SYMPOSIUM: WHY ARE WE HERE?

• COMMUNICATE UROLOGIC ISSUES THAT IMPACT PRIMARY CARE
• PROVIDE A UNIFIED/CLEAR MESSAGE TO PATIENTS
• TREATMENT STRATEGIES FOR UROLOGIC PROBLEMS HAVE EVOLVED
• TECHNOLOGY IS RAPIDLY PROGRESSING
• NEW ERA: VALUE = QUALITY/COST
UROLOGY FOR PRIMARY CARE SYMPOSIUM:
BEYOND THE PSA

R. SCOTT OWENS, M.D.
UROLOGY OF CENTRAL PENNSYLVANIA
PROSTATE CANCER TESTING WITH PSA

USPSTF (UNITED STATES PREVENTIVE SERVICES TASK FORCE) RECOMMENDED AGAINST PSA BASED SCREENING FOR PROSTATE CANCER

INDICATING THAT THE HARMs OF SCREENING ARE GREATER THAN THE POTENTIAL BENEFIT. GRADE D MAY, 2012
USPSTF RECOMMENDATIONS: IMPACT

UROLOGISTS/ONCOLOGISTS: WAKE UP CALL

PRIMARY CARE: GUIDELINES

PATIENTS: CONFUSION
PROSTATE CANCER SYMPOSIUM:
ULTIMATE GOAL

ESTABLISH A CLEAR, UNIFIED MESSAGE TO PATIENTS ON

PROSTATE CANCER / PSA TESTING THAT ENCOMPASSES CLINICAL SIGNIFICANCE, RISKS, TESTING AND TREATMENT
OBJECTIVES PROSTATE CANCER/PSA SYMPOSIUM:

• RECOGNIZE NOT ALL PROSTATE CANCERS ARE THE SAME: SIGNIFICANT VS. INSIGNIFICANT

• FIND INHERENT VALUE IN PSA TESTING AND ITS DERIVATIVES

• ESTABLISH A CLINICAL ALGORITHM FOR PSA TESTING

• RECOGNIZE PROSTATE CANCER’S IMPACT ON OUR COMMUNITY
PROSTATE CANCER FACTS:

• 220,000 new cases each year

• 27,500 deaths

• 1 in 6 men

• 100% 5 year survival for localized disease

• 28% 5 year survival for advanced disease
PROSTATE CANCER: PENNSYLVANIA STATISTICS (2014)

• **MOST COMMON CANCER DIAGNOSED IN MEN** - **9,065 CASES**

• **SECOND LEADING CAUSE OF MALE CANCER DEATHS**

• **AFRICAN AMERICAN MEN HAVE A 30% HIGHER INCIDENCE THAN WHITES AND TWICE THE MORTALITY RATE**

• **BY COUNTY:** **PHILADELPHIA 890 CASES, ALLEGHENY 825 CASES, CUMBERLAND 112 CASES, AND DAUPHIN 104 CASES**
PROSTATE CANCER: ANATOMY

The prostate is located just below the bladder.

Bladder neck
Urethra
Prostate

Normal
Cancer
PROSTATE CANCER DIAGNOSIS:

**EXAM/PSA**

**BIOPSY**
PROSTATE SPECIFIC ANTIGEN (PSA)

- Glycoprotein enzyme secreted by prostate epithelial cells
- Not cancer specific
- Normal levels based on age
- Useful for monitoring recurrent disease
- Controversial role in screening
PROSTATE SPECIFIC ANTIGEN (PSA) DERIVATIVES

- **PSA DENSITY**
- **PSA VELOCITY**
- **AGE RELATED PSA**
- **TOTAL AND FREE PSA**
- **PROSTATE HEALTH INDEX (PHI)**
- **4KSCORE TEST**
TOTAL AND FREE PSA

Table 2. Free Prostate-Specific Antigen

<table>
<thead>
<tr>
<th>% Free PSA</th>
<th>Probability of Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>25%</td>
<td>8%</td>
</tr>
<tr>
<td>20%–25%</td>
<td>16%</td>
</tr>
<tr>
<td>15%–20%</td>
<td>20%</td>
</tr>
<tr>
<td>10%–15%</td>
<td>28%</td>
</tr>
<tr>
<td>0%–10%</td>
<td>56%</td>
</tr>
</tbody>
</table>

PSA = prostate-specific antigen.
PROSTATE HEALTH INDEX (PHI) SCORE

• **COMBINES TOTAL PSA, FREE PSA AND NEW BIOMARKER p2 PSA INTO A FORMULA THAT MORE ACCURATELY IDENTIFIES CANCER**

• **COMMERCIALY AVAILABLE**

• **HIGHER SENSITIVITY AND SPECIFICITY THAN FREE PSA**

• **USEFUL IN MONITORING PTS IN A SURVEILLANCE PROTOCOL**
4KSCORE TEST: IMPROVING PSA TESTING:

- Measures four kallikrein proteins: PSA, free PSA, intact PSA, and humankallikrein 2
- Plus includes clinical information: DRE, age, and history of a previous neg biopsy
- Uses proprietary algorithm to calculate risk of Gleason 7 or greater cancer (1 – 95 %)
- Commercially available in March 2014
1) Before you ordered the 4Kscore Test, were you considering a prostate biopsy for this patient?

2) After you received the 4Kscore Test results, did the patient either a) have a prostate biopsy performed by you, b) get scheduled for a prostate biopsy, or c) get referred by you to have a prostate biopsy within 90 days of the 4Kscore Test result?

3) Do you feel the 4Kscore Test influenced the decision for the patient to have (or not have) a prostate biopsy?

4) What were the results of the prostate biopsy (if the patient went on to have the biopsy)?
## DIAGNOSTIC ALTERNATIVES

### PCA 3
- **Gene expressed in the urine from prostate cancer cells**
- **Useful in pts with persistently elevated PSA**
- **Collected after prostate massage**

### MRI Prostate
- **Use of an endorectal coil**
- **Identifies higher grade tumors**
- **Useful in targeting lesions**
- **Plays a role in surveillance**
PROSTATE CANCER: DIAGNOSIS

MRI/DIAGNOSTIC

MRI/DIRECTED BIOPSY

DCE MRI: PCa increased vascular permeability
PROSTATE CANCER PSA TESTING: A NEW STRATEGY

• **PSA SCREENING**: VALUE IS NOT FULLY SUPPORTED

• **SELECTIVE SCREENING OF HIGH RISK GROUPS**
  (FAMILY HISTORY AND AFRICAN AMERICANS)

• **BASELINE TESTING** (AGE 45)

• **DIAGNOSTIC PSA**
PROSTATE CANCER: BASELINE PSA

- **STRATIFIES MEN INTO RISK GROUPS**

- **ELIMINATES NEED FOR ANNUAL TESTING IN MAJORITY**

- **REPLACES CONCEPT OF SCREENING**
PROSTATE CANCER: DIAGNOSTIC PSA

• HEMATURIA
• BPH WITH OBSTRUCTION
• NODULE
• FREQUENCY
• NOCTURIA
• URGENCY
Prostate Cancer Early Detection

**BASELINE EVALUATION**
- History and physical (H&P) including:
  - Family history
  - Medications
  - History of prostate disease and screening, including prior PSA and/or isoforms, exams, and biopsies
  - Race
  - Family history of BRCA1/2 mutations

**RISK ASSESSMENT**
- Start risk and benefit discussion about offering prostate screening:
  - Baseline PSA
  - Consider baseline digital rectal examination (DRE)

**EARLY DETECTION EVALUATION**
- **Age 45-75 y**
  - PSA <1 ng/mL, DRE normal (if done) → Repeat testing at 2–4 year intervals
  - PSA 1-3 ng/mL, DRE normal (if done) → Repeat testing at 1–2 year intervals
  - PSA >3 ng/mL or very suspicious DRE → See Indications for Biopsy (PROST-3)

- **Age >75 y, in select patients (category 2B)**
  - PSA <3 ng/mL, DRE normal (if done), and no other indications for biopsy → Repeat testing in select patients at 1–4 year intervals
PSA “OPENS” THE DOOR,

BUT THE BIOPSY

DIRECTS CARE
PROSTATE CANCER GRADING:

GLEASON SCORE  PROGNOSTIC
GLEASON GRADE/SCORE: PROGNOSIS

GLEASON 6

• Well differentiated tumor
• 20% positive margin rate
• 16 year disease specific survival

GLEASON 7 or higher

• Moderately-poorly differentiated tumor
• 48% positive margin rate
• 10 year disease specific survival
PROSTATE CANCER: “BAD ACTORS”

• **GLEASON 3 + 4** (MORTALITY RATE: 2.1)

• **GLEASON 4 + 3** (MORTALITY RATE: 6.3)

• **GLEASON 4 + 4** (MORTALITY RATE: 14.5)

• **GLEASON 5 + ?** (MORTALITY RATE: 39.1)
PROSTATE CANCER: PSA TESTING: WHY IS IT IMPORTANT?

- IDENTIFIES EARLY STAGE CANCER (WHEN COMBINED WITH DRE)
- MAJORITY OF LOCALIZED CANCERS ARE ASYMPTOMATIC
- DOES NOT CORRELATE WITH GRADE OF CANCER
- NO OTHER TEST AVAILABLE
- 60-70% OF PROSTATE CANCERS ARE CLINICALLY SIGNIFICANT
- 30-40% OF PATIENTS WITH ELEVATED PSA ARE DIAGNOSED WITH CANCER IN OUR COMMUNITY

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PROSTATE CANCER IMPACT ON OUR COMMUNITY:

UCPA DATA
UCPA DATA

UCPA
Elevated PSAs by Year
New Pt. Visits/Consults with dx code 790.93

<table>
<thead>
<tr>
<th>Year</th>
<th>Visits/Consults</th>
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<tbody>
<tr>
<td>2009</td>
<td>587</td>
</tr>
<tr>
<td>2010</td>
<td>672</td>
</tr>
<tr>
<td>2011</td>
<td>641</td>
</tr>
<tr>
<td>2012</td>
<td>457</td>
</tr>
<tr>
<td>2013</td>
<td>480</td>
</tr>
<tr>
<td>2014</td>
<td>352</td>
</tr>
</tbody>
</table>
UCPA Prostate Bx Malignancy Rates 2009-2015

2009: 32.8%
2010: 36.4%
2011: 36.4%
2012: 37.3%
2013: 39.4%
2014: 37.8%
2015*: 41.0%
UCPA - Prostate Malignancies by Age Group
1/1/12 to 7/31/15 (43 months/936 Cases)

- 60 to 69: 44%
- 50 to 59: 20%
- 70 to 79: 27%
- 80 to 89: 7%
- 90+: 0%
- 40 to 49: 2%

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UCPA - Prostate Malignancies by PSA Result
1/1/12 to 7/31/15 (43 months/933 Cases)

- 4 to 10.0 (63%)
- 10.1 to 20.0 (17%)
- 20.1+ (10%)
- Less than 4 (10%)
UCPA - Prostate Malignancies by Gleason
1/1/12 to 7/31/15 (43 months/935 Cases)

Gleason 7 54%
Gleason 6 26%
Gleason 8 15%
Gleason 9 4%
Gleason 10 1%
UCPA Prostate Malignancies (1/1/12 to 7/31/15)
Gleason Scores by PSA Results

UCPA DATA
UCPA - Prostate Cancer Treatments
1/1/12 to 12/31/14 (36 months/791 Cases)

- IMRT: 44%
- Prostatectomy: 31%
- Observation: 11%
- Androgen Deprivation: 6%
- Brachytherapy: 1%
- Undecided: 4%
- Cryotherapy: 0%
- Deceased: 1%
- Not Documented: 2%
PROSTATE CANCER/PSA TESTING

CONCLUSIONS

• 40% OF PTS WITH AN ELEVATED PSA WERE FOUND TO HAVE CANCER
• 70% OF CANCERS WERE GLEASON 7 OR HIGHER
• TREATMENTS SHOULD BE TAILORED TO RISK OF CANCER
• PSA TESTING HAS VALUE
• 4Kscore Test WILL PROVIDE ADDITIONAL VALUE
• PSA DETECTED CANCER IS CLINICALLY SIGNIFICANT