of the Colon Cancer Alliance and placed them throughout the booklet. Provider stakeholder contributions largely focused on ensuring accuracy and clarity.

Acceptability testing sample characteristics: Table 4 presents characteristics of the 57 patient advocates and 25 oncology practitioners who participated in acceptability testing.

Perspectives on existing chemotherapy educational materials: Only 20% (5 of 25) of practitioners were satisfied with the chemotherapy educational materials used in their current practice (Figure 2). Although most agreed that risks were explained thoroughly, few agreed that benefits or alternatives were adequately explained. Among the 22 advocates who had received chemotherapy educational materials, only 45% (10 of 22) found them to be useful.

Intervention ratings: Patient advocates rated the organization, clarity, balance, and tone of the intervention highly (see Figures 3a-3c). Most agreed it would be useful and help patients make more informed treatment decisions. All advocates agreed (10 of 57, 17.5%) or strongly agreed (47 or 57, 82.5%) that patient voices strengthened the intervention. Two items met our criteria for unacceptable: More than 20% of advocates perceived treatment alternatives to be biased within the video and booklet, prompting revisions. Oncology practitioners rated the intervention highly on every domain (see Figures 3d-3f). When asked how often they would distribute the intervention to patients, 64% (16 of 25) stated "usually" and 36% (9 of 25) said "always."

Table 4. Patient Advocate and Oncology Practitioner Cohorts Participating in Acceptability Testing

Sample Characteristic	Patient Advocate Cohort n (%); N = 57	Practitioner Cohort n (%); N = 25
Advocacy Perspective		
Cancer patient/survivor	26 (46)	-
Caregiver	7 (12)	-
Both patient and caregiver	7 (12)	-
Neither patient nor caregiver	16 (28)	-
Colorectal Cancer Primary Focus of Advocacy Work		
Yes	12 (21)	-
No	45 (79)	-
Prior Chemotherapy Receipt (advocate or patient for whom the advocate served as caregiver)		
Yes	35 (61)	-
Advanced Cancer Diagnosis (advocate or patient for whom the advocate served as caregiver)		
Yes	28 (49)	-
Professional Role		
Medical oncologist	-	22 (88)
Medical oncology midlevel provider	-	3 (12)
Practice Site		
Academic medical center	-	22 (88)
Community practice	-	3 (12)
Gender		
Male	6 (11)	14 (56)
Female	34 (60)	11 (44)
Age		
≤39	7 (12)	14 (56)
40-49	7 (12)	4 (16)
50-59	13 (26)	6 (24)
60-69	9 (16)	1 (4)
≥70	4 (7)	0
Race/Ethnicity		
White	35 (61)	21 (84)
Black	6 (11)	1 (4)
Asian/other	1 (2)	3 (12)
Hispanic	2 (4)	1 (4)
Education		
High school or some college	2 (4)	-
College graduate	18 (32)	-
Graduate or professional degree	22 (39)	-

Colum percentages may not add to 100% due to missing data.

Figure 2. Practitioner Perspectives on Chemotherapy Educational Materials Used in Current Practice (N = 25)

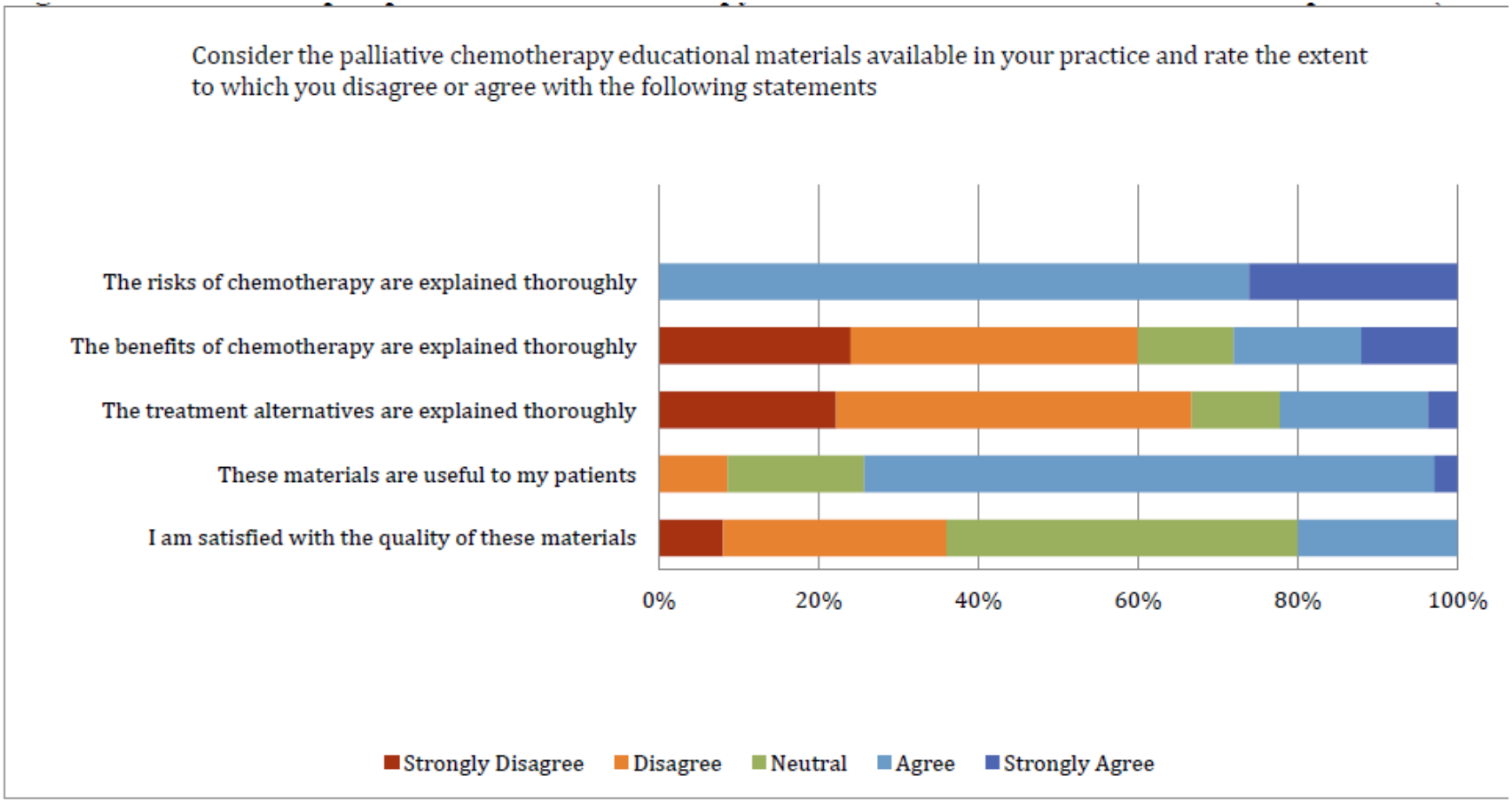


Figure 3. Patient Advocate (N = 57) and Oncology Practitioner Ratings (N = 25) of Prototype IC Intervention

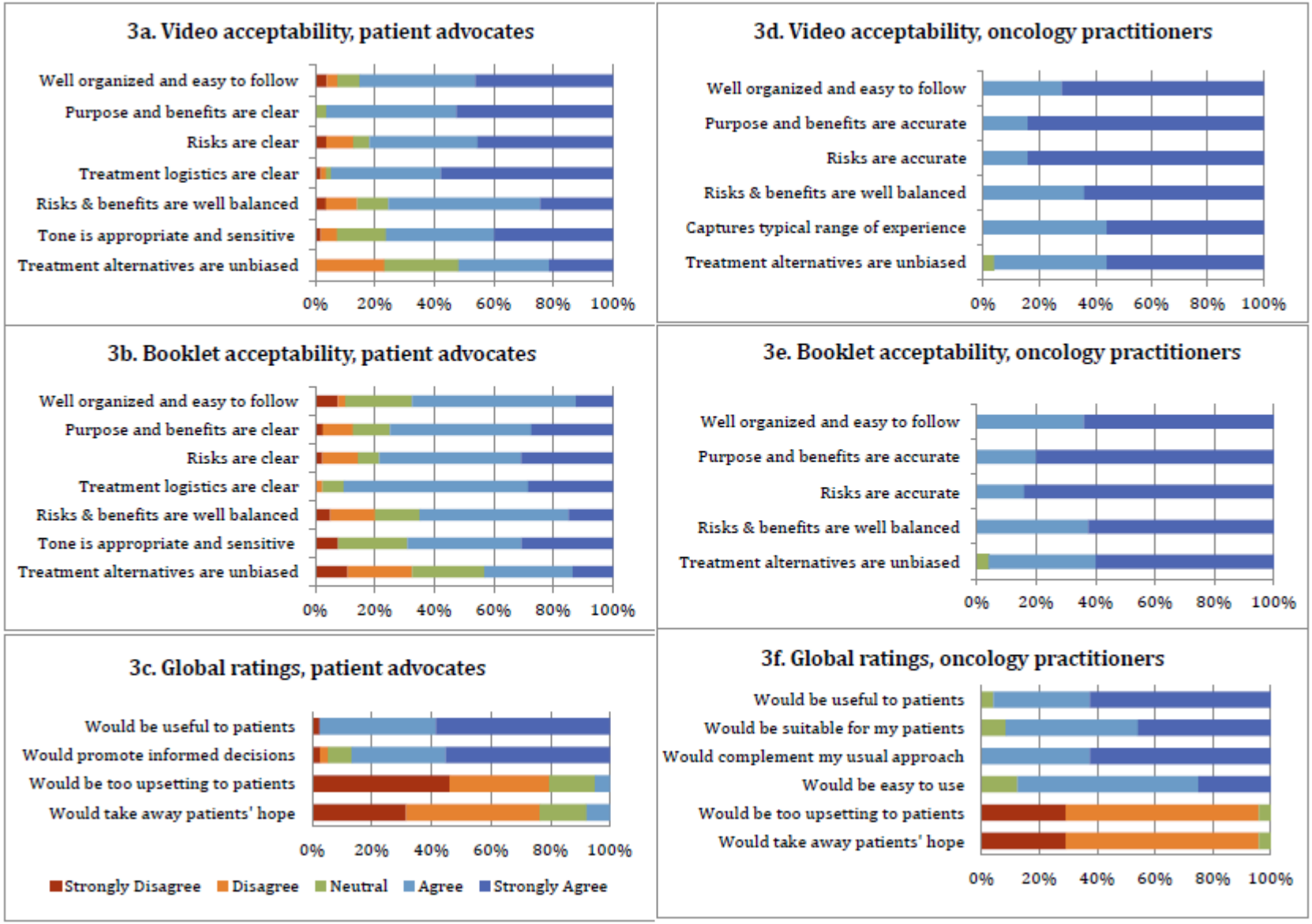
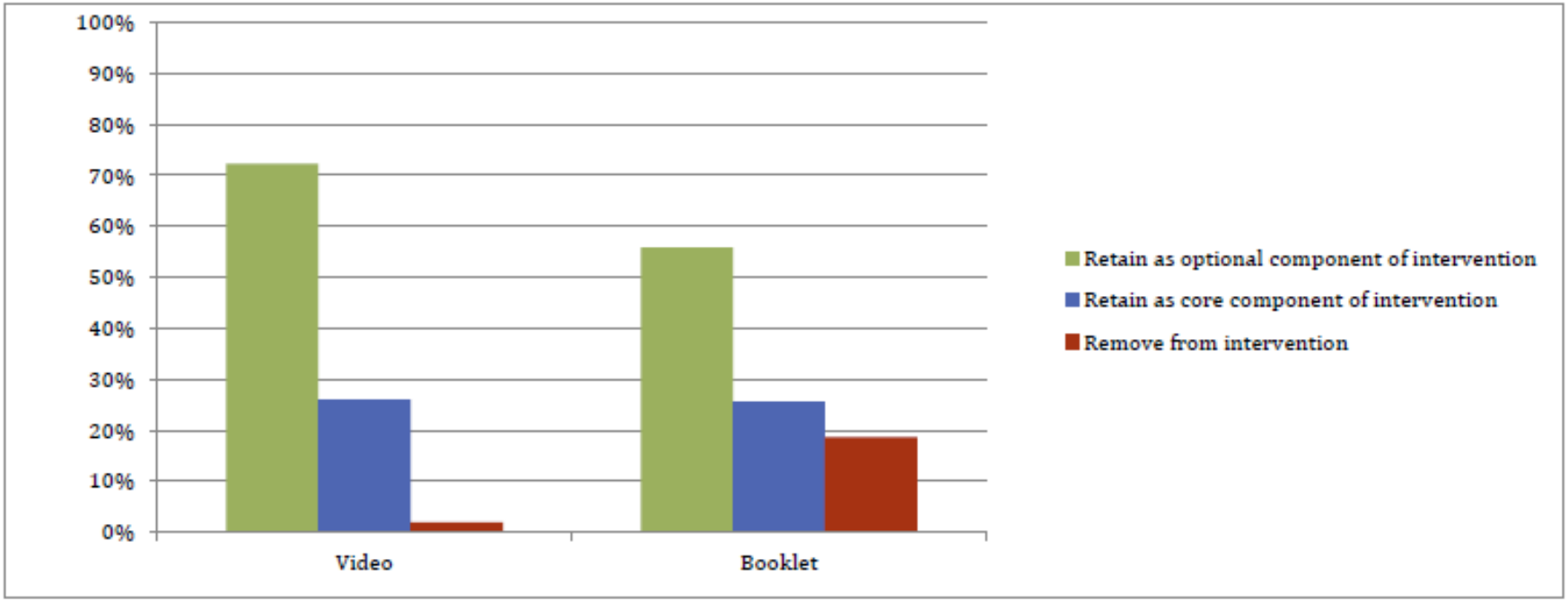


Figure 4. Patient Advocate Perspectives About Sections Communicating the Impact of Chemotherapy on Prognosis



Perspectives on prognostic communication: Most advocates agreed that response rates (50 of 56, 89%) and life expectancy (51 of 56, 91%) were important to patients. Advocates preferred the video prognosis segment to be accessed by an optional hyperlink, as compared with making it a core feature or eliminating it from the intervention (39 of 54 [72%], 14 of 54 [26%], 1 of 54 [1.9%], respectively; $p < .01$ for both comparisons). Advocates preferred for the written prognosis segment to be placed at the booklet's end (24 of 43, 55.8%) rather than featuring it within its main body (11 of 43, 25.6%; $p = .04$) or removing it (8 of 43, 18.6%; $p < .01$). Advocates expressed concern that end placement might not adequately protect against unwanted information and suggested sealing this section with a sticker, a solution we ultimately adopted. Similarly, 84% (21 of 25) of practitioners preferred an optional approach to prognostic communication sections.

Qualitative evaluations and responsive revisions: Most advocate and practitioner comments were favorable. Several advocates perceived bias in favor of FOLFOX, mostly driven by a mistaken impression that the intervention would be distributed to patients independently from an oncologist's treatment recommendation. In response to advocates' suggestions, we more clearly framed FOLFOX as one of several treatment options and explicitly stated our independence from industry. Several advocates requested more attention to bevacizumab, which we added. Advocates and practitioners criticized clinician footage and suggested refilming oncologists looking directly into the camera. We enacted these suggestions in all subsequent videos. Three advocates and 1 oncologist criticized footage of patients laughing and smiling, suggesting this led to a "rosy" picture of chemotherapy. Although our core stakeholder panels upheld this as an authentic representation, we added more somber segments for balance. Several advocates and oncologists indicated the intervention was too long. We shortened, where possible, and added a table of contents to make the booklet easier to navigate. At participants' suggestions, we made its colors bolder, clarified our palliative care definition, added more patient photographs, and more clearly attributed patient quotes.

Qualitative interviews and intervention refinements: Five mCRC patients were interviewed after reviewing the intervention. Overall, the patients accurately understood the intervention and perceived it to be highly useful. Qualitative feedback prompted several phrasing modifications, reconciliation of minor inconsistencies, redesign of the booklet cover,

photograph replacements, and a more prominent warning before prognosis information.[30]

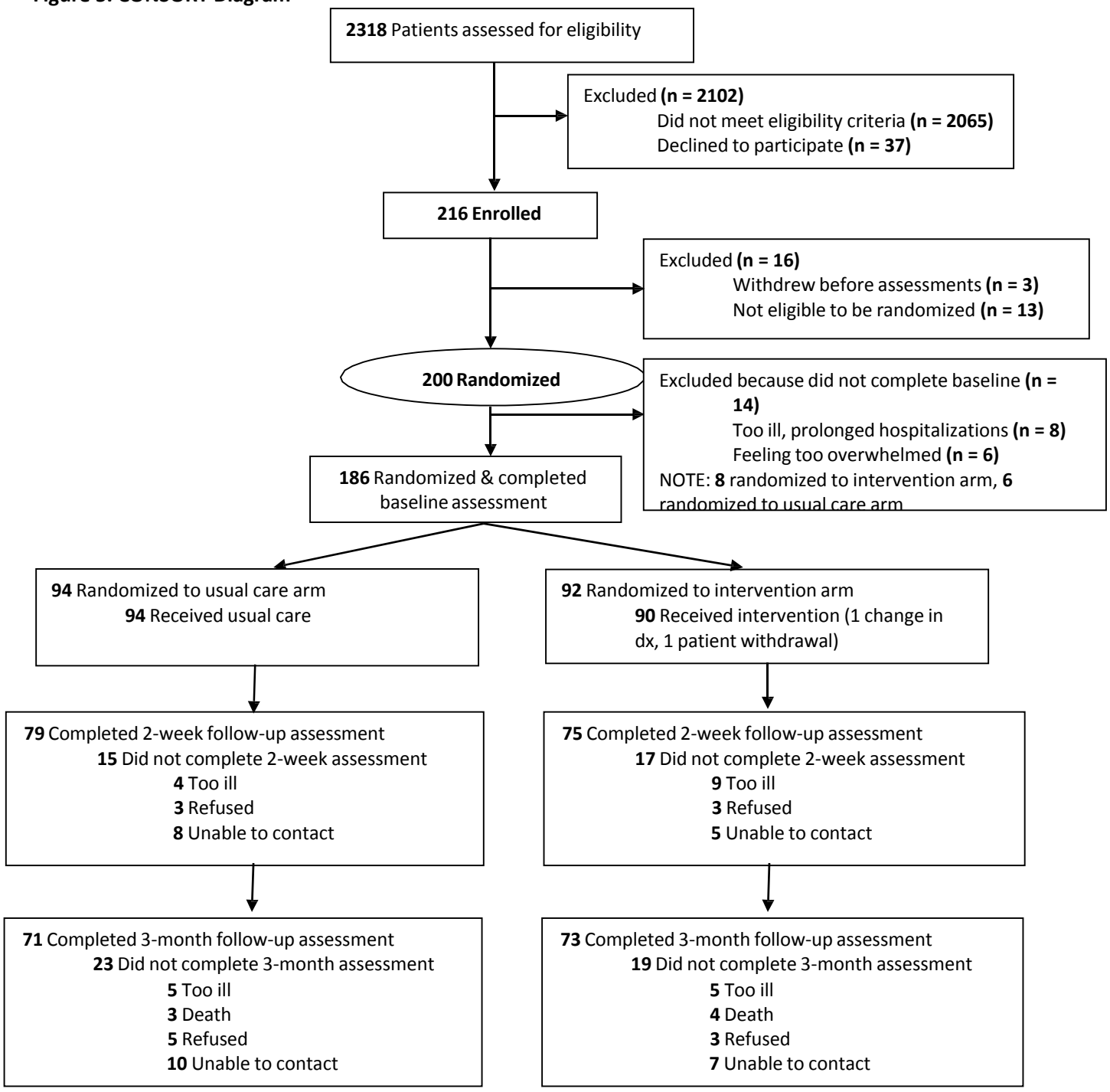
Development of the remaining suite of IC tools: Following the development, acceptability testing, and refinement of our prototype intervention describing FOLFOX +/– bev for advanced CRC cancer, we then extended this prototype to create a similar IC booklet and video for FOLFIRI +/– bev for advanced CRC cancer. Next, we created 3 additional IC videos and companion booklets to describe the most commonly administered treatments for advanced pancreatic cancer: FOLFIRINOX, gemcitabine, and gemcitabine + nab-paclitaxel.
We made these materials with the involvement of a stakeholder panel of pancreatic cancer patients and caregivers as well as an additional provider stakeholder panel, following a similar process as described for the FOLFOX intervention. Each of these interventions can be found at www.chemovideo.org (*username*/*password* 1: *FOLFOX/FOLFOX*, 2: *FOLFIRI/FOLFIRI*, 3: *GEM/GEM*, 4: *GEMPLUS/GEMPLUS*, 5: *FOLFIRINOX/FOLFIRINOX*).

Aims 2 and 3 Results

Participants: A total of 216 patients consented and were enrolled in the study (see Figure 5). Among these 216 patients, 200 were randomized to the intervention or to control conditions. A total of 14 patients (8 in the intervention group and 6 in the control group) were randomized but did not complete any of the 3 study assessments and are therefore excluded from our analyses, yielding an analytic cohort of 186 patients (92 in the intervention group and 94 in the control group).

Participant follow-up: Of the 186 patients included in our cohort, 154 (83%) completed the 2-week assessment and 144 (77.4%) completed the 3-month assessment. Reasons for loss to follow-up included inability to reach the participant after 3 attempts, active withdrawals, illness, and deaths. The frequency of these events reflects the natural history of advanced GI malignancies, and cohort recruitment and retention meet standards from other similar studies.[56]

Figure 5. CONSORT Diagram



Patient characteristics: Table 5 presents patient sociodemographic and clinical characteristics. Participants on this study were predominantly white and highly educated, with 106 (57%) having at least a college degree. Overall, 68 patients (36%) had advanced pancreatic cancer, and 119 (64%) had advanced CRC cancer. Most participants (80%) were making a treatment decision about first-line chemotherapy. Of the 119 participants with mCRC cancer, 60 were considering treatment with the FOLFOX or FOLFOX + bevacizumab, and 58 were considering FOLFIRI or FOLFIRI + bevacizumab. Of the 68 participants with advanced pancreatic cancer, 44 were considering FOLFIRINOX, 2 were considering gemcitabine, and 22 were considering gemcitabine + nab-paclitaxel. Most participants (93%) had an ECOG performance status of 0 or 1, indicating minimal or no functional limitations. Sociodemographic and clinical characteristics did not differ significantly between study arms, except for ECOG performance status, which was better in the intervention arm (0.048).

Patients' baseline preferences for decision making, information about chemotherapy, communications, and expectations of cure from chemotherapy: As shown in Table 6, most patients wanted maximal information about both the risks and the benefits of chemotherapy—including its likelihood to achieve cure and impact on life expectancy. Most patients preferred shared decision making, with fewer preferring patient-controlled choices and very few preferring physician-controlled decision making. Of note, among patients in the intervention arm, there was a statistically nonsignificant result indicating a preference for less information about likelihood of cure and the impact of chemotherapy on length of life. Most participants (86%) indicated that their doctor had discussed whether their cancer was curable, yet less than half of patients at baseline correctly responded that their cancer was "not at all likely" to be cured (45% usual care arm, 47% intervention arm).

Intervention use, and satisfaction with standard versus investigational chemotherapy educational materials: As shown in Table 7, 84% (47 of 56) of patients randomized to the control group reported reviewing standard chemotherapy educational materials provided by their doctor. The significant number of survey respondents who did not answer this item (38) may indicate lack of receipt or recall of these materials. Among the patients randomized to the intervention who completed the postdecision assessment, 80% (59 of 64) had reviewed the IC

booklet, but only 41% (30 of 66) had watched the IC video. Of the 59 participants who had read the IC booklet, 36 (61%) had read the optional life expectancy chapter. Among the 30 participants who had watched the IC video, 21 (70%) had watched the optional life expectancy chapter. Satisfaction ratings were similar between standard chemotherapy educational materials (mean [SD], 7.9 [1.7]) and the IC intervention (mean [SD], 7.8 [1.9]).

Table 5. Patient Baseline Characteristics (N = 186)

Characteristic		Control (%)	Intervention (%)	Total (%)	*p*
		94	92	186	
Age	Mean (SD)	59.2 (13.0)	59.4 (12.1)	59.3 (12.6)	0.913
Gender	Male	54 (57)	53 (58)	107 (58)	1.000
	Female	40 (43)	39 (42)	79 (42)	
Ethnicity	Non-Hispanic/Latino				
	Hispanic/Latino				
Race	White	76 (83)	84 (91)	160 (87)	0.206
	Black	11 (12)	6 (7)	17 (9)	
	Asian/other	5 (5)	2 (2)	7 (4)	
Diagnosis	Metastatic colorectal cancer	59 (63)	59 (64)	119 (64)	0.880
	Advanced pancreatic cancer	35 (37)	33 (36)	68 (36)	
Line of therapy	First line	74 (80)	71 (79)	145 (80)	0.940
	Second line	18 (20)	19 (21)	37 (20)	
Chemo under consideration	FOLFOX	14 (15)	6 (7)	20 (11)	0.227
	FOLFOX + bev	17 (18)	23 (25)	40 (22)	
	FOLIRI	2 (2)	6 (7)	8 (4)	
	FOLFIRI + bev	26 (28)	24 (26)	50 (27)	
	FOLFIRINOX	22 (23)	22 (24)	44 (24)	
	Gemcitabine	2 (2)	0 (0)	2 (1)	
	Gemcitabine + nab-paclitaxel	11 (12)	11 (12)	22 (12)	
Stage at diagnosis	Stage I, II, or III				
	Stage IV				
Education	Grade school or less	8 (9)	5 (5)	13 (7)	0.751
	High school graduate, some vocational school or college	36 (39)	29 (32)	65 (35)	

	College degree or higher	49 (52)	57 (62)	106 (58)	
Live alone	No	76 (83)	79 (87)	155 (85)	0.559
	Yes	16 (17)	12 (13)	28 (15)	
Difficulty paying bills	Not at all, not very, somewhat difficult	85 (90)	86 (93)	171 (92)	
	Very/extremely difficult	9 (10)	6 (6)	15 (8)	
ECOG performance status	0 - Fully active	31 (40)	44 (58)	75 (49)	**0.048**
	1 - Restricted in physically strenuous activity but ambulatory	42 (54)	26 (34)	68 (44)	
	2 - Ambulatory but unable to work	5 (6)	6 (8)	11 (7)	
	3 - Capable of limited self-care	0 (0)	0 (0)	0 (0)	
	4 - Completely disabled	0 (0)	0 (0)	0 (0)	
	Unknown/missing	16	16	32	
Comorbidities	0	37 (39)	33 (36)	70 (38)	0.186
	1	44 (47)	53 (58)	97 (52)	
	2	10 (11)	3 (3)	13 (7)	
	3+	3 (3)	3 (3)	6 (3)	
Prior adjuvant chemo	No	10 (43)	9 (47)	19 (45)	1.000
	Yes	13 (57)	10 (53)	23 (55)	
	Not applicable (because diagnosed at stage IV)/ unknown/missing	71	73	144	

Table 6. Baseline Information Preferences, Decision-making Preferences, Prior Communications and Expectations of Cure From Palliative Chemotherapy

Variable		Control (%)	Intervention (%)	Total (%)	
		94	92	186	
Preferences for information about chemotherapy risks and benefits					
Side effects	No information	1 (1)	0 (0)	1 (1)	0.52
	A little bit of information	2 (2)	1 (1)	3 (2)	
	A moderate amount of information	13 (14)	20 (22)	33 (18)	
	A lot of information	17 (18)	14 (15)	31 (17)	
	As much information as possible	61 (65)	57 (62)	118 (63)	
Likelihood of cancer control	No information	1 (1)	1 (1)	2 (1)	0.48
	A little bit of information	2 (2)	1 (1)	3 (2)	
	A moderate amount of information	10 (11)	14 (15)	24 (13)	
	A lot of information	13 (14)	20 (22)	33 (18)	
	As much information as possible	67 (72)	56 (61)	123 (66)	
Impact on QOL	No information	1 (1)	0 (0)	1 (1)	0.40
	A little bit of information	1 (1)	4 (4)	5 (3)	
	A moderate amount of information	14 (15)	18 (20)	32 (17)	
	A lot of information	15 (16)	16 (17)	31 (17)	
	As much information as possible	63 (67)	54 (59)	117 (63)	
Likelihood of cure	No information	2 (2)	2 (2)	4 (2)	0.20
	A little bit of information	4 (4)	4 (4)	8 (4)	
	A moderate amount of information	8 (9)	17 (19)	25 (14)	
	A lot of information	12 (13)	16 (18)	28 (15)	
	As much information as possible	68 (72)	52 (57)	120 (65)	0.12
Impact on length of life	No information	3 (3)	3 (3)	6 (3)	
	A little bit of information	2 (2)	4 (4)	6 (3)	
	A moderate amount of information	7 (8)	16 (18)	23 (13)	
	A lot of information	13 (14)	17 (19)	30 (16)	
	As much information as possible	68 (73)	50 (56)	118 (64)	

Preferred role in decision making[a]	Patient controlled	18 (19)	14 (15)	32 (17)	0.48
	Shared	65 (70)	65 (71)	130 (71)	
	Physician controlled	10 (11)	12 (13)	22 (12)	
Physician has previously discussed curability	Yes	78 (84)	82 (89)	160 (86)	0.54
Expectations of cure[b]	Very likely	14 (15)	11 (12)	25 (14)	0.19
	Somewhat likely	12 (13)	15 (16)	27 (15)	
	A little likely	9 (10)	16 (17)	25 (14)	
	Not at all likely	42 (45)	43 (47)	85 (46)	
	I don't know	16 (17)	7 (8)	23 (12)	

[a] Assessed by Control Preferences Scale.

[b] Responses to the question, "How likely do you think that chemotherapy is to cure your cancer?"

Table 7. Use and Satisfaction With Informed Consent Materials, Standard or Investigational[a]

Outcome		Control (%)	Intervention (%)	*p*
		94	**92**	
Read standard educational materials	Yes	47 (84)	-	
	No	9 (16)	-	
	Missing	38	-	
Read IC booklet	Yes		59 (80)	
	No		15 (20)	
	Missing		18	
Read life expectancy chapter	Yes		36/59 (61)	
Watched IC video	Yes		30 (41)	
	No		43 (59)	
	Missing		19	
Watched life expectancy chapter	Yes		21/30 (70)	
Satisfaction with standard or interventional IC materials	Mean (SD)	7.9 (1.7)	7.8 (1.9)	0.70
	Median (Q1, Q3)	8 (7, 9)	8 (7, 9)	
	Freq. of missing	39	30	

[a] Use and satisfaction were assessed at the postdecision survey.

Impact of intervention on understanding chemotherapy risks and benefits: The proportion of patients who accurately reported that chemotherapy was "not at all likely" to cure their cancer did not differ between the usual care arm and the intervention arm at all 3 time points (baseline, 2 weeks, 3 months; see Table 8). At 3 months, the time of our primary outcome assessment, a similar proportion of patients in the 2 groups accurately responded that chemotherapy was "not at all likely" to cure their cancer (55.5%, 95% CI, 45.1-66.0 versus 52.6%, 95% CI, 40.3-65.0; $p = 0.72$). Patients in the intervention arm were slightly less optimistic about the likelihood of response to chemotherapy, although differences between study arms were not significant ($p = 0.15$). Although a substantial proportion of patients reported inaccurate expectations of cure from palliative chemotherapy, most participants in both groups accurately responded that "according to their doctor," the goal of treatment was to control cancer growth, palliate symptoms, and/or prolong life, but not to cure (85.1%, 95% CI, 76.6-93.6

versus 86.5%, 95% CI, 77.5-95.6; $p = 0.83$). This discrepancy suggests that patients' expectations for cure may represent hope and optimism, rather than knowledge gaps or misunderstandings.

Patients' understanding of chemotherapy risks was generally poor; however, patients in the intervention arm were slightly more likely to have accurate understanding of the risks associated with their chemotherapy regimen, as compared with patients in the control arm (56.0%, 95% CI, 44.3-67.7 versus 40.2%, 95% CI, 29.5%-50.9%; $p = 0.05$).

Because of the low intervention uptake, we explored differences in understanding between study arms by patients' use of the intervention at 2 weeks: reviewed IC booklet or video (N = 62); reviewed IC booklet and video (N = 27); and reviewed optional prognostic information in either the video or booklet (N = 39). As Table 9 shows, expectations of cure and understanding of treatment goals did not differ between study arms across any subgroup. As compared with the control group, patients who chose to review optional prognostic information in intervention arm were less optimistic about the likelihood of response to chemotherapy, although this did not meet statistical significance ($p = 0.06$). As compared with the control arm, patients who reviewed both the video and the booklet were significantly more likely to have an accurate understanding of the risks associated with their chemotherapy regimen (40% versus 70%; $p = 0.007$).

Table 8. Impact of IC Intervention on Understanding the Risks and Benefits of Palliative Chemotherapy

Outcome	Survey	Response	Complete Case Analysis		
Patient Expectations of Chemotherapy Benefits			**Control n (%)**	**Intervention n (%)**	***p***
Expectations of cure from chemo[a]	3 mos	Very likely	2 (3)	3 (4)	0.95
		Somewhat likely	9 (13)	9 (13)	
		A little likely	12 (17)	14 (20)	
		Not at all likely	39 (57)	39 (56)	
		Don't know	7 (10)	5 (7)	
Understanding treatment goals[b]	2 wk	Cure	8 (9)	9 (10)	0.83
		Shrink cancer	65 (69)	65 (71)	
		Help symptoms	26 (28)	31 (34)	
		Prolong life	50 (53)	48 (52)	
		Other	2 (2)	0 (0)	
Expectations of cancer control[c]	2 wk	Very likely	31 (41)	21 (29)	0.15
		Somewhat likely	28 (37)	38 (52)	
		A little likely	12 (16)	6 (8)	
		Not at all likely	0 (0)	1 (1)	
		Don't know	5 (7)	7 (10)	

Rates of <u>Accurate</u> Expectations About Chemotherapy Benefits and Risks

			Complete Case Analysis			Analysis Using Multiple Imputation		
			Control	Intervention		Control	Intervention	
			n (%)	n (%)	*p*	% (95% CI)	% (95% CI)	*p*
Expectations of cure[a]	3 mos		39 (57)	39 (56)	1.000	55.5 (45.1-66.0)	52.6 (40.3-65.0)	0.72
	2 wk		42 (55)	35 (49)	0.575	52.9 (41.6-64.1)	49.1 (38.0-60.2)	0.64
Treatment goals[b]	2 wk		68 (87)	65 (88)	1.000	85.1 (76.6-93.6)	86.5 (77.5-95.6)	0.83
Chemotherapy risks	2 wk		31 (40)	41 (55)	0.077	40.2 (29.5-50.9)	56.0 (44.3-67.7)	0.05

[a] "How likely do you think that chemotherapy is to cure your cancer?" Accurate defined as "not at all likely"; we considered all other responses inaccurate.

[b] "According to your doctor, what is the goal of chemotherapy?" with response options of (1) cure, (2) shrink cancer, (3) improve symptoms, (4) prolong life, and (5) other. We considered patient responses of options 2, 3, or 4 accurate. We considered all others inaccurate. *P* value reflects comparison of accurate understanding of treatment goals across study groups.

[c] "How likely do you think that chemotherapy is to control the growth of your cancer?" We did not dichotomize answers into accurate/inaccurate, given the subjectivity of the item wording.

Table 9. Exploratory Analysis of Understanding Chemotherapy Risks and Benefits by Use of Intervention

			Intention to Treat			By Intervention Use					
Outcome	**Survey**	**Result**	**Control (%)**	**Intervention (%)**		**Reviewed IC Booklet or Video**		**Reviewed IC Booklet and Video**		**Reviewed Optional Prognostic Info**	
			94	**92**	***p***	**62**	***p***	**27**	***p***	**39**	***p***
Expectations of cure[a]	3 mo	Accurate	39 (57)	39 (56)	1.000	28 (55)	1.00	15 (65)	0.625	19 (58)	1.00
Understanding of treatment goal[b]	2 wk	Accurate	68 (87)	65 (88)	1.000	53 (87)	1.000	12 (92)	0.948	34 (89)	0.96
Expectations of cancer control[c]	2 wk	Very likely	31 (41)	21 (29)	0.152	16 (26)	0.157	6 (22)	0.206	8 (21)	0.06
		Somewhat likely	28 (37)	38 (52)		33 (54)		16 (59)		24 (62)	
		A little likely	12 (16)	6 (8)		6 (10)		3 (11)		4 (10)	
		Not at all likely	0 (0)	1 (1)		1 (2)		0 (0)		1 (3)	
		Don't know	5 (7)	7 (10)		5 (8)		2 (7)		2 (5)	
Understanding of chemotherapy risks	2 wk	Accurate	31 (40)	41 (55)	0.077	34 (56)	0.088	19 (73)	0.007	23 (61)	0.06

[a]Responses to "How likely do you think that chemotherapy is to cure your cancer?" Accurate response is defined as "not at all likely"; we considered all other responses inaccurate.

[b] "According to your doctor, what is the goal of chemotherapy?" with response options of (1) cure, (2) shrink cancer, (3) improve symptoms, (4) prolong life, and (5) other. We considered patient responses of options 2, 3, or 4 accurate. We considered all others inaccurate.

[c] Response to "How likely do you think that chemotherapy is to control the growth of your cancer?"

Impact of IC intervention on decision-making process, communication satisfaction, and distress: As reported in Table 10, decisional conflict did not differ between the control and intervention arms (5.2, 95% CI, 1.9-8.5 versus 5.5, 95% CI, 3.2-7.8; $p = 0.87$). Similarly, decisional regret, communication satisfaction, and achievement of decisional control preferences did not differ by study arms. The intervention did not appear to harm patients' emotional well-being, as measured by the emotional well-being subscale from the FACT-G instrument.

Impact of intervention on prognostic discussions, prognostic understanding, and advance care planning: As reported in Table 11, 51% of patients in the control arm and 64% of patients in the intervention arm reported discussing life expectancy with their care team ($p = 0.17$). Patients in both arms were optimistic about their own life expectancy, with 45% of patients in the control arm and 49% of participants in the intervention arm anticipating that they would live for more than 5 years. Patients' understanding of the typical prognosis for their cancer type were more realistic than their own personal expectations. The vast majority of patients had completed a health care proxy and had discussed their care wishes with their health care proxy; however, only about 20% of patients had discussed their care wishes with their doctor.

Table 10. Impact of IC Intervention on Decision Making, Communication Satisfaction, and Distress

		Complete Case Analysis			Analysis Using Multiple Imputation		
Outcome		**Control**	**Intervention**	***p***	**Control 95% CI**	**Intervention 95% CI**	***p***
Decision conflict[a]	Mean (SD)	5.2 (1.7)	5.5 (1.2)	0.309	5.2 (1.9-8.5)	5.5 (3.2-7.8)	0.87
Decisional regret[b]	Mean (SD)	79.6 (19.3)	84.7 (14.4)	0.179	77.3 (37.1-100)	84.7 (55.9-100)	0.77
Satisfaction with communications during decision making[c]	Mean (SD)	3.6 (0.5)	3.7 (0.4)	0.514	7.8 (4.1-10)	7.6 (3.7-10)	0.94
Achievement of preferred role in decision making[d]	n (%)	30 (38)	35 (47)	0.314	38 (27.7-48.3)	48.4 (36.2-60.5)	0.21
Emotional distress[e]	Mean (SD)	16.5 (4.6)	17.3 (4.5)	0.314	16.3 (6.9-25.7)	17.3 (8.2-26.3)	0.89

[a] We assessed decisional conflict at the 2-week survey by a modified version of the SURE scale. Scores range from 0 to 6, with 6 indicating absence of conflict and 0 indicating maximal conflict.

[b] We assessed decisional regret at the 3-month survey using Brehaut's 5-item Decisional Regret Scale, with scores ranging from 0 to 100, where 100 indicates maximal regret and 0 indicates no regret.

[c] At 2 weeks, patients responded to 5 items from Mazor's PACE scale relating to the treatment decision-making process (eg, "I got clear, understandable information about the treatments we were considering."). Scores range from 1 to 4, with 4 being the most satisfied.

[d] Assessed using Control Preferences Scale. At baseline patients indicate whether they prefer patient-controlled, shared, or physician-controlled decision making. At 2 weeks patients indicate which of these roles they played in their treatment decision. Responses are compared to determine whether their preferred role was achieved

[e] Assessed via the emotional well-being subscale of the FACT-G. Scores range from 0 to 24, with higher scores being more desirable.

Table 11. Prognostic Communications and Understanding as Reported by Patients at 3 Months

Outcome		Control (%)	Intervention (%)	*p*
		94	**92**	
Discussed prognosis with care team by 3 months	Yes	36 (51)	45 (64)	0.17
Person initiating life expectancy discussion	Patient	19 (53)	19 (43)	0.65
	Caregiver/friend	3 (8)	2 (5)	
	Doctor	12 (33)	19 (43)	
	Don't recall	2 (6)	4 (9)	
Understanding of typical prognosis of patient's cancer type	>10 yrs	3 (5)	3 (5)	0.73
	5-10 yrs	6 (11)	6 (10)	
	3-5 yrs	12 (21)	14 (24)	
	2-3 yrs	17 (30)	10 (17)	
	1-2 yrs	10 (18)	14 (24)	
	<1 yr	9 (16)	11 (19)	
	Unknown/Missing	37	34	
Expectations for patient's own prognosis	>10 yrs	18 (29)	17 (29)	0.86
	5-10 yrs	10 (16)	12 (20)	
	3-5 yrs	8 (13)	5 (8)	
	2-3 yrs	8 (13)	9 (15)	
	1-2 yrs	13 (21)	9 (15)	
	<1 yr	5 (8)	7 (12)	
	Unknown/missing	32	33	
Completion of health care proxy by 3 months	Yes	58 (83)	63 (88)	0.59
Discussions with health care proxy about care wishes	Yes	48 (83)	54 (86)	0.84
Discussions with doctor about care wishes	Yes	10 (14)	16 (23)	0.30

G. Discussion

Aim 1 discussion

The recent ASCO position statement, "Toward individualized care for patients with advanced cancer," asserts that "realistic conversations about prognosis, the potential benefits, and limitations of disease-directed therapy . . . occur late in the course of illness or not at all" and that these omissions impede quality, patient-centered care.[1] Despite critical need, few interventions exist to support these communications. Using stakeholder-driven methods, we developed a dual-format video/print-based intervention targeting the chemotherapy IC process to offer patients upfront, realistic information about prognosis and palliative chemotherapy outcomes in a patient-centered manner. Advocates and oncologists rated the resulting intervention highly, which stands in sharp contrast with their dissatisfaction with existing chemotherapy educational materials.

Our intervention has several unique strengths. First, it leverages the IC process to promote accurate expectations from the *outset* of treatment; this may help patients better plan and prepare for the future. Second, it uses dual mediums so that patients can access information in a preferred format. Third, it presents difficult prognostic information from multiple credible experts, thereby supporting oncologists in one of their most challenging communication tasks.[4,38] The intervention is unambiguous about the noncurative potential of palliative chemotherapy; however, life expectancy statistics are presented in a way that gives patients control over whether/when to access this information. This optional approach was strongly preferred by advocates and oncologists, and it aligns with prevailing expert recommendations that patient preferences should be respected in disclosing prognostic information.[26,27,39,40] Finally, by incorporating patient voices, our intervention challenges the current paradigm of patient education. Clinician perspectives are unavoidably shaped by their training, professional roles, and culture.[29] As a result, oncologists often struggle to communicate effectively,[6,28,41] they underestimate the impact of treatment on QOL,[42] and they overlook patient-centered concerns.[43] Advocates were unanimous about the value of incorporating patient voices.

Our experience illustrates many advantages of partnering with patient stakeholders in

the development of patient education interventions. Patients' worldview is shaped by personal experiences, which can help investigators overcome inherent biases and better meet the needs of end users.[29,44] Patient engagement unquestionably made our intervention more relevant to the concerns and priorities of patients. Our use of flexible and varied engagement methods allowed us to consider the perspectives of diverse participants in the IC process, and it facilitated efficient stakeholder-driven revisions throughout the project.

Patient engagement is common in the development of educational or decision support interventions[45-50] and upheld in best practices.[45,51] Often, however, patients are relegated to narrow project roles that lack true influence over the process.[52,53] Patients commonly participate in advisory panels,[45,46,51] focus groups (eg, to set content priorities),[47,49] or participate in alpha and beta testing.[50,51] Though useful, these processes are not necessarily sufficient to promote meaningful stakeholder research exchanges and true impact. We sought genuine partnerships by integrating stakeholders into our core research team, providing longitudinal guidance, drafting portions of the intervention, and helping our team interpret and act upon survey results. Perhaps most importantly, we allowed patients to directly share their experiences and perspectives within the IC intervention.

Despite the clear benefits, patient engagement is challenging and time consuming—and it requires significant investment.[53,54] Similar to others,[54] our stakeholders' enthusiasm often led to ideas beyond our project scope. Stakeholders also had differences of opinion that required balancing. Perhaps unique to our project, many of our stakeholders had metastatic cancer. This made in-person meetings difficult and required extra flexibility to meet patients individually or to exchange ideas via phone or email.

Aims 2 and 3 discussion

We conducted an RCT in which patients making a decision about palliative chemotherapy for advanced CRC and pancreatic cancers were randomized to the usual process of chemotherapy IC/education versus the usual process supplemented by our multimedia chemotherapy IC tools, developed in aim 1. Within our population of highly educated patients cared for at large academic cancer centers, the intervention did not increase the proportion of

patients who reported an accurate understanding that chemotherapy was very unlikely to cure their cancer, nor did it reduce decisional conflict as compared with standard care. The intervention modestly improved patients' understanding of chemotherapy side effects, which was most significant among patients who reviewed both video and booklet. Nevertheless, this was a negative study that had no impact on our primary outcome or on the vast majority of our secondary outcomes.

Although we were underpowered to detect differences in our primary outcome, it is unlikely that lack of power explains our null result. It seems likely that the intervention did not affect patients' expectations of cure because these expectations may have been primarily driven by hope or optimism, rather than by cognitive misunderstanding—which was the primary target of our intervention. Of note, when patients were asked, "According to your doctor, what is the goal of the chemotherapy?" only 12% of participants responded "cure." It may be that our primary outcome assessment ("What is your understanding of how likely chemotherapy is to cure your cancer?") taps more into patients' personal expectations/hope, rather than their cognitive understanding.

Another possible explanation relates to our study population, which was highly educated and motivated to receive care at tertiary referral centers. This may explain why nearly half of participants understood that palliative chemotherapy was unlikely to cure their cancer, whereas only 19% of CRC patients and 31% of lung cancer patients in the national sample of more than 2500 patients in CanCORS reported accurate expectations.[4] Our knowledge-targeted intervention might have been more impactful in community settings.

Finally, and perhaps most importantly, low use of the intervention, particularly the video, likely weakened its effect. Although most patients in the study indicated desire for maximal information about treatment risks and benefits, only 80% of participants read the booklet and only 41% watched the video—despite ready access to the intervention. These findings highlight the difference between stated and revealed preferences—and raise the importance of timing with respect to delivering information to a very vulnerable and stressed patient population. Our study staff noted that by the time of study enrollment, most patients were overwhelmed from their oncology consultation, and many of them had already been

approached and consented for several other therapeutic or tissue-banking research protocols. This may explain why very few patients opted to review the IC video or booklet in clinic and why many did not review the materials at home. We did not assess for home internet access, but this may have also contributed. Future interventions should pay close attention to the timing of intervention delivery, setting, and sensitivity to patients' preferred format for receiving information. Our data suggest that print media may be more accessible to patients, although our subset analyses (Table 9) indicate that it may also be less effective than video for enhancing knowledge. This is consistent with data from recent video decision aids in the advanced illness setting[22,57] demonstrating improvements in understanding, preferences, and completion of advance directives.

Satisfaction ratings with chemotherapy educational materials were high in both study arms, likely reflecting a general bias of patients to approve of their care team and the care provided them. This ceiling effect limits our ability to discriminate differences in satisfaction between study arms. Decisional conflict between the 2 study arms also did not differ. This may similarly relate to limitations of the intervention in its ability to impact patients' knowledge of chemotherapy risks and benefits.

Our findings highlight the challenge of affecting advanced cancer patients' illness understanding and decision making at one of the most vulnerable moments in their care: a new diagnosis and/or change in treatment. Patients are typically emotionally and cognitively overloaded at the time of diagnosis and treatment decision making, which may lessen their receptivity to educational interventions. Moreover, our findings suggest that patients' expectations of cure/treatment benefit may reflect emotional processes such as hope or acceptance to a larger extent than cognitive processes. Indeed, very few randomized intervention studies in the advanced cancer setting have demonstrated benefits to prognostic understanding or decision-making quality. Of the 3 published randomized studies of palliative chemotherapy decision aids, only 1 of these demonstrated delayed (but not immediate) impact on patient knowledge,[21] and none of them impacted any other outcomes relevant to decision-making quality or satisfaction.[60,61] Beyond the uncertain benefit of decision aids, they are an impractical solution in the advanced cancer setting because of the complex clinical issues

that factor into treatment recommendations and the rapidly evolving menu of chemotherapy options. Other investigators have sought to impact illness and treatment understanding by coaching cancer patients with question prompt lists to be more engaged in clinical conversations, although question prompt lists have not been examined the time of chemotherapy decision making. Studies of question prompt lists have shown greater question-asking by patients (including prognostic questions), but none have demonstrated concrete knowledge gains.[24,62] Other researchers have sought to impact physician communication skills through communication training. These studies have shown impact on physician behaviors (eg, acknowledging emotion) and inconsistent and sometimes negative effects on patient satisfaction/trust, with none demonstrating impact on patients' illness/prognostic understanding, informed decision making, or end-of-life care quality.[62,63,64] These findings highlight the challenge of influencing prognostic understanding and decision-making quality in the advanced cancer setting and suggest the need for a multipronged approach.

Implementation

We encountered several barriers to implementing the intervention during this study, most of which were related to barriers inherent to testing the intervention in the context of a research protocol. Patients were often too overwhelmed to enroll in a research study immediately after an oncology consultation, and if they did enroll, they were often cognitively overloaded. Moreover, the procedures inherent to a patient-level randomized study (eg, confirmation of eligibility, research consent, baseline assessment, randomization) interfered with optimal delivery of the IC materials and patient–provider interactions related to their content. A pragmatic or cluster randomized study of the intervention would have been more feasible and might have yielded different results. In aim 1, every oncologist surveyed from 9 practices reported that they would regularly distribute our IC tools to patients if they had access to them. In future dissemination and implementation work, we would likely partner with oncologists to help them implement the educational materials into their clinical practice in a way that synergized with their usual workflow. This could include keeping the materials within examination rooms or on a readily accessible web portal, or distributing the materials during routine chemotherapy teaching sessions that are often led by oncology nurses.

Generalizability

Our study was primarily conducted at large academic cancer centers and predominantly accrued white and highly educated patients. Although we included centers across the United States, our findings may not be generalizable to community practice settings or to settings with large proportions of underrepresented minorities. It is likely that our intervention may have a stronger effect in these settings, where patients may not have as ready access to quality information about their illness and the risks/benefits of their treatment options. We are currently in the process of adapting and testing the intervention among Latino patients, who face significant barriers to having their information needs met regarding advanced cancer. Future studies could examine whether our findings are generalizable to community settings, to other vulnerable populations (eg, low literacy), or to other cancer diagnoses.

Study limitations

Although our study has several strengths—including stakeholder involvement to create a patient-centered intervention (aim 1) and its use of randomization to minimize bias (aims 2 and 3)—there are a number of limitations. As discussed above, use of the intervention was low, which may have limited its effect. Second, assessments of satisfaction with standard versus our interventional chemotherapy IC materials may have been subject to approval bias, resulting in a ceiling effect that limited our ability to detect a difference between study arms. Finally, our study population was very educated and motivated to receive care at tertiary referral centers. The intervention may be more salient and have more impact for less educated populations or those from community practice settings.

Future research

We have current National Cancer Institute funding to adapt and test this intervention among Latino cancer patients, a population particularly vulnerable to misunderstandings and uninformed treatment decisions. Because of the disappointing uptake of the intervention and lack of impact, we are also considering going back to pilot various ways to implement the intervention more effectively. Smaller-scale pilots may refine the intervention to make it more usable (eg, shortening, integrating written and video content), and we may subsequently pilot the intervention in facilitated environments such as nurse-led teaching sessions to determine

feasibility/acceptability. The intervention could also be combined with patient coaching and/or question prompt lists to better engage patients in the process and promote better communication.

Physicians, nurse practitioners, oncology pharmacists, patients, and caregivers have uniformly regarded the materials developed as part of this project as unique, valuable, and superior to others that exist.. There was a recommendation to distribute the materials. Consideration of dissemination and implementation plans through ASCO and GI patient advocacy organizations was advised. The fact that the trial was negative was not viewed as evidence that the intervention was valueless; rather, the clear consensus was that the intervention on face value is far preferable to existing chemotherapy educational tools. Beyond challenges of conducting the trial, stakeholders pointed out that the constructs at issue here—that is, prognostic understanding—are hard to grasp and elicit in short surveys.

H. Conclusions

Aim 1 Conclusions

Previous research has shown that the current chemotherapy IC process is flawed and that existing tools are inadequate to meet patients' needs.[4,6,9,55] By partnering with stakeholders we successfully created a patient-centered chemotherapy IC tool acceptable to patient advocates and oncologists.

Aims 2 and 3 Conclusions

Our study did not demonstrate that our patient-centered chemotherapy IC videos and booklets corrected patients' expectations of cure from palliative chemotherapy, nor did it impact other measures of informed decision making. The intervention modestly improved patients' understanding of chemotherapy risks. Secondary analyses suggest that the video component of the intervention may have the most impact on patient knowledge, although low rates of use limited our ability to fully examine this aspect. Given the paucity of existing resources supporting chemotherapy education and IC, the intervention still could still be a valuable tool to make available for patients.

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J. Publications

1. Enzinger AC, Wind JK, Frank E, et al. A stakeholder-driven approach to improve the informed consent process for palliative chemotherapy. Patient Educ Couns. 2017;100(8):1527-1536. doi: 10.1016/j.pec.2017.03.024.

2. Andrea Enzinger, Jen Wind, Liz Frank, Nadine McCleary, Christine Cronin, Hanna Sanoff, Katherine Van Loon, Khalid Matin, Andrea Bullock, Neal Meropol, Hajime Uno, Deborah Schrag. Understanding the non-curative potential of palliative chemotherapy: do patients hear what they want to hear? 2017 35:15_suppl, 6575-6575.

3. Enzinger, AC, et al, unpublished data, June 2017. RCT Comparing Usual Care Palliative Chemotherapy Education Materials to Newly Developed Multi-Media Materials for Use in Advance GI Cancer.

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