

SYMPTOM ASSESSMENT: PRINCIPLES AND TOOLS

Tatyana I. Ionova, PhD
Multinational Center of Quality of Life Research
National Pirogov Medical Surgical Center, St.Petersburg Campus, RF



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Agenda

- **Background of symptom assessment in advanced cancer**
- **Principles of symptom assessment**
- **Pain assessment: recommended tool**
- **Fatigue assessment: recommended tool**
- **Multiple symptom assessment: recommended tool**
- **Final comments**

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Symptoms in Advanced Cancer

- **Symptoms are the patient's perceptions of abnormal physiologic stress due to disease or its treatment**
- **Symptoms are states (they change over time)**
- **The majority of patients experience cancer-related symptoms**

Common Symptoms in Advanced Cancer

- ❖ **Pain**
- ❖ **Fatigue**
- ❖ **Depression**
- ❖ **Sleep disturbance**
- ❖ **Nausea**
- ❖ **Dyspnea**
- ❖ **Constipation**

Why to Assess Symptoms

- + Symptom management – major focus of care**
- + Many cancer patients suffering from severe symptoms are seeking therapies for symptom control**

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Standards of Care for Symptom Management

- ❑ Screening**
- ❑ Assessment**
- ❑ Management**
- ❑ Re-assessment**

Principles of Symptom Assessment

- ❑ **Self-report approach**
- ❑ **Measure the concept of interest**
- ❑ **Multidimensional approach**
- ❑ **Charaterization, evaluation, monitoring,
re-evaluation of symptoms**

Principles of Symptom Assessment

- ❖ **In clinical practice - systematically, regularly, with relevant time recall**
- ❖ **In clinical research - depending of the goals**

Development of Symptom Assessment Tools: Criteria for a "Gold Standard"

- **Simple**
- **Brief**
- **Easy for interpretation**
- **Multiple items but not necessarily multiple scales**
- **Psychometrically validated (published info about reliability and validity)**
- **Appropriate for clinical trials and clinical practice**
- **Relatively invariant across cultures**

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Pain in Advanced Cancer

- **Pain – a subjective sensation which can be described according to several relevant features or attributes (quality, location, intensity, emotional impact, frequency, etc.)**
- **Prevalence – 75 - 90%**
- **One of the symptoms patients fear most**
- **Unrelieved pain causes significant distress**
- **Inadequate pain management – 40-70% patients (differs across countries)**
- **Availability of excellent therapies**

Pain Assessment

- **Failure to assess pain is the most common cause of poor pain control**
- **Patient's self-reports**
- **Comprehensive pain assessment**
 - **intensity – key issue**
 - **interference with activities – additional issue**

NCCN V.1, 2005

Components of Pain

- **Sensory**
 - **Intensity**
 - **Quality**
- **Reactive**
 - **Affective**
 - **Motivational**
 - **Interference with activities**

Pain Assessment Tools

- **Unidimensional**
 - Visual analogue scales (VAS)
 - Categorical verbal rating scales (VRS)
 - Categorical numerical rating scales (NRS)
- **Multidimensional**
 - **Brief Pain Inventory**
 - McGill Pain Questionnaire
 - Memorial Pain Assessment Card
 - Wisconsin Brief Pain Questionnaire

Brief Pain Inventory (BPI)

**Author - C.S. Cleeland et.al. , MD Anderson Cancer
Center, Houston**

Created - 1989



Date: / /
(month) (day) (year)

Study Name: _____

Subject's Initials : _____

Protocol #: _____

Study Subject #:

PI: _____

Revision: 07/01/05

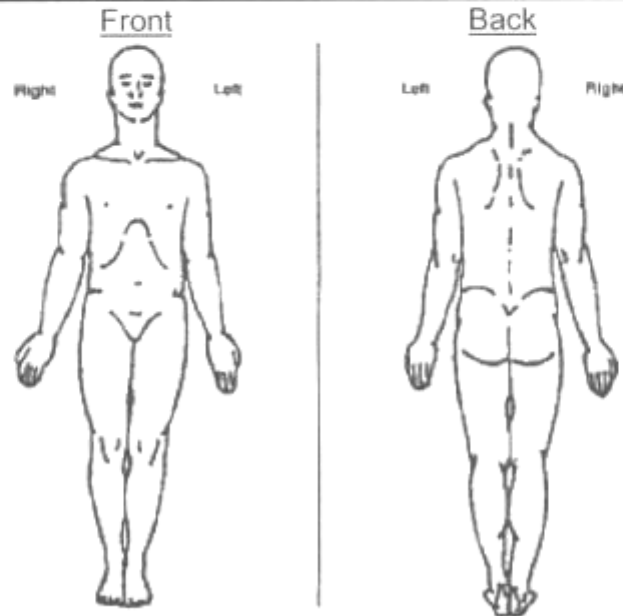
PLEASE USE
BLACK INK PEN

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

Yes No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by marking the box beside the number that best describes your pain at its **worst** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10

Brief Pain Inventory

- **Easy to administer**
- **Information about history, intensity, location, and quality of pain**
- **Clear in interpretation**
- **Translated and validated in many different languages**
- **Intuitive classification of mild, moderate and severe pain**

Serlin RC et.al., 1995; Cleeland et.al. 1997

Brief Pain Inventory

- **Used in clinical practice**
- **Used in assessing efficacy of pain interventions, facilitating cross-national trials in pain management**
- **Recommended by an Expert Working Group of the EAPC for use in clinical research in palliative care**

Brief Pain Inventory

BPI Features

- **Responsiveness:** Responds to both behavioral and pharmacological pain interventions
- **Reliability:** Cronbach alpha reliability ranges from .77 to .91
- **Validation:** The BPI has been validated in 20 different languages by examining the consistency of its two factor structure (factors: severity of pain and impact of pain).

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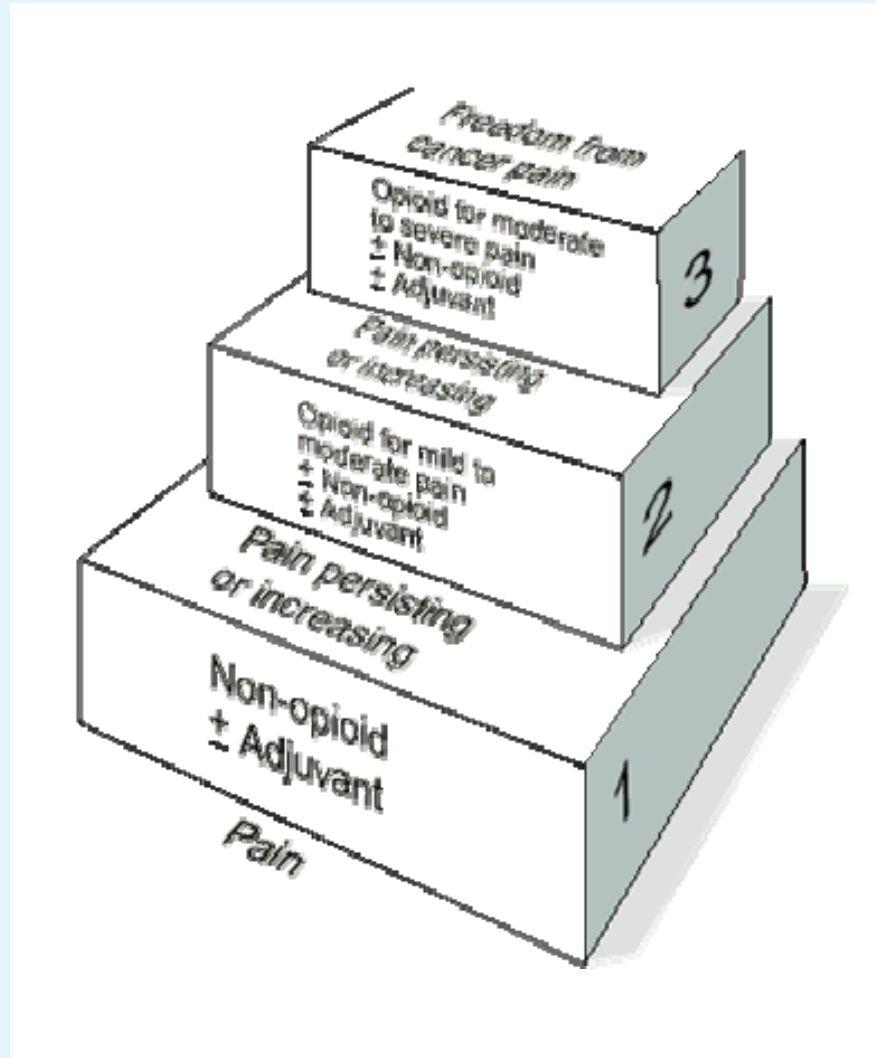
Brief Pain Inventory

BPI Features

- **Purpose:** To assess the severity of pain and the impact of pain on daily functions
- **Population:** Patients with cancer pain and pain from other chronic diseases
- **Assessment Areas:** Severity of pain, impact of pain on daily function, location of pain, pain medications, and amount of pain relief in the past 24 hours or the past week
- **Method:** Self-report, interview, or via an Interactive Voice Response System (IVR)
- **Time required:** 5 minutes (short form), 10 minutes (long form)
- **Scoring:** No scoring algorithm, but "worst pain" or the arithmetic mean of the 4 severity items can be used as measures of pain severity and the arithmetic mean of the 7 interference items can be used as a measure of pain interference

MD Anderson Cancer Center website

WHO 3-step Analgesic Ladder



Cancer pain management is considered adequate when there is congruence between the patient's reported level of pain and the potency of the prescribed analgesic drug

Pain Ratings

- **Mild** **1-4**
- **Moderate** **5-6**
- **Severe** **7-10**

Serlin RC et.al., 1995

Pain Management Index (PMI)

(Cleeland CS, 1991)

- **Compares the most potent analgesic prescribed for a patient relative to the level of the pain reported by the patient**
- **To construct the PMI the level of analgesic drug therapy should be compared with level of pain**

Pain Management Index

Level of pain	Level of analgesic drug therapy
0 (no pain)	0 (no analgesic drug)
1 (mild pain)	1 (non-opioid)
2 (moderate pain)	2 (weak opioid)
3 (severe pain)	3 (strong opioid)

Pain Management Index

- The PMI is computed by subtracting the pain level from the analgesic level
- Ranges in value from -3 (a patient with severe pain receiving no analgesic drug) to +3 (a patient receiving morphine or equivalent, and reporting no pain)
- **Negative PMI scores are considered to be an indicator of inadequate orders for analgesic drugs**

Pain Management Index Matrix

	0 no pain	1 mild pain	2 moderate pain	3 severe pain
0 No drug	0	-1	-2	-3
1 Non-opioid	1	0	-1	-2
2 Weak opioid	2	1	0	-1
3 Strong opioid	3	2	1	0

Pain Management Index in the population of advanced cancer patients (data from Russian cooperative study, 2002)

	0 no pain	1 mild pain (1-4)	2 moderate pain (5-6)	3 severe pain (7-10)
0 No drug	81	25	4	6
1 Non-opioid	12	44	27	37
2 Weak opioid	0	6	7	17
3 Strong opioid	7	5	4	9

Among a total of **191** patients who had pain (pain worst >0), not having surgery, and understanding rating system, the percentage of negative PMI was **60,7%** (**N=116**). The PMI included 3 percent of “-3”, 22 percent of “-2”, 42 percent of “-1”.

Pain in Patients with Cognitive Impairment

- **Common in palliative care patients**
- **No valid instrument at present**
- **Doloplus2, Checklist of Non-verbal Pain Indicators– feasible observational tools to assess pain in patients with cognitive impairment (*J.C. Holen et.al., 2005, S. Songe-Moller, 2005*)**
- **Further research is needed**

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FATIGUE

Fatigue – a subjective sense of lack of energy to perform usual physical and mental activities, followed by a variety of individually experienced manifestations (symptoms).

Novik A., 2004

Fatigue in Advanced Cancer

- **Prevalence 75-100%**
- **Under-reported**
- **Underdiagnosed**
- **Undertreated**

NCCN, V.1, 2006

Fatigue Diagnostic Algorithm

Screening



No fatigue

Mild

Moderate or Severe



Intervention



Re-evaluation



Monitoring

Fatigue Assessment

- **Self-report**
- **Additional information**
 - **history**
 - **physical examination**
 - **laboratory data**
 - **description of patient behavior by family members**

Fatigue Rating

- **Mild** **1-3**
- **Moderate** **4-6**
- **Severe** **7-10**

NCCNV.1, 2006

Fatigue Assessment Tools

Unidimensional

- Visual analogue scales (VAS)
- Categorical verbal rating scales (VRS)
- Categorical numerical rating scales (NRS)

Multidimensional

- **Brief Fatigue Inventory (BFI)**
- **Fatigue Assessment Instrument (FAI)**
- **Fatigue Symptom Inventory (FSI)**
- **Cancer Fatigue Scale**

Brief Fatigue Inventory

**Authors - C.S. Cleeland, T.Mendoza , MD Anderson
Cancer Center, Houston**

Created - 1999

Brief Fatigue Inventory

STUDY ID# _____

HOSPITAL # _____

Date: ____/____/____

Time: _____

Name _____

Last

First

Middle Initial

Throughout our lives, most of us have times when we feel very tired or fatigued. Have you felt unusually tired or fatigued in the last week? Yes No

1. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your fatigue right NOW.

0 1 2 3 4 5 6 7 8 9 10
No Fatigue As bad as you can imagine

2. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your USUAL level of fatigue during past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Fatigue As bad as you can imagine

3. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your WORST level of fatigue during past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Fatigue As bad as you can imagine

4. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your:

A. General activity

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely Interferes

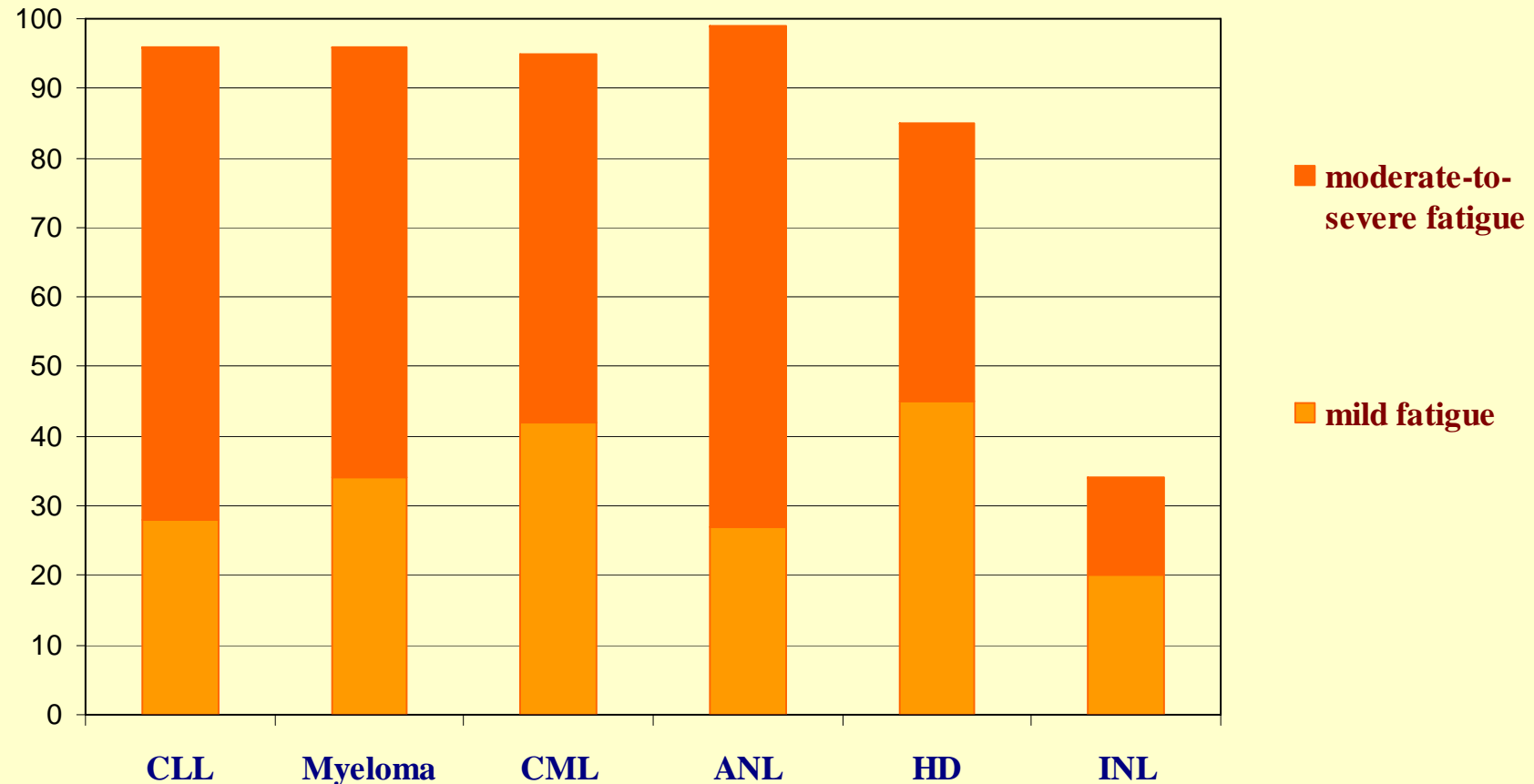
Brief Fatigue Inventory (BFI)

Features of the BFI

- **Purpose:** To assess the severity of fatigue and the impact of fatigue on daily functioning
- **Population:** Patients with fatigue due to cancer and cancer treatment
- **Assessment Areas:** Severity of fatigue and the impact of fatigue on daily functioning in the past 24 hours
- **Method:** Self-report, interview, or via an Interactive Voice Response system (IVR)
- **Time required:** 5 minutes
- **Scoring:** A global fatigue score can be obtained by averaging all the items on the BFI
- **Reliability:** Cronbach's alpha reliability ranges from 0.82 to 0.97

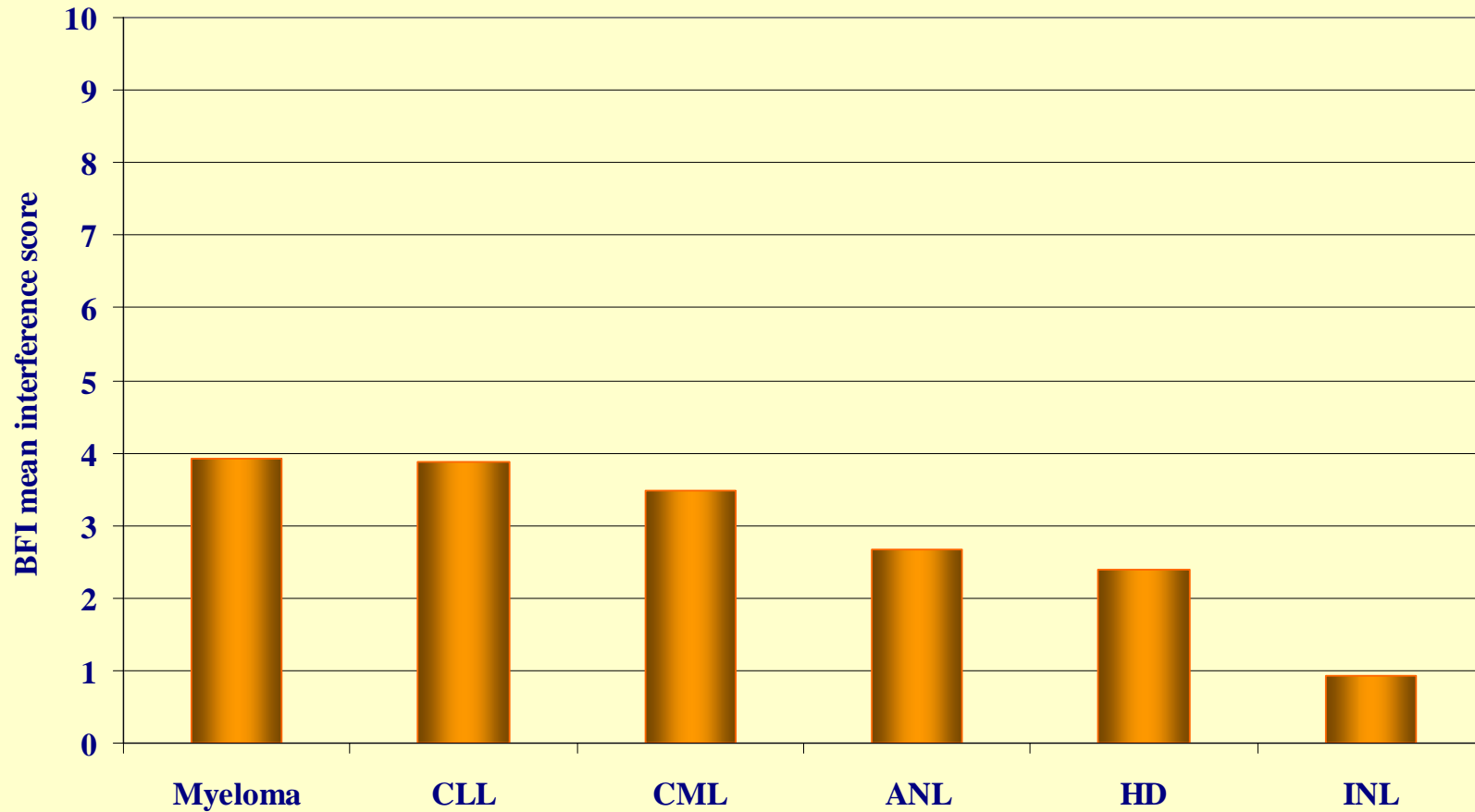
MD Anderson Cancer Center website

Fatigue Prevalence in Patients With Advanced Hematological Malignancies



$p < 0.001$

Fatigue Interference in Patients With Advanced Hematological Malignancies



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Symptom Clusters in Advanced Cancer

- **Symptom clusters are defined as the co-occurrence of two or more symptoms (pain, fatigue, depression) that typically follow the same time course in response to disease or treatment**
- **Most symptom clusters are defined by patient subjective report of multiple symptoms simultaneously**
- **Some symptoms (cognitive impairment, neurosensory deficit) need to be verified by additional objective testing**

Measurement of Multiple Symptoms

- **Measure symptom severity and interference**
- **Define a set of “core” symptoms**
- **Employ a simple structure for ease of comprehension**
- **Ease of structure for translation to use in international clinical trials**

Symptom Measurement Tools

- ❑ **M.D. Anderson Symptom Inventory**
- ❑ **Memorial Symptom Assessment Scale**
- ❑ **Edmonton Symptom Assessment System**

The M.D Anderson Symptom Inventory

**Authors - C.S. Cleeland, T.Mendoza , MD
Anderson Cancer Center, Houston**

Created - 2000

The M.D Anderson Symptom Inventory (MDASI)

- **13 core items measure symptoms severity,
6 items measure symptom interference**
- **0-10 scale is friendly for clinical and research applications**
- **Option for module development for specific diseases or treatments**
- **Available in many languages**
- **Used in clinical trials and clinical practice**

M.D.Anderson Symptom Inventory

13 Symptoms

- Pain
- Fatigue (tiredness)
- Nausea
- Disturbed sleep
- Distress
- Shortness of breath
- Remembering things
- Lack of appetite
- Drowsiness
- Dry mouth
- Sadness
- Vomiting
- Numbness or tingling

Symptoms interference with

- General activity
- Mood
- Work
- Relations with other people
- Walking
- Enjoyment of life

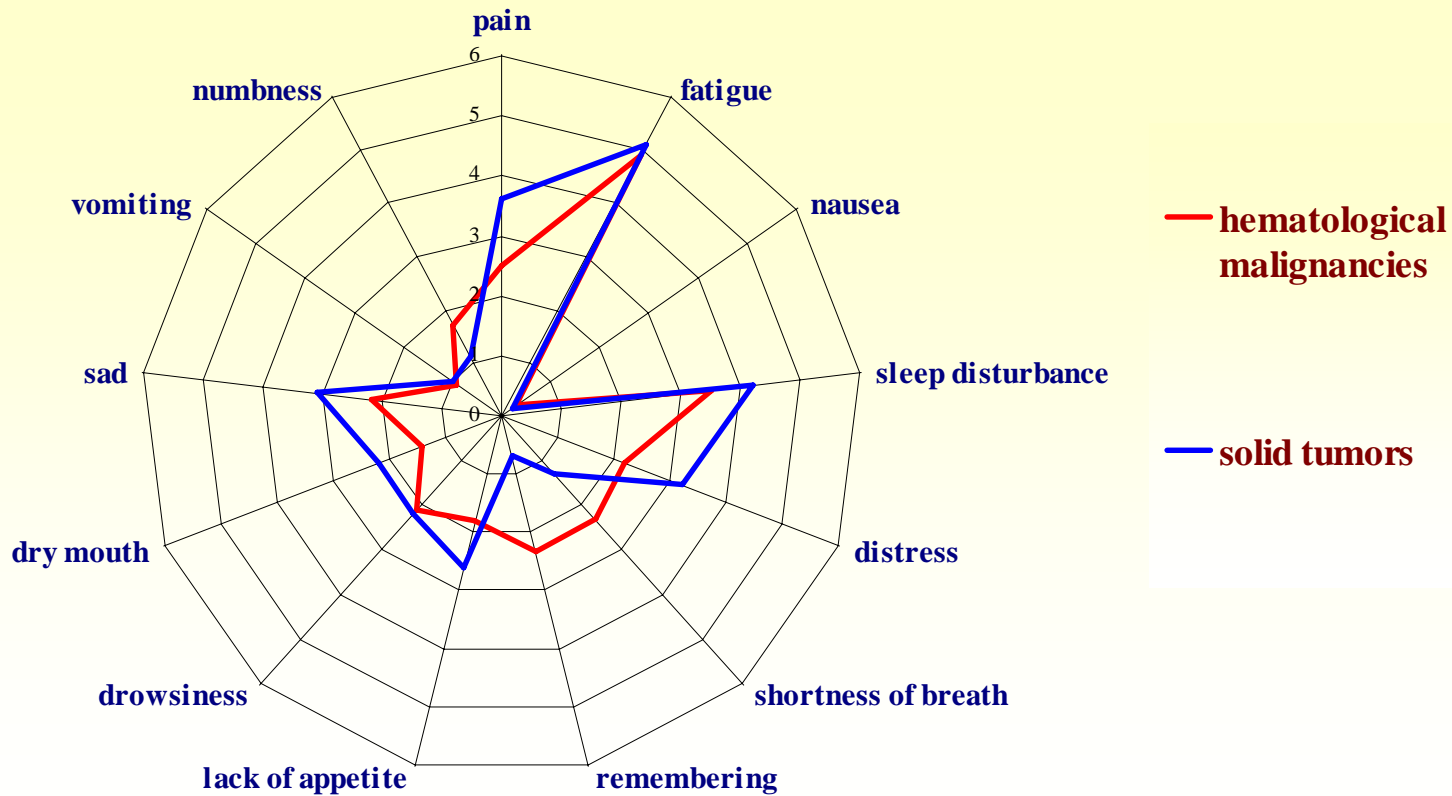
The M.D Anderson Symptom Inventory

MDASI Features

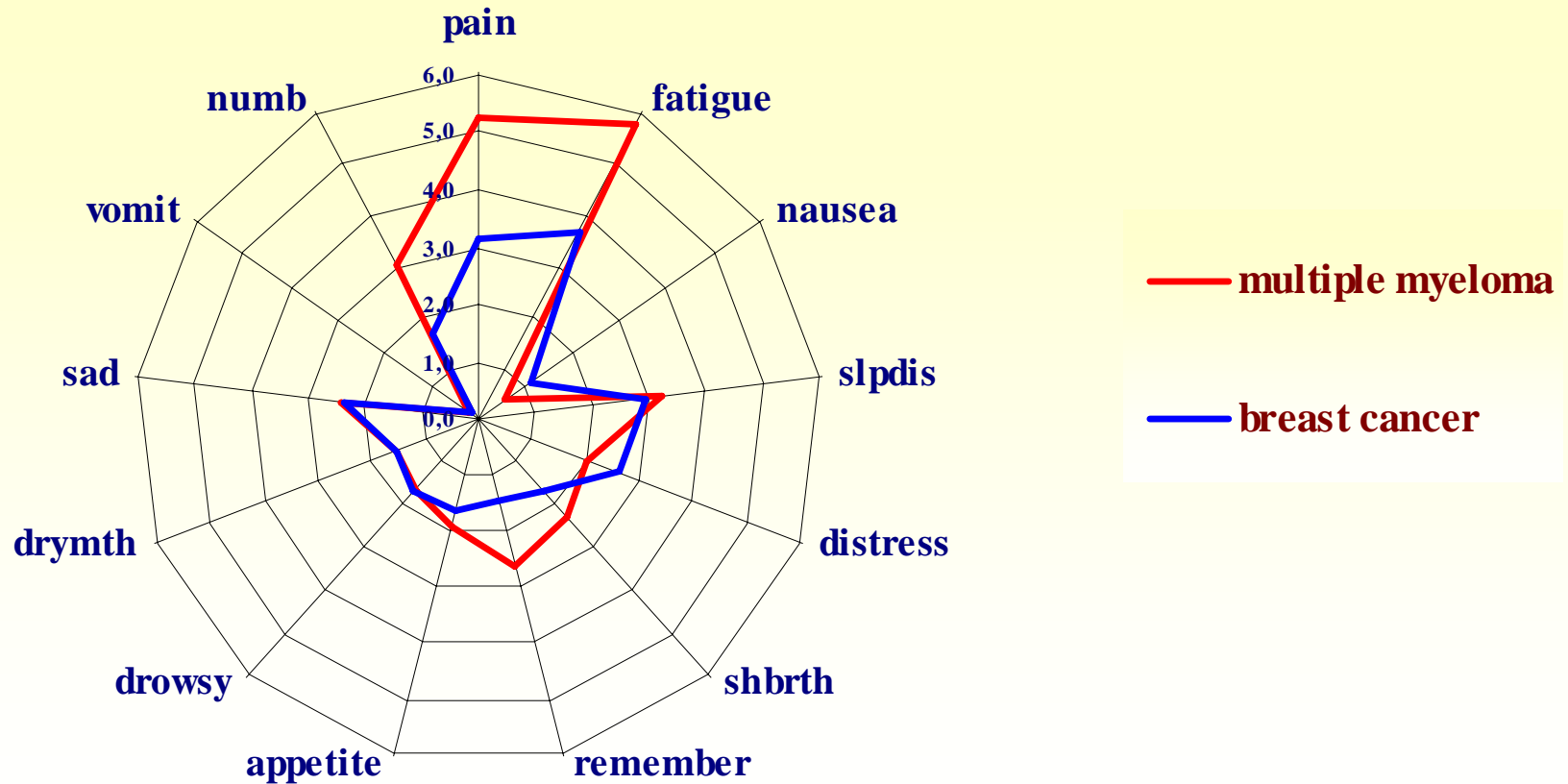
- **Purpose:** To assess the severity of multiple symptoms and the impact of symptoms on daily functioning
- **Population:** Patients with symptoms due to cancer and cancer treatment
- **Assessment Areas:** Severity of multiple symptoms and the impact of symptoms on daily functioning during the last 24 hours
- **Method:** Self-report, interview, or via a telephone-based interactive voice response system
- **Time required:** 5 minutes
- **Psychometric validation:** 9 languages
- **Linguistic validation:** 22 languages

MD Anderson Cancer Center website

Symptom Profiles in Patients with Solid Tumors and Hematological Malignancies



Symptom Profiles in Patients with Breast Cancer and Multiple Myeloma



Symptom Assessment Tools – BPI, BFI, MDASI Ease of Use and Readability

- **Symptom assessment tools are understandable even by grade-school children, according to the Flesch scoring systems described below.**
- **Flesch Reading Ease score: Rates text on a 100-point scale; the higher the score, the easier it is to understand the document. Most standard documents aim for a score of approximately 60 to 70.**
- **Flesch-Kincaid Grade Level score: Rates text on a U.S. grade-school level. For example, a score of 8.0 means that an eighth grader can understand the document. Most standard documents aim for a score of approximately 7.0 to 8.0.**

	Flesch Reading Ease Score	Flesch-KincaidGradeLevel
BPI-SF	83.5	5.1
BFI	70.7	6.4
MDASI	82.3	3.6

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Lessons to be Learned

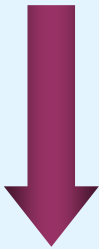
- ❑ Each patient has a right to symptom assessment and symptom management**
- ❑ Appropriate symptom assessment tools to assess symptoms in patients with advanced cancer are available**
- ❑ Symptom assessment should be provided systematically and regularly in clinical practice**
- ❑ Further studies in symptom research are needed to improve symptom assessment**

QUALITY OF CANCER CARE

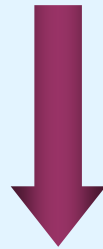


MAJOR ELEMENTS

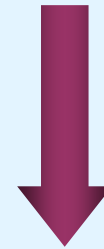
**Use of
evidence-based
treatment**



**Treatment is
being done well**

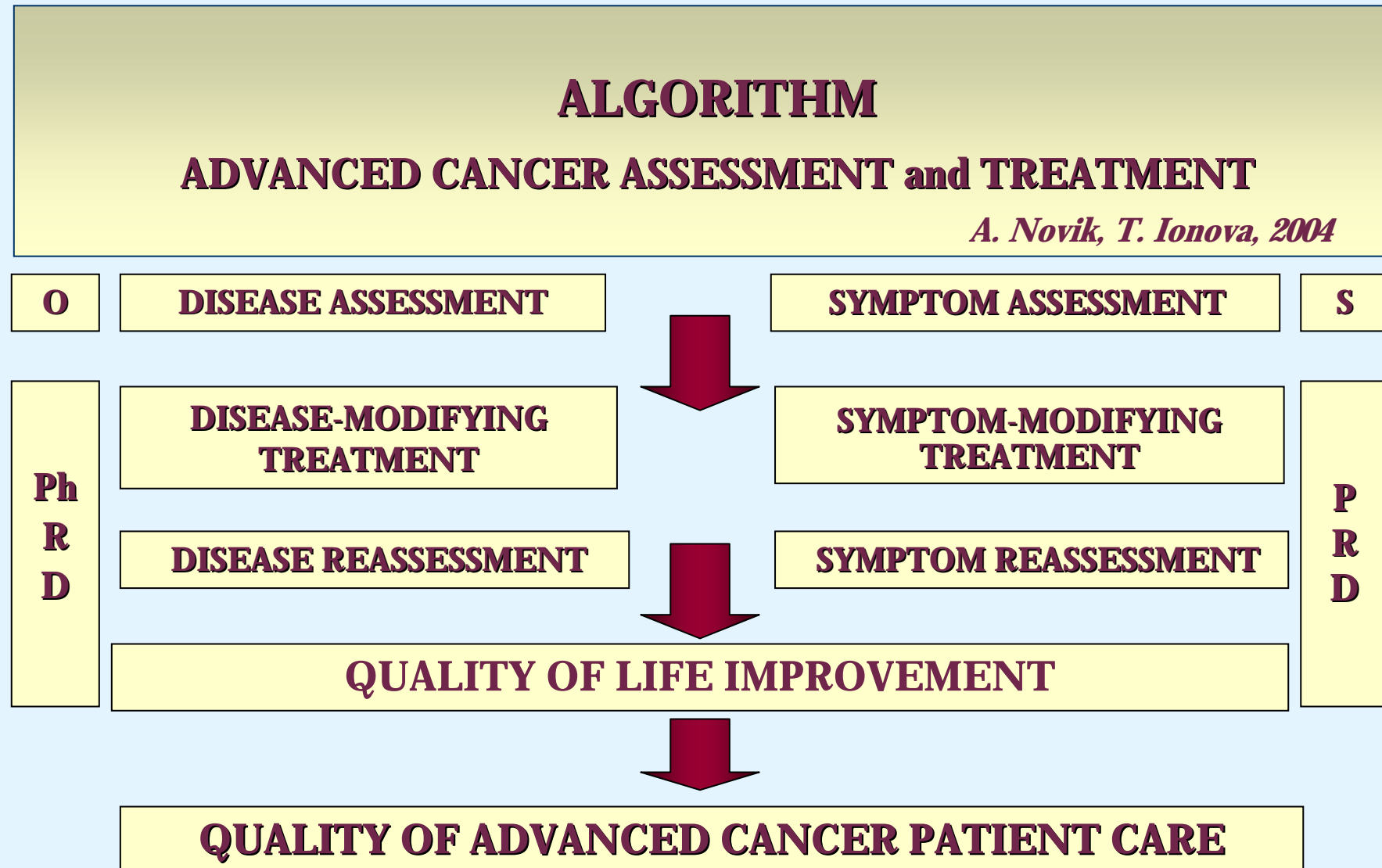


**Treatment of
a patient, not
just a disease**



Quality of cancer care

How can we incorporate PRD in clinical practice?



O – objective, **PhRD** – Physician Reported Data **S** - subjective, **PRD** – Patient Reported Data