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The impact of an educational DVD on cancer patients considering participation in a phase I clinical trial

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Abstract *Goals of work:* The quality of informed consent in phase I trials is controversial, partially due to gaps in patient understanding. We assessed an educational DVD's impact on knowledge and satisfaction in cancer patients newly referred to a phase I clinic. *Materials and methods:* Forty-nine patients were randomly assigned to view an educational DVD (n=22) which explained phase I trials or a placebo DVD (n=27). Patients completed a questionnaire assessing knowledge of phase I studies and satisfaction with the DVD. The blinded interviewing physician (n=8) rated the patient's understanding of phase I trials. *Main results:* The mean patient age was 56; 61% were male. Patients who viewed the educational DVD were less likely to believe that phase I trials determine drug efficacy (p=0.019), more likely to know that phase I drugs have not been thoroughly studied in humans (p=0.003), and less likely to believe that these agents have proven activity against human cancers (p=0.008). More patients who viewed the educational DVD agreed/strongly agreed that the DVD provided useful information (p<0.001), were confident in their knowledge of phase I trials (p=0.031), felt aided in their decision to enter a phase I study (p=0.011), and would have more questions for their physicians because of the DVD (p=0.017). No statistically significant difference in physician perception of patient understanding or phase I trial accrual was observed between the educational and placebo DVD groups. *Conclusions:* An educational DVD increased patient knowledge and satisfaction regarding participation in phase I clinical trials.

Keywords Education · Informed consent · Phase I clinical trials

Introduction

Phase I trials, the first level of clinical investigation for a new drug or drug combination, provide necessary foundations for the development of safe and more effective anticancer therapies. The primary endpoint of a phase I trial is to determine a new drug's recommended dose for phase II evaluations and to establish its toxicity profile [7]. Earlier series reported in the literature have demonstrated that less than 5% of phase I study participants experience a clinical response to novel therapies [6, 17, 25, 28]. In a recent review of over 10,000 patients participating in phase I trials sponsored by the National Cancer Institute, the overall response rate was 10.6%, with variations among different types of phase I trials. "Classic" phase I trials of single investigational chemotherapeutic agents had an average response rate of only 4.4% [13]. As such, patients recruited into phase I trials typically have malignancies, which have progressed on standard regimens, or for which there is no standard therapy of known benefit [22].

Ethical issues surrounding phase I trials are complex. In an editorial commenting upon one of the first studies of phase I patient comprehension by Daugherty et al. [5], Emanuel expressed concern over phase I participants' lack of personal benefit and significant risk of toxicity and questioned the quality of a patient's informed consent in this context [8]. Subsequently, multiple investigations assessing the altruistic disposition and vulnerability of phase I patients have been undertaken. Whereas the vulnerability of this population secondary to their advanced malignant disease shortened life expectancy and lack of established treatment options has been debated, it has become apparent that altruism plays a less significant role than considerations of self-interest in a patient's decision to participate in phase I clinical trials [1, 3, 4, 14, 20, 22, 26, 33]. The dichotomy between the high expectations of patients participating in phase I research and the low likelihood of objective benefit as a result of study participation has prompted the need for measures to bridge this gap.

Factors predisposing to inappropriate patient expectations of therapeutic benefit in phase I trials have been identified, namely, hope, relational dynamics, and the quality of information conveyed. Hope has been isolated as a potential survival mechanism for oncology patients, as it allows patients to wish for, but not to expect, health gains while participating in early phase trials [2, 14, 15, 23]. The relational dynamics under which the details of phase I trials are communicated may also be a downfall in the consent process. A deficiency in the voluntariness of phase I trial consent has been revealed in several studies wherein a patient's decision to participate has largely been governed by physician advice [5, 23]. This controversy is compounded when phase I physicians serve as investigators for the studies which they are recruiting [16]. Lastly, the quality of information conveyed to patients about phase I trials may impact perceptions of therapeutic likelihood. Early studies reported that research oncologists significantly overestimated response rates of novel therapeutic agents, which may have contributed to poor patient comprehension of study risks [5, 24]. Improved patient communication has been proposed as a method of overcoming these barriers [20, 21].

Interventional efforts to improve patient comprehension of realistic outcomes in phase I cancer trials have been investigated. Supplemental literature has heightened patient satisfaction with the informed consent process, and in combination with oral communication, supports decision making [15]. In a randomized trial, Hlubocky et al. [12] compared the effects of educational CD-ROM containing information on trial enrollment issues including prognosis against a printed pamphlet about clinical trials lacking prognostic information in advanced cancer patients enrolling in early phase trials. A modest improvement in patient understanding of prognosis was observed with CD-ROM viewing.

The role of multimedia tools as supplements to the informed consent process in clinical studies has been examined in non-oncology phase II/III trial settings; the impact of these tools has been largely non-significant, although video-viewing has demonstrated heightened information retention [10, 11, 27, 31, 32]. In this study, we assess the impact of an educational DVD reviewing phase I clinical trials in oncology patients who are potentially eligible for participation in such trials.

Materials and methods

Study subjects

All patients newly referred to the weekly phase I clinic at Princess Margaret Hospital in Toronto, Canada from August 2005 until January 2006 were eligible for study enrollment in a prospective, consecutive manner. Inclusion criteria consisted of: age of 18 years or older; possession of a general understanding of the English language for reading, writing and listening; and initial eligibility assessment for a phase I clinical trial due to metastatic disease for which standard treatment approaches have either failed, have low expectations, or do not exist. Potential participants were approached by the clinic nurse (MM) for their interest in taking part in the study. Written informed consent was obtained by study coordinators (ELS and CN) before patient enrollment. Each patient's interviewing physician also served as a study subject, and all participating medical oncologists provided informed consent before study participation.

Enrolled patients were randomized in a blinded fashion to view either an educational DVD, which discussed pertinent components of phase I clinical trials, or a placebo DVD. DVD viewing occurred in a private room on a laptop computer with earphones provided. Upon completion of DVD viewing, patients completed a standardized self-administered questionnaire assessing demographics, patient knowledge of phase I trials, and patient satisfaction (Appendix I). Patients then proceeded to their scheduled physician consultation and assessment. Consenting physicians, who were blinded to the intervention, completed a standardized questionnaire directly after each consultation to assess their perception of the patient's understanding of phase I clinical trials (Appendix II). Clinic physicians, nurses, and patients were blinded to the DVD intervention; only the study coordinators, who had no direct role in patient care, were not blinded. Physicians participating in the study were instructed not to ask patients direct

questions about the DVD to maintain blinding. Patient charts were subsequently reviewed to determine whether consent for phase I trial participation was obtained, as well as the reasons for non-entry into a phase I trial.

DVDs and questionnaires

The educational DVD provided general information on phase I clinical trials. Video was filmed in a documentary style, with inclusion of graphics and/or text to augment dialogue and enacted scenes. DVD domains included types of clinical trials, goals of phase I trials, early phase drug development, frequency of diagnostic testing, requirement for research-related tests such as pharmacokinetic sampling, eligible patient populations, toxicity and side effects, likelihood of positive clinical outcome, and appropriate patient expectations. The placebo DVD did not contain information relevant to phase I clinical trials, but described research accomplishments of scientists and investigators at our health institute. Both DVDs were 8 min in duration. The educational DVD was developed by study investigators based upon knowledge deficits described in the literature in the phase I population; script content was reviewed and modified by medical oncologists involved in drug development at the Princess Margaret Hospital before DVD filming.

The questionnaires were designed to concisely assess patient demographics, knowledge of phase I clinical trials, and satisfaction with the DVD (Appendices I and II). Knowledge questions were in the form of multiple choice and True or False answers. Satisfaction questions employed a 5-point Likert scale for evaluating patient opinion for various domains ranging from 1 to 5 correlating with "strongly disagree" to "strongly agree". Questionnaires took approximately 5 min to complete and were initiated directly after DVD viewing. Questionnaires were reviewed and modified by medical oncologists, as well as patients currently enrolled in phase I trials to assess for content and clarity before to inclusion in the study protocol.

All materials used for this study, including DVDs, questionnaires, consent forms, and protocol, were approved by the University Health Network Research Ethics Board before project initiation.

Statistical analysis

The study was designed to accrue about 50 participants, based on the number of new patients expected to be seen between August 2005 and January 2006 in our facility's Phase I clinic, and afforded a power of greater than 80% to detect a difference of at least 40% between the two arms, which was felt to be clinically relevant. Patients were randomized to view either the educational or placebo DVD in a 1:1 fashion based upon a computer-generated randomization scheme. Descriptive statistics, such as mean, standard deviation, frequency, and proportion, were used to summarize patient characteristics. An exact χ^2 test was used to compare the patients who viewed the educational DVD with the patients who viewed the placebo DVD in terms of their responses to the content and satisfaction questions. For the purpose of data analysis, patients who responded "don't know" to the two content questions related to prior thorough human testing and proven anticancer activity of phase I drugs in humans were counted as providing incorrect answers to these questions. Physician responses to questions addressing their perceptions of patient understanding were also compared by study arms. A p value of 0.05 or less was considered statistically significant, and all tests were two-sided. Exact p values were given for each test, and no adjustments for multiple comparisons were performed. SAS for Windows (version 9, Cary, NC) was used for all statistical analyses.

Results

Patient characteristics

Seventy new patients presented to phase I clinic within the study period, and 49 patients (70%) were enrolled into this study (30 men and 19 women). Twenty-two patients were randomized to the educational DVD arm, and 27 patients were randomized to the placebo DVD arm. A summary of patient characteristics is listed in Table 1. The demographics of patients randomized into the educational DVD and the placebo DVD groups were similar. The characteristics of the patients who refused entry into our DVD study are represented in Table 2. Eight physicians who regularly attended the phase I clinics and were involved in phase I trials participated in this study (Table 3).

DVD impact on patient knowledge

Included within the post-DVD questionnaire, patients were asked to complete content questions assessing their knowledge of phase I clinical trials (Table 4). Most patients (86%) had previously heard of clinical trials, but only 49% had heard of phase I studies before visiting the phase I clinic. Patients who viewed the educational DVD were less likely to believe that the goal of phase I clinical trials was to decide if a new drug is more effective than an old drug (p=0.019), more likely to know that the study drug had been tested in animals but not thoroughly in humans

Table 1 Characteristics of patients who participated in the DVD study (n=49)

	Total		Educational DVD		Placebo DVD	
	No. pts	Percentage	No. pts	Percentage	No. pts	Percentage
Total	49	100	22	100	27	100
Age (years) Mean±SD	56.3±12.1		57.7±11.8		55.2±12.4	
Sex						
Male	30	61	15	68	15	56
Female	19	39	7	32	12	44
Education						
None	0	0	0	0	0	0
Grade school	1	2	1	5	0	0
High school	18	37	8	36	10	37
College/university	29	59	12	55	17	63
Missing	1	2	1	5	0	0
Malignancy						
Adenoid cystic	1	2	1	5	–	–
Bladder	1	2	1	5	–	–
Breast	1	2	–	–	1	4
Cervical	1	2	–	–	1	4
Cholangiocarcinoma	4	8	–	–	4	15
Colorectal	16	33	8	36	8	30
Esophageal	2	4	1	5	1	4
Hodgkin's disease	1	2	–	–	1	4
Lung	2	4	1	5	1	4
Nasopharyngeal	2	4	1	–	1	4
Non-Hodgkins lymphoma	3	6	2	9	1	4
Ovarian	3	6	–	–	3	11
Pancreatic	4	8	2	9	2	7
Prostate	1	2	1	5	–	–
Renal	1	2	–	–	1	4
Thyroid	3	6	2	9	1	4
Unknown primary	3	6	2	9	1	4
Previous clinical trial participation	7	14	2	9	5	19
Internal (PMH) referral	28	57	10	45	18	67

No Number, *Pts* patients, *SD* standard deviation, *PMH* Princess Margaret Hospital

(p=0.003), and less likely to believe phase I drugs have proven activity against cancers in humans (p=0.008).

DVD impact on patient satisfaction

Table 5 summarizes study participants' perception-based responses to a series of questions assessing the utility of viewing a DVD before enrollment in a phase I clinical study. Five of the 49 study participants (two who viewed the educational DVD and three who viewed the placebo DVD) did not complete this aspect of the questionnaire. Individuals who viewed the educational DVD were more likely to agree/strongly agree that the video provided useful information (p<0.001) and that they had a good knowledge of a phase I clinical trial (p<0.031). When compared to patients who viewed the placebo DVD, patients exposed to the educational DVD were more likely to agree/strongly agree that the DVD prompted them to have more questions for their physicians (p=0.017) and that the DVD helped them to decide whether to enter a phase I clinical trial (p=0.011).

DVD impact on physician perception of patient knowledge of phase I trials

A total of eight physicians, who were blinded to the nature of the DVD viewed by the study participants, answered a

Table 2 Characteristics of patients who declined participation in the DVD study (n=21)

	Total	
	No. pts	Percentage
Total	21	100
Age (years)		
Mean	58.4	
Median	59	
Range	36 to 76	
Sex		
Male	9	43
Female	12	57
Internal (PMH) referral		
Yes	11	52
No	10	48
Consented to entry into a phase I clinical study		
Yes	4	19
No	17	81
Reason for Not Consenting to Phase I Study		
Concern for toxicity on trial/high investigational nature of trial	2	12
Other approved treatment options available	6	35
Too ill for study enrollment	7	41
Distance too far to travel	1	6
No study available	1	6

No Number, *Pts* patients, *SD* standard deviation, *PMH* Princess Margaret Hospital

perception-based questionnaire upon completion of patient consultation. Domains of the questionnaire assessed physicians' views of patient knowledge of phase I clinical trials, ability to provide informed consent, and the amount of time required to explain phase I studies (Table 6). No statistically significant difference in physician perceptions was observed between the two study arms.

Table 3 Physician characteristics

	Mean	Median	Range
Age (years)	36	42	29–46
Gender	Number (%)		
Male	6 (75)		
Female	2 (25)		
Role	Number (%)		
Staff physician	3 (38)		
Junior staff physician	1 (13)		
Fellow	4 (50)		
Year of medical school graduation	1995	1997	1983–2000
Year of internal medicine certification	1999	2001	1992–2005
Year of medical oncology certification	1999	2001	1986–2005
Phase I clinic experience (years)	3	1	0.5–11

DVD impact on phase I study consent/enrollment

No statistically significant difference (p=0.10) was noted between the three (14%) individuals in the educational DVD arm and ten individuals in the placebo group (37%) who consented to phase I trial participation. Cited reasons for non-entry into a phase I study included concern of trial toxicity and its highly investigational nature, availability of other approved treatment options, poor functional status excluding study participation, and insufficient capacity to provide informed consent (Table 7). No significant difference was noted between the two groups for their reasons of non-participation in a phase I trial.

Discussion

Discrepancies between patient and physician expectations for treatment outcomes in early phase clinical trials call for enhanced patient–physician communication [20, 29]. Educational aids have been employed to supplement the informed consent process in cancer care. These tools enhance patient comprehension via exposure to a standardized educational medium. The phase I cancer patient population, which grapples with advanced malignant disease, shortened life expectancy, and lack of established treatment options, pose additional challenges to communication and the classical informed consent process [3, 8, 14, 20, 26, 33]. DVD was selected as our choice of educational vehicle in an effort to inform patients in a non-threatening, familiar context.

Patients in both arms of the study shared similar characteristics. There was a higher proportion of males in the educational DVD group, but the groups were of similar age, educational background, and malignancy type. A higher proportion of the placebo group had previously participated in a clinical trial and been internally referred to the phase I clinic by a physician at our institution. The 21 individuals who declined study participation shared similar demographics with participants; however, the potential for non-responder bias may restrict the applicability of our data to all phase I patient populations.

Our data indicate that exposure to the educational DVD improved cancer patients' understanding of phase I clinical trials. Given that only 49% of patients in our study had previously been aware of phase I trials, these objective gains in knowledge are significant. Patients exposed to the educational DVD demonstrated improved understanding of

Table 4 DVD impact on patient knowledge

	Educational DVD		Placebo DVD		*p* value
	No. pts	Percentage	No. pts	Percentage	
Total	22	45	27	55	n/a
Have you heard about "clinical trials" before this visit?					
No	3	14	4	15	
Yes	19	86	23	85	1.00
Have you heard about "phase I clinical trials" before this visit?					
No	11	50	14	52	
Yes	11	50	13	48	1.00
A treatment clinical trial (choose one answer)[a]					
(a) Is performed in a research laboratory	0	0	0	0	
(b) Sees if a new drug works in animals to fight disease	1	5	0	0	
(c) Studies how a new treatment works in people	21	95	25	96	
(d) Tests new drugs in computer-based simulations	0	0	1	4	0.71
Please state whether each of the following is a goal of a phase I clinical trial (choose Yes or No)?[b]					
(a) Decide how much of a new drug can be given safely	21	95	22	81	0.20
(b) Decide how often a new drug needs to be given	15	68	23	85	0.19
(c) Decide if a new drug is more effective than an old drug	8	38	20	74	0.019
(d) Decide what the side effects of a new drug are	19	86	24	89	1.00
Phase I clinical trials evaluate drugs or drug combinations have previously been studied in animals, but have not been thoroughly studied in humans					
No	1	5	12	44	
Yes	21	95	15	56	0.003
Drugs or drug combinations which are being evaluated in phase I clinical trials have proven activity against cancers in human beings[c]					
No	15	71	8	30	
Yes	6	29	19	70	0.008

[a]One missing response in the placebo DVD group
[b]Numbers and percentages of patients that provided correct responses to these statements are listed.
[c]One missing response in the educational DVD group
No Number, *Pts* patients

Table 5 DVD impact on patient satisfaction

	Educational DVD		Placebo DVD		*p* value
	No. pts	Percentage	No. pts	Percentage	
Total	20	49	24	51	n/a
Agree/strongly agree					
The video provided useful information regarding my participation in a clinical trial	15	75	5	21	<0.001
Agree/strongly agree					
I have a good knowledge of what is involved in a phase I clinical trial	12	60	6	25	0.031
Agree/strongly agree					
DVD video viewing is a useful way to provide patient education	17	85	17	71	0.31
Agree/strongly agree					
I will have more questions for my physicians because of the education I have received with the DVD	15	75	9	38	0.017
Agree/strongly agree					
The DVD helped me decide whether I would like to participate in a phase I clinical trial	11	55	4	17	0.011

No Number, *Pts* patients

Table 6 DVD impact on physician perception of patient knowledge of phase I trials

	Educational DVD		Placebo DVD		*p* value
	No. physician responses	Percentage	No. physician responses	Percentage	
Total	22	45	27	55	n/a
Agree/strongly agree					
My patient demonstrated an adequate knowledge base about phase I clinical trials that had been established before our interaction	8	36	9	33	1.00
Agree/strongly agree					
My patient's level of pre-existing knowledge regarding phase I clinical trials was helpful for our interaction	7	32	8	30	1.00
Agree/strongly agree					
The time my patient required to become fully informed about participation in phase I clinical trials was within an acceptable (normal) limit	12	55	17	63	0.57
Agree/strongly agree					
My patient readily grasped the clinical concepts involved in phase I clinical trials	14	64	18	67	1.00
Agree/strongly agree					
I feel that my patient is able to make an appropriately informed decision regarding participation in phase I clinical trials after our interaction	15	68	21	78	0.53
Duration of time required to inform my patient					
Was less than ≤15 minutes	8	36	5	19	0.20
15–30 min	11	50	16	59	
30–45 min	2	9	2	19	
45–60 min	1	5	1	4	
>60 min	0	0	0	0	

No Number

Table 7 DVD impact on phase I study consent/enrollment

	Educational DVD		Placebo DVD		*p* value
	No. pts	Percentage	No. pts	Percentage	
Total	22	45	27	55	n/a
Consent obtained to participate in a phase I clinical trial					0.10
Yes	3	14	10	37	
No	19	86	17	63	
Patient entry in phase I clinical trial after consent					1.00
Yes	3	100	9	90	
No	0	0	1	10	
Reason for not consenting to participation in a phase I clinical trial					1.00[a]
Concern for toxicity on trial/high investigational nature of trial	5	26	4	24	
Other approved treatment options available	9	47	8	47	
Too ill for study enrollment	4	21	5	29	
Not capable of informed consent	1	5	0	0	

[a]Test of concern for trial toxicity versus others
No Number, *Pts* patients

the primary objective of phase I trials, as well as the highly investigational nature of these studies.

The educational DVD was also favorably received by phase I cancer patients. The majority of patients in both the educational and placebo DVD groups felt that DVD viewing was a useful way to conduct patient education. The well-accepted, conversation-stimulating aspects of DVD implementation in this study support the use of video-viewing as a supplement to physician consultation in early phase cancer trials.

Whereas the DVD impacted patient knowledge and satisfaction, no significant difference was observed in physician perception of patient understanding. In our study, the majority of physicians did not believe that their patients' pre-existing knowledge base of phase I trials was sufficient. Despite DVD viewing, physicians in both arms often found that the amount of time their patients required to become satisfactorily informed about participation in phase I trials exceeded their perception of an acceptable range. Whereas these findings suggest that the effect of the educational DVD was not large enough to alter the informed consent process, they support the role of these tools as supplements rather than replacements for adequate physician–patient communication [19]. Thirty percent of the physicians disagreed with the statement that their patient was able to make an appropriately informed decision regarding participation in phase I clinical trials. This suggests that the decision making abilities of some patients may be resistant to the impact of communication in the initial physician–patient assessment.

Viewing of the educational DVD did not significantly impact phase I trial accrual; however, a trend towards decreased participation in the educational DVD group was observed. It is difficult to interpret this finding, as the number of phase I trial enrollees in both educational and placebo DVD arms were very small (three and ten, respectively). The majority of patients in both groups were not offered phase I trial participation due to the availability of other approved treatment options or their degree of medical unfitness for trial. Hence, it is not possible to draw conclusions from these reasons, which were largely beyond patients' own control. However, among those patients who did not enter a phase I trial because of their concern for trial toxicity and its highly investigational nature, there was no difference in the frequency of this decision between the two groups.

This study is limited by its relatively small sample size of both patients and physicians at a single institution. As the physician questionnaire was subjective, the potential for individual biases of physicians may confound results. Furthermore, our study cannot demonstrate a change in patient decision making based upon the implementation of DVD-viewing; rather, gains in patient knowledge and satisfaction may only be inferred to improve informed consent. Long-term retention of DVD content by patients was not assessed, nor was expectations of benefit. Study strengths include the randomized and blinded nature of our trial, utilization of a standardized educational intervention, conduction of the study within the parameters of a real-time clinic, and the time-efficient and economical nature of the intervention.

Informed consent for ethically valid participation in a research study requires patient capacity, comprehensive disclosure, patient comprehension, and voluntariness [9]. The quality of informed consent for patients participating in phase I clinical trials has been debated, particularly given multiple reports of inappropriately elevated patient expectations of therapeutic benefit on these studies [1, 22, 30]. Possible mechanisms to explain these discrepancies include patient hope and denial, insufficient disclosure of information, poor patient comprehension, and lack of autonomy. Provision of supplemental knowledge on phase I trials augments the consent process, improves and standardizes information disclosure, as well as bolsters patient comprehension. Whereas informed consent will remain a challenging issue in phase I studies [18], our preliminary study supports the use of educational DVD-viewing as a valuable adjunct to enhance both patient knowledge and satisfaction with the decision making process. Implementation of this educational modality into the early phase clinical trial setting deserves further attention and evaluation.

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Appendix I: Patient post-DVD survey

A. DEMOGRAPHICS

Age: _____
Date of Birth (D/M/Y): _____

Gender: M ☐ F ☐
City of Residence: _____

Highest Level of Education:

No Formal Education ☐ Grade School (1-8) ☐
High School (9-13) ☐ College / University ☐

B. CONTENT QUESTIONS

1. Have you heard about “clinical trials” before coming to this visit?

Yes ☐ No ☐

2. Have you heard about “phase I clinical trials” before coming to this visit?

Yes ☐ No ☐

3. A treatment clinical trial (choose one answer): ☐

a) Is performed in a research laboratory
b) Sees if a new drug works in animals to fight disease
c) Studies how a new treatment works in people
d) Tests new drugs in computer-based simulations

4. Please state whether each of the following is a goal of a phase I clinical trial?

a) decide how much of a new drug can be given safely Yes ☐ No ☐
b) decide how often a new drug needs to be given Yes ☐ No ☐
c) decide if a new drug is more effective than an old drug Yes ☐ No ☐
d) decide what the side effects of a new drug are Yes ☐ No ☐

5. Phase I clinical trials evaluate drugs or drug combinations have previously been studied in animals, but have not been thoroughly studied in humans.

True ☐ False ☐ Don’t Know ☐

6. Drugs or drug combinations which are being evaluated in phase I clinical trials have proven activity against cancers in human beings.

True ☐ False ☐ Don't Know ☐

C. PATIENT SATISFACTION QUESTIONS

Please rate the following questions by the scoring system listed below:

1 – Strongly disagree
2 – Disagree
3 – Neither agree or disagree
4 – Agree
5 – Strongly agree

Circle the number that best represents your opinion.

1. The video provided useful information regarding my participation in a clinical trial.
   1 2 3 4 5

2. I have a good knowledge of what is involved in a phase I clinical trial.
   1 2 3 4 5

3. DVD video viewing is a useful way to provide patient education.
   1 2 3 4 5

4. I will have more questions for my physicians because of the education I have received with the DVD.
   1 2 3 4 5

5. The DVD helped me decide whether I would like to participate in a phase I clinical trial.
   1 2 3 4 5

Appendix II: Physician post-DVD survey

PHYSICIAN SATISFACTION

Please rate the following questions by the scoring system listed below:

1 – Strongly disagree
2 – Disagree
3 – Neither agree or disagree
4 – Agree
5 – Strongly agree

Circle the number that best represents your opinion.

1. My patient demonstrated an adequate knowledge base about phase I clinical trials that had been established before our interaction.
   1 2 3 4 5

2. My patient's level of pre-existing knowledge regarding phase I clinical trials was helpful for our interaction.
   1 2 3 4 5

3. The time my patient required to become fully informed about participation in phase I clinical trials was within an acceptable (normal) limit.
   1 2 3 4 5

4. My patient readily grasped the clinical concepts involved in phase I clinical trials.
   1 2 3 4 5

5. I feel that my patient is able to make an appropriately informed decision regarding participation in phase I clinical trials after our interaction.
   1 2 3 4 5

The duration of time required to inform my patient about phase I clinical trials was:

1) <15 minutes
2) 15 to 30 minutes
3) 30 to 45 minutes
4) 45 to 60 minutes
5) >60 minutes

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