Patient-Centered Communication on Clinical Trial Enrollment

- Nana E. Tchabo, M.D., FACOG
- Women’s Cancer Center
- Division of Gynecologic Oncology
- Department of OB/GYN and Women’s Health
- Overlook and Morristown Medical Centers

Carol G. Simon
Cancer Center
ATLANTIC HEALTH

THE PASSION TO LEAD

Financial Disclosure

- I have nothing to disclose.

Objectives

At the end of this session, the participant will be able to:

1) Discuss the purpose of patient-centered communication.
2) Discuss the impact of patient-centered communication for Clinical Trial Enrollment.
3) Understand how to facilitate patient-centered communication for clinical trials.
4) Understand the benefits of patient-centered communication versus lack of patient discussions about clinical trials.
5) Identify strategies to incorporating patient-centered practices (e.g. clinical trial education, interventions for oncologists, patients and caregivers).

What are cancer clinical trials?

- Research studies that involve people.

- Designed to test new ways to:
  - Treat cancer
  - Find and diagnose cancer
  - Prevent cancer
  - Manage symptoms of cancer or side effects from its treatment

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Why are Clinical Trials Important?

- Key to developing new methods to prevent, detect, and treat cancer.
- Researchers can determine whether new treatments are safe and effective and work better than current treatments.
- Participation in a clinical trials adds to knowledge about cancer and helps improve cancer care.

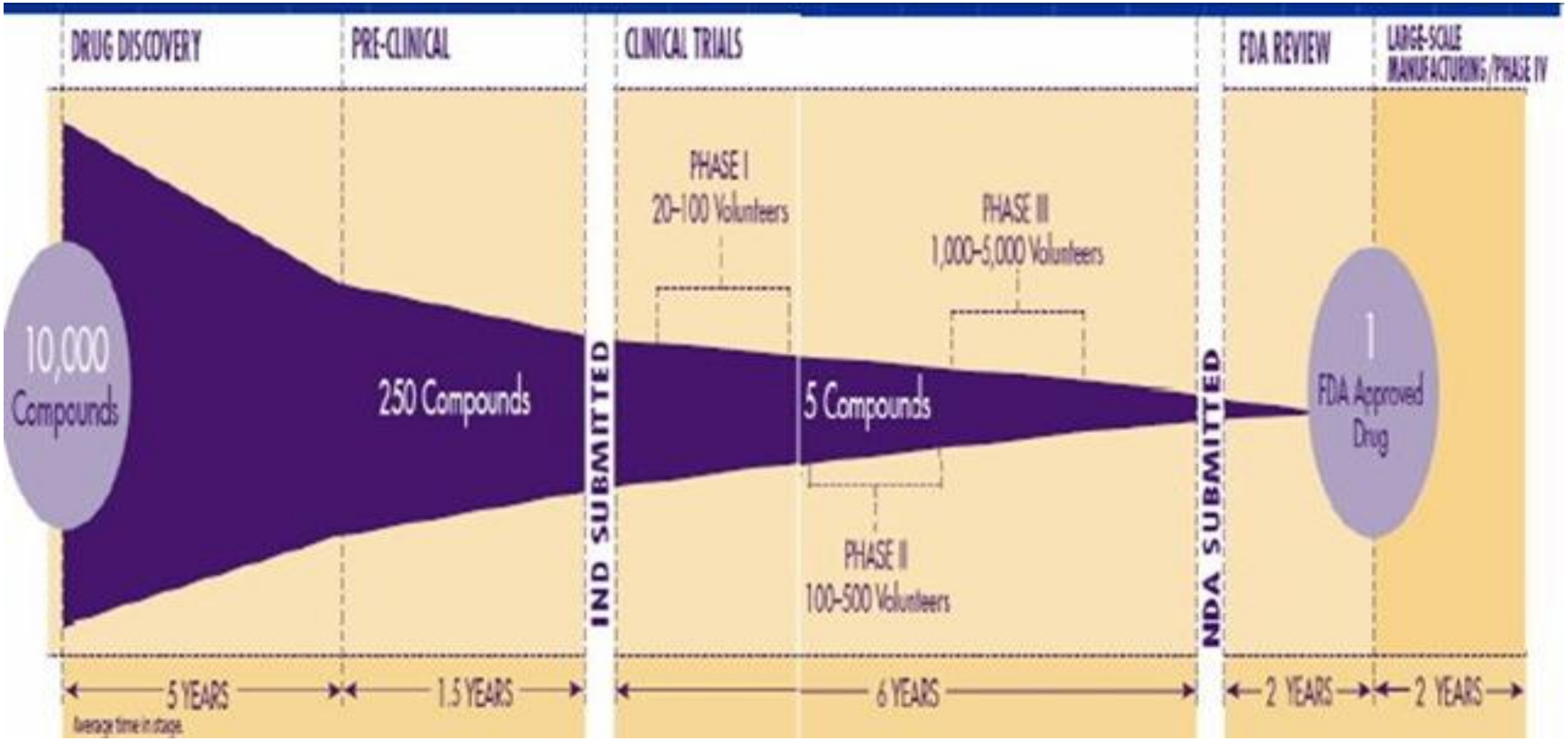
Important reminders about Clinical Trials

- 1) Clinical trials are not a "last resort."
- 2) Clinical trials involve close monitoring of patient safety and response to therapy.
- 3) Study sponsors generally cover costs associated with participating in a clinical trial.

Clinical trials and cancer care: Six points patients need to know by Special to NJ.com, August 10, 2015.

Important reminders about Clinical Trials

- 4) There are different types of trials, with varying sizes, structures, and objectives.



Clinical trials and cancer care: Six points patients need to know by Special to NJ.com, August 10, 2015.
http://media.pharmacologycorner.com/wp-content/uploads/2009/02/drugdevelopmentphases.jpg

Important reminders about Clinical Trials

5) Not receiving the study drug does not mean not receiving care.

6) Making progress against cancer is dependent on clinical trials.

- Surgery-1950’s-present
- Radiation-1960’s
- Melphelan-1960’s
- Cis-platinum-1970’s
- Hexamethylene-1970’s
- Paclitaxel-1980’s
- Carboplatin-1990’s
- Liposomal Doxorubicin-1990’s
- Topotecan-1990’s
- Gemcitabine-1990’s

- Pemetrexate-2000’s
- Bevacizumab (Angiogenesis inhibitors)-2000’s
- *Olaparib (Parp inhibitors)-2010*

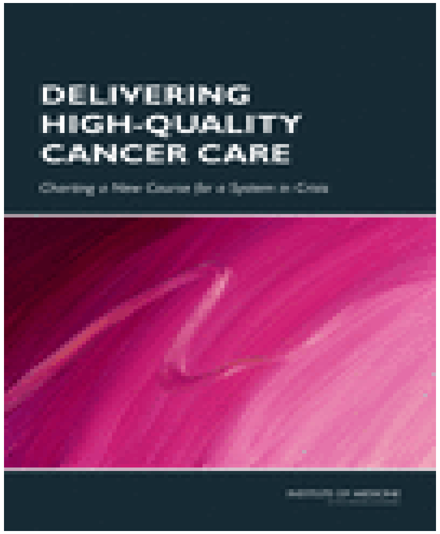
Clinical trials and cancer care: Six points patients need to know by Special to NJ.com, August 10, 2015.

Reality of clinical trial participation

- Despite the opportunity to access a cutting-edge treatment that could improve the quality of life or prognosis, as well as to be a part of research that could benefit future patients,
  - only 2-4% of adult cancer patients in the U.S. enroll in a trial
  - Why?
  - Lack of awareness
  - Misperceptions about what joining a clinical trial entails
  - However, in several surveys, 70% of patients express a willingness to join a clinical trial

Patient understanding of Clinical Trials

- Studies show that after discussions about clinical trials, patients and family members commonly misunderstand fundamental concepts. Although one of the top reasons patients cite for enrolling in a clinical trial is "trust in the doctor,“ it is clear that trust does not necessarily translate into understanding.
- A study of patients entering phase I trials showed that 85% had decided to participate because of possible therapeutic benefit, and only 33% were able to state the purpose of the trial.
- In a multicenter study of childhood leukemia trials in the United States, postconsent interviews showed that 50% of parents did not understand randomization.
- A survey of 600 patients in the UK comparing preferences for different explanations of randomization used by major cancer organization websites and information sheets showed that only 54% to 61% of patients rated the explanations as "very clear," and only weak consensus could be found as to which explanations were most preferred and disliked.



The Institute of Medicine

- 2001: *Crossing the Quality Chasm: A New Health System for the 21st Century*
  - *Defined patient-centeredness as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that* ***patient values guide all clinical decisions."***

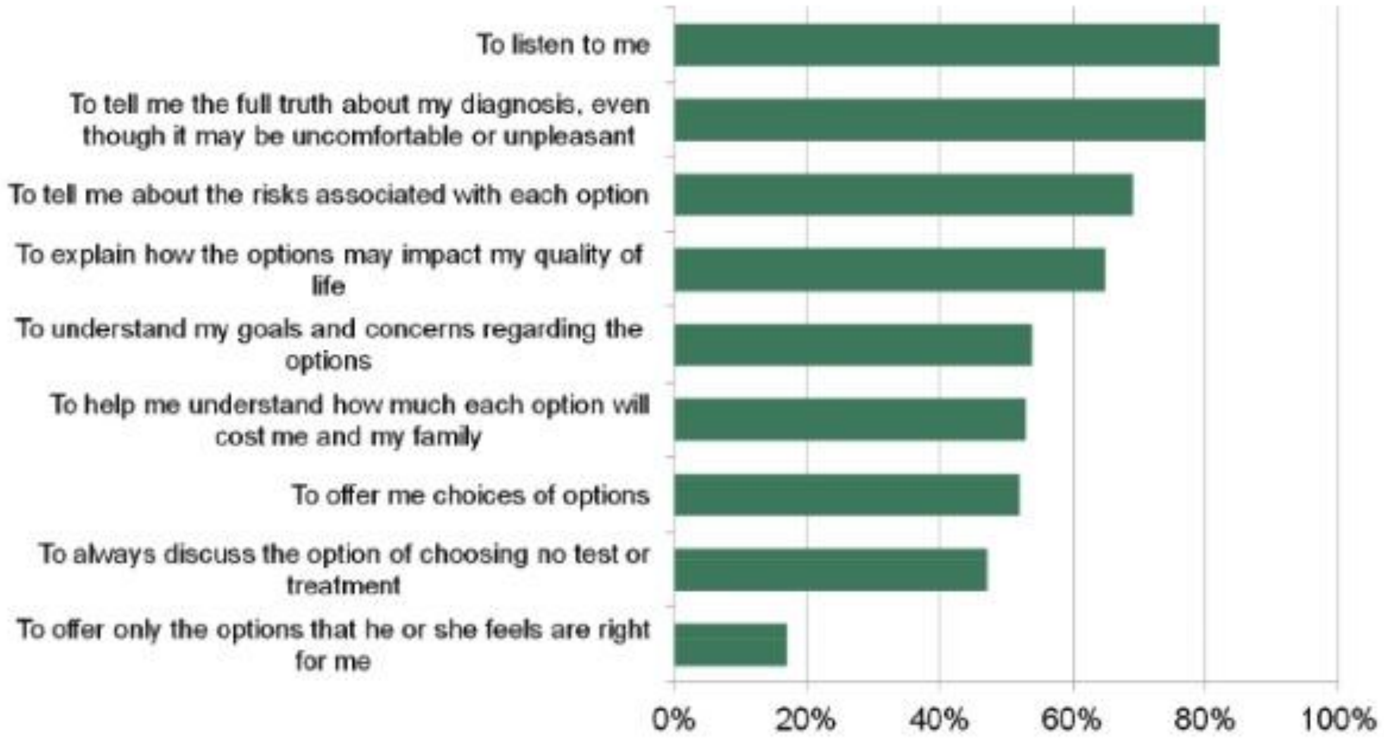


Figure 1. People want involvement in evidence and decisions
Bars show the percent of people surveyed who strongly agree with the statement: "I want my provider…"

FIGURE 3-2 People want to be involved in understanding evidence and making decisions about their care. The IOM surveyed a nationally representative sample of 1,068 U.S. adults who had seen at least one healthcare clinician in the previous year. The majority of adults strongly agreed that they should be actively involved in understanding and making decisions about their care.
SOURCE: Alston et al., 2012.

Why patient-centeredness and shared decision making?

- Cancer care is complex.
  - Different modalities treat cancer with often multiple treatment options that require coordination.
    - The goals of treatment must be decided (for example, how much to prioritize quality of life or duration of life and whether these even conflict). Each of these elements shift over time and must therefore be revisited over time.
  - There are limitations to the evidence base.

  - Different patients will weigh tradeoffs between options differently and will do so differently at different times in their care.

http://cancergrace.org/cancer-101/2013/11/14

What are obstacles to shared decision making?

- Patient-derived
  - New diagnosis of cancer can be emotionally, financially, and logistically overwhelming
  - Health literacy

- Provider-derived
  - Current reimbursement system
  - Shortage of oncologists
  - Lack of training in quality communication

- System-derived
  - Physical and procedural characteristics of the health care system
  - Fragmented system with various medical record systems

http://cancergrace.org/cancer-101/2013/11/14

Patient centered communication

- Eliciting and understanding patient perspectives (concerns, ideas, expectations, needs, feelings, and functioning)
- Understanding the patient within his or her unique psychosocial and cultural contexts
- Reaching a shared understanding of patient problems and the treatments that are concordant with patient values

Epstein RM, Street RL Jr, Patient-Centered Communication in Cancer Care: Promoting Healing and Reducing Suffering. Bethesda, MD: National Cancer Institute; 2007. National Institutes of Health Publication 07-6225.

What is the evidence in Support of Communications Skills?

Patient satisfaction

- Task-oriented behaviors – drawing out patients with active listening responses and providing detailed information
- Affective behaviors –socioemotional exchanges, such as responding empathically, showing caring, and addressing the patient’s main concerns

Recall, Understanding and Adherence

- Association of outcomes is less consistent than patient satisfaction
- Be uncomplicated
- Be specific
- Use some repetition
- Minimize jargon
- Check patient understanding

King A, Hoppe RB. “Best Practice” for Patient-Centered Communication: A Narrative Review. *Journal of Graduate Medical Education*, September 2013: Vol. 5, No. 3, pp. 385-393.

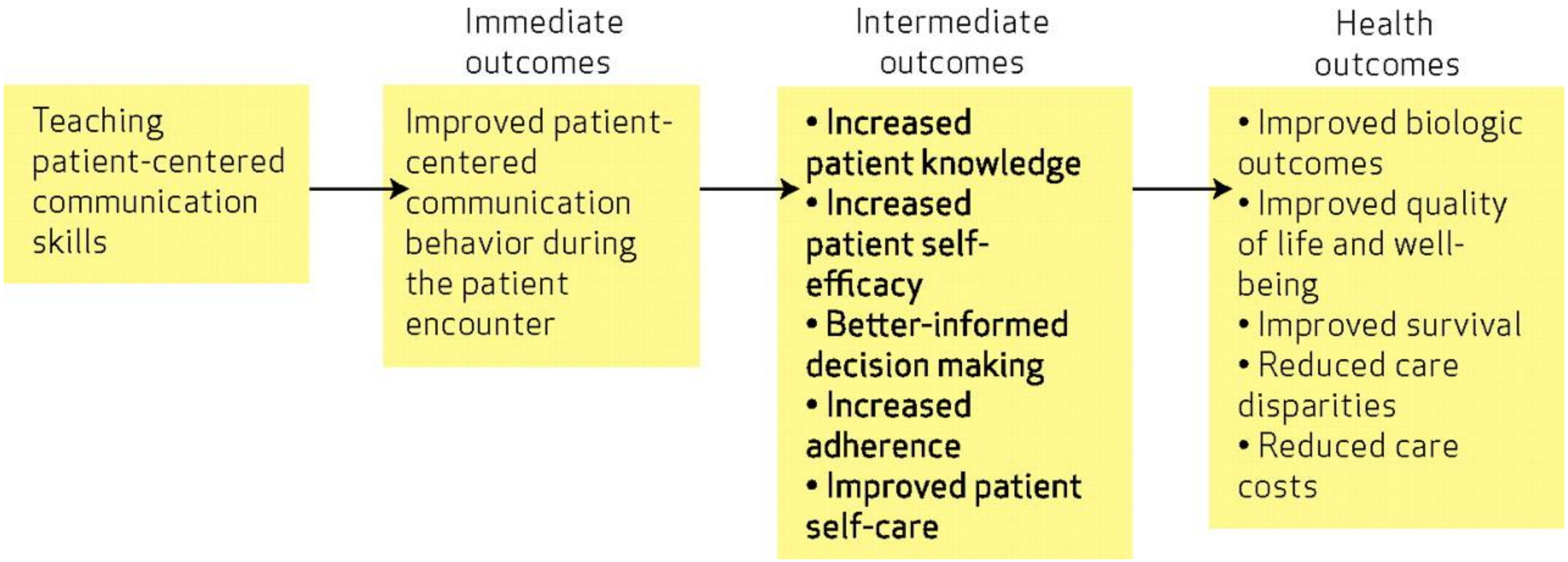
What is the evidence in Support of Communications Skills?

- Health Outcomes

- Communication and Negative Outcomes – patients of physicians with high malpractice claims have twice as many complaints related to communication than do physicians with low malpractice claims

King A, Hoppe RB. “Best Practice” for Patient-Centered Communication: A Narrative Review. *Journal of Graduate Medical Education*, September 2013: Vol. 5, No. 3, pp. 385-393.

Link Between Teaching Patient-Centered Communication Skills And Various Outcomes.



Teaching patient-centered communication skills

Immediate outcomes

Improved patient-centered communication behavior during the patient encounter

Intermediate outcomes

- **Increased patient knowledge**
- **Increased patient self-efficacy**
- **Better-informed decision making**
- **Increased adherence**
- **Improved patient self-care**

Health outcomes

- Improved biologic outcomes
- Improved quality of life and well-being
- Improved survival
- Reduced care disparities
- Reduced care costs

Wendy Levinson et al. Health Aff 2010;29:1310-1318

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Patient View of Physician-Patient Communication

- Patients expressed the wish that their physicians would:
  - Explore the patient’s ideas about the problem (thoughts, worries, feelings, expectations) and take the patient’s input seriously
  - Try to understand the whole person and family influences and how the problem affects the patient’s life
  - Tell the patient what is wrong in plain language
  - Seek common ground and partnership: agree on the nature of the problem, on the priorities, and on the goals of treatment; make management decisions and clarify the respective roles of the physician and patient
  - Strive for an enhanced physician-patient relationship: be approachable and friendly, share decision making, show genuine care, and be respectful

King A, Hoppe RB. “Best Practice” for Patient-Centered Communication: A Narrative Review. *Journal of Graduate Medical Education*, September 2013: Vol. 5, No. 3, pp. 385-393.

Patient-Centered vs. Doctor-Centered Approaches to Communication

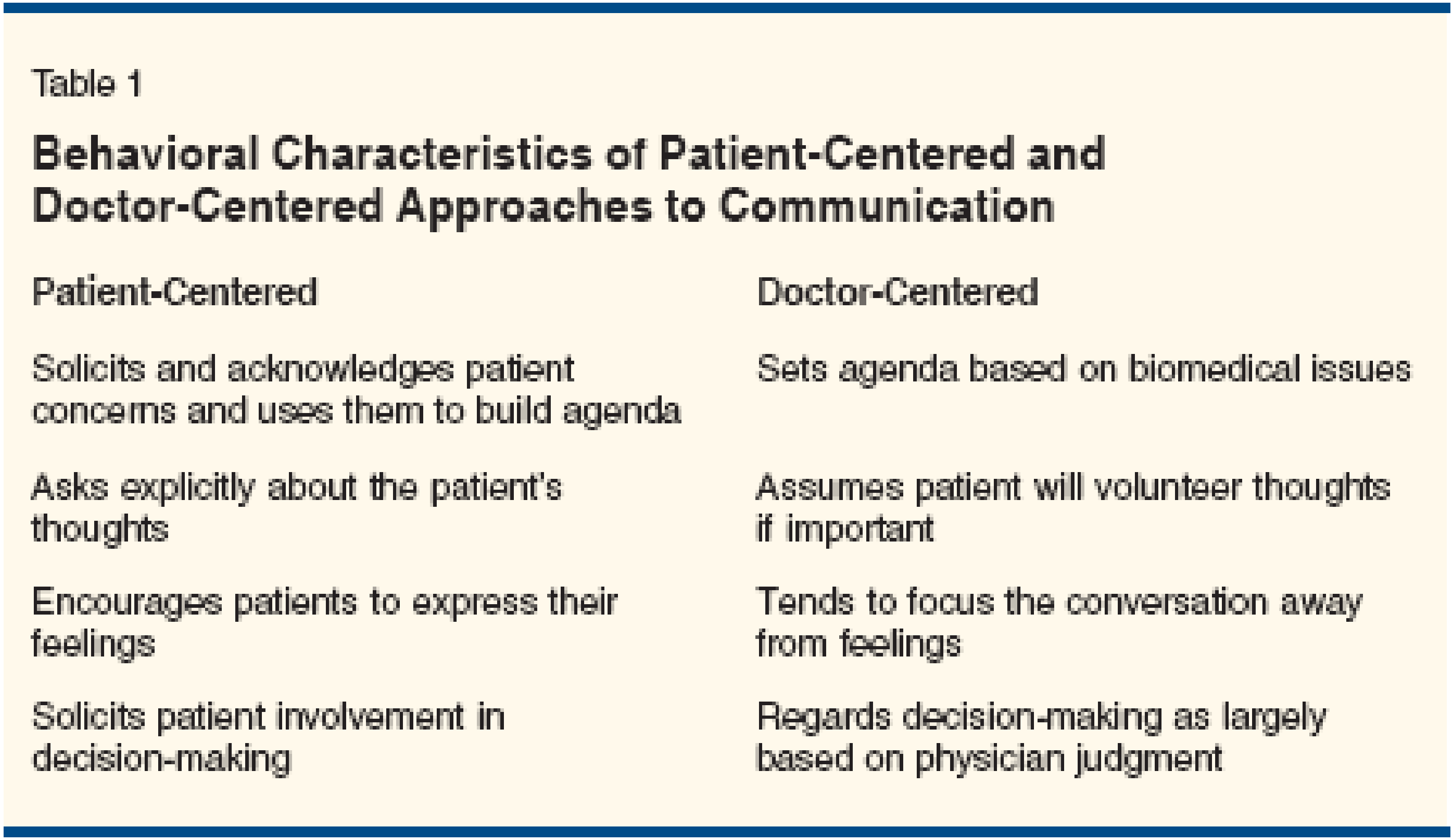

Table 1

Behavioral Characteristics of Patient-Centered and Doctor-Centered Approaches to Communication

Patient-Centered	Doctor-Centered
Solicits and acknowledges patient concerns and uses them to build agenda	Sets agenda based on biomedical issues
Asks explicitly about the patient's thoughts	Assumes patient will volunteer thoughts if important
Encourages patients to express their feelings	Tends to focus the conversation away from feelings
Solicits patient involvement in decision-making	Regards decision-making as largely based on physician judgment

Back A. Patient-Physician Communication in Oncology: What Does the Evidence Show? *Oncology*, January 1, 2006.

Goals for Communication in Medical Encounters

The 6-Function Model of Epstein and Street, 2007	The 6-Function Model of de Heas and Bensing, 2009
Fostering healing relationships	Fostering the relationship
Exchanging information	Gathering information
	Information provision
Making decisions	Decision making
Enabling patient self-management	Enabling disease-and treatment-related behavior
Responding to emotions	Responding to emotions
Managing uncertainty	

King A, Hoppe RB. “Best Practice” for Patient-Centered Communication: A Narrative Review. *Journal of Graduate Medical Education*, September 2013: Vol. 5, No. 3, pp. 385-393.

Improving Patient-Centered Communication and Decision Making in Cancer: The IOM's Prescription

- Increasing the availability of information (requires knowledge of cost)
- Use of decision aids (written information, web sites, web-based tools, and videos)
- Prioritize clinician training in communication
- Use of care plans
- Use of new models of payment to incentivize patient-centered communication and shared decision-making

Sue Sheridan

pcori

Director of Patient Engagement,
Patient-Centered Outcomes Research Institute (PCORI)

- ***“There are two areas of focus regarding patient centricity in research: patient centeredness and patient engagement. Patient centeredness is defined as research that is based on outcomes that are important to patients. Patient engagement in research is the active participation of patients throughout the entire research process – the planning, the conduct and the dissemination. Patient engagement is the means to the patient centeredness.”***

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Jeremy Gilbert

patientslikeme™

VP, Product and Strategy, **PatientsLikeMe**

- ***Measuring what matters to the patient in the trial itself, and designing the trial as much as possible to accommodate the impact on the patient's life."***

Values and options in cancer care (VOICE): study design

- The intervention targets four key communication skills:
- ***Engaging*** patients and their caregivers to participate in consultations and decisions regarding the patient's care,
- ***Responding*** to patients' concerns,
- ***Informing*** patients about treatment choices, and
- ***Framing*** prognosis using balanced information about best and worst case scenarios.

Hoerger M. et al. Values and options in cancer care (VOICE): study design and rationale for a patient-centered communication and decision-making intervention for physicians, patients with advanced cancer, and their Caregivers. BMC Cancer. 2013; 13: 188.

Patient-Centered Outcomes Research Institute (PCORI)

- United States based non-governmental institute created as part of a modification to the Social Security Act by clauses in the 2010 Patient Protection and Affordable Care Act.

- It is a government-sponsored organization charged with investigating the relative effectiveness of various medical treatments.

- Medicare may consider the Institute’s research in the determining what sorts of therapies it will cover.

Best Practices in Recruiting Strategies

- Involve families in clinical trials outreach and education.
- Include minorities on clinical trials research staff.
- Involve social workers in the accrual and retention of patients in clinical trials.
- Establish cancer centers in institutions that directly serve hard-to-reach populations.
- Concurrently address protocol design issues and patient recruitment.
- Conduct marketing research to determine effective approaches to patient recruitment

http://cro.rbhs.rutgers.edu/documents/clinical_trials_recruitment_and_enrollment.pdf

Patient Navigator Research Program

- $25 million in five-year grants awarded to eight research institutions to develop innovative Patient Navigator programs

- Focuses on cancer patients from racial/ethnic groups and low SES or medically underserved

- Sets up *Community Advisory Panels* in each grant area: community leaders, *community-based researchers and clinicians*

Mark Clanton, M.D., M.P.H., U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES NIH/NCI

PATIENT-CENTERED CLINICAL TRIALS

- Patients participate in:

- •Formulating research questions (RQ)
  - Assess patient participation in:
  - Identifying the RQ
  - Designing the intervention
  - Identifying the goals & outcomes
  - Describe the qualifications of subjects
- •Study design
- •Trial conduct
- •Disseminating study results

Howley, Michael, Associate Clinical Professor, LeBow College of Business, Drexel University


KNOW THE SYMPTOMS • SHARE THE KNOWLEDGE