

# IMPROVING OUTCOMES IN RADICAL CYSTECTOMY

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UNC  
LINEBERGER

## Cystectomy: M&M

- 90-day complication rate: 64%- 78%
  - Clavien: 0 (36%), 1-2 (51%), 3-5 (13%)
  - 29% GI, 25% infectious, 15% wound
- 90-day readmission rate: 25-43%
- 90-day mortality rate: 7%-10%

*Challenge = Opportunity for Quality Improvement*

Shabsigh et al., *Eur Urol* 2009; Stimson et al, *J Urol* 2011

# Improving Outcomes

- Refining Multimodal Therapy
  - Improving utilization of perioperative chemo
  - Development of new agents
- Improving Peri-operative Outcomes
  - Clinical care pathways
  - Refining the role of Robotics
  - Overcoming obstacles to optimal care

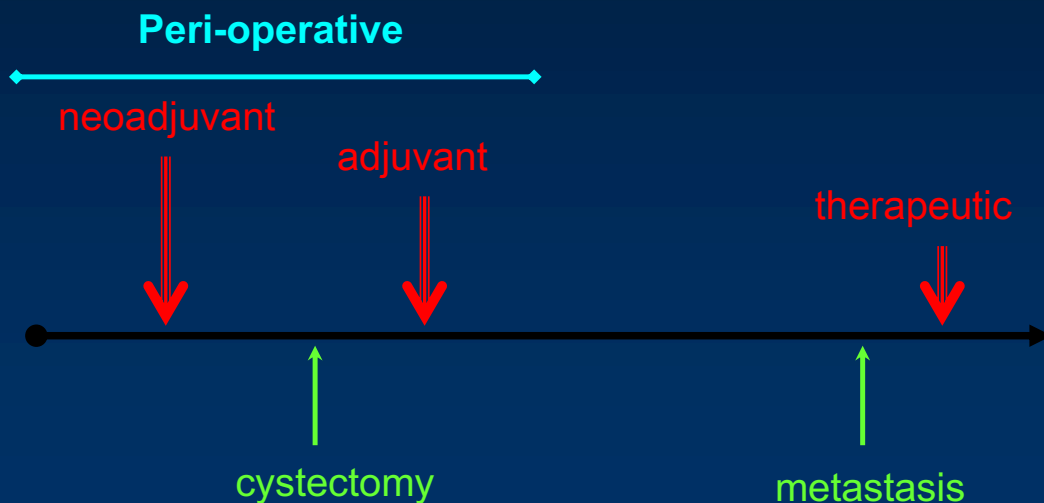
# Improving Outcomes

- *Refining Multimodal Therapy*
  - *Improving utilization of perioperative chemo*
  - *Development of new agents*
- Improving Peri-operative Outcomes
  - Clinical care pathways
  - Refining the Role of Robotic Cystectomy
  - Overcoming obstacles to optimal care

# Radical Cystectomy

- Cystectomy provides best treatment for localized disease
- Is it possible to improve outcomes with peri-operative chemotherapy?

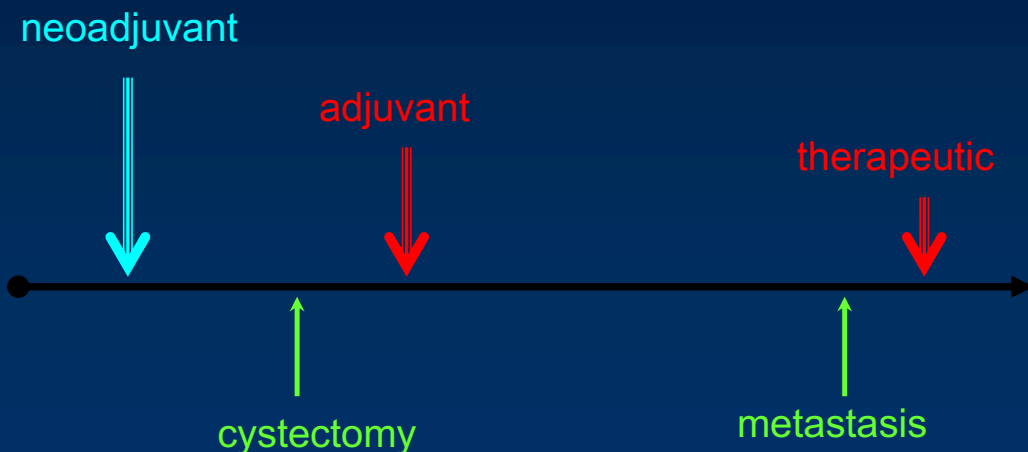
## Cystectomy + Chemotherapy



# Cystectomy + Chemotherapy

- Rationale for early chemotherapy
  - Early treatment of micrometastatic disease
  - Increased chemosensitivity of small volume tumors
  - Inverse relationship of tumor burden + cure
  - Ascertain chemosensitivity

# Cystectomy + Chemotherapy

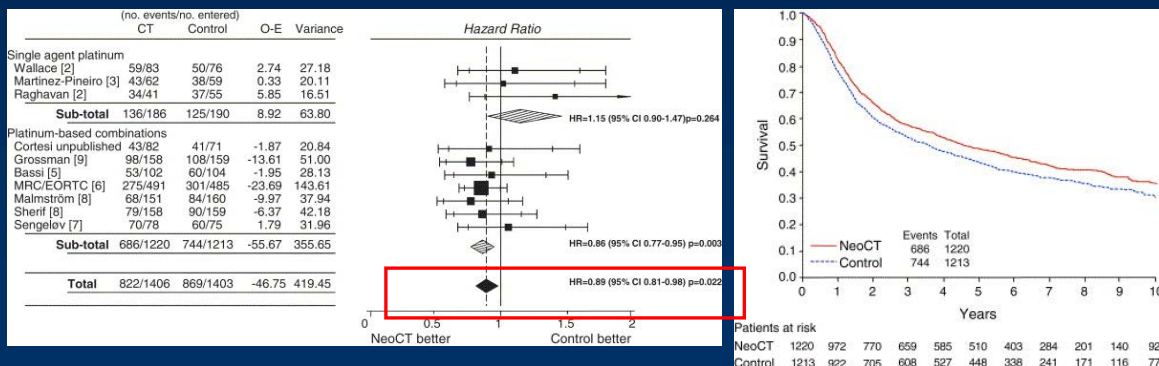


# Neoadjuvant Chemotherapy: Potential Benefits

- Early treatment of occult metastases
- Downstaging primary tumor
  - Pathologic response rates = 60-70%
  - P0 in 25-38% patients
  - *unresectable* → *resectable*
- Possible to assess response
- Survival benefit

# Neoadjuvant Chemotherapy: Meta-analysis

- >3000 pts; 11 RCTs; Cisplatin-based chemo
  - Significant benefit
    - OS (HR 0.86, CI 0.77 - 0.95),  $p=0.003$
    - 5% absolute survival benefit at 5 years

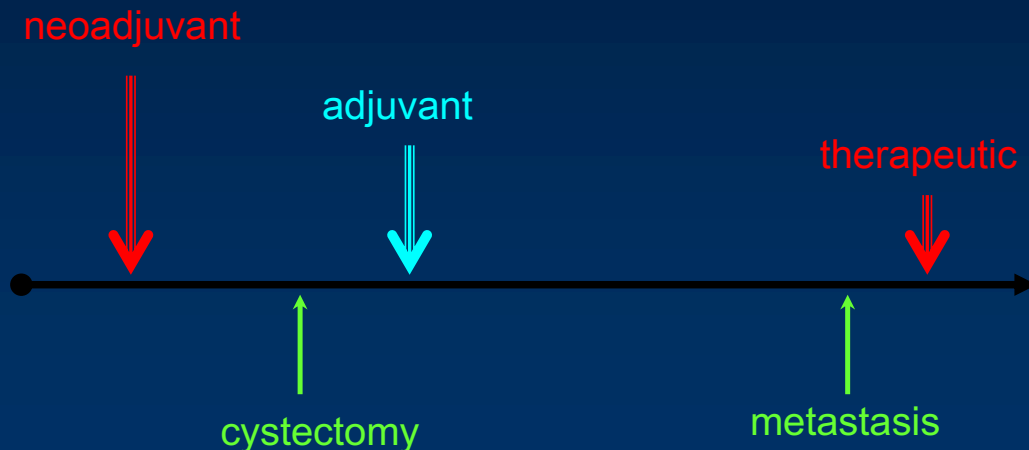


ABC Collaboration (2005)

## Neoadjuvant Chemotherapy

- Platinum-based therapies
  - MVAC, CMV, Gem-cisplat
  - *Carbo is not an effective substitute*
- 3 cycles X 28 days/cycle
- Approx. delay in surgery = 4 months.

## Cystectomy + Chemotherapy



## Adjuvant Chemotherapy: Potential Benefits

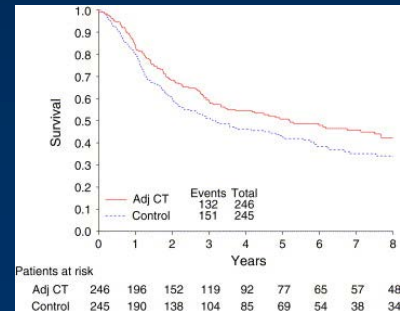
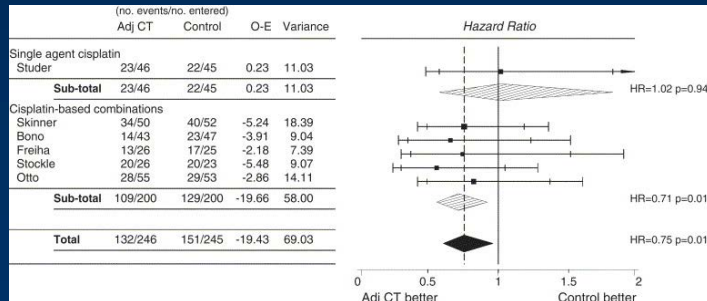
- Early treatment of occult metastatic disease
- Need for treatment based on pathologic (not clinical) criteria
  - Staging error of cT vs. pT
  - Avoid toxicities in those potentially-cured by surgery
- Minimal tumor volume
- ? Survival benefit

## Adjuvant Chemotherapy

- Potential Deficits
  - Inability to assess response
  - Enhanced toxicity (after surgery)
  - Delay in receipt of systemic therapy

# Adjuvant Chemotherapy: Meta-analysis

- 491 pts; 6 RCTs; Cisplatin-based chemo
  - Significant benefit
    - OS (HR 0.75, CI 0.60 - 0.96),  $p = 0.019$
    - 9% absolute survival benefit at 5 years



ABC Collaboration (2006)

## Perioperative Chemotherapy

- Increased use of platinum-based peri-operative chemotherapy
  - 12% (1997-2003) → 30% (2003-2007) per NCDB
  - 2% → 23% in Alberta GU Onc Grp after establishing CPG
- BCAN QoC Survey: n=4541 (Feifer, AUA 2011 #405)
  - 34% (12% NAC, 22% AC); 35% non-Cis-Pt regimens
- Neoadjuvant versus adjuvant – still uncertain
- Need for alternative (less toxic) agents



# Radical Cystectomy: 2018

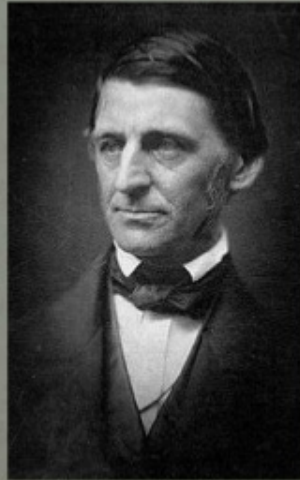
- Refining Multimodal Therapy
  - Improving utilization of perioperative chemo
  - Development of new agents
- *Innovation to improve peri-operative Outcomes*
  - *Clinical care pathways*
  - *Refining the role of Robotics*
  - *Overcoming obstacles to optimal care*

## Innovation

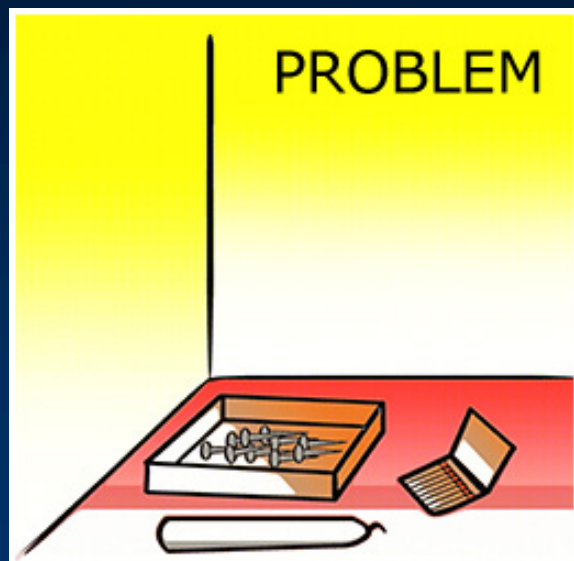
- Product innovation
  - e.g. robotics
- Process innovation
  - Care pathways
  - Telecare, outpatient management, task transfer

“People only see what they are prepared to see...”

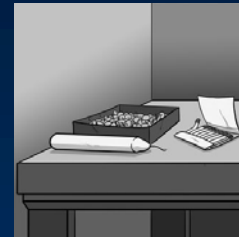
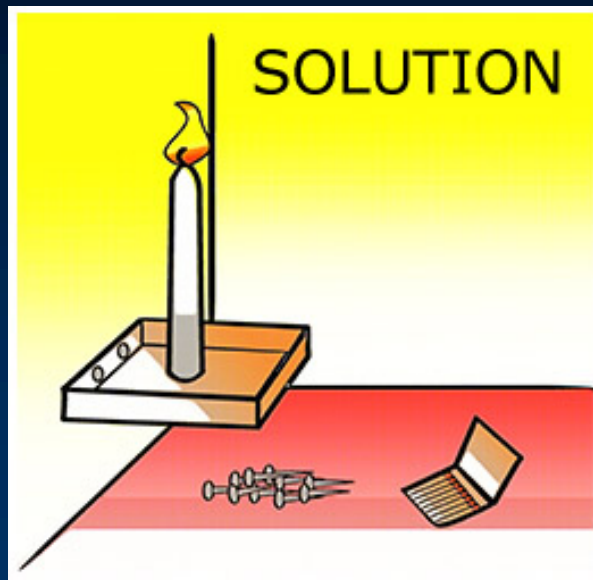
*Ralph Waldo Emerson*



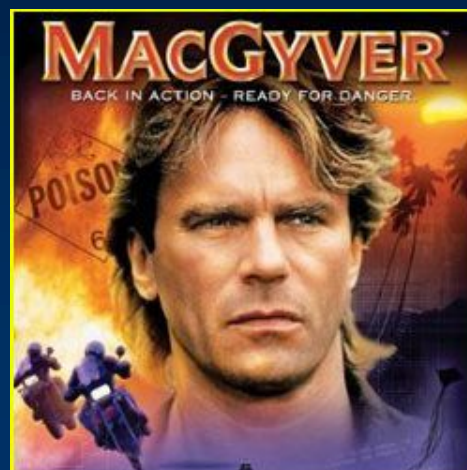
## The Candle Problem



Karl Duncker (1945)



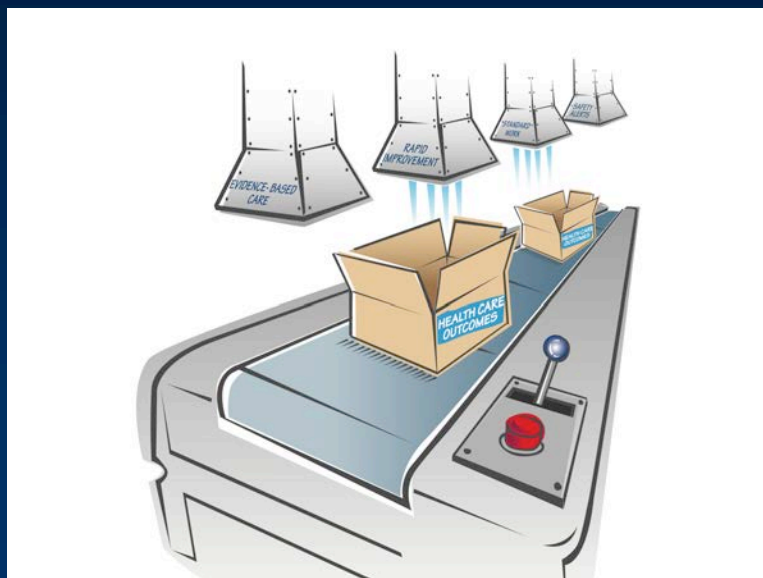
## Overcoming Functional Fixedness



# Innovation

- Process innovation
  - *Care pathways*
  - Telecare, outpatient management, task transfer
- Product innovation
  - e.g. robotics

## Care Pathways



# Potential for Clinical Pathways

- Cost reduction
- Improve quality of care / error reduction
- Transparency of treatment
- Staff satisfaction
- Training/education
- *Standardization*

## Cost Reduction

- Most important for decision-makers / administrators
- Focus of much research on CP
- Cost reduction seen for all surgeries
  - Colorectal, hepatic, pancreatic, cardiac, ortho, transplant, bariatric, thoracic, hernia, obstetric, and urologic

*Ruchlin (2001)*

*Chang (2005)*

*Ronellenfitsch (2004)*

*Melbert (2005)*

*Joh (2003)*

*Rouse (1998)*

*Jacavone (1999)*

# Cost Reduction

- Length of Stay
- OR time
- Parallelization of processes
- Diagnostic tests
- Materials
  - Surgical equipment, meds
- Avoid duplication

*Ruchlin (2001)*

*Chang (2005)*

*Ronellenfitsch (2008)*



# Quality of Care

- Morbidity
  - Decrease pneumonia, nausea, wound infections, overall complications (error reduction)
  - Early NGT removal and feeding
  - Mortality

*Lemmens (2008)*

*Pruthi (2004)*

*Chang (2001)*

*Ronellenfitsch (2008)*

*Pitt (1999)*



# Transparency of Treatment

- Structure and organization
- Steps in a well-defined continuum
  - Available
  - Documented
  - Evidenced-based
- Physicians, staff, patients

*Parker (1999)*

*Holzbeierlein (2000)*

*Ronellenfitsch (2008)*



# Staff Training / Satisfaction

- Education - implementation of structured, evidenced-based approaches
  - Move away from “guild” system
  - Mode of translating scientific evidence to clinical practice in multidisciplinary setting
- CP lead to increased staff satisfaction
- Increased quality of care --> increased staff satisfaction

*Goede (1995)*

*Holzbeierlein (2000)*

*Ronellenfitsch (2008)*



# Which cases make sense?

- High volume
- Relatively complex
- Resource intensive
- Potential for variation
- High morbidity

★ *Radical Cystectomy*

*Ruchlin (2001)*

*Ronellenfitsch (2008)*

*Melbert (2005)*



## University of North Carolina Clinical Care Pathway for Radical Cystectomy

- Pre-op counseling
  - Probably the most important step
  - Inform about clinical pathway and what to expect
  - Provide pre-op literature regarding peri-operative course
  - Expected hospital stay should be 4 days
    - If you tell them a week they will stay a week

*Pruthi (2003)*





# General Concepts

- Antibiotics
  - 24 hrs peri-operative
  - Start within 1 hr before incision
  - Ertapenem or Ancef/Flagyl
- Cardiovascular
  - Anti-coagulation / anti-platelet therapy
  - Development institutional policy w/ cards and anesthesia

# General Concepts

- DVT/PE prophylaxis
  - Early and frequent ambulation
  - TED / SCD
  - SQ Heparin or Lovenox
- Pulmonary
  - IS -- little data to support use, but inexpensive (< \$5)
- Multi-modal use of non-narcotic analgesics

# Pre-op

- Bowel prep
  - Regular diet all day before; NPO after MN
  - Fleets® enema morning of surgery
  - *(no po antibiotics)*
- No pre-op admission
- *Antibiotics*
  - 24 hrs peri-operative - Start within 1 hr before incision
  - Ertapenem or Ancef/Flagyl
    - Pregabalin (Lyrica) 150 mg po
- Alvimopan po
- VTE prophylaxis begun pre-op in holding area
  - Heparin SQ 5000 units

# Day of Surgery

- *OG removed at end of case*
- *Use of Exparel 20 mg SQ -- ? Better than bupivacaine ?*
- Post-op labs
- DVT/PE - Ambulation; TED/SCD
- Pulmonary - IS
- Pain
  - IV Ketorolac 30mg IV then 15mg IV q 6h X 48h (if renal function OK)
  - *(and/or IV Acetaminophen)*
  - Pregabalin (Lyrica) 75mg bid
  - IV narcotics (MSO4) prn
- GI
  - PPI until D/C
  - Alvimopan
  - *Pro-motility agents - metoclopramide (less N/V)*
- Diet -- NPO
- Catheter / drain management

# POD #1

- AM labs
- Antibiotics -- peri-op X 24h
- DVT/PE - Ambulation; TED/SCD; *start lovenox or heparin SQ*
- Pulmonary - IS
- Pain
  - Ketorolac
  - Pregabalin (Lyrica) 75mg bid
  - (and/or IV Acetaminophen)
  - IV narcotics (MSO4) prn
- GI -- PPI; metoclopramide; alvimopan; *chewing gum*
- Diet – *clears (irrespective of bowel function)*
- Catheter / stoma / drain management and teaching
- *Discharge planning*

# POD #2

- (AM labs prn)
- DVT/PE - Ambulation; TED/SCD (LMWH)
- Pulmonary - IS
- Pain
  - *Convert to po meds (oxycodone/acetaminophen; celecoxib, lyrica)*
  - IV narcotics (MSO4) prn
- GI -- PPI; metoclopramide; stool softener; alvimopan; chewing gum
- Diet -- *clears (irrespective of bowel function)*
- Catheter / stoma / drain management and teaching
- Discharge planning

## POD #3

- AM labs
- DVT/PE - Ambulation; TED/SCD (LMWH)
- Pulmonary - IS
- Pain
  - po meds (oxycodone/acetaminophen; celecoxib, lyrica)
  - IV narcotics (MSO4) prn
- GI -- PPI; stool softener; chewing gum
- Diet – *regular diet (irrespective of bowel function)*
- Catheter / stoma / drain management and teaching
- Discharge planning

## POD #4

- (AM labs prn)
- DVT/PE - Ambulation; TED/SCD (LMWH)
- Pulmonary - IS
- Pain
  - po meds (oxycodone/acetaminophen; celecoxib, lyrica)
- GI -- PPI; stool softener; chewing gum
- Diet -- regular diet
- Catheter / stoma / drain management and teaching
- Discharge planning
- *? Discharge*

# Discharge

- Remove drain (unless leak)
- Meds
  - *Pain meds (e.g. oxycodone/acetaminophen) = #15*
  - *(median use = 10 (+/- 4))*
  - *Pregabalin (Lyrica) 75mg bid X 2 weeks*
  - *Celecoxib 200mg bid X 2 weeks*
  - Stool softener
  - Resume ASA
- *VTE prophylaxis - Lovenox 40 mg SQ X 4 weeks*
- Catheter / stoma teaching
- Home health coordination
- RTC POD #7-10 for stent removal
- (RTC 2-3 wks for cystogram + catheter removal for neobladder)

## UNC Experience

	<u>2004-2005</u>	<u>1999-2000</u>	<u>1996-1997</u>
ICU stay (days)	0.0	0.8	1.8
Time (days) to clears	2.0	5.3	6.9
Time (days) to reg diet	3.9	7.9	8.3
Time (days) to D/C	5.1	10.0	11.2
Day of Discharge (%)			
-POD 4-5	79%	0%	0%
-POD 6-7	17%	23%	13%
-POD > 8	4%	77%	87%
Hospital costs	\$4290	\$10375	\$13155
OR costs	\$3480	\$5069	\$6257
Total costs	\$7770	\$15444	\$19412

Evans (2005)

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# Summary Points: Clinical Pathways

- Positive effects on:
  - Quality of care
  - Health care costs
  - Education
  - Staff satisfaction
  - Patient expectations
  - Translating scientific evidence to clinical practice
- Encourage more widespread use in urologic surgery
  - Multidisciplinary fashion led by surgeon

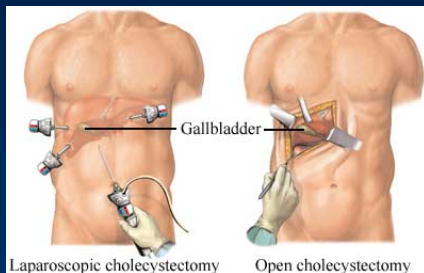
# Improving Outcomes in Radical Cystectomy

- *Clinical care pathways*
  - *Method to improve outcomes and reduce costs*
- *Role of robotics/minimally-invasive surgery*

# Robotic Cystectomy

- Has emerged from growing experience with robotic assisted prostatectomy
- May offer viable alternative to open radical cystectomy in select patients

## Benefits of Minimally-invasive Surgery



cholecystectomy

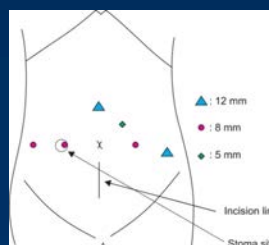
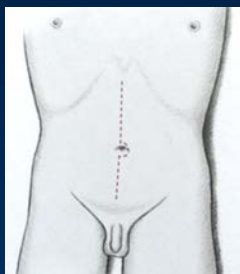


nephrectomy



# Radical Cystectomy

ORC



RARC



## Minimally-invasive Surgery: Robotic Radical Cystectomy

- Potential benefits
  - Reduced ebl
  - Decreased incision / pain
  - Less fluid imbalances
  - Decreased bowel manipulation
- Potential Concerns
  - Maintain oncological principles
    - Margins, bladder entry, tumor seeding, LN's
  - Prolonged OR times
  - Costs
  - Learning curve



Menon (2004)  
Pruthi and Wallen (2006)

# UNC Contributions to Robotic Cystectomy Literature



Articles  
Publication



## Robotic vs. Open

- **Comparable**

- Survival – RFS and OS
- Surgical margin status
- Lymph node yield
- 

- Costs
- Long-term QOL

- **Potential Benefits**

- EBL
- Pain
- Recovery of bowel function

- Complications
- LOS

- **Potential Negatives**

- OR time

# Value



Value

=

EBL/Transfusion, Pain,  
LOS, Complications

OR Time

No difference for  
oncologic outcomes,  
survival, costs, or QOL

Porter (2010)

## Summary: Robotic Cystectomy

- Improves patient outcomes – EBL, transfusions, pain, LOS, and complications
- Provides thorough extirpative procedure – preserves oncologic integrity
- Increases in OR time

***Adds value to care of patients undergoing radical cystectomy***

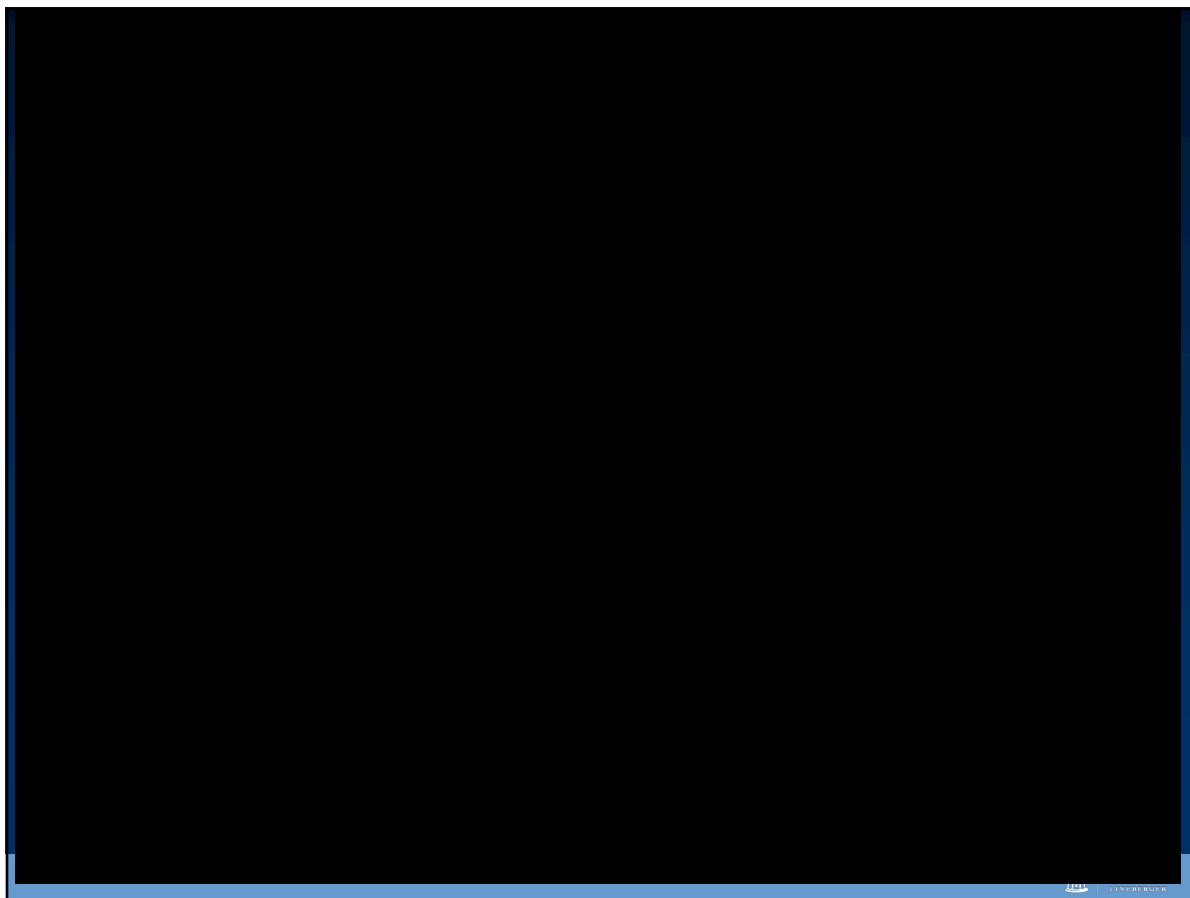
## Future Directions

- Increased worldwide experience
- Long-term oncologic assessment
- Multi-institutional RCT
- *Intracorporeal urinary diversion*



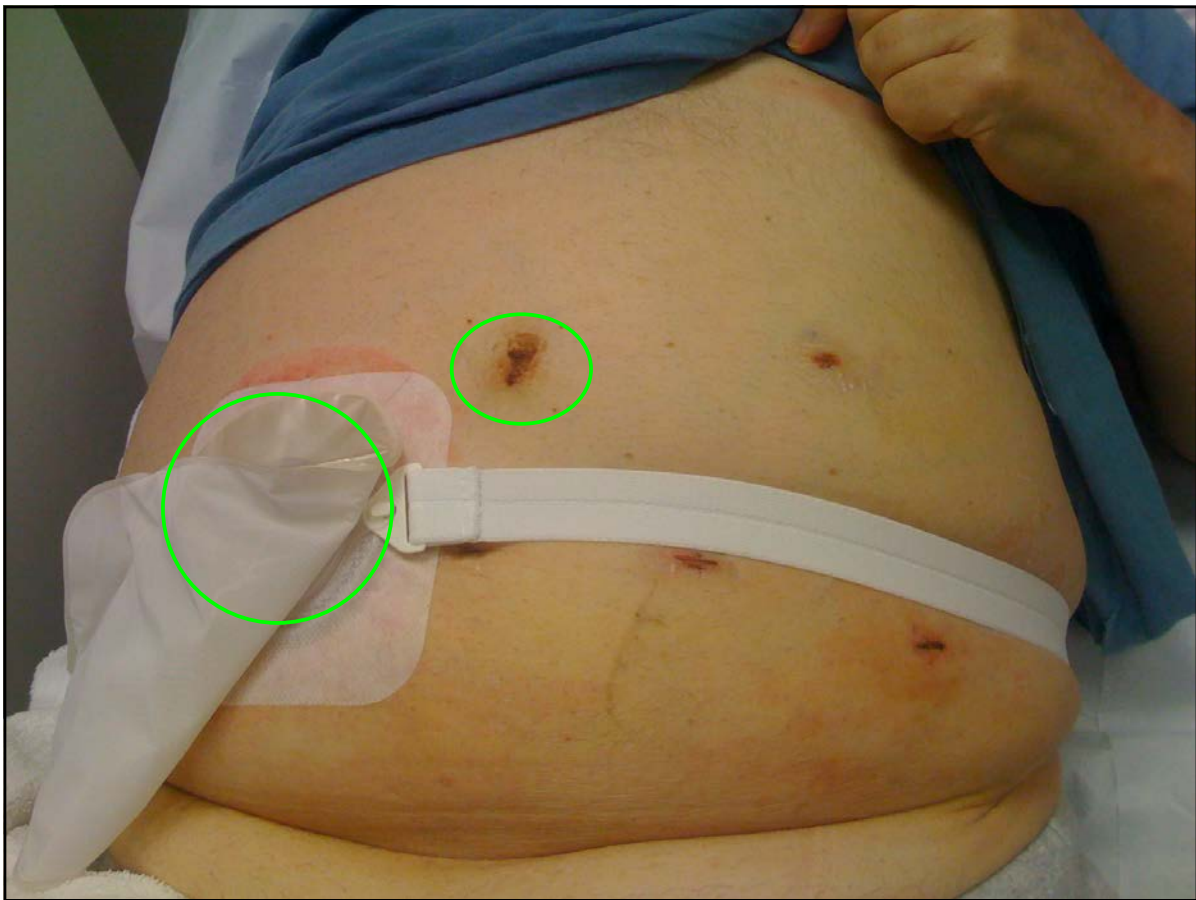
## Robotic-assisted Laparoscopic Intracorporeal Urinary Diversion





## UNC Initial Experience

	IC Diversion (n=40)	EC Diversion (n=40)	p value
Mean EBL (range)	223 (50-400)	266 (50-900)	0.304
Mean OR Time (range)	5.3 hrs (3.9 – 7.3 hrs)	4.2 hrs (3.8 – 4.8 hrs)	< 0.001
Post-op			
-- Mean time to flatus	2.2 d	2.4 d	0.427
-- Mean time to BM	3.1 d	3.3 d	0.762
-- Mean time to DC	4.5 d	5.2 d	0.209
Inpatient narc use (MSO4 eq)	57.6	93.2	0.034

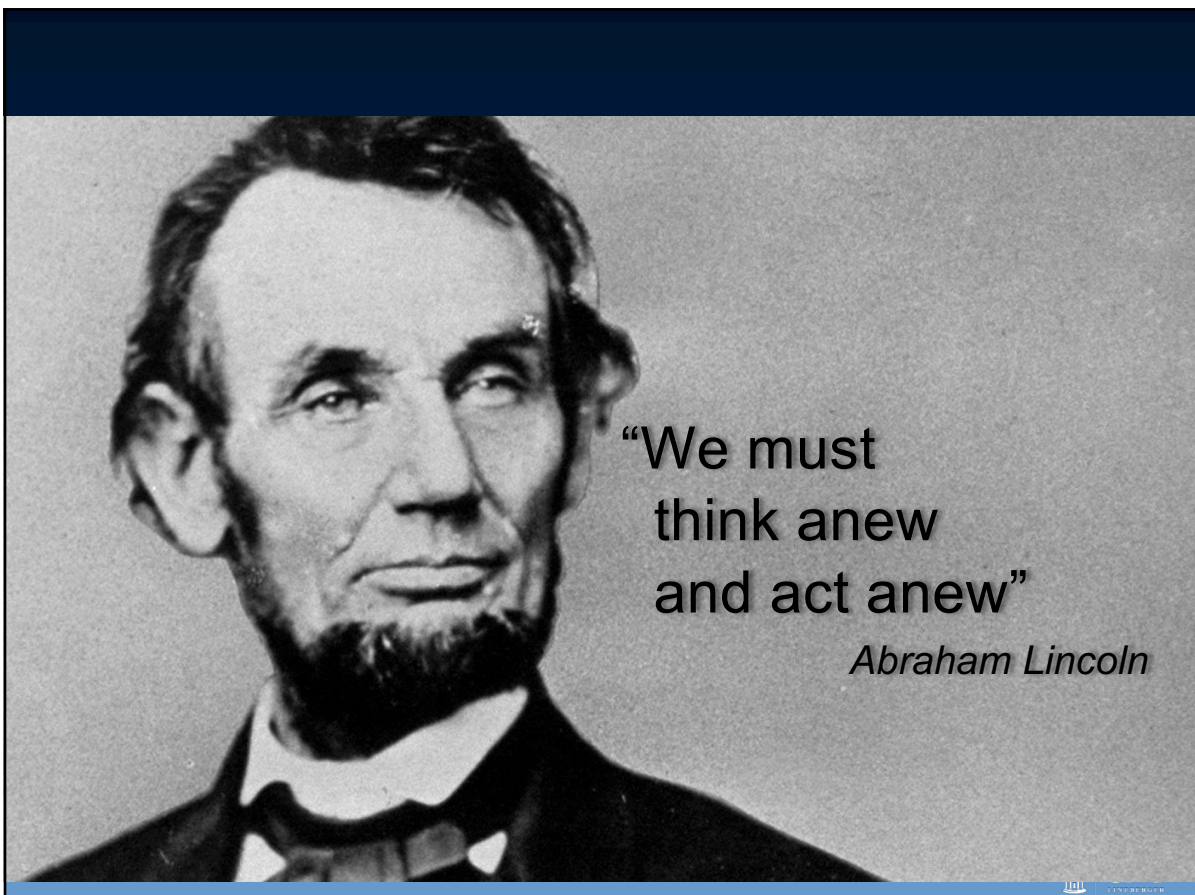


Transvaginal extraction  
Via posterior vaginal incision



# Improving Outcomes in Radical Cystectomy

- *Clinical care pathways*
  - *Method to improve outcomes and reduce costs*
- *Role of robotics/minimally-invasive surgery*
- *Overcoming obstacles to optimal care*



## Obstacles to optimal healthcare delivery in bladder cancer

- Travel Distance
- Financial Toxicity
- Nutrition

## Obstacles to optimal healthcare delivery in bladder cancer

- *Travel Distance*
- Financial Toxicity
- Nutrition



# Travel Distance

- National trend toward regionalization of health care and major surgery such as cystectomy
- Recent studies indicate an association between high-volume centers & improved post-op outcomes for major surgery
- Spurred interest in association of patient travel distance on cystectomy care and outcomes.

  
The NEW ENGLAND  
JOURNAL of MEDICINE

## HOSPITAL VOLUME AND SURGICAL MORTALITY IN THE UNITED STATES

JOHN D. BIRKMEYER, M.D., ANDREA E. SIEWERS, M.P.H., EMILY V.A. FINLAYSON, M.D., THERESE A. STUKEL, Ph.D.,  
F. LEE LUCAS, Ph.D., IDA BATISTA, B.A., H. GILBERT WELCH, M.D., M.P.H., AND DAVID E. WENNBORG, M.D., M.P.H.



# Background

- 90-day complication rate = 64 - 78%
- Population-based estimates of readmissions following cystectomy range from 25-43%

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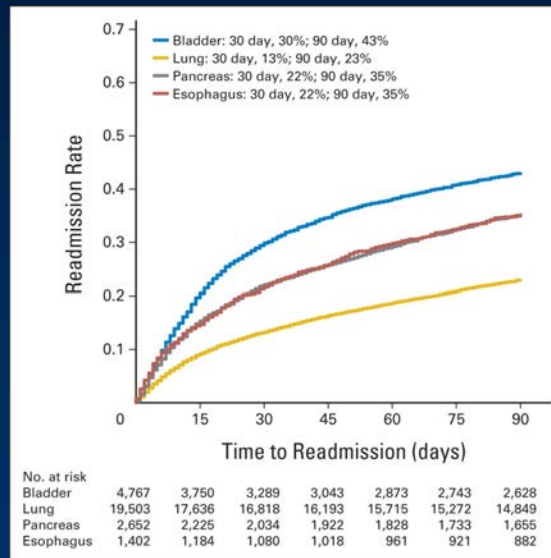


Official Journal of the  
American  
Urological  
Association

## A SYSTEMATIC REVIEW AND CRITIQUE OF THE LITERATURE RELATING HOSPITAL OR SURGEON VOLUME TO HEALTH OUTCOMES FOR 3 UROLOGICAL CANCER PROCEDURES

MARTIN NUTTALL,\* JAN VAN DER MEULEN, NIRREE PHILLIPS, CARLOS SHARPIN,  
DAVID GILLATT, GREGOR MCINTOSH AND MARK EMBERTON

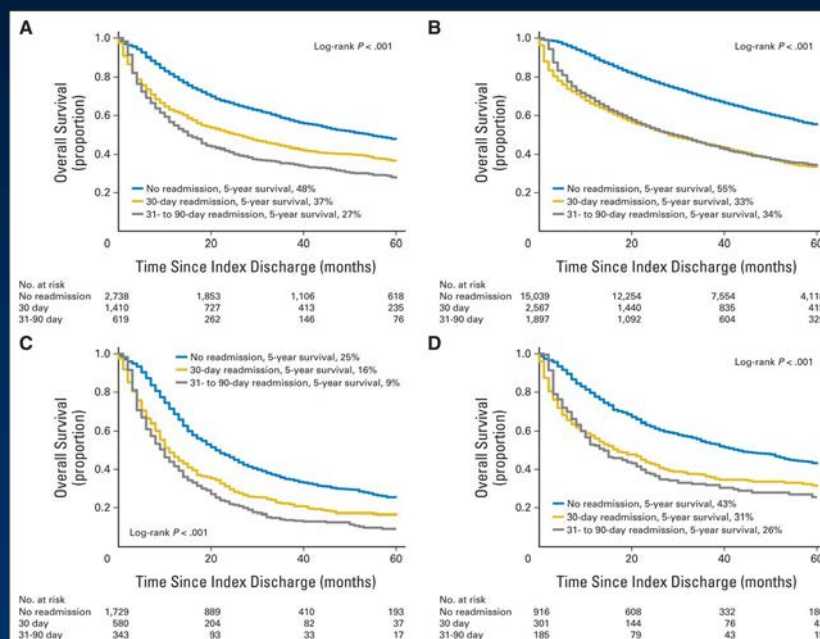
# Readmission rates by disease site



Stitzenberg et al. JCO 2015;33:455-464



## K-M estimates of survival by readmission group for (A) bladder cancer, (B) lung cancer, (C) pancreas cancer, and (D) esophagus cancer.



Stitzenberg et al. JCO 2015;33:455-464



# Background

- 30% of bladder cancer re-admissions are to a different hospital
  - More likely later, lower socioeconomic status, through the ED, and for medical DRGs
  - Decreased survival (HR 1.35)
  - Only 8% transferred – majority to index hospital
- The relationship between distanced traveled for surgery and risk of readmission and complications remains unclear

Annals of

**SURGICAL ONCOLOGY**

Impact of Location of Readmission on Outcomes After Major Cancer Surgery

Karyn B. Sittenberg, MD, MPH<sup>1,2</sup>, Yunkyoung Chang, PhD, MPH<sup>1</sup>, Angela B. Smith, MD, MS<sup>3,4</sup>, Michael G. Meyers, MD<sup>1,2</sup>, and Matthew E. Nielsen, MD, MS<sup>1,2</sup>



# Question

*How does distance traveled for surgery affects risk of readmissions and other outcomes following radical cystectomy for bladder cancer.*



# Methods

- Using linked data resource combining North Carolina Cancer Registry with administrative claims data from Medicare, Medicaid, and private insurance
  - Integrated Cancer Information and Surveillance System (ICISS)
- Included adult patients diagnosed with bladder cancer from 2003–2010 who received RC.
- Complications coded and grouped based on previously published standards\*
- Travel distances calculated using straight-line distance between patient zip code & cystectomy provider

\* Konety et al., Birkmeyer et al., Hollenbeck et al.



# Results

- 735 cystectomy patients for bladder ca.
  - n = 171 (23%) readmitted within 30 days
  - n = 156 (21%) readmitted between 31-90 days
- Mean age higher among readmitted, but not statistically significant
- No significant differences in readmission
  - race, gender, pathology stage, neoadjuvant chemotherapy, discharge to SNF comorbidity status, or complication type.



# Results

## Distance & 30-day readmission at different hospital

Characteristic		30-day Readmission into different Hospital		P-Value
	Total (N = 171)	No (N = 107)	Yes (N = 64)	
Distance <= 30 miles	75 (44%)	56 (52%)	19 (30%)	<b>0.004</b>
Distance > 30 miles	95 (56%)	51 (48%)	45 (70%)	

## Distance & 31-90-day readmission at different hospital

Characteristic		31-90-day Readmission into different Hospital		P-Value
	Total (N = 156)	No (N = 80)	Yes (N = 76)	
Distance <= 30 miles	77 (49%)	53 (66%)	24 (32%)	<b>&lt;0.001</b>
Distance > 30 miles	79 (51%)	27 (34%)	52 (68%)	



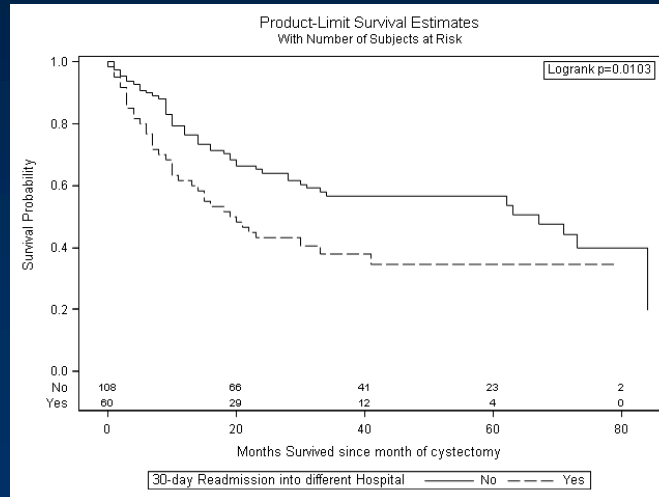
## Multivariable Analysis:

### Predictors of 30-day readmission

Variable		Odds Ratio	95% CI	p-value
Distance between residence & cystectomy provider (Ref <=30mi)	>30 miles	1.27	1.05, 1.54	<b>0.014</b>
Gender (Ref = Male)	Female	0.96	0.76, 1.20	0.707
Race (Ref = Non-white)	White	1.17	0.81, 1.67	0.402
Age (Ref = 65-74)	19-64	1.05	0.72, 1.54	0.798
	75+	1.06	0.78, 1.43	0.706
Pathologic Stage (Ref = T0-T2)	Ta-Tis-Tx	0.88	0.62, 1.25	0.480
	T3-T4	0.98	0.70, 1.37	0.892
	Missing	1.02	0.62, 1.68	0.931
Major complication	Yes	0.89	0.73, 1.08	0.245
Distance to SNF	Yes	0.74	0.50, 1.08	0.116
Imaging during Initial Hospitalization	Yes	1.05	0.77, 1.42	0.769
Neoadjuvant chemotherapy	Yes	1.35	0.93, 1.97	0.114
Length of stay < = 7 days	Yes	0.91	0.73, 1.13	0.394
Comorbidity (Ref = 0)	1	1.16	0.94, 1.43	0.180
	>=2	0.98	0.68, 1.41	0.924
Insurance type (Ref = Medicare)	Private	0.97	0.68, 1.39	0.870
	Medicaid	1.06	0.69, 1.64	0.788

# Results

## Survival Curve By Readmission Into Different Hospital



< 30d re-admission to a different hospital has lower survival probability

# Conclusions

- Longer travel distance to a cystectomy provider is associated with higher 30-d readmission rates, readmission to a different hospital (closer to home), and worse survival
- Travel distance may indeed be a barrier to high quality care

# Conclusions

- Patients with longer travel distance may benefit from shorter and more frequent follow-up via phone, virtual post-op check, and PCP visits.
- Highlights need for better care coordination between index hospital and surrounding hospitals

# Future Directions

- Identify and compare early and late post-operative complications.
- Explore reasons for underlying disparities between outside versus index hospitals – which can be managed by outside and which should be transferred

## Obstacles to optimal healthcare delivery in bladder cancer

- Travel Distance
- *Financial Toxicity*
- Nutrition

## The burden of cancer isn't just cancer

By Carolyn Y. Johnson April 8



(Rachel Orr/The Washington Post)



# Introduction

- Financial Toxicity - “an adverse financial condition as a consequence of medical treatment”
- Cancer patients are 2.7X more likely to declare bankruptcy than those without cancer (even higher for younger cancer patients).

Ramsey et al, Health Affairs (2013)



# Financial Toxicity

- 13 percent of non-elderly patients with cancer spend at least a fifth of their income on treatment.
- Medicare cancer patients spent an average of \$4,727 of their own money on health care -- about \$1,000 more than people without cancer.

Davidoff et al, Cancer (2013)

Bernard et al, JCO (2011)



# Financial Toxicity

- Of the 20 million cancer survivors evaluated, 29 percent reported financial burden of some kind
  - Bankruptcy to borrowing money to not being able to pay for medical visits.
- Among those reporting FT, 86% had health insurance

Hrishikesh et al, Cancer (2014)



# Financial Toxicity

- *Is FT a health issue - does it affect QOL? Survival? Were people skipping doctor's visits, drugs or other treatments?*
- A copay of \$50 a month kept nearly a fifth of patients from continuing to fill prescriptions for TKI therapy for CML.
- For oral TKIs, patients more likely to stop or delay drug therapy as the portion they paid increased.
  - 13-20% increase stopping/delaying use per \$10 increase in OOP costs

Dusetzina JCO (2014)

Kaisaeng et al, JMCP (2014)



# Financial Toxicity

- Half of insured cancer patients cut spending on food and clothing or dipped into savings to pay for their treatment.
  - Majority cut back on leisure activities
  - Three-quarters received financial assistance with their drug copayments.

Zafar et al, The Oncologist (2013)



# Financial Toxicity

- Cancer patients who declared bankruptcy are 1.8X likely to die (any cause) (HR = 1.79) than cancer patients who didn't declare
  - Highest for colorectal (HR= 2.47) and prostate (HR=2.07)
  - More likely to be younger, female, and non-white, to have local- or regional- (v distant-) stage disease at diagnosis
  - Mean age was 53.0 years, men (54%), mean income \$49,000, and white (86%), married (60%), and urban (91%) and had local- or regional-stage disease at diagnosis (84%)

Ramsey et al, JCO (2016)



# Financial Toxicity and Bladder Cancer

- GU malignancies require expensive treatments and long-term surveillance
- Bladder cancer is estimated to be the most expensive cancer from diagnosis to death
- The effect of Financial Toxicity on GU malignancies has not been well defined

## Methodology

- UNC Health Registry/Cancer Survivorship Cohort
- 144 bladder cancer patients enrolled; 138 completed baseline questionnaire
- Patients surveyed via phone within 2 weeks of enrollment

# Methodology

- Financial Toxicity (FT) defined as agreement with the statement “you have to pay more for medical care than you can afford” via PSQ - 18
- HR-QOL measured using FACT-G, FACT-BI and PROMIS questionnaires

## Patient Demographic Characteristics

		N = 138 (%)
Age (years)	<56	22 (15.9%)
	56-72	68 (49.3%)
	>72	48 (34.8%)
Gender	Female	34 (24.6%)
	Male	104 (75.4%)
Race	Black	14 (10.1%)
	Hispanic	1 (0.7%)
	White	123 (89.1%)
Bladder Cancer Clinical T Stage	Non-invasive (Tis, Ta, T1)	69 (51.1%)
	Invasive (T2-T4)	66 (48.9%)
Financial Toxicity	Yes	33 (24%)
	No	105 (76%)

## Patient Characteristics and Financial Toxicity

		Overall N= (%)	Financial toxicity N= (%)	No Financial toxicity N= (%)	p-value
Age (yrs)	<56	22 (15.9%)	10 (45.5%)	12 (54.5%)	<.0001
	56-72	68 (49.3%)	21 (30.9%)	47 (69.1%)	
	>72	48 (34.8%)	2 (4.2%)	46 (95.8%)	
Gender	Female	34 (24.6%)	8 (23.5%)	26 (76.5%)	1.000
	Male	104 (75.4%)	25 (24.0%)	79 (76.0%)	
Race	Black	14 (10.1%)	8 (57.1%)	6 (42.9%)	0.005
	Hispanic	1 (0.7%)	0 (0.0%)	1 (100.0%)	
	White	123 (89.1%)	25 (20.3%)	98 (79.7%)	
BMI (kg/m <sup>2</sup> )	<18.5	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.554
	18.5-24.9	41 (29.7%)	8 (19.5%)	33 (80.5%)	
	25-29.9	52 (37.7%)	11 (21.2%)	41 (78.8%)	
	30-34.9	24 (17.4%)	8 (33.3%)	16 (66.7%)	
	>35	21 (15.2%)	6 (28.6%)	15 (71.4%)	

## Patient Characteristics and Financial Toxicity

		Overall	Financial toxicity	No Financial toxicity	p-value
Marital Status	Single	14 (10.2%)	3 (21.4%)	11 (78.6%)	0.949
	Married/Living with partner	95 (69.3%)	22 (23.2%)	73 (76.8%)	
	Divorced/Separated/Widowed	28 (20.4%)	7 (25.0%)	21 (75.0%)	
Education	Eighth grade or less	4 (2.9%)	1 (25.0%)	3 (75.0%)	0.014
	Some high school	9 (6.5%)	4 (44.4%)	5 (55.6%)	
	High school degree/GED	45 (32.6%)	13 (28.9%)	32 (71.1%)	
	Some college or Technical school	33 (23.9%)	11 (33.3%)	22 (66.7%)	
	Some graduate/masters	28 (20.3%)	4 (14.3%)	24 (85.7%)	
	Completed postgraduate/Professional	19 (13.8%)	0 (0.0%)	19 (100.0%)	
Bladder Cancer Clinical T Stage	Non-invasive (Tis, Ta, T1)	69 (51.1%)	48 (69.6%)	21 (30.4%)	0.042
	Invasive (T2-T4)	66 (48.9%)	56 (84.8%)	10 (15.2%)	

## Patient Quality of Life and Financial Toxicity

	Overall Mean (SD)	Financial toxicity, Mean (SD)	No Financial toxicity, Mean (SD)	p-value
FACT-GP <sup>1</sup> , Total score	79.4 (18.3)	72.2 (21.4)	81.5 (16.7)	0.01
FACT-GP <sup>1</sup> , Physical well being	22.3 (5.3)	20.3 (5.7)	23.0 (5.0)	0.01
FACT-GP <sup>1</sup> , Social/family well being	20.6 (5.8)	19.2 (6.6)	21.1 (5.5)	0.11
FACT-GP <sup>1</sup> , Emotional well being	19.2 (5.0)	18.3 (5.3)	19.5 (4.9)	0.21
FACT-GP <sup>1</sup> , Functional well being	17.1 (8.0)	14.6 (9.2)	17.8 (7.5)	0.05
FACT-BL <sup>2</sup> , Bladder cancer specific	33.3 (6.6)	32.4 (7.5)	33.5 (6.3)	0.41
PROMIS <sup>3</sup> Global Physical Health T-Score	46.4 (9.8)	43.2 (11.2)	47.4 (9.2)	0.03
PROMIS <sup>3</sup> Global Mental Health T-Score	49.9 (9.7)	45.5 (10.0)	51.3 (9.3)	<0.01

<sup>1</sup>FACT-GP: Functional Assessment of Cancer Therapy- General Population

<sup>2</sup>FACT-BL: Functional Assessment of Cancer Therapy- Bladder Cancer

<sup>3</sup>Patient-Reported Outcomes Measurement Information System

## Observations

- 24% of bladder cancer patients endorsed FT
- Younger patients more likely to experience FT;  
may be related to Medicare Eligibility
- Increased prevalence of FT among
  - African Americans
  - those with less education

# Observations

- Higher rates of FT among patients with non-invasive disease
  - Frequency and length of surveillance
  - Expensive surveillance procedures
- FT negatively associated with physical, functional and mental health-related QoL

# Next Steps

- Does FT effect healthcare adherence?
- Does FT have an effect of mortality?
- When and how does FT develop?
- What is the prevalence of FT in other GU malignances?
- What strategies can be put in place to limit the development of FT?



## What are the obstacles to optimal healthcare delivery in bladder cancer?

- Travel Distance
- Financial Toxicity
- *Nutrition*

## Nutritional Deficiency

- Inadequacy of nutrients in tissues; result of inadequate dietary intake or impairment of digestion, absorption, transport, or metabolism.

# Nutritional Deficiency

- Elderly at increased risk for nutritional deficiency
  - Mean age of bladder cancer patient = 73 years
- 40-80% of cancer patients are Nutritionally Deficient
- *Elderly cancer patient are at particularly high risk*

## Anecdotal Case

- 70 year-old male presented with bladder cancer
- Complaints of “bad taste” and weight loss in preceding months before surgery (cystectomy)
- Postoperative course was complicated wound problems, readmission, prolonged stay, and need for IV nutrition (TPN)

*Could this have been prevented by a preoperative evaluation and intervention?*

# Nutrition & Surgery

- Nutritional deficiency is a well-known risk factor for complications in surgery patients
  - Infections
  - Poor wound healing
  - Mortality
  - Decreased overall survival
- Several studies have demonstrated correlation between malnutrition and high clinical and economic effect
  - Increased morbidity
  - Prolonged hospital stay
  - Substantial increased cost of healthcare
  - Increased mortality



# Urology & Nutrition

- Urologic surgery represents an exceptional position in surgery
- Many patients who undergo a major procedure are  $\geq 70$  years
- Using NRS-2002 tool, patients  $\geq 70$  who undergo major surgery will have a score  $\geq 3$  (at risk of malnutrition), independent of other factors.
- Malignancy is another risk factor

# Terry & Bueschen, 1986

- Retrospective review of 69 radical cystectomies
- Preop nutritional status assessed by WBC & serum albumin
- 75% with severe nutritional depletion had severe complications

## COMPLICATIONS OF RADICAL CYSTECTOMY AND CORRELATION WITH NUTRITIONAL ASSESSMENT

WILLIAM J. TERRY, M.D.  
ANTON J. BUESCHEN, M.D.

From the Division of Urology, Department of Surgery,  
University of Alabama at Birmingham, Birmingham, Alabama

## Recent Studies

- 2011 (Gregg et al)
  - 103 of 538 (19%) met criteria for ND
  - 90-day mortality 16% ND vs. 5% non-ND
  - Overall survival at 3 years was 44% for ND vs. 68% for non-ND
- 2013 (Johnson et al)
  - Analysis of 1092 cystectomy patients in NSQIP
  - Low albumin was strongest predictor of complications
- 2014 (Smith et al)
  - Sarcopenia (muscle wasting) measured on CT scan
  - Predictor of complications and trend towards 2-yr survival

# Assessment of Nutritional Status

- Not straightforward
- No standardized definition of nutritional depletion
- Traditional markers of nutritional status
  - Weight
  - Serum albumin
  - Pre-albumin
  - CRP
  - Immune competence
  - Appetite, GI symptoms, energy level, loss of SQ fat, muscle wasting, edema, ascites
  - Hand-grip strength
  - Nutritional Indices



## Nutrition Markers

- Ideally should consider multiple factors:
  - Patient's physiologic requirements
  - Nutritional intake
  - Functional Status
  - Body composition
- Ideal nutritional marker:
  - Sensitive enough to identify alterations in early stage
  - Specific enough to modify only due nutritional imbalances
  - A nutritional intervention would correct its alteration
  - Correction of its levels would result in a better outcome



# Albumin

- Albumin
  - Hepatic protein, 60% of plasma proteins
  - 20-day half-life – marker of chronic malnourishment
  - Negative acute phase reactant
- Hypoalbuminemia – non-specific
  - Liver disease, nephrotic syndrome, burns, protein-losing enteropathy, malignancy, malnutrition
  - May be better surrogate of disease state

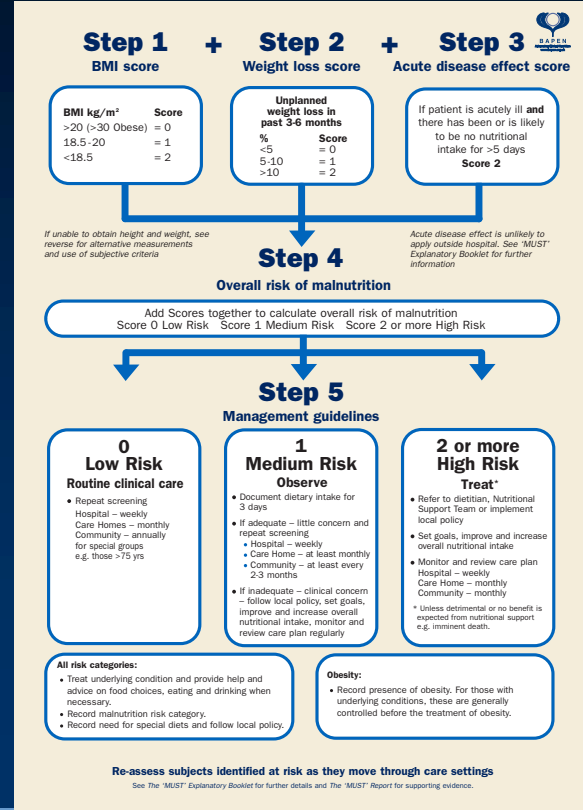
## Nutritional Indices



- Absence of a single gold standard objective measure has led to nutritional indices
  - Nutritional Risk Index & Maastricht Index
  - Mini Nutritional Assessment
  - Malnutrition Universal Screening Tool
  - Nutritional Risk Index-2002
  - Patient-Generated Subjective Global Assessment (PG-SGA)

# Malnutrition Universal Screening Tool

- [http://www.bapen.org/uk/pdfs/must/must\\_full.pdf](http://www.bapen.org/uk/pdfs/must/must_full.pdf)



## Scored Patient-Generated Subjective Global Assessment (PG-SGA)

History (Boxes 1-4 are designed to be completed by the patient.)

Patient ID Information

### 1. Weight (See Worksheet 1)

In summary of my current and recent weight:

I currently weigh about \_\_\_\_\_ pounds

I am about \_\_\_\_\_ feet \_\_\_\_\_ tall

One month ago I weighed about \_\_\_\_\_ pounds

Six months ago I weighed about \_\_\_\_\_ pounds

During the past two weeks my weight has:

☐ decreased <sub>(1)</sub> ☐ not changed <sub>(0)</sub> ☐ increased <sub>(2)</sub>

Box 1

### 2. Food Intake: As compared to my normal intake, I would rate my food intake during the past month as:

- ☐ unchanged <sub>(0)</sub>  
☐ more than usual <sub>(2)</sub>  
☐ less than usual <sub>(1)</sub>

I am now taking:

- ☐ normal food but less than normal amount <sub>(1)</sub>  
☐ little solid food <sub>(2)</sub>  
☐ only liquids <sub>(3)</sub>  
☐ only nutritional supplements <sub>(3)</sub>  
☐ very little of anything <sub>(4)</sub>  
☐ only tube feedings or only nutrition by vein <sub>(5)</sub>

Box 2

### 3. Symptoms: I have had the following problems that have kept me from eating enough during the past two weeks (check all that apply):

- ☐ no problems eating <sub>(0)</sub>  
☐ no appetite, just did not feel like eating <sub>(1)</sub>  
☐ nausea <sub>(1)</sub>  
☐ constipation <sub>(1)</sub>  
☐ mouth sores <sub>(2)</sub>  
☐ things taste funny or have no taste <sub>(3)</sub>  
☐ problems swallowing <sub>(2)</sub>  
☐ pain; where? <sub>(1)</sub> \_\_\_\_\_  
☐ other\*\* <sub>(3)</sub> \_\_\_\_\_
- ☐ vomiting <sub>(1)</sub>  
☐ diarrhea <sub>(1)</sub>  
☐ dry mouth <sub>(2)</sub>  
☐ smells bother me <sub>(1)</sub>  
☐ feel full quickly <sub>(2)</sub>  
☐ fatigue <sub>(1)</sub>

\*\* Examples: depression, money, or dental problems

Box 3

### 4. Activities and Function: Over the past month, I would generally rate my activity as:

- ☐ normal with no limitations <sub>(0)</sub>  
☐ not my normal self, but able to be up and about with fairly normal activities <sub>(1)</sub>  
☐ not feeling up to most things, but in bed or chair less than half the day <sub>(2)</sub>  
☐ able to do little activity and spend most of the day in bed or chair <sub>(3)</sub>  
☐ pretty much bedridden, rarely out of bed <sub>(4)</sub>

Box 4

Additive Score of the Boxes 1-4  A

The remainder of this form will be completed by your doctor, nurse, dietitian, or therapist. Thank you.

### Scored Patient-Generated Subjective Global Assessment (PG-SGA)

<p><b>Worksheet 1 - Scoring Weight (Wt) Loss</b></p> <p>To determine score, use 1 month weight data if available. Use 6 month data only if there is no 1 month weight data. Use points below to score weight change and add one extra point if patient has lost weight during the past 2 months.</p> <table style="width: 100%;"> <tr> <th style="text-align: left;">Wt loss in 1 month</th> <th style="text-align: left;">Points</th> <th style="text-align: left;">Wt loss in 6 months</th> <th style="text-align: left;">Points</th> </tr> <tr> <td>10% or greater</td> <td>4</td> <td>20% or greater</td> <td>4</td> </tr> <tr> <td>5-9.9%</td> <td>3</td> <td>10 - 19.9%</td> <td>3</td> </tr> <tr> <td>3-4.9%</td> <td>2</td> <td>6 - 9.9%</td> <td>2</td> </tr> <tr> <td>2-2.9%</td> <td>1</td> <td>2 - 5.9%</td> <td>1</td> </tr> <tr> <td>0-1.9%</td> <td>0</td> <td>0 - 1.9%</td> <td>0</td> </tr> </table> <p>Numerical score from Worksheet 1 <input style="width: 50px;" type="text"/></p>	Wt loss in 1 month	Points	Wt loss in 6 months	Points	10% or greater	4	20% or greater	4	5-9.9%	3	10 - 19.9%	3	3-4.9%	2	6 - 9.9%	2	2-2.9%	1	2 - 5.9%	1	0-1.9%	0	0 - 1.9%	0	<p style="text-align: right;"><b>Additive Score of the Boxes 1-4</b> (See Side 1) <input style="width: 50px;" type="text"/> <b>A</b></p> <p><b>5. Worksheet 2 - Disease and its relation to nutritional requirements</b></p> <p>All relevant diagnoses (specify) _____</p> <p>One point each:</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Cancer   <input type="checkbox"/> AIDS   <input type="checkbox"/> Pulmonary or cardiac cachexia  <input type="checkbox"/> Presence of trauma   <input type="checkbox"/> Age greater than 65 years         </div> <div> <input type="checkbox"/> Presence of decubitus, open wound, or fistula  <input type="checkbox"/> Chronic renal insufficiency         </div> </div> <p>Numerical score from Worksheet 2 <input style="width: 50px;" type="text"/> <b>B</b></p>																																																								
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<p><b>6. Worksheet 3 - Metabolic Demand</b></p> <p>Score for metabolic stress is determined by a number of variables known to increase protein &amp; calorie needs. The score is additive so that a patient who has a fever of &gt; 102 degrees (3 points) and is on 10 mg of prednisone chronically (2 points) would have an additive score for this section of 5 points.</p> <table style="width: 100%;"> <tr> <th style="text-align: left;">Stress</th> <th style="text-align: left;">none (0)</th> <th style="text-align: left;">low (1)</th> <th style="text-align: left;">moderate (2)</th> <th style="text-align: left;">high (3)</th> <th style="text-align: right;">Numerical score from Worksheet 3 <input style="width: 50px;" type="text"/> <b>C</b></th> </tr> <tr> <td>Fever</td> <td>no fever</td> <td>&gt;99 and &lt;101</td> <td>≥101 and &lt;102</td> <td>≥102</td> <td rowspan="3"></td> </tr> <tr> <td>Fever duration</td> <td>no fever</td> <td>&lt;72 hrs</td> <td>72 hrs</td> <td>&gt; 72 hrs</td> </tr> <tr> <td>Corticosteroids</td> <td>no corticosteroids</td> <td>low dose (&lt;10mg prednisone equivalents/day)</td> <td>moderate dose (≥10 and &lt;30mg prednisone equivalents/day)</td> <td>high dose steroid (≥30mg prednisone equivalents/day)</td> </tr> </table>		Stress	none (0)	low (1)	moderate (2)	high (3)	Numerical score from Worksheet 3 <input style="width: 50px;" type="text"/> <b>C</b>	Fever	no fever	>99 and <101	≥101 and <102	≥102		Fever duration	no fever	<72 hrs	72 hrs	> 72 hrs	Corticosteroids	no corticosteroids	low dose (<10mg prednisone equivalents/day)	moderate dose (≥10 and <30mg prednisone equivalents/day)	high dose steroid (≥30mg prednisone equivalents/day)																																																										
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<p><b>7. Worksheet 4 - Physical Exam</b></p> <p>Physical exam includes a subjective evaluation of 3 aspects of body composition: fat, muscle, &amp; fluid status. Since this is subjective, each aspect of the exam is rated for degree of deficit. Muscle deficit impacts point score more than fat deficit. Definition of categories: 0 = no deficit, 1+ = mild deficit, 2+ = moderate, 3+ = severe.</p> <div style="display: flex;"> <div style="flex: 1;"> <p><b>Muscle Status:</b></p> <table style="width: 100%;"> <tr> <td>temples (temporalis muscle)</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>clavicles (pectoralis &amp; deltoids)</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>shoulders (deltoids)</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>interscapular muscles</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>Scapula (latissimus dorsi, trapezius, deltoids)</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>thigh (quadriceps)</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>calf (gastrocnemius)</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>Global muscle status rating</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> </table> <p><b>Fat Stores:</b></p> <table style="width: 100%;"> <tr> <td>orbital fat pads</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>triceps skin fold</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>fat overlying lower ribs</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>Global fat deficit rating</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> </table> </div> <div style="flex: 1;"> <p><b>Fluid Status:</b></p> <table style="width: 100%;"> <tr> <td>ankle edema</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>sacral edema</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>ascites</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> <tr> <td>Global fluid status rating</td> <td>0</td> <td>1+</td> <td>2+</td> <td>3+</td> </tr> </table> </div> </div> <p>Numerical score from Worksheet 4 <input style="width: 50px;" type="text"/> <b>D</b></p> <p style="text-align: right;"><b>Total PG-SGA score</b> <input style="width: 50px;" type="text"/></p> <p style="text-align: right;">(Total numerical score of A+B+C+D above)</p> <p style="text-align: right;">(See triage recommendations below)</p> <p style="text-align: right;">Global PG-SGA rating (A, B, or C) = <input style="width: 50px;" type="text"/></p> <p>Clinician Signature _____ RD RN PA MD DO Other _____ Date _____</p>		temples (temporalis muscle)	0	1+	2+	3+	clavicles (pectoralis & deltoids)	0	1+	2+	3+	shoulders (deltoids)	0	1+	2+	3+	interscapular muscles	0	1+	2+	3+	Scapula (latissimus dorsi, trapezius, deltoids)	0	1+	2+	3+	thigh (quadriceps)	0	1+	2+	3+	calf (gastrocnemius)	0	1+	2+	3+	Global muscle status rating	0	1+	2+	3+	orbital fat pads	0	1+	2+	3+	triceps skin fold	0	1+	2+	3+	fat overlying lower ribs	0	1+	2+	3+	Global fat deficit rating	0	1+	2+	3+	ankle edema	0	1+	2+	3+	sacral edema	0	1+	2+	3+	ascites	0	1+	2+	3+	Global fluid status rating	0	1+	2+	3+
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Scapula (latissimus dorsi, trapezius, deltoids)	0	1+	2+	3+																																																																													
thigh (quadriceps)	0	1+	2+	3+																																																																													
calf (gastrocnemius)	0	1+	2+	3+																																																																													
Global muscle status rating	0	1+	2+	3+																																																																													
orbital fat pads	0	1+	2+	3+																																																																													
triceps skin fold	0	1+	2+	3+																																																																													
fat overlying lower ribs	0	1+	2+	3+																																																																													
Global fat deficit rating	0	1+	2+	3+																																																																													
ankle edema	0	1+	2+	3+																																																																													
sacral edema	0	1+	2+	3+																																																																													
ascites	0	1+	2+	3+																																																																													
Global fluid status rating	0	1+	2+	3+																																																																													
<p><b>Worksheet 5 - PG-SGA Global Assessment Categories</b></p> <table style="width: 100%;"> <tr> <th></th> <th style="text-align: left;">Stage A</th> <th style="text-align: left;">Stage B</th> <th style="text-align: left;">Stage C</th> </tr> <tr> <td>Category</td> <td>Well nourished</td> <td>Moderately malnourished</td> <td>Severely malnourished</td> </tr> <tr> <td>Weight</td> <td>No wt loss</td> <td>≤ 5% wt loss in 1 month (or 10% in 6 mos)</td> <td>&gt; 5% wt loss in 1 month (or &gt; 20% in 6 mos)</td> </tr> <tr> <td>Intake</td> <td>No deficit</td> <td>Deficient decrease in intake</td> <td>Severe deficit in intake</td> </tr> <tr> <td>Nutrition Impact</td> <td>OR Significant recent improvement</td> <td>OR Present of nutrition impact symptoms (PG-SGA Box 3)</td> <td>OR Present of nutrition impact symptoms (PG-SGA Box 3)</td> </tr> <tr> <td>Functioning</td> <td>No deficit OR Recent improvement</td> <td>Moderate functional deficit</td> <td>Severe functional deficit</td> </tr> <tr> <td>Physical Exam</td> <td>No deficit OR Chronic deficit but recent improvement</td> <td>Evidence of mild to moderate loss of muscle mass / SQ fat / muscle tone on palpation</td> <td>OR recent significant deterioration Clinical signs of malnutrition (eg. severe loss muscle, SQ tissue, possible edema)</td> </tr> </table>			Stage A	Stage B	Stage C	Category	Well nourished	Moderately malnourished	Severely malnourished	Weight	No wt loss	≤ 5% wt loss in 1 month (or 10% in 6 mos)	> 5% wt loss in 1 month (or > 20% in 6 mos)	Intake	No deficit	Deficient decrease in intake	Severe deficit in intake	Nutrition Impact	OR Significant recent improvement	OR Present of nutrition impact symptoms (PG-SGA Box 3)	OR Present of nutrition impact symptoms (PG-SGA Box 3)	Functioning	No deficit OR Recent improvement	Moderate functional deficit	Severe functional deficit	Physical Exam	No deficit OR Chronic deficit but recent improvement	Evidence of mild to moderate loss of muscle mass / SQ fat / muscle tone on palpation	OR recent significant deterioration Clinical signs of malnutrition (eg. severe loss muscle, SQ tissue, possible edema)																																																				
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<p><b>Nutritional Triage Recommendations:</b> Additive score is used to define specific nutritional interventions including patient &amp; family education, symptom management including pharmacologic intervention, and appropriate nutrient intervention (food, nutritional supplements, enteral, or parenteral triage).</p> <p><b>First line nutrition intervention includes optimal symptom management.</b></p> <p><b>Triage based on PG-SGA point score</b></p> <p><b>0-1</b> No intervention required at this time. Re-assessment on routine and regular basis during treatment.</p> <p><b>2-3</b> Patient &amp; family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (Box 3) and lab values as appropriate.</p> <p><b>4-8</b> Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms (Box 3).</p> <p><b>≥ 9</b> Indicates a critical need for improved symptom management and/or nutrient intervention options.</p>																																																																																	

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## Interventions: Role of Patient and Referring MD

- Arguably play the most important role in nutrition
- Provides the largest window between diagnosis and surgical therapy
- Nutrition optimization needs to begin at time of diagnosis to provide the most impact



# Nutrition Supplementation

- Encourage nutrition supplementation
  - Boost
  - Ensure
- Daily multivitamin
- Referral to dietitian/nutritionist
- Exercise program



## A quick word about other preoperative factors...

- Smoking cessation
- Weight loss in obese patients
- Exercise/Prehab

**Prehab** FOR PHYSICAL OPTIMIZATION

# UNC Cystectomy Nutrition Protocol

## Visit 1 – at initial consultation in MDC (+ FU at time of pre-op if NAC)

- All patients seen by RD in adjoining clinic
- Patient-Generated Subjective Global Assessment (PG-SGA)
- Labs (at visit and repeat at pre-op)
  - Prealbumin
  - CRP
  - Albumin

# UNC Cystectomy Nutrition Protocol

## Visit 1 (cont'd)

- Preoperative diet optimization & possible carb loading
  - e.g.
    - Prealbumin <18mg/dL → check nitrogen balance preop, increase protein to >1.5 gm/kg/d
    - If prealbumin is <18mg/dL with negative nitrogen balance, increase protein to 1.8-2gm/kg/d
    - Recheck in 2-3 weeks
- Receive nutrition packet with individual protein recommendations, meal plans, protein lists, protein loading,

# UNC Cystectomy Nutrition Protocol

## Visit 2 – In-patient after cystectomy

- RD consult on POD #3
- Reiterate home recommendations & decide on improvements for nutrition
- Multivitamin use (i.e. zinc deficiency relates to possible taste alterations?)

## Visit 3 - Post-operative Visit (2-3 weeks postop)

- Further review of recommendations and improvements

# UNC Cystectomy Nutrition Protocol

## Visit 4 – Post-operative FU (3 months) (optional)

- Repeat ND assessment
- Further review of recommendations and improvements
- Labs
  - Prealbumin
  - CRP
  - Albumin

# Conclusion

- Malnutrition is an important risk factor for all patients undergoing urologic surgery
- Multiple nutrition assessment indices exist
  - PG-SGA
- Further nutrition studies are needed identify malnutrition and best source of nutrition
- Need to identify and intervene early
  - Diet, exercise, other health-related behaviors

# Radical Cystectomy: 2019

- Refining Multimodal Therapy
  - Improving utilization of perioperative chemo
  - Development of new agents
- *Innovation to improve peri-operative Outcomes*
  - *Clinical care pathways*
  - *Refining the role of Robotics*
  - *Overcoming obstacles to optimal care*

# Improving Outcomes

- Increasing number of patients with invasive / advanced disease
  - Aging population = more bladder cancer
  - Referral practices: ad hoc regionalization
  - Reimbursement environment: QI
- *Need for Innovation in the treatment of bladder cancer patients to improve outcomes*

# Future Directions

- Optimizing patient
  - Nutrition
  - Pre-hab
- Better care coordination (role of travel distance)
- Financial toxicity
- mHealth

## At home PROs

- Structured patient phone calls by APP
  - question categories: symptoms, emotional/social, functional assessment.
  - Weekly < 30 days; bi-weekly 30-90 days
- Reduced ER visits and re-admissions
- High patient satisfaction
- *Improved communication*

Smith et al (2017)

## mHealth

- Address preventable complications / re-admissions Use of HIT – e.g. mobile health (mHealth)
- Tracks PROs and allows real-time feedback via internet-enabled devices



# mHealth

- Patient-centered care
- Increase quality
- Timely intervention of complications (UTIs, dehydration, fevers)
- High patient satisfaction
- Reduce morbidity, healthcare utilization (costs/penalties), death



## Improving Outcomes

- Increasing number of patients with invasive / advanced disease
  - Aging population = more bladder cancer
  - Referral practices: ad hoc regionalization
  - Reimbursement environment: QI
- *Need for Innovation in the treatment of bladder cancer patients to improve outcomes*

*“The fundamental problem with the quality of American medicine is that we’ve failed to view delivery of health care as a science.”*

- Peter Pronovost MD

