Clinical Utility of BSI in Sweden

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LUND UNIVERSITY

Skåne University Hospital

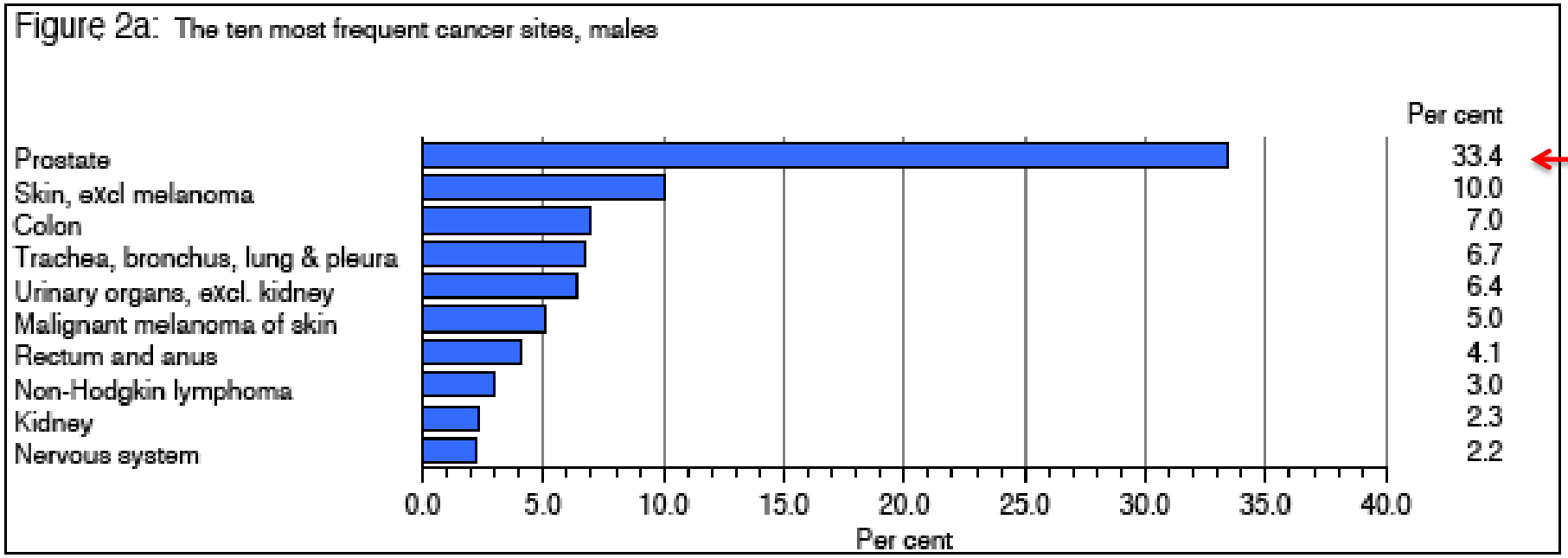
Agenda

- Incidence and mortality of prostate cancer in Sweden
- National Prostate Cancer Registry in Sweden (NPCR)
- Guidelines for staging and monitoring of bone metastases
- On-going and future activities related to BSI

In Sweden 1/6 will be diagnosed with prostate cancer

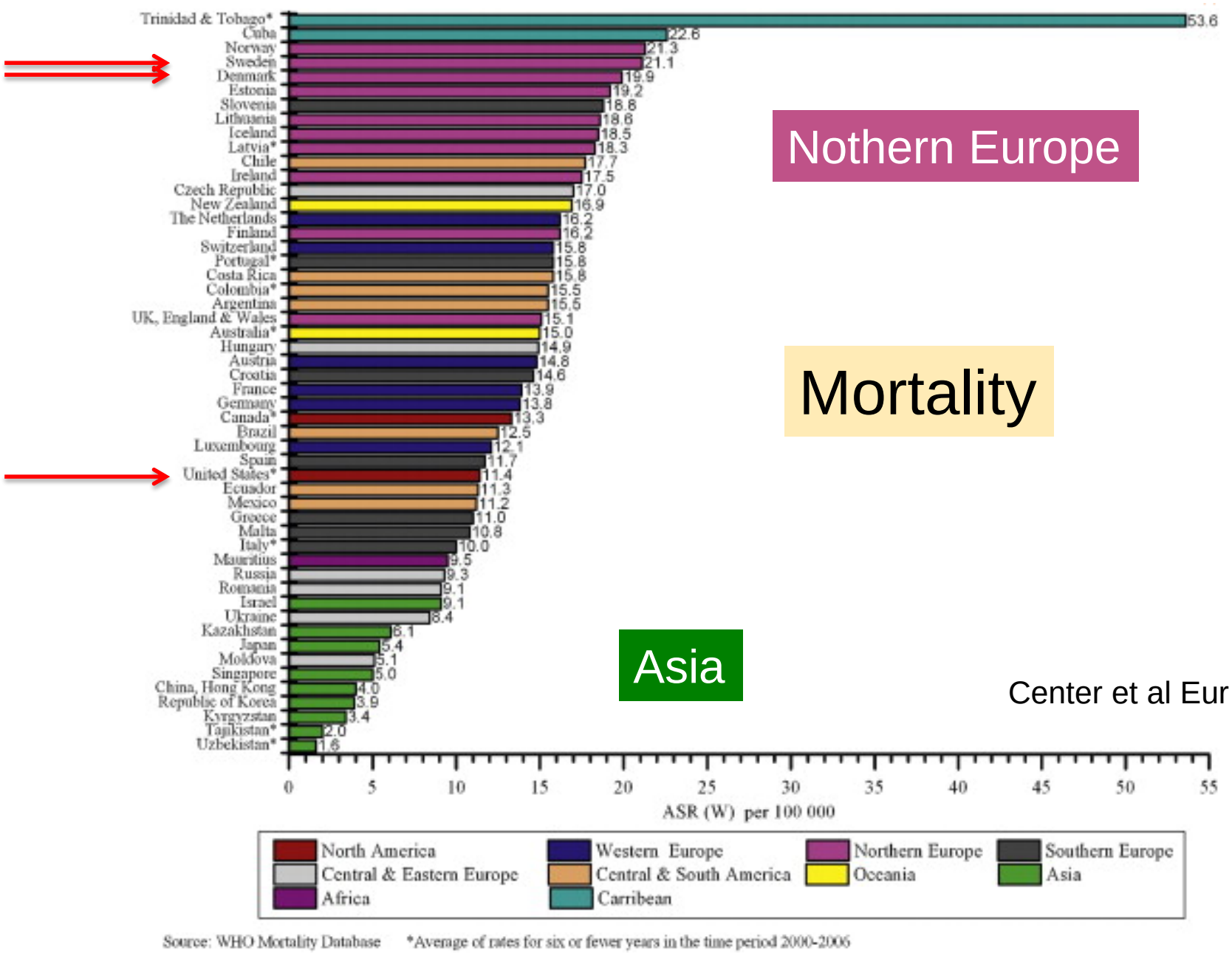
Incidence 10 000
Mortality 2 400

Figure 2a: The ten most frequent cancer sites, males



OFFICIAL STATISTICS OF SWEDEN
Statistics – Health and Medical Care
Cancer Incidence in Sweden 2009

Socialstyrelsen



Nothern Europe

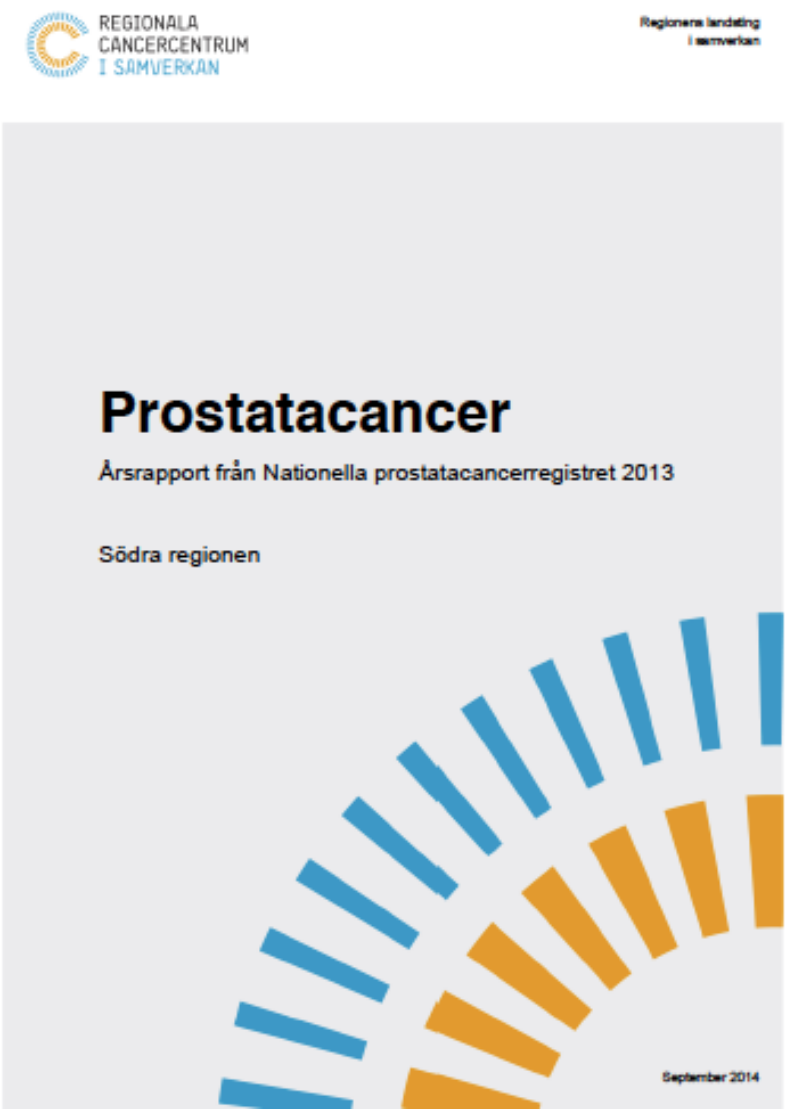
Mortality

Asia

Center et al Eur Urol 2012

Prostate cancer mortality rates for select countries, 2000â2006. *Average of rates for â¤6 yr in the time period 2000â2006. Source: World Health Organization mortality database [22].ASR (W) = age-standardized rate (world).

National prostate cancer registry in Sweden



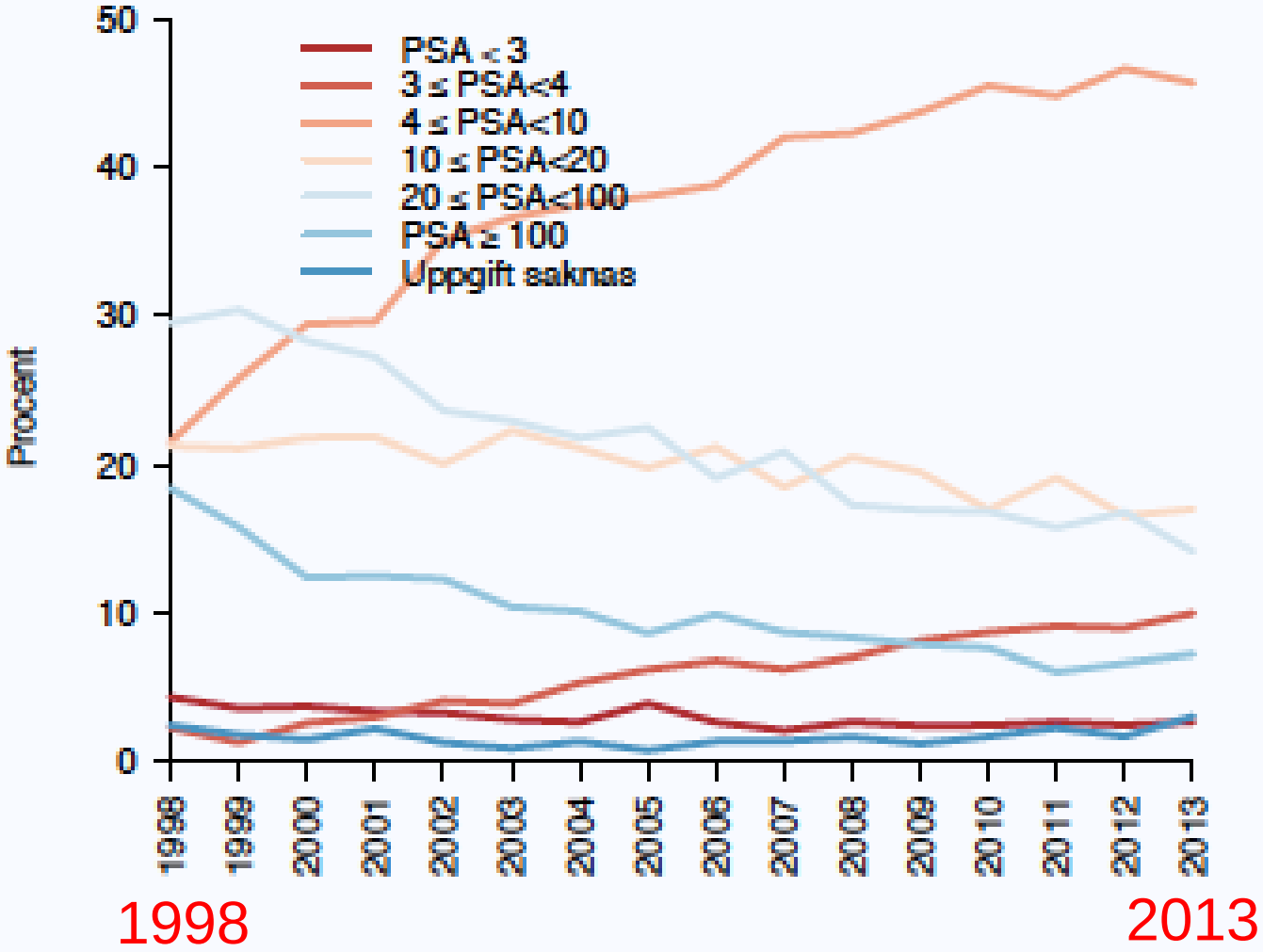
On-line reporting

>120 000 PCa cases in 2012

Capture rate 98%

National prostate cancer registry in Sweden

PSA level at diagnosis



1998 2013

PSA 4-10

PSA >100

Guidelines for prostate cancer in Sweden 2014

Risk stratification according to D´Amico (modified)

Intermediate risk	High risk
cT2b	cT2c-T3
and/or	and/or
Gleason 7	Gleason 8-10
and/or	and/or
PSA = 10-19,9	PSA ≥ 20

Guidelines for prostate cancer in Sweden 2014

Bone scan is the golden standard for M-staging

High-risk patients: always

Intermediate risk: before treatment

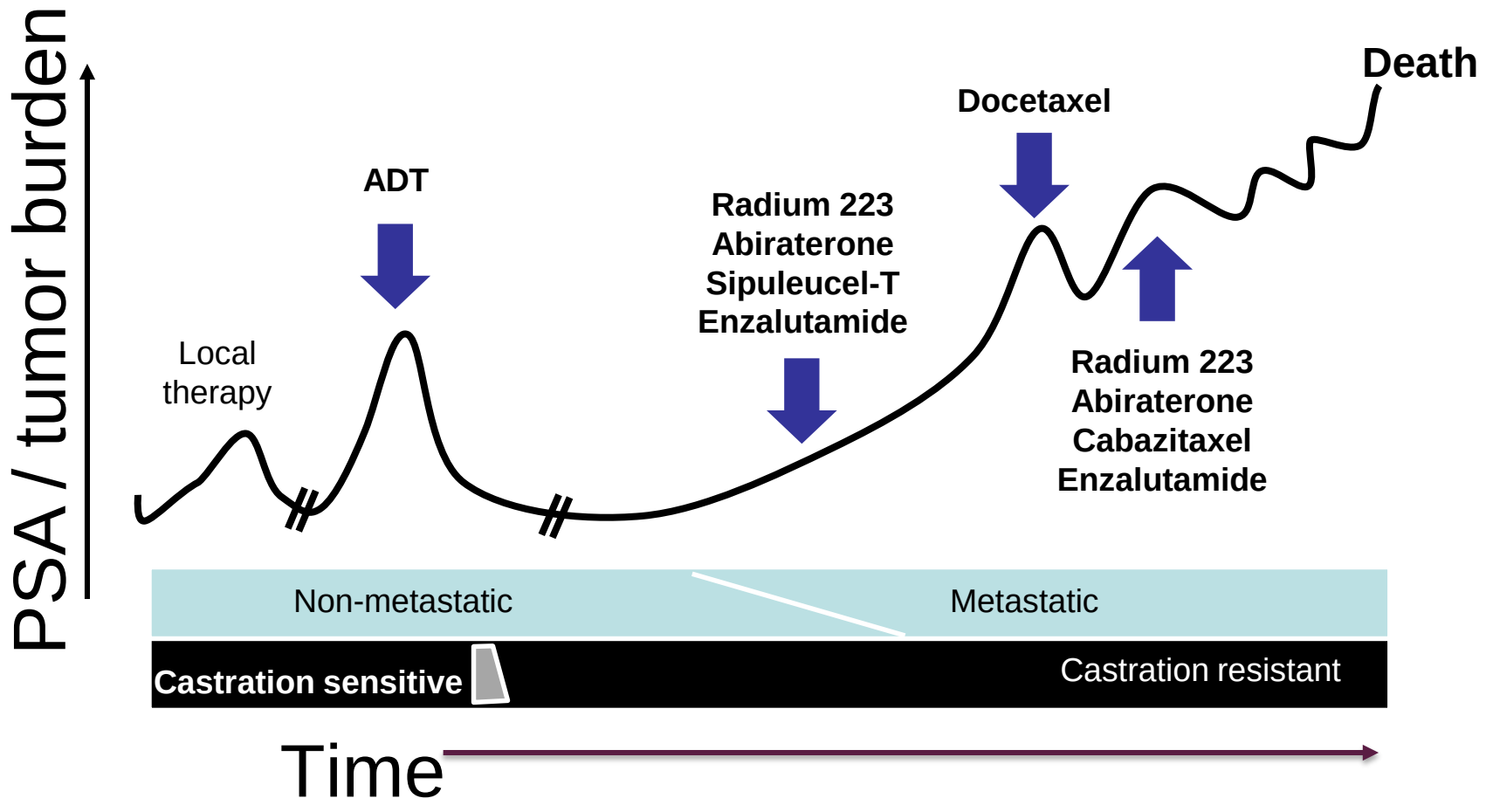
>73% undergoes bone scan

Guidelines for prostate cancer in Sweden 2014

Castration-resistant prostate cancer

- Clarify dissemination (symptoms?)
- Clinical trials available?
- Discuss at MDT
- On-line registration in NPCR (new)
- Individualized follow-up - QoL

Prostate cancer disease continuum:
mCRPC treatment options 2014



We need to predict and evaluate response

PSA is not always a good biomarker…

- Interpreting PSA declines in the context of novel targeted therapies must be done with caution, based on proposed mechanism of action
  - After anti-androgen treatment (eg, enzalutamide, abiraterone), PSA transcripts are quickly downregulated because PSA expression is directly regulated by androgen receptors
  - Sipuleucel-T has shown significant overall survival benefit with no PSA change, raising questions about the value of PSA response for non-hormonal non-cytotoxic drugs
- Guidelines state that PSA response data should be viewed together with other clinical data
- Recent studies had radiographic progression and not PSA as primary endpoint

Prostate Cancer Nomogram for “Hormone Refractory” disease with clinical parameters and biomarkers included

For patients with advanced, metastatic prostate cancer that has been treated maximally with hormone therapy to control the effects of the male hormone, androgen. The nomogram predicts the survival probability one to two years later. To learn more, visit our frequently asked questions.

Enter Your Information Clear Calculate

To gather the information required below, download our PDF worksheet.

Current Age 75 (40 to 85 yrs)

KPS (Karnofsky Performance Status) 80
KPS value, assigned by a physician, nearest to the planned treatment start date or today's date.

Hemoglobin 13 (6 to 17 g/dl)
HGB value from the laboratory report nearest to the planned treatment start date or today's date.

PSA 350 (0.01 and 8450 ng/ml)
PSA value from the laboratory report closest to the planned treatment start date or today's date.

LDH (Lactate Dehydrogrnase) 1400 (116 to 1955 IU/L)
LDH value from the laboratory report closest to the planned treatment start date or today's date.

ALK (Alkaline Phosphatase) 60 (19 to 3079 IU/L)
ALK value from the laboratory report closest to the planned treatment start date or today's date.

Albumin 3 (2.6 to 5.2 g/dl)
Albumin value from the laboratory report closest to

Your Results

Learn more about your results below.

Survival Probability	1 Year	17%
	2 Year	2%
Median Survival Months		6

Print These Results

Make an Appointment

Call us to schedule an appointment or contact us online

Contact Us

www.nomograms.org

More biological tools included!

Halabi nomogram – predicting OS probability

Updated Prognostic Model for Predicting Overall Survival in First-Line Chemotherapy for Patients With Metastatic Castration-Resistant Prostate Cancer

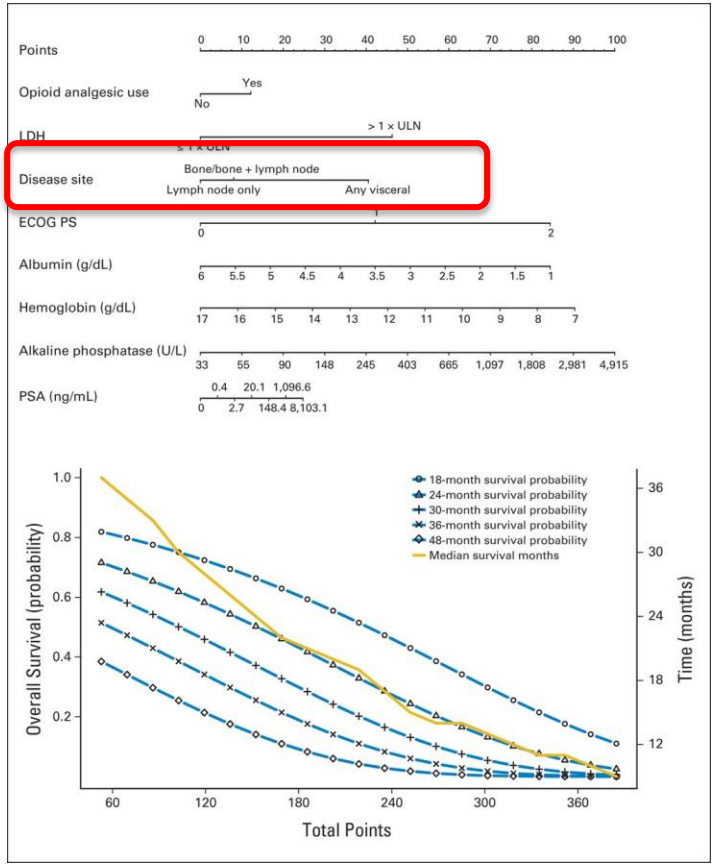
Susan Halabi, Chen-Yen Lin, W. Kevin Kelly, Karim Fizazi, Judd W. Moul, Ellen B. Kaplan, Michael J. Morris, and Eric J. Small

Halabi S et al. JCO 2014;32:671-677

Opioid use, ECOG

Hemoglobin, PSA, ALP, LDH

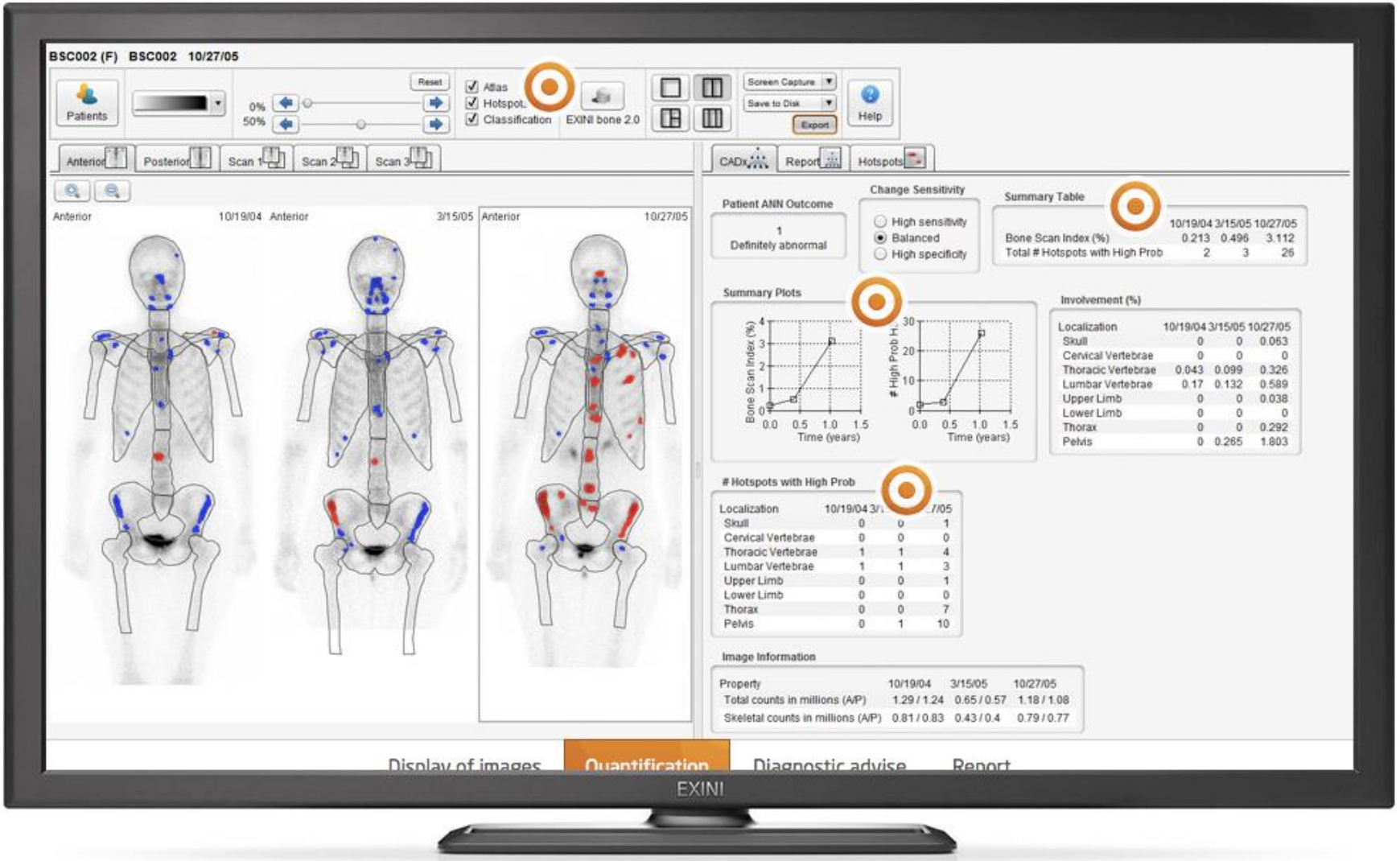
Disease site:
Lymph-node, bone, visceral



An online calculator is available at:

https://www.cancer.duke.edu/Nomogram/firstlinechemotherapy.html.

Exini Bone ™


BSC002 (F) BSC002 10/27/05
Patients
Reset
0%
50%
Atlas
Hotspot
Classification
EXINI bone 2.0
Screen Capture
Save to Disk
Export
Help
Anterior
Posterior
Scan 1
Scan 2
Scan 3
CADx
Report
Hotspots
Anterior 10/19/04
Anterior 3/15/05
Anterior 10/27/05
Patient ANN Outcome
1
Definitely abnormal
Change Sensitivity
High sensitivity
Balanced
High specificity
Summary Table
10/19/04 3/15/05 10/27/05
Bone Scan Index (%) 0.213 0.496 3.112
Total # Hotspots with High Prob 2 3 26
Summary Plots
Bone Scan Index (%)
High Prob Hotspots
Time (years)
Involvement (%)
Localization 10/19/04 3/15/05 10/27/05
Skull 0 0 0.063
Cervical Vertebrae 0 0 0
Thoracic Vertebrae 0.043 0.099 0.326
Lumbar Vertebrae 0.17 0.132 0.589
Upper Limb 0 0 0.038
Lower Limb 0 0 0
Thorax 0 0 0.292
Pelvis 0 0.265 1.803
Hotspots with High Prob
Localization 10/19/04
Skull 0 0 1
Cervical Vertebrae 0 0 0
Thoracic Vertebrae 1 1 4
Lumbar Vertebrae 1 1 3
Upper Limb 0 0 1
Lower Limb 0 0 0
Thorax 0 0 7
Pelvis 0 1 10
Image Information
Property 10/19/04 3/15/05 10/27/05
Total counts in millions (A/P) 1.29 / 1.24 0.65 / 0.57 1.18 / 1.08
Skeletal counts in millions (A/P) 0.81 / 0.83 0.43 / 0.4 0.79 / 0.77
Display of images
Quantification
Diagnostic advise
Report
EXINI

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

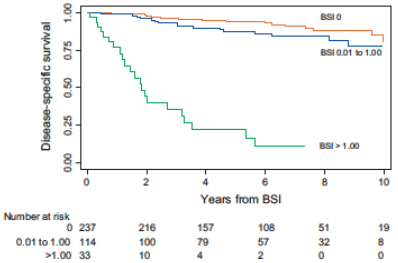
European Association of Urology

Platinum Priority – Prostate Cancer

Editorial by Guru Sonpavde and Andrew J. Armstrong on pp. 85–87 of this issue

n=795

A Novel Automated Platform for Quantifying the Extent of Skeletal Tumour Involvement in Prostate Cancer Patients Using the Bone Scan Index



David Ulmert[a,b,c,1], *Reza Kaboteh*[d,1], *Josef J. Fox*[e], *Caroline Savage*[f], *Michael J. Evans*[g], *Hans Lilja*[a,c,h,i], *Per-Anders Abrahamsson*[b], *Thomas Björk*[b], *Axel Gerdtsson*[b], *Anders Bjartell*[b], *Peter Gjertsson*[d], *Peter Höglund*[j], *Milan Lomsky*[d], *Mattias Ohlsson*[k,l], *Jens Richter*[l], *May Sadik*[d],

Manual and automated BSI measurements were strongly correlated (r = 0.80), correlated more closely (r = 0.93) when excluding cases with BSI scores 10 (1.8%), and were independently associated with PCa death (p < 0.0001 for each) when added to the prediction model.

Predictive accuracy of the base model (C-index: 0.768; 95% confidence interval [CI], 0.702–0.837) increased to 0.794 (95% CI, 0.727– 0.860) by adding manual BSI scoring, and increased to 0.825 (95% CI, 0.754–0.881) by adding automated BSI scoring to the base model.

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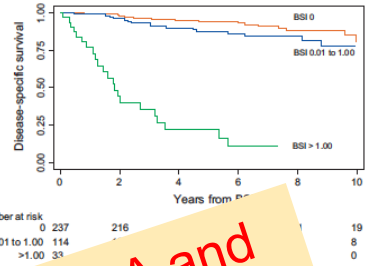

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(95% CI, 0.727– 0.860) by adding manual BSI scoring,
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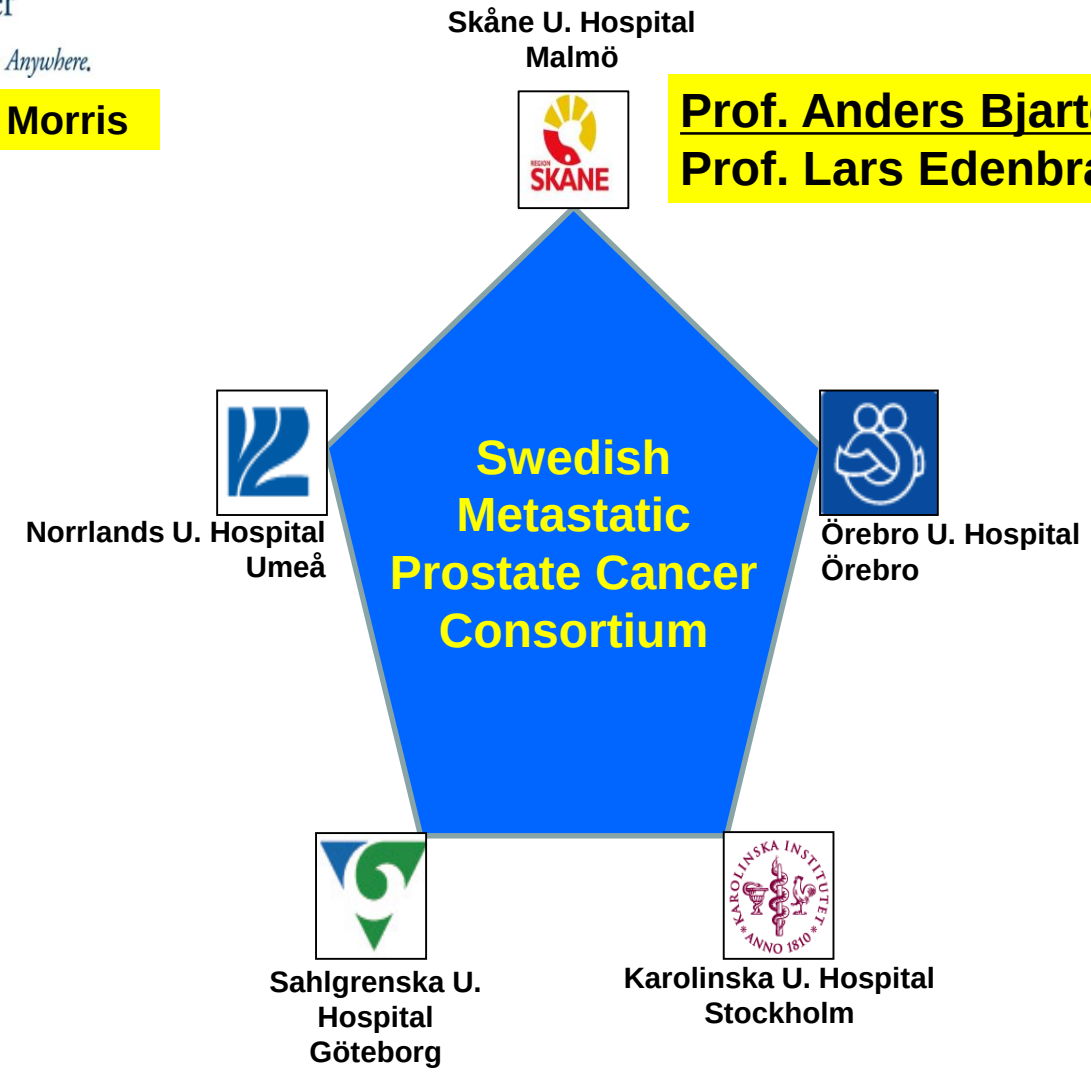
- This predictive imaging biomarker may prove complementary to PSA and ALP for an objective treatment response evaluation and prediction of survival in the management of patients with prostate cancer

Memorial Sloan-Kettering Cancer Center

The Best Cancer Care. Anywhere.

Dr. Michael Morris



NewYork-Presbyterian

The University Hospital of Columbia and Cornell

Dr. Lawrence Schwartz

Clinical utility of BSI in Sweden

- Exini bone™ implemented at prostate cancer centers
- Support decision-making to initiate and continue CRPC treatment.
- Retrospective studies on value of BSI to predict outcome and response to treatment published (ADT)
- Retrospective multicenter studies on-going (abiraterone, enzalutamide, Ra-223, tasquinimode, cabazitaxel)
- Prospective trials initiated
- BSI report in National Prostate Cancer Registry

Conclusions I

- A paradigm shift: New treament options in CRPC are pushing us towards a need for quantification of tumor burden
- BSI provides an opportunity to start utilizing quantitative measurement of bone metastases
- We can then better select ”suitable patients”
- We can more objectively evaluate response to treatment

Conclusions II

- Bone scan is the golden standard in monitoring patients with bone metastases
- BSI provides additive value in using bone scan
  - Useful at MDT conferences
- BSI can be integrated in prediction models with multiplexing of clinical characteristics and other biomarkers