Implementation of research into clinical practice: Building structure and culture

Patient's Problems

- **Pain (80%)**
- **Fatigue (90%)**
- **Weight Loss (80%)**
- **Lack of Appetite (80%)**
- **Nausea, Vomiting (90%)**
- **Anxiety (25%)**
- **Shortness of Breath (50%)**
- **Confusion-Agitation (80%)**

What does palliative care do?

- Symptom assessment
- Symptom management
- Psychosocial support for patients
- Psychosocial support for families
- Discharge planning
- Research and education in all these areas

Appendix C Symptom Assessment System

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Patient Name: _____
MDACC #: _____
Date: _____

SYMPTOM CONTROL & PALLIATIVE CARE
SYMPTOM ASSESSMENT

No Pain	0 1 2 3 4 5 6 7 8 9 10	Worst Pain Imaginable
No Fatigue	0 1 2 3 4 5 6 7 8 9 10	Worst Fatigue Imaginable
No Nausea	0 1 2 3 4 5 6 7 8 9 10	Worst Nausea Imaginable
No Depression	0 1 2 3 4 5 6 7 8 9 10	Worst Depression Imaginable
No Anxiety	0 1 2 3 4 5 6 7 8 9 10	Worst Anxiety Imaginable
No Drowsiness	0 1 2 3 4 5 6 7 8 9 10	Worst Drowsiness Imaginable
No Shortness Of Breath	0 1 2 3 4 5 6 7 8 9 10	Worst Shortness of Breath Imaginable
Best Appetite	0 1 2 3 4 5 6 7 8 9 10	Worst Appetite Imaginable
Best Sleep	0 1 2 3 4 5 6 7 8 9 10	Worst Sleep Imaginable
Best Feeling Of Wellbeing	0 1 2 3 4 5 6 7 8 9 10	Worst Feeling of Wellbeing Imaginable

Assessed by: _____

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FOLLOW-UP AND PROGRESS NOTES

PATIENT IDENTIFICATION

DATE

Symptom Control & Palliative Care Symptom Assessment Scale

↑Morphine → ← PE → Heparin

Date: April	4	5	6	7	8	9	10	11	12	13	14	15
Pain (0-10)*												
Fatigue (0-10)*												
Nausea (0-10)*												
Depression (0-10)*												
Anxiety (0-10) *												
Drowsiness (0-10)*												
Shortness of Breath (0-10)*												
Appetite (0-10)*												
Sleep (0-10)*												
Feeling of Wellbeing (0-10)*												
Mini Mental State Score (0 – 30)	30		28		30		29		30		27	
Assessment from: Pt/SO/HCP (If SO or HCP – use red ink)												
Total Opioid MEDD:____mg/day												
Staff Initials (Signature & Title Below)												

* 0 = No Symptom/Best 10 = Worst Imaginable

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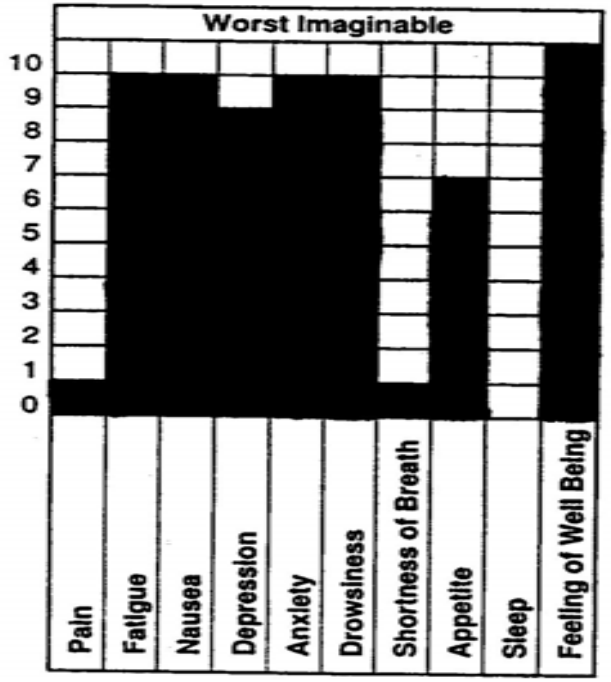
SYMPTOM CONTROL & PALLIATIVE CARE CENTER

PATIENT IDENTIFICATION

1/27/99

Interdisciplinary Assessment & Plan of Care

SYMPTOM ASSESSMENT



Mini Mental Status Score	29 / 30
Number of years of schooling?	
Mini Mental Status Score Normal for age and education	24
Cage Questionnaire Score (2/4 = a positive Cage)	0 / 4

Information obtain from: Patient _____

Other (specify) _____

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CANCER CENTER

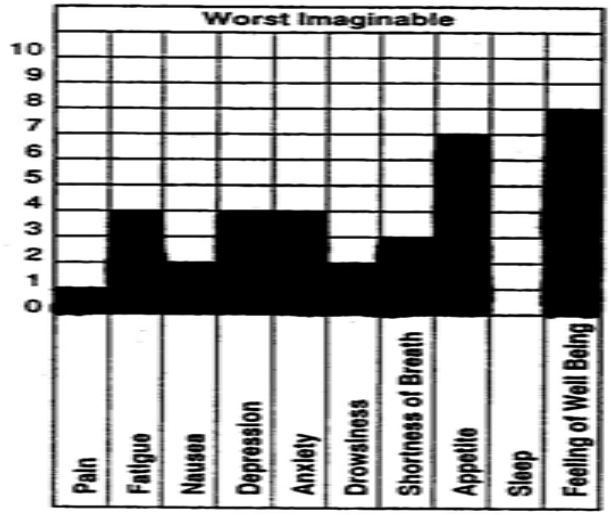
SYMPTOM CONTROL & PALLIATIVE CARE CENTER

PATIENT IDENTIFICATION

Interdisciplinary Assessment & Plan of Care

SYMPTOM ASSESSMENT

1/20/99



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Information obtain from: Patient _____

Other (specify) _____

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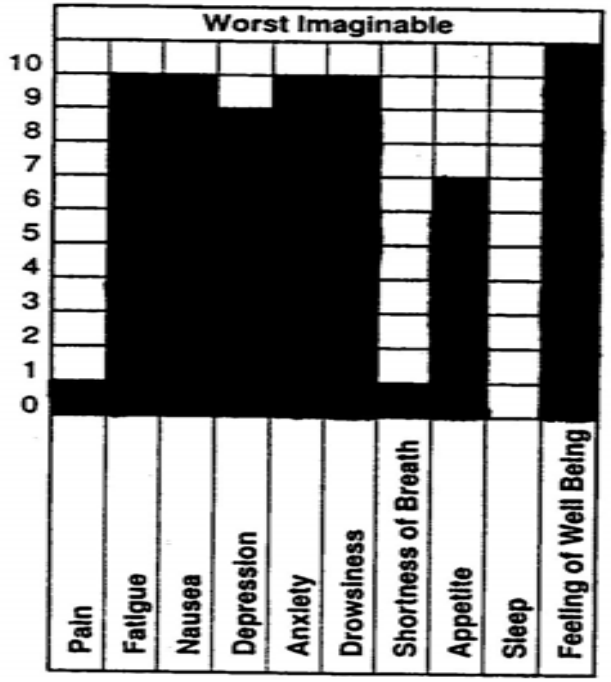
SYMPTOM ASSESSMENT

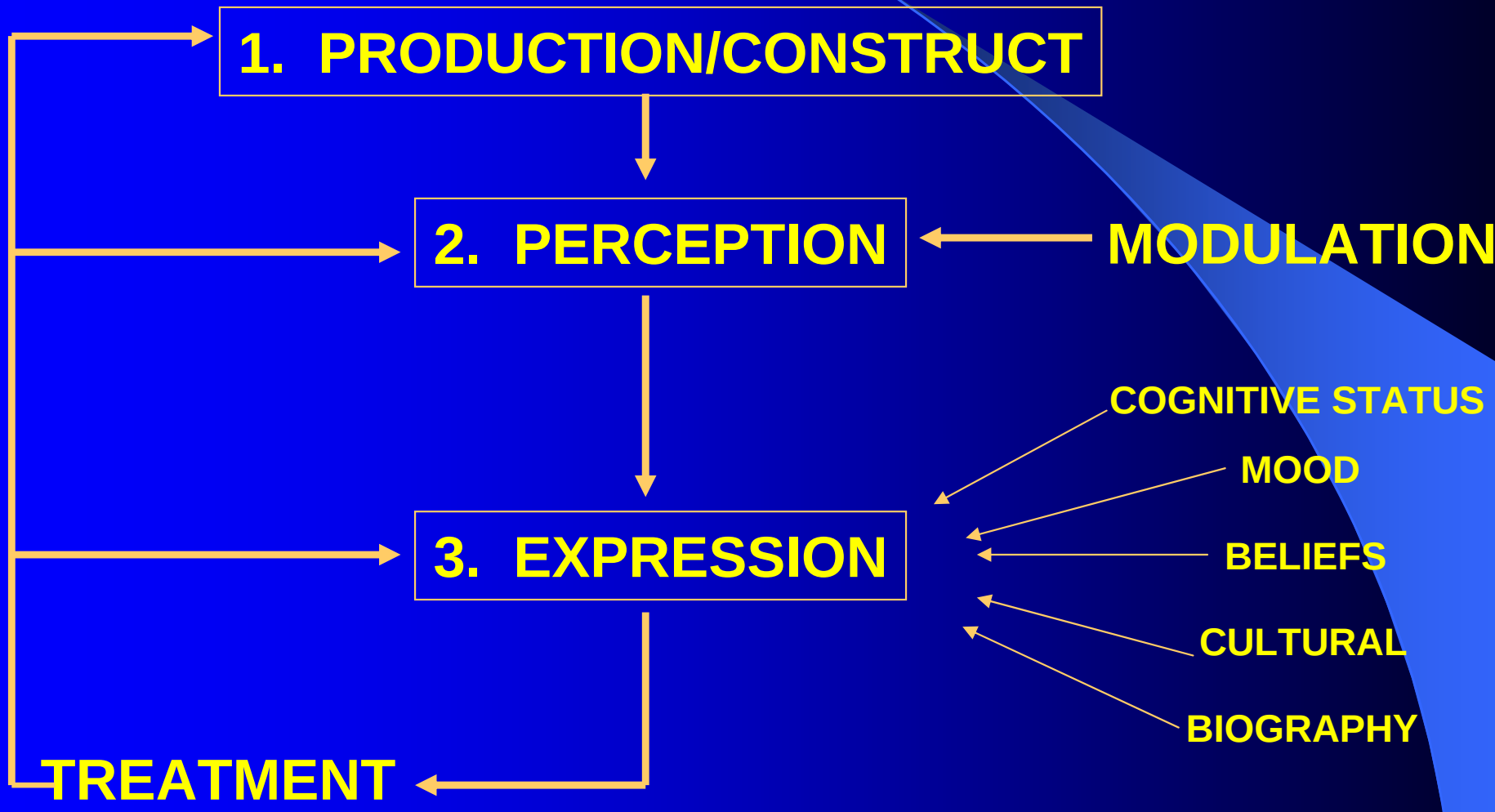


Mini Mental Status Score	29 / 30
Number of years of schooling?	
Mini Mental Status Score Normal for age and education	24
Cage Questionnaire Score (2/4 = a positive Cage)	0 / 4

Information obtain from: Patient _____

Other (specify) _____

Schema of Symptom Construct



Pain Intensity 8/10

	Patient #1	Patient #2
Nociception	85%	30%
Somatization	5%	20%
Coping Chemically	5%	30%
Tolerance	5%	0%
Incidental Pain	0%	20%
	100%	100%

Fatigue 8/10

	Patient 1	Patient 2
Depression	60%	10%
Cachexia	10%	50%
Anemia	10%	30%
Opioids	20%	0%
Autonomic	0%	10%

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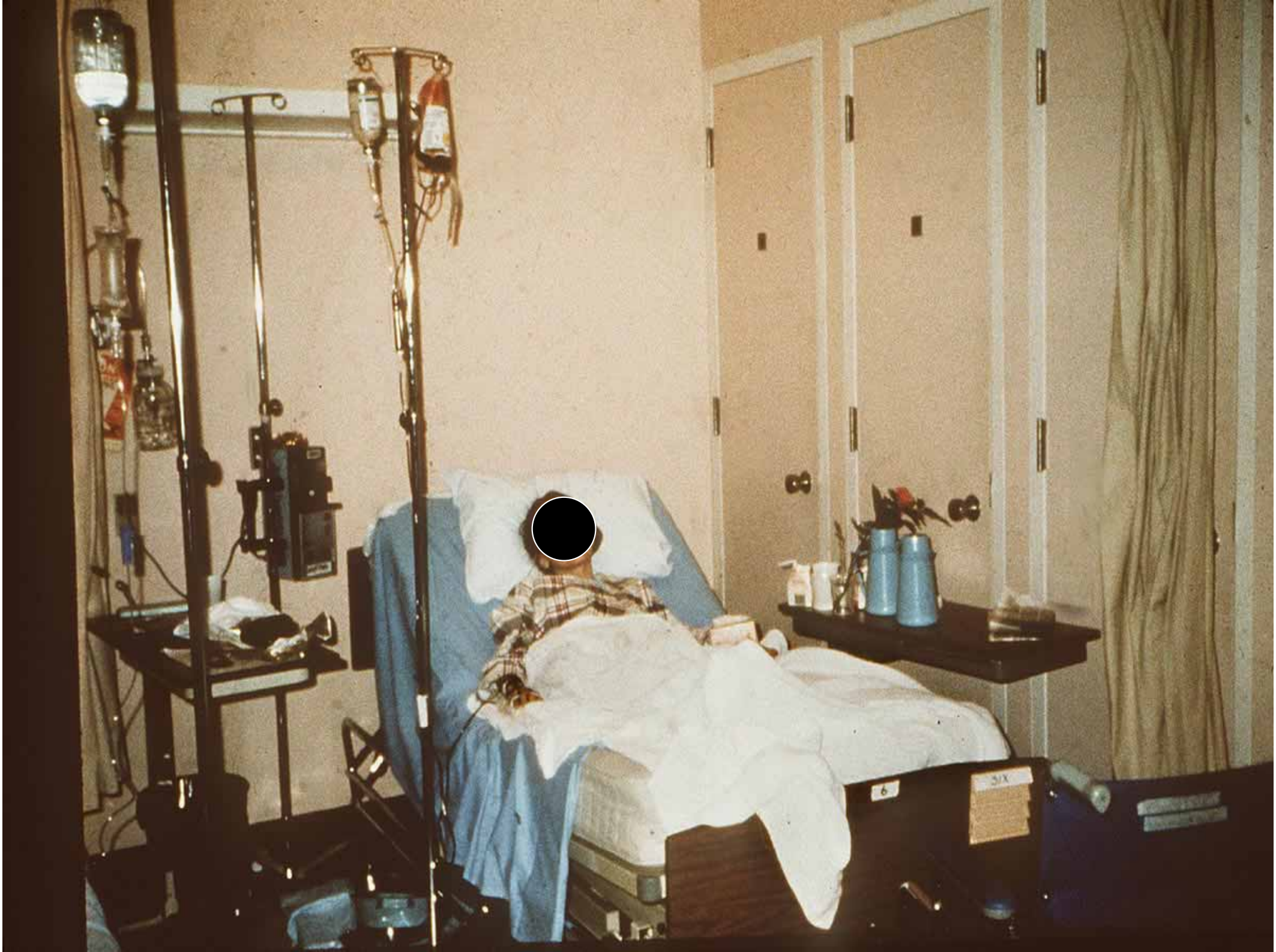
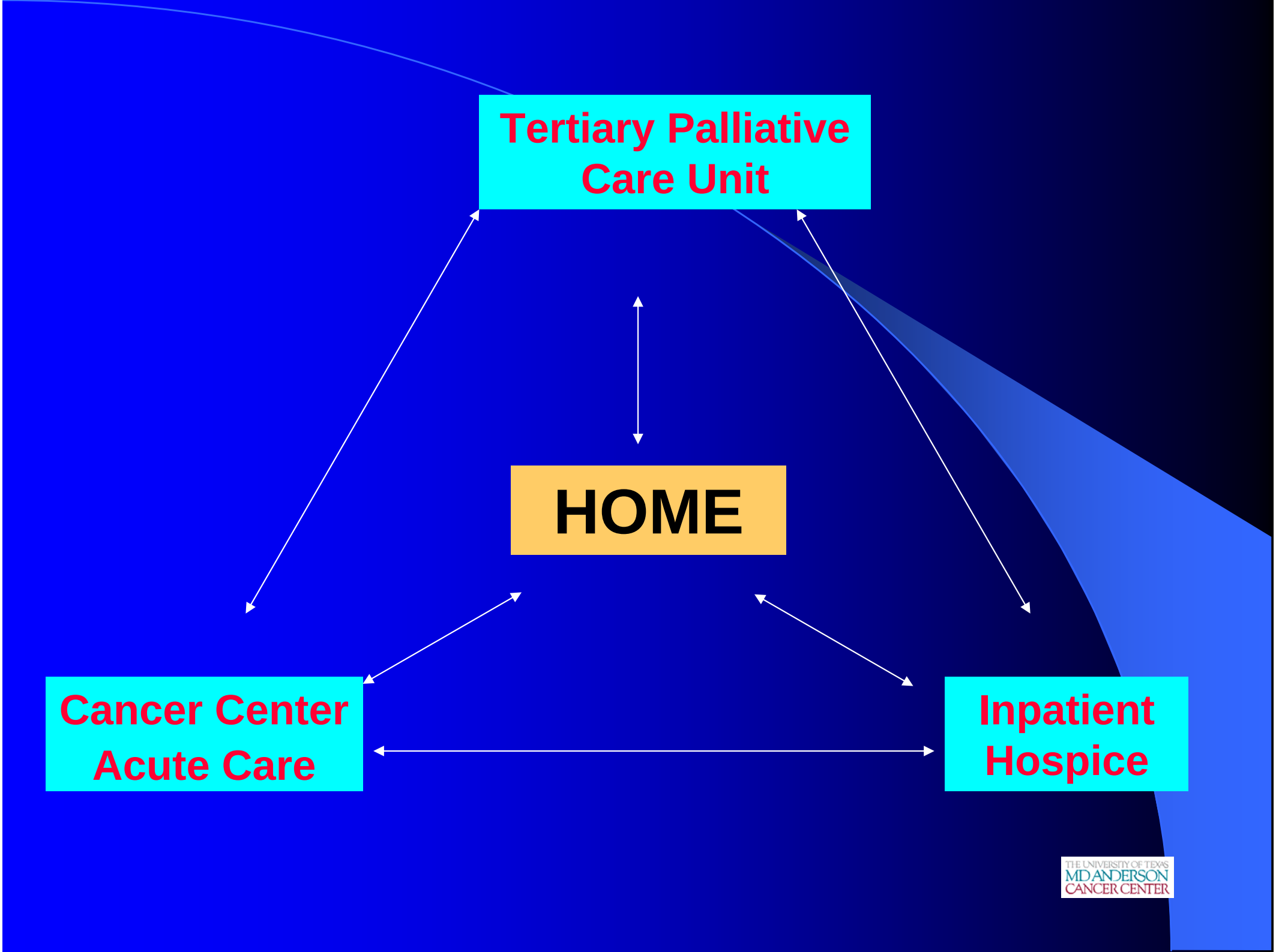
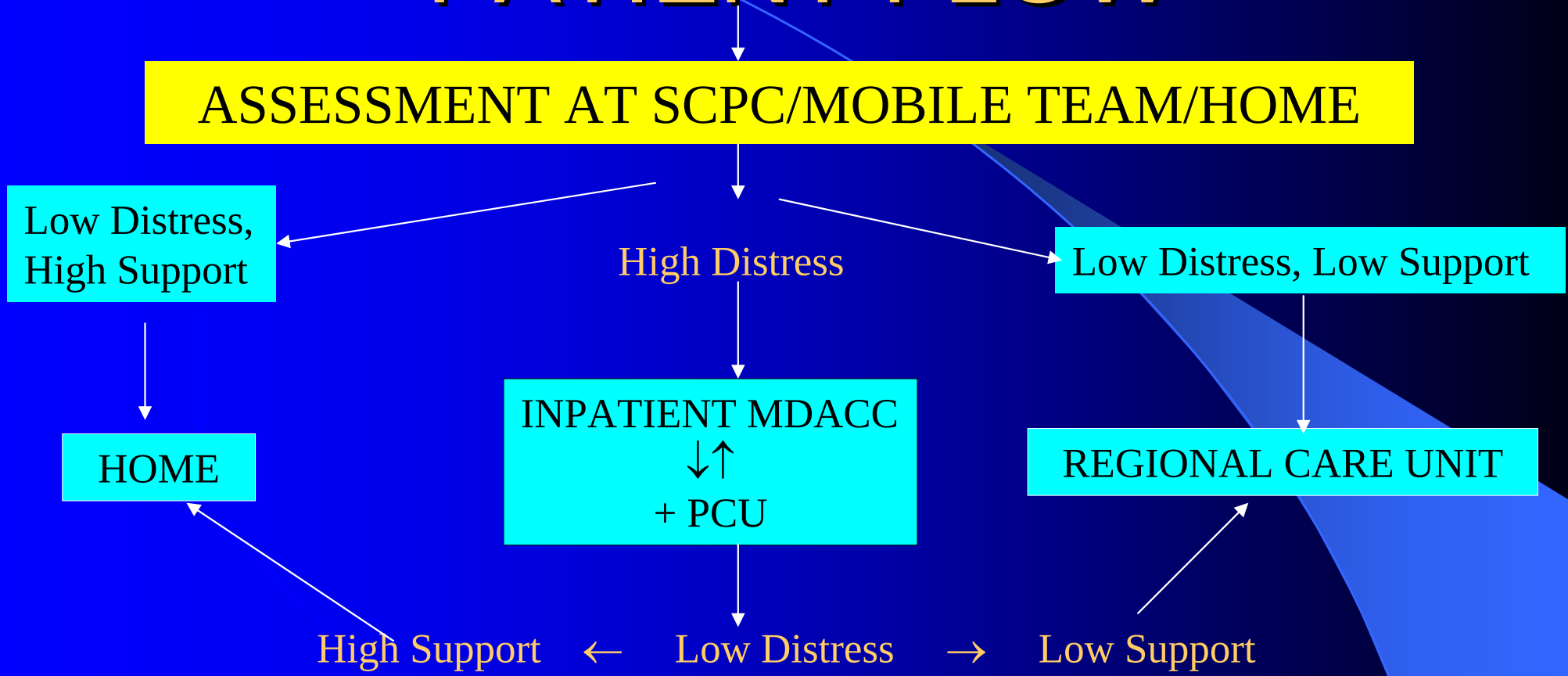



Tertiary Palliative Care Unit
HOME
Cancer Center Acute Care
Inpatient Hospice
THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

PATIENT FLOW



Main Difference with Hospice: 1) All patients will remain in contact with their primary oncologist and will qualify for phase I and Research treatments; 2) Patients will remain as UT MDACC patients.

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1967- 2008: major and succesful clinical infrastructrure

- Critical care medicine
- Emergency medicine

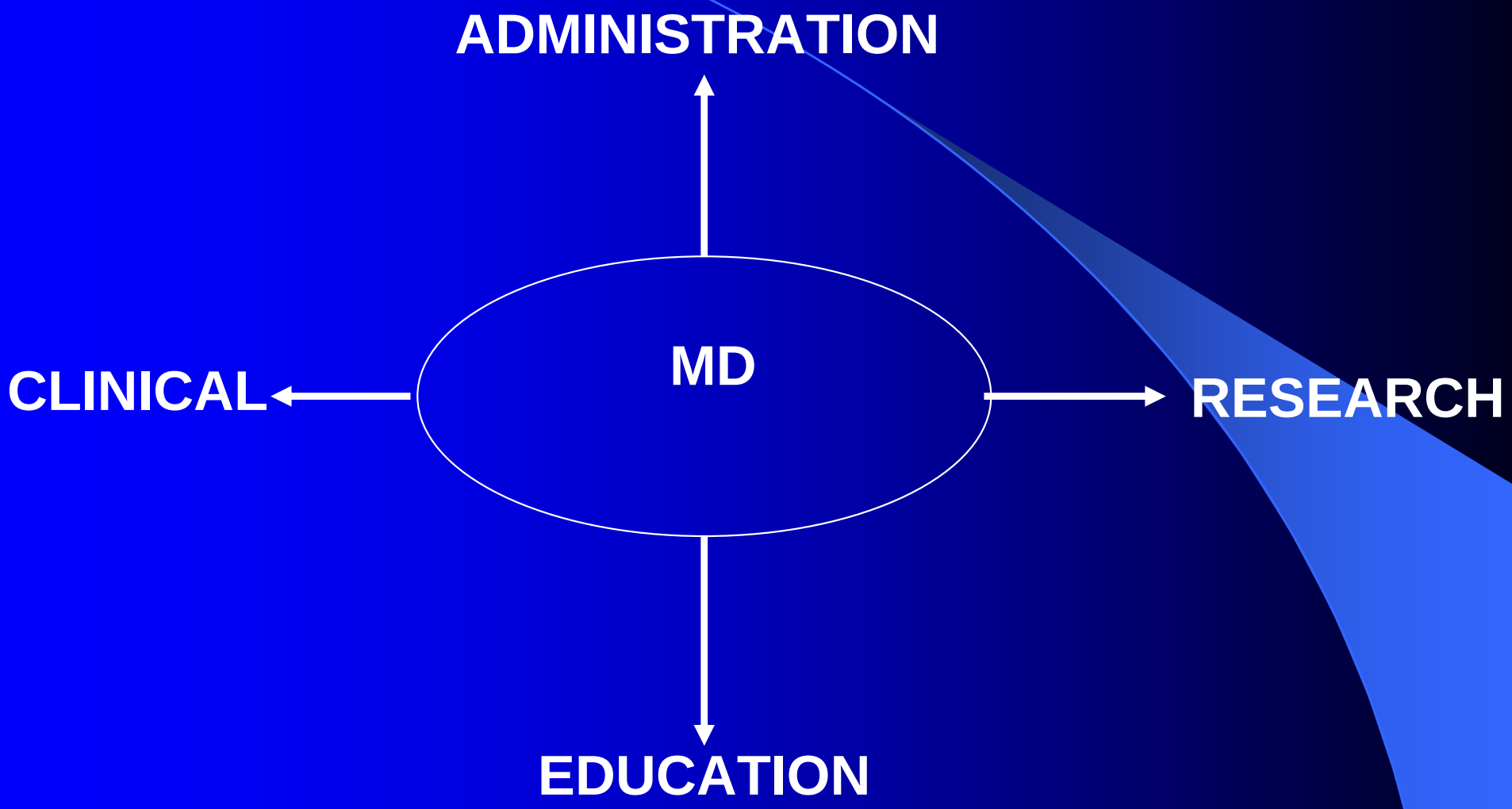
Younger clinical specialties with larger research component

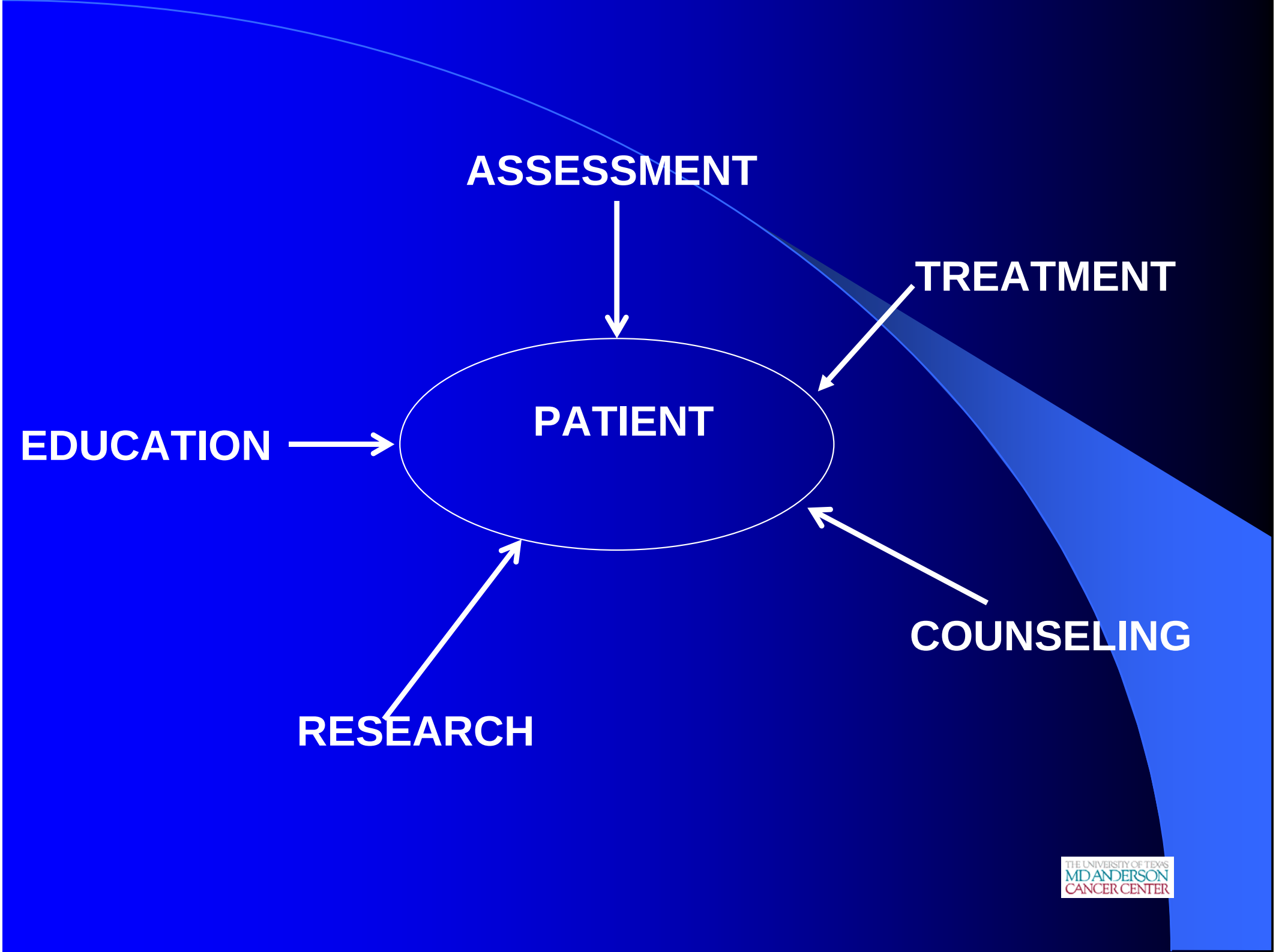
Historical developments

- Emergency medicine, critical care medicine
- Oncology, geriatrics, psychiatry (National Institutes, Administrative structures): mainstream products of organized medicine
- Palliative care: Fringe product

USA and Canada-

- “palliative care research” :geriatricians, oncologists, internists, psychiatrists
- Minimal or even NO clinical programs
- Publish or perish: these publishing MDs decide education and clinical program development even though they have minimal clinical practices, no PCUs, no coordination with community.
- Friendly take over or monkeys with machine guns?




ASSESSMENT
TREATMENT
EDUCATION
PATIENT
COUNSELING
RESEARCH

URGENT (Clinical)

vs

IMPORTANT (Research)

Benchmarks for success

- Clinical care (# pts, days on call)
- Education (lectures, assessment by students)
- Administration (committee participation, preparation of reports)
- Research ? (papers, presentations, grants, collaboration)

Research is a team sport

- PC researchers are CONTENT experts.
- Methodology experts grow on trees.
- Statisticians also

The team

1. Content expert
2. Methodology expert
3. Biostatistician
4. Clinical expert
5. Research nurse, data coordinator

The first meeting

- Principal investigator does EVERYTHING. The rest of the team advice and help in small and quite specific parts
- Avoid meeting too much!!!
- Discuss authorship from the start
- Discuss $$$ from the start
- Set dates for completion of each stage

Study administration

Principal investigator is responsible

- Ethics committee
- Logistic problems
- Statistica analysis
- Presentation/ publication

Maintaining the team

1. Eliminate non productive members rapidly!
2. Share 1st authorship and secondary studies
3. End studies that do not work fast!
4. Review what happened in each case, success or failure.

Publication

- Always try the best journal
- Do NOT get discouraged by rejections, take advantage for the next journal!!
- Submit letters, retrospective studies, negative studies

VOLUME 22 · NUMBER 1 · JANUARY 1 2004

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Methadone Versus Morphine As a First-Line Strong Opioid for Cancer Pain: A Randomized, Double-Blind Study

Eduardo Bruera, J. Lynn Palmer, Snezana Bosnjak, Maria Antonieta Rico, Jairo Moyano, Catherine Sweeney, Florian Strasser, Jie Willey, Mariela Bertolino, Clarissa Mathias, Odette Spruyt, and Michael J. Fisch

Clinical Note

Nebulized Versus Subcutaneous Morphine for Patients with Cancer Dyspnea: A Preliminary Study

Eduardo Bruera, MD, Raul Sala, MD, Odette Spruyt, MD, J. Lynn Palmer, PhD, Tao Zhang, MS, and Jie Willey, MSN

The University of Texas M. D. Anderson Cancer Center (E.B., J.L.P., T.Z., J.W.), Houston, Texas, USA; Hospital Escuela Eva Peron (R.S.), Rosario, Argentina; and Peter MacCallum Cancer Institute (O.S.), East Melbourne, Victoria, Australia

Original Article

Dexamethasone in Addition to Metoclopramide for Chronic Nausea in Patients with Advanced Cancer: A Randomized Controlled Trial

Eduardo Bruera, MD, Jario Ricardo Moyano, MD, Raul Sala, MD, Maria Antonieta Rico, MD, Snezanna Bosnjak, MD, Mariela Bertolino, MD, Jie Willey, RN, MSN, Florian Strasser, MD, and J. Lynn Palmer, PhD

Department of Palliative Care & Rehabilitation Medicine (E.B., J.W., F.S., J.L.P.), The University of Texas M. D. Anderson Cancer Center, Houston, Texas, USA; Instituto Nacional de Cancerologia (J.R.M.), Bogota, Colombia; Hospital Escala/Eva Peron-Rosario (R.S.), Rosario, Argentina; Instituto Nacional del Cancer (M.A.R.), Santiago, Chile; Institute for Oncology and Radiology of Serbia (S.B.), Belgrade, Serbia, and Unidad de Cuidados Paliativos (M.B.), Buenos Aires, Argentina

VOLUME 23 · NUMBER 10 · APRIL 1 2005

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Effects of Parenteral Hydration in Terminally Ill Cancer Patients: A Preliminary Study

Eduardo Bruera, Raul Sala, Maria Antonieta Rico, Jairo Moyano, Carlos Centeno, Jie Willey, and J. Lynn Palmer

From The University of Texas M.D.

The coach (mentor)

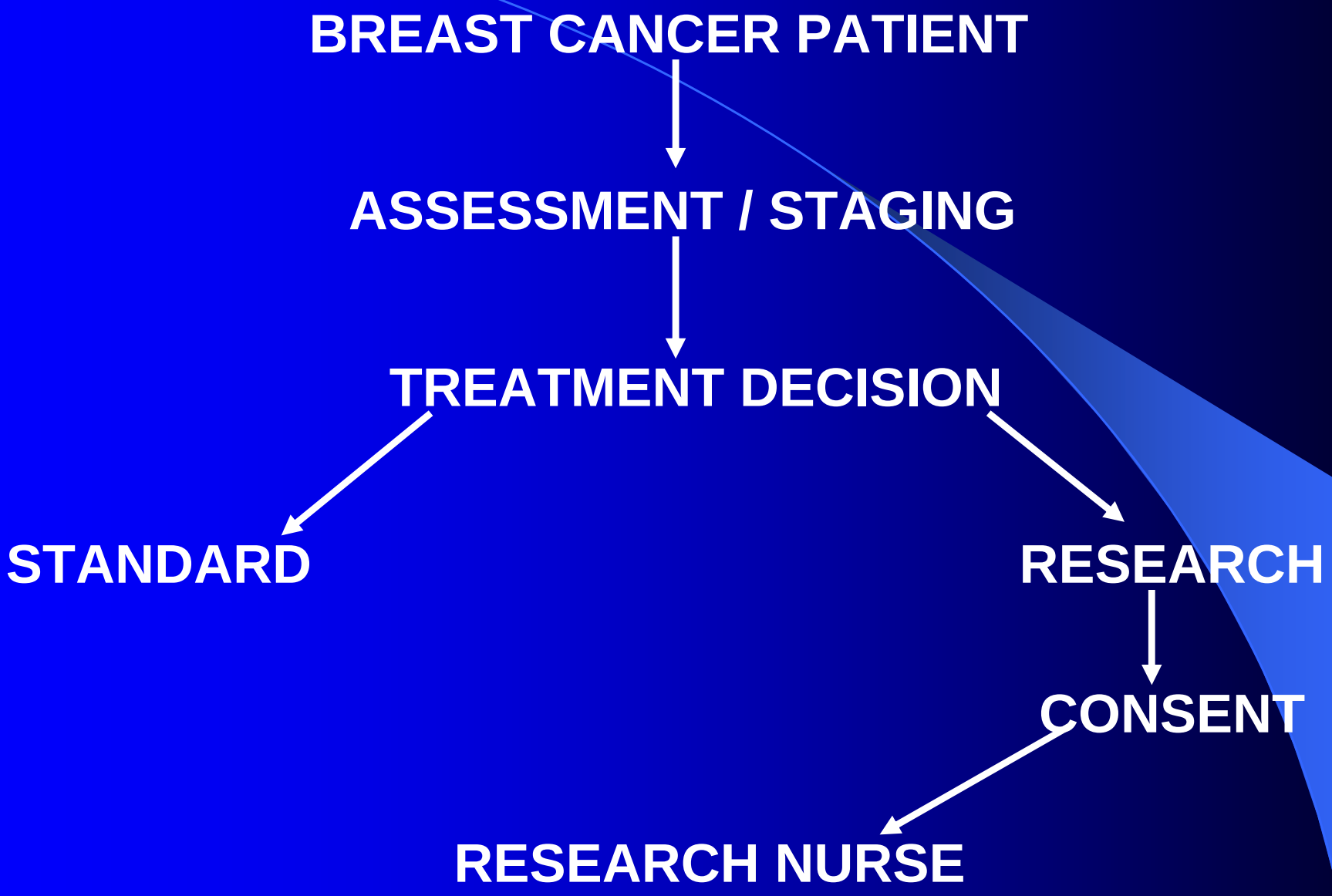
- Important player for initial proposals (usually first 4-5 years as faculty)
- Famous usually means narcisissistic, not good coach
- History of building leaders?
- Too many 1st authorship papers?
- Not enough last authorship papers?
- Distance CAN work (Email/ phone)
- Listen to the mentor!!!

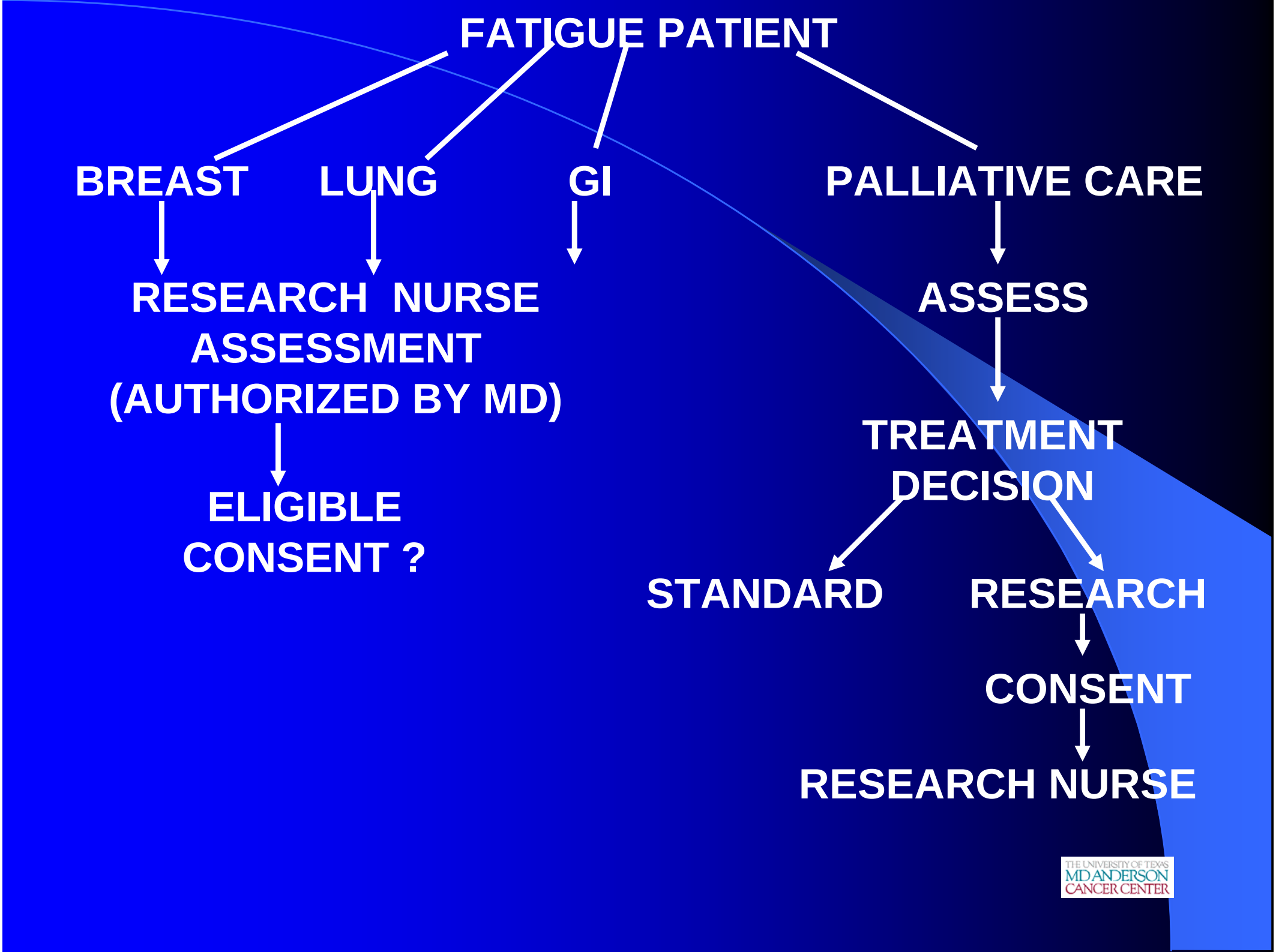
The role of the coach

- Advice about what is lkely to work (or NOT!!!)
- Help put together the team
- Help get some starting moneys and support staff
- Help solve content and methodology problems by ASKING, not answering
- Inspire trust on the mentee and team

PALLIATIVE CARE CLINIC

- MULTIPLE SYMPTOMS
- 1 – 3 VISITS
- 30% NO SHOW RATE
- DELIRIUM




FATIGUE PATIENT
BREAST
LUNG
GI
PALLIATIVE CARE
RESEARCH NURSE ASSESSMENT (AUTHORIZED BY MD)
ELIGIBLE CONSENT ?
ASSESS
TREATMENT DECISION
STANDARD
RESEARCH
CONSENT
RESEARCH NURSE
THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

RESEARCH NURSE TIME

- Cancer clinic: Starts when patients eligible
- Palliative Care: 70% of time **SEARCHING** for patients!

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CLINICAL DATA COLLECTION

- Less than 30% complete data sets
- Multiple Operators
- Variable Training
- 0-10 PAIN: SAME DAY Agreement 30%!!

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Clinical Tool	Research Tool
SIMPLE!	Comprehensive
Short	Not Important
Graphic Display	Not Important
Multiple Settings	One Setting
Clinically Meaningful	Not Important
Validated	Validated

What type of research?

- Retrospective studies
- Case reports
- Letters to the editor
- Prospective pilot studies
- Controlled trials

What about the level?

- Pharma can buy level I research with 75% positive outcomes
- Non pharma research 50% Positive outcomes

- What about impact?

Impact of the research

- One more slow release opioid?
- Hydration- nutrition- oxygen- nebulized opioids- methadone- thalidomide- methylphenidate- SC ATBs – other drugs
- Assessment in unresponsive pts
- Communication techniques/ aids

A BALANCED PORTOFOLIO

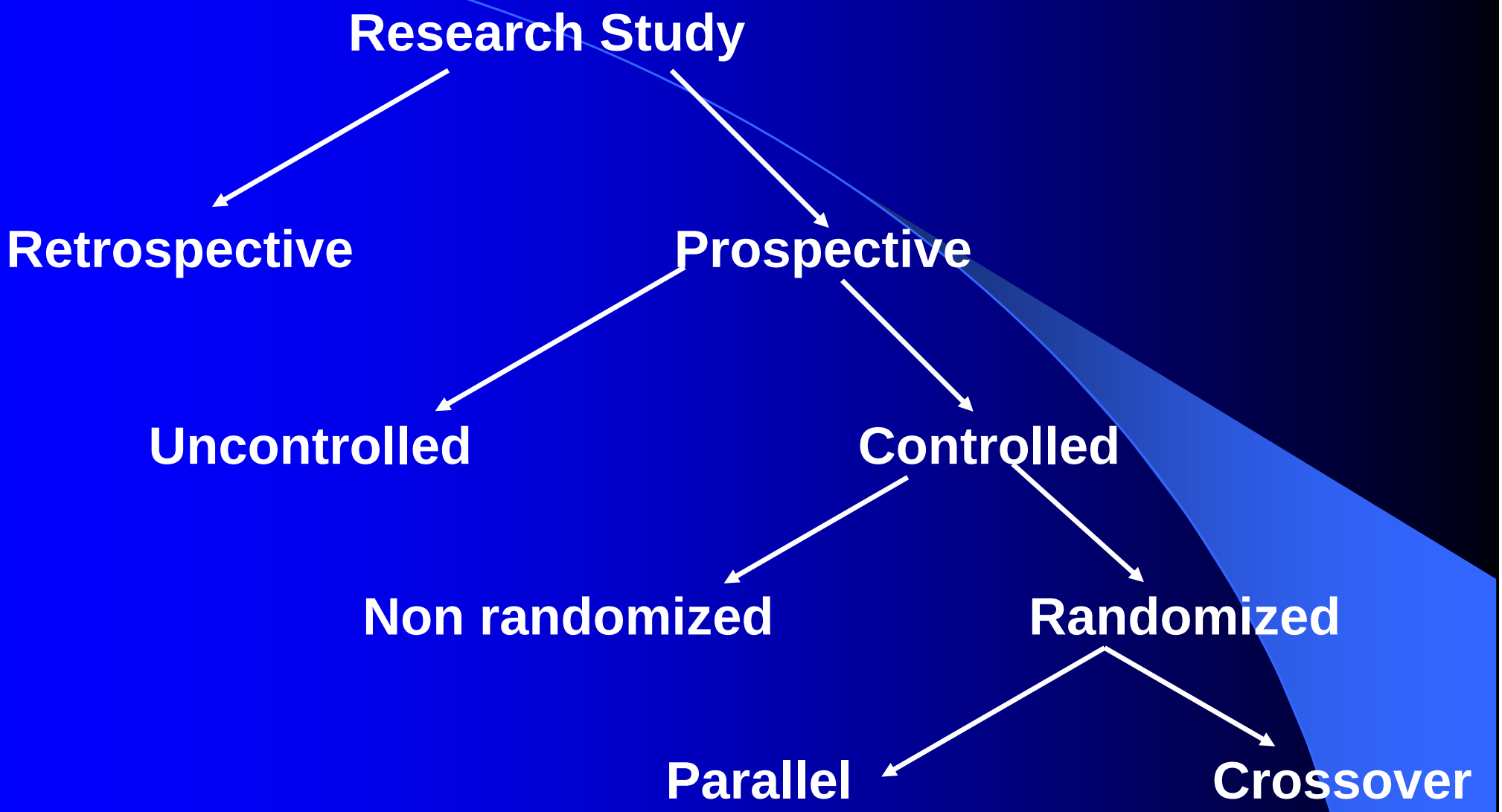
- Short term: retrospective, case reports, letters
- Medium term: pilot studies, case control, systematic reviews
- Long term: RCT,

Where's the money?

- What money?
- Identify novel sources if most commons not available
- Granting agencies are now funding PC research

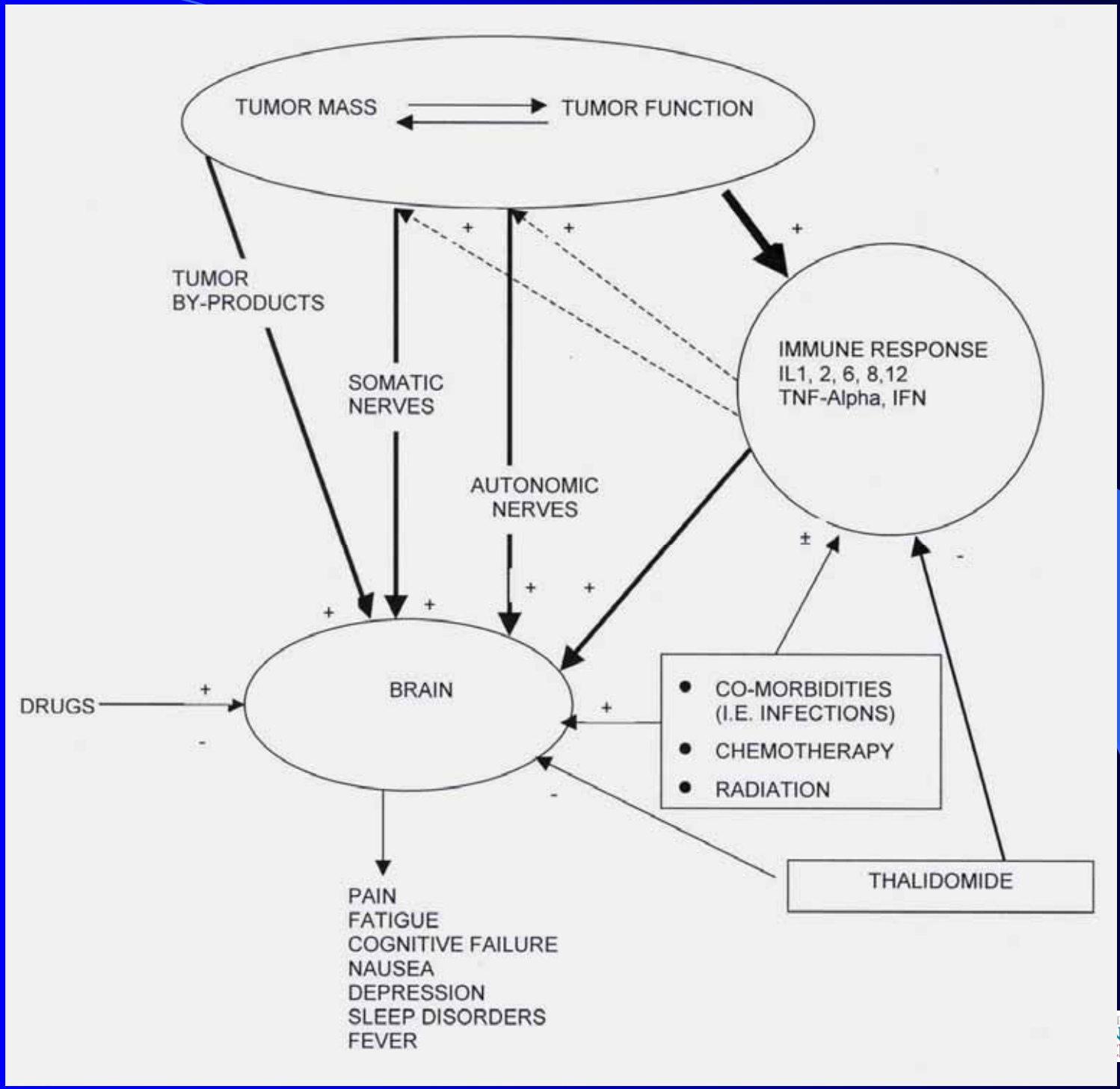
Implications for design

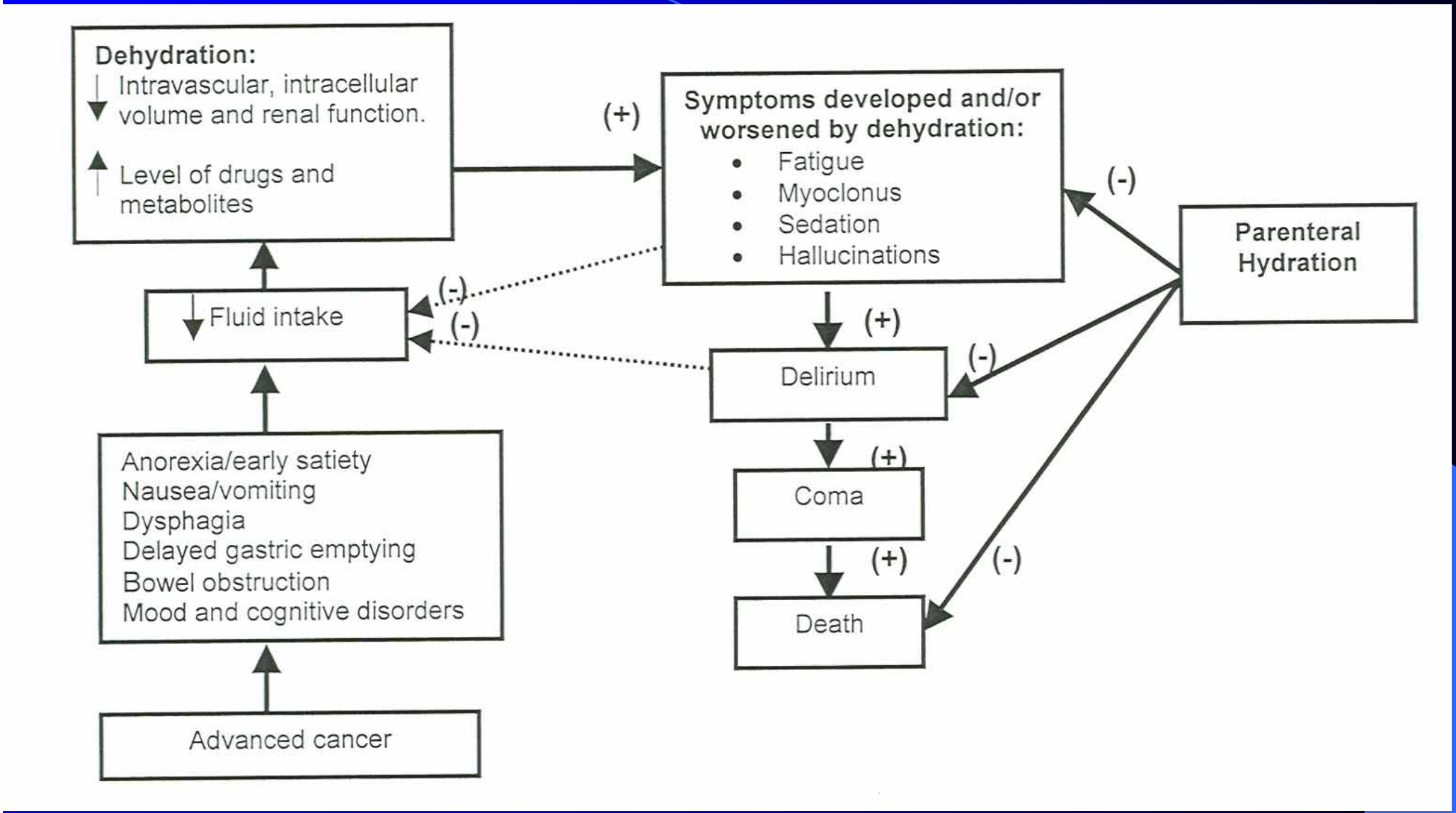
- Duration >2 wks: 24-30% drop-out
- Multiple endpoints unavoidable



CONCEPTUAL FRAMEWORK

- Calman's Gap
- Utility
  - Trade Off – Twist
    QALY
- Meaning
  - Logotherapy
- Reintegration
  - CARES (Rehabilitation)


TUMOR MASS
TUMOR FUNCTION
TUMOR
BY-PRODUCTS
SOMATIC
NERVES
AUTONOMIC
NERVES
IMMUNE RESPONSE
IL1, 2, 6, 8,12
TNF-Alpha, IFN
DRUGS
BRAIN
CO-MORBIDITIES
(I.E. INFECTIONS)
CHEMOTHERAPY
RADIATION
THALIDOMIDE
PAIN
FATIGUE
COGNITIVE FAILURE
NAUSEA
DEPRESSION
SLEEP DISORDERS
FEVER



TIPS FOR GOOD TEAM FUNCTION

1. Research as primary job: Fellow – Research RN
2. Research Data Collection separate from clinical for clinical trials
3. Clinical Data useful for epidemiological research
4. STATISTICS ? → STATISTICIAN!
5. VALUE RESEARCH !

Cultural issues

- National identity, race, religion, gender
- Discipline: oncology, pain, supportive care, hospice, nursing
- Hospital/ institution: mission- “making cancer history”; “we do not hydrate”; “we do not use assessment tools”
- University: curriculum wars

Developmental stages of a palliative culture

- Individuals, and groups (hospitals, governments and universities) usually progress slowly but regression can happen at any time.
- Frequent coexistence of signs of different stages in the same person/ group

1. Denial

- “We don’t have those problems here”
- “Our symptom control is very good; our patients and families are happy!!”
- “Hospice takes care of all our problems”
- “Research on problems that do not exist”

Who needs education?

- Health ministers: Break the acute/ long term interests, get the $$$ moving
- Dean of Medical School- Importance of education and research
- Directors of cancer agencies- cancer research Vs cancer patient research
- Home care programs- intensity Vs nice numbers, research ethical mandate
- Hospital CEOs- patients dying in hospital with no palliative care – research is care

2. Palliphobia

- Panic episodes when the “P” word is mentioned.

  Most common among oncologists, pain specialists and deans of medical school

  “we will lose patients”; “it is covert euthanasia”; “there is no science”

3. Pallilallia

- Repetitive nonsense talking about Palliative care without any accompanying actions
- Collective pallilalia: affects organizations and governments
- “Do a study to document/demonstrate”; “consensus group”; “this is VERY important”
- Randomized controlled study of the specialty

4. Palliactive

- Appoint MDs/ RNs
- Physical space: Unit/clinic.
- Research team
- Administrative space: Division – Department
- $$$$$$$$$!!!

Palliative care research

- Clinical programs in academic institutions
- Independent administrative structures (independent means $$$$ control)
- PC review panels in granting agencies