A TRIAL ON PATIENT’S EVALUATION OF A PHYSICIAN CONVEYING AN OPTIMISTIC VERSUS A LESS OPTIMISTIC MESSAGE

SHORT TITLE: MESSAGE

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OBJECTIVES and HYPOTHESES

Primary objectives

1. To examine patients’ perception of physician’s compassion. Hypothesis: We hypothesize that most of the patients will consider more compassionate the physician that provides the optimistic message.

Secondary objectives

1. To examine which type of physician the patients would prefer after watching the two videos. Hypothesis: Patients will prefer the physician that conveyed the optimistic message over the physician that conveyed the realistic message.

2. To assess the association between the patients’ physician perception and the type of message that is conveyed by the physician in the video. Hypothesis: There is a high correlation between the patient’s preferences regarding the physician they would choose as a preferred provider and the type of message they would like to hear.

3. To establish demographic and clinical predictors of physician preference. Hypothesis:
   a. Patients who are more anxious and depressed will further prefer the optimistic style over the one that is more accurate but hopeless.
   b. Patients who have a lower acceptance of their illness will prefer the optimistic physician.
   c. Patients who trust the medical profession will rate physicians as more compassionate.
   d. Patients who are more hopeful will prefer the optimistic physician.
BACKGROUND

Information regarding treatment options and prognosis is essential for patient decision making at the end-of-life (EOL). Patients report the need to have access to this information in order to make a decision about future planning [1]. It is known that when this information is delivered sensitively it can have a positive impact on patient’s feelings and promote patient reassurance [2-4]. The timing, amount and quality of the information provided should be tailored to patient’s specific needs, given that information preferences do vary among patients and through the disease trajectory [2, 5-8].

A common concern in the palliative care community is that, despite efforts in promoting discussions regarding treatment options and prognostic information between physicians and patients, still a large proportion of patients reach the end of life phase without having discussed these issues [1]. One of the factors identified is physician’s reluctance to discuss this topic with patients [8].

Physicians, usually oncologists, are the ones that provide patients with treatment and prognostic information [9]. It is recognized in the literature that physicians have difficulties in delivering bad news and that many doctors find this process stressful and demanding [10-12]. Factors that influence the reluctance of physicians to deliver bad news to patients with advanced cancer include, among others, fear of being blamed, fear of destroying hope or provoking emotional distress and fear of confronting own emotions and death [8, 12, 13]. Physicians also report that delivering bad news exposes them to the risk of losing control [12, 13].

Therefore, the provision of optimistic and hopeful treatment and prognostic information could be a strategy for physician’s emotional and personal protection [11]. Likewise, from a physician’s perspective, physicians that provide optimistic information might be more likeable than physicians who provide less optimistic information.

Factors that influence communication at the end of life:

We can identify four components of EOL patient-physician communication: the physician, the message itself, the patient and the environment. Several factors influence each of these elements.

How, what and when physicians provide information about treatment options to a patient with advanced cancer is influenced by physician’s personal characteristics, such as educational and cultural background, physician’s specialty, psychological factors and ability to communicate [14]. Also, it is affected by the information and expertise the physician has on the patient’s specific cancer, his knowledge regarding possible treatments and prognosis and previous experiences [15]. Finally, it is influenced by the physician’s perception on the amount of information the patient wants, the patient’s levels of anxiety related to the disease and patient’s coping mechanisms (e.g. acceptance, denial or avoidance) among others [15]. Nevertheless, physicians are not always accurate at assessing patient’s information needs and preferences [4, 16].

The message itself is composed by two elements: the CONTENT, what is being said, and the MANNER, the way in which it is said [17]. Patients report that when listening to bad news, the content of the message delivered is rated as the most important aspect of communication, while supportive aspects of
communication are rated lower although still important [18]. Several publications have addressed the importance of non-verbal aspects of communication on patient-physician EOL discussions such as eye-contact [19-21]. Factors such as body position, use of lay terms, physician behavior and voice pitch, have been identified as a factor that influence the way the message is delivered [1, 7, 19, 20, 22]. Today, there are important controversies regarding communication at the end of life, particularly related to the content delivered. It is still uncertain whether is better to provide detailed information or to provide more general statements to a patient, and it is unclear how to promote hope in the context of giving bad news [5, 6].

It has also been recognized that patient factors, such as age, gender and cultural background, influence communication and information preferences [6, 23, 24]. Patients’ psychological state can modify what patients understand from what is being said [3, 14, 25, 26]. It is not uncommon that patients experience ambiguity regarding information preferences and that these information preferences change over the course of the disease [3, 8, 27]. For example, patient’s information preferences decrease as the disease progresses [3, 27].

Besides these known factors, it is possible that other patient characteristics could affect communication in the context of advanced cancer. From studies analyzing treatment preferences, it has been shown that patient’s understanding of disease status and the level of acceptance of the disease influence decision making at the end-of-life [28, 29]. Also, patients who are less accepting of their prognosis tend to have more difficulties communicating with friends and families [30]. Therefore, it is possible that these factors might also influence communication between patients and physicians in the context of advanced cancer. Other possible patient factors that could influence communication at the end-of-life are patient’s hopefulness, as it modulates patients ability to cope with advanced illness [31], and patient’s trust in the medical profession, as it has been associated with a better understanding of their illness [32].

Environmental factors also influence patient physician communication. Factors such as privacy and uninterrupted time to discuss issues are valued by patients as important, and they also improve patient understanding and satisfaction with end of life discussions [7, 17].

**Patient’s preferences when discussing treatment options and prognosis**

There is abundant literature describing the patient’s information preferences regarding treatment and prognosis in the context of advanced cancer, how they would like to receive the information and what is their evaluation of physician communication and interpersonal skills [1, 5, 18, 27, 33]. For example, patients favor ending a bad news conversation with hopeful statements. They also often express a need for hope, even against all odds [7]. At the same time, patients often hope for attainable goals such as optimal comfort in the remaining time and not necessarily unrealistic expectations [6]. On the other hand, some patients express the need to receive realistic information even if less optimistic [27]. Some people argue that realistic information may nurture hope, while others argue that it destroys hope [6].
Factors that influence patient’s perceptions of physicians

It is known that oncologists who are both empathic and medically competent during bad news conversations are the most valued [34]. Furthermore, physicians who empathically respond to emotions when discussing EOL issues are associated with lower levels of patient psychological distress [8].

Despite the large amount of information about end-of-life communication, it has not been explored yet whether the content of the message itself (e.g. optimistic versus less optimistic) delivered by the physician is a factor that modifies the evaluation that the patient has on physician characteristics such as compassion and professionalism.

The **GOAL OF OUR STUDY** is to examine patients’ perception of physician’s compassion assessed by exposing the patient to two different videos: one that shows a physician conveying an optimistic message about treatment options to a patient with advanced cancer, and a second that shows another physician conveying to the same patient a less optimistic message about treatment options.
CONCEPTUAL MODEL

As previously described, we identified four components in the communication process between physicians and patients: the physician, the patient, the message and the environment. In order to correctly analyze the relationship between the message delivered and patient perception of physicians, we will standardize the other aspects of the communication process including: the physician and physician factors that influence how the physician is communicating with the patient, the “manner” component of the message and the environment.

FIGURE 1: Conceptual Model

- Demographic factors
  - Specialty
  - Psychological factors
  - Communication training
  - Personal experiences

- Demographic factors:
  - Age
  - Gender
  - Race
  - Education

- Psychological factors:
  - Anxiety and depression (HADS)
  - Understanding of current health status (Q)
  - Acceptance of illness (PEACE)
  - Hope (Herth Hope Index)
  - Trust in medical profession (Q)

- Cancer related factors:
  - Cancer type
  - Stage
  - Treatment
  - Prognosis
  - Performance Status (ECOG)
  - Symptoms (ESAS)

- PATIENT’S PERCEPTION ABOUT THE PHYSICIAN

- PATIENT’S PERCEPTION ABOUT THE CONTENT
PATIENTS AND METHODS

ELIGIBILITY CRITERIA:

1. Diagnosis of advanced cancer, defined as locally advanced, recurrent or metastatic disease
2. Patients treated as outpatients by the Supportive and Palliative Care team.
3. Age $\geq$ 18 years-old
4. English speaking
5. Normal cognitive status as determined by the interviewer based on the ability to understand the nature of the study and consent process.

EXCLUSION CRITERIA:

1. Patients suffering from a severe psychiatric disorder or condition that would significantly interfere with study participation, as determined by the Principal Investigator or by the attending palliative care physician.

All adult patients with advanced cancer seen at the Supportive Care Clinic will be eligible for the study. This randomized controlled trial will not interfere with routine clinical practice in the clinic.

INTERVENTION:

After appropriate patient screening and randomization, we will show two videos to each patient that we will produce especially for this study. We will use the video as a way of delivering standardized information to patients.

Each video will have approximately a length of 4 minutes. The videos will show a physician discussing treatment and prognostic information with a patient who has advanced cancer, who has received several lines of chemotherapy and who is not a good candidate for further therapy. In one video, the physician will provide accurate and explicit information about the lack of further treatment options and prognosis (Video 1: Less Optimistic). In the other video, the physician will provide vague information about future treatments and prognosis, including a statement emphasizing the possibility of further treatments if the patient improves in functional status (Video 2: Optimistic).

In each video, the physician role will be played by different professional actors, but who will have similar physical characteristics (e.g. sex, age and race). These characteristics will be chosen to reflect typical consultations at M.D. Anderson Cancer Center: The physician will be a Caucasian male 40 to 50 years old. In order to account for possible bias in the interpretation of the role, we will ask each actor to record videos with the two messages.

The two actors (physician) will act the same way and we will play the role of the less optimistic as well as the optimistic. The video will be randomly assigned to the patients to make sure that in the analysis, there’s no need to control for the actors’ characteristics.
It is important that we expose the patients to two actors having exactly the same numbers of empathetic statement and non-verbal communication but that the physician in the two different videos are different individuals, so that the patient can make a choice. The two actors will be from the same gender, age and ethnicity to control for potential confounders.

In the videos, the patient will be always the same in both videos: a Caucasian woman around 50 to 60 years old with advanced cancer and poor performance status.

The script will reflect a physician with average EOL communication skills and emotionally neutral. We need the physician to be neutral (not too likeable or unlikeable), so we can better assess the influence of the message on the patient’s perception of the physician.

In order to decrease the influence of the physician’s body language and nonverbal communication, we will perform an independent review of the videos without sound, to be sure that the physician’s expression when delivering the different messages is similar. Therefore, we will compare the observed compassion of each physician delivering the two different messages, and also the observed compassion of both physicians delivering each of the messages. We will also ask the reviewers to compare the performance of the two listening only to the audio, to assess for any possible voice bias. We will also write the two different scripts with the same number of empathetic statements (n=5).

In summary, the main difference between the 2 messages is as follows. In video #1, the oncologist states quite clearly that there are no possible treatments for cancer, followed by the empathetic statement, "I wish it could be different." On the other hand, in video #2 (optimistic), the oncologist states that at this time, the patient is very weak and not a candidate for treatment. However, if they get strong enough, they may be considered for new treatment. The empathetic statement remains unchanged as "I wish it could be different."

**RANDOMIZATION AND BLINDING**

Using the CTC website, patients will be randomized equally (1:1:1:1) into the four video/doctor sequence arms. The objective of this randomization strategy is to first, control for the order in which the messages are heard, and second to control for the physician’s personal characteristics. In previous studies we have seen that the sequence patients watch a video had an impact on their perception of physician compassion. These studies suggest that patients generally prefer the doctor they see in the second video [19, 35]. Therefore, a randomization of the order will help us control for this bias. As our goal is to assess patient’s perception of physician compassion related to the message delivered, we need to control for personal characteristics of the actors that will play the role of the doctor. To do this, we will also randomize the physicians who will deliver the messages, to control for this possible confounder. With this randomization strategy we will have four possible groups (Figure 2).

The research coordinator will be blind to the allocation sequence throughout the study. Actors and patients will be blinded to the specific hypothesis of the study. In the consent process, patients will be told that they will be asked to: “watch two videos and complete 3 surveys one before the first video and one survey after each video”. Although we are using survey questionnaires, this study is an experimental design.
Regarding patients’ caregivers, we will ask them to leave the room while the videos are played. In case they decide to stay, we will ask them to keep silent.

**STUDY OUTCOMES MEASURES**

We will ask the patients to complete 3 sets of surveys during the experimental phase of the study. One set will be handed to the patient before showing the first video and one set of surveys after each video is played. In the first set, we will assess patient’s current psychological factors that could influence patient’s preferences: presence of psychiatric illness, hope, disease acceptance and general trust in the medical profession. After each video, we will ask the patient to evaluate the physician that delivered the information. In the third set of surveys, we will add a question to ask the patient to choose which physician the patient would prefer as a primary physician.

The main outcome will be patient’s rating of physician’s compassion by using a 5-item tool consisting of five 0-10 numerical rating scales assessing five dimensions: warm-cold, pleasant-unpleasant, compassionate-distant, sensitive insensitive, caring-uncaring. The sum of the five scales will give a final score representing physician’s compassion with a 0 to 50 scale.

Table 1 summarizes all the assessments that will be done during the study.

**Baseline assessment:**

At the beginning of this prospective observational study, we will collect:

1. Patient demographics, baseline - gender, date of birth, ethnicity, marital status, education, religion, type of cancer, date of cancer diagnosis, treatments received, current cancer treatments, performance status (Appendix A). This information will be obtained from reviewing the patients’ medical record in ClinicStation.
2. Signs and symptom - Edmonton Symptom Assessment Scale (ESAS) (Appendix B).
3. Depression and Anxiety - Hospital Anxiety Depression Scale (HADS) (Appendix C). Patients who appear distressed or express emotional distress will be referred to the Supportive Care staff or physicians for further evaluation.
4. Current health status and disease acceptance: Peace, equanimity and acceptance in the cancer experience (PEACE) scale (Appendix D) [28]. We will use the Peace subscale which includes only five of the twelve questions.
5. Trust in Medical Profession questionnaire (Appendix E) [36].
6. Hope: Herth Hope Index (Appendix F) [31, 37].
7. The message they would prefer to listen to (Appendix G).

**After first video:**

The patients will watch the two short videos with a 4-minute interval between the two of them. The PI will complete a preliminary review of the videos before they are administered to the patients. After the first video all patients will be asked to rate physician’s characteristics related to different domains:

1. General Impression of the physician and perceived level of physician hopefulness (Appendix H).
2. Physician compassion assessed by validated 5-item tool consisting of 0–10 numerical rating scales (Appendix H) [19, 38].
3. Physician professionalism, adapted from the General Medical Council Questionnaire (Appendix I) [39].

After second video:

After the second video, all patients will undergo the last set of assessments:

1. General Impression of the physician and perceived level of physician hopefulness (Appendix J).
2. Physician compassion assessed by validated 5-item tool consisting of 0–10 numerical rating scales (Appendix J) [19, 38].
3. Physician professionalism, adapted from the General Medical Council Questionnaire (Appendix K) [39].
4. Final choice of the physician: after completing the assessments, patients will be asked to choose which physician they preferred (first video, second video or no preference) and then to rate again physician overall impression and compassion perception. We will also ask the patient to describe the reasons for the preference (Appendixes L and M).

It should take about 38 minutes to watch the videos and complete all of the questionnaires (Table 2 – 8 min for the videos and 30 minutes for questionnaires). In order to capture all possible patient’s thoughts and comments, we will ask the patient for their permission to record the conversation between the nurse/research assistant/Principal Investigator and the patient while the patient completes the surveys after the videos (Optional Procedure in informed consent document). Patient might decline to have the conversation recorded without modifying their eligibility and enrollment. If the patient needs any assistance in completing the questionnaires, the research nurse/research assistant/Principal Investigator may help in completing them. The audio recordings will be destroyed along with the data collected 5 years after publication of the findings.

Distress Plan – If any patients experience significant and high levels of distress while they are participating in the study, we will refer them to their primary care physician or physician on call in the unit.

**TABLE 1: Summary of patient’s assessments**

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<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>After First Video</th>
<th>After Second Video</th>
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<tbody>
<tr>
<td>Demographics (Appendix A)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer status and performance status (Appendix A)</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Edmonton Symptom Assessment Scale (Appendix B)</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Hospital Anxiety Depression Scale (Appendix C)</td>
<td>X</td>
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<tr>
<td>Acceptance (Appendix D)</td>
<td>X</td>
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<tr>
<td>Trust in medical profession (Appendix E)</td>
<td>X</td>
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<tr>
<td>Hopefulness (Appendix F)</td>
<td>X</td>
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<tr>
<td>Patient information preferences (Appendix G)</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>General Impression (Appendix H and J)</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Physician’s hopefulness (Appendix H)</td>
<td>X----</td>
<td>X</td>
<td></td>
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<tr>
<td>Assessment</td>
<td>Estimated time (min)</td>
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<tr>
<td>Edmonton Symptom Assessment Scale (Appendix B)</td>
<td>5 minutes</td>
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<tr>
<td>Hospital Anxiety Depression Scale (Appendix C)</td>
<td>5 minutes</td>
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<tr>
<td>Acceptance (Appendix D)</td>
<td>3 minutes</td>
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<tr>
<td>Trust in medical profession (Appendix E)</td>
<td>3 minutes</td>
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<tr>
<td>Hopefulness (Appendix F)</td>
<td>3 minutes</td>
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<tr>
<td>Patient information preferences (Appendix G)</td>
<td>2 minutes</td>
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<tr>
<td>General Impression (Appendix H and J)</td>
<td>1 minute</td>
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<tr>
<td>Physician’s compassion (Appendix H and J)</td>
<td>3 minutes</td>
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<tr>
<td>Physician’s professionalism (Appendix I and K)</td>
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<tr>
<td>Preference of the physician (Appendix L)</td>
<td>1 minute</td>
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<tr>
<td>Reasons for preference (Appendix M)</td>
<td>1 minute</td>
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</table>
FIGURE 2: Study Design

Patient Information and consent

SURVEY 1: Assessment of psychological factors
Psychiatric illness, hope, trust in the physician,
CHART: Demographics, cancer related factors

RANDOMIZATION

VIDEO 1: Realistic
Physician A

VIDEO 2: Optimistic
Physician A

VIDEO 1: Realistic
Physician B

VIDEO 2: Optimistic
Physician B

SURVEY 1: Assessment of physician’s compassion

VIDEO 2: Optimistic
Physician B

VIDEO 1: Realistic
Physician B

VIDEO 1: Realistic
Physician A

VIDEO 1: Realistic
Physician A

SURVEY 2: Assessment of physician’s compassion
SURVEY 3: What doctor would you prefer?
STATISTICAL CONSIDERATIONS

PRIMARY HYPOTHESIS and SAMPLE SIZE

The primary outcome of physician compassion will be tested using compassion data from the first video viewed by each patient. 50 patients per group (“Realistic” and “Optimistic”) provides 80% power for a two-sided two-sample t-test to detect an effect size as small as 0.57 when the Type I error rate is set at 5%.

SECONDARY

We wish to determine whether the proportion of patients who prefer the optimistic message is different from proportion of patients who prefer the realistic message. To this end we will assess the patient’s preference for physician as a surrogate for the message (Survey 3). A sample size of 100 achieves 83% power to detect a difference of 0.15 using a two-sided binomial test. The target significance level is 0.05. These results assume that the population proportion under the null hypothesis is 0.5 (NCSS PASS 2005). We will test whether the proportion of patients preferring the optimistic message differs by video sequence using a chi-square test.

Standard descriptive statistics including means, medians, standard deviations, ranges, proportions and frequencies, together with 95% confidence intervals will be computed for all study variables. Mixed model techniques will be used to further explore the primary hypothesis using compassion results from both videos for each patient. Adjusted logistic regression will be used to explore demographic and clinical predictors of physician preference.

Since this study is of minimal risk to the patient, we will not conduct an intermediate analysis. In the case of patient withdrawal or loss to follow-up, leading to patient inevaluability, such patients will be replaced.

Analysis will be performed using SAS version 9.2 (Cary, NC).

INFORMED CONSENT, DATA CONFIDENTIALITY AND PROTECTION

Data and Confidentiality Procedures

Because of the extremely low risk of adverse events we will obtain a waiver for DSMB review. Written consent will be obtained for enrollment.

We will obtain authorization for use and disclosure of Protected Health Information (PHI) from patients.

Informed consent will be obtained from patients by the Project Coordinator, Research Nurses or Research Staff involved in the protocol. The informed consent will be done according to the MD Anderson Policies and Standards.

Health information will be protected and we will maintain the confidentiality of the data obtained from the patient’s chart.

Collection of identifiers: We will collect and securely store patients’ identifiers (including name, medical record number and demographic specifications). Each patient will be assigned a study number that will be
the only identifier to figure in the analytical file and personal data will not be disclosed in any form. The key linking these numbers will be retained in a securely locked file by the investigator.

Data Storage: Protection of electronic and paper records will be guaranteed. All electronic records will be stored on password-protected institution computers behind the institution firewall. Any paper records will be classified and stored in locked files inside a locked office.

Training of personnel: Only MDACC personnel trained in maintaining confidentiality, the principal investigators and co-investigators, will have access to study records.

Data sharing: Study data will not be shared with any individuals or entities. The data will be kept by the principal investigator in a locked file cabinet.

Final disposition of study records: These data will be used only for this research study. Data files will be destroyed 5 years after publication of the findings.
REFERENCES

36. Dugan, E., F. Trachtenberg, and M.A. Hall, Development of abbreviated measures to assess patient trust in a physician, a health insurer, and the medical profession. BMC Health Serv Res, 2005. 5: p. 64.