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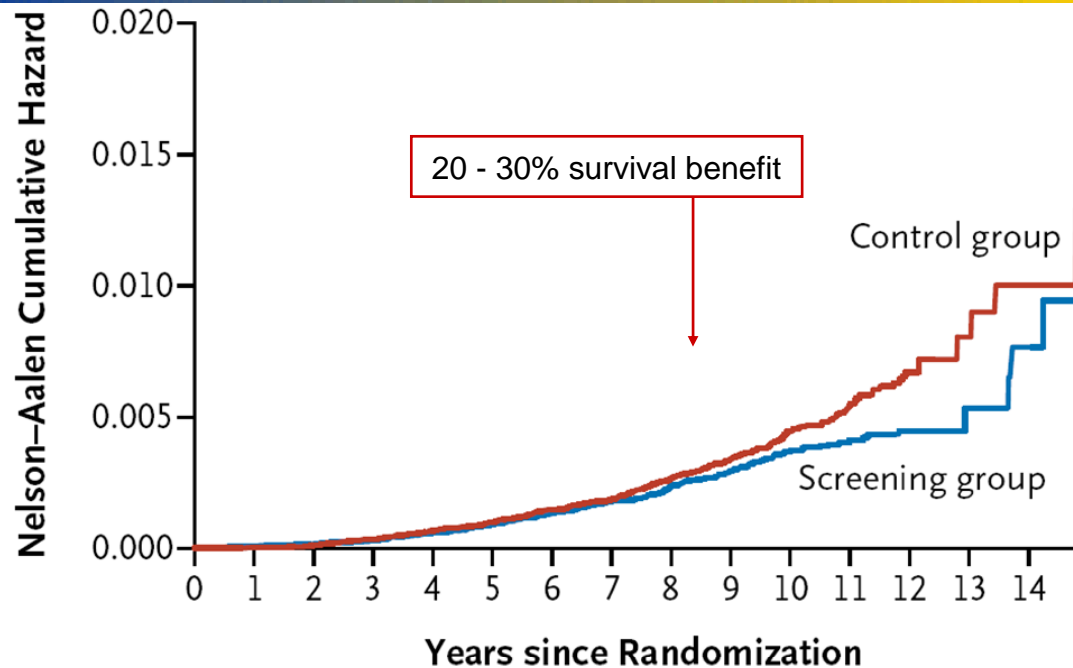
Quantifying the Economic Value of *phi*

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Discussion Points

- Prostate Cancer Screening and Detection
- Prostate Biopsies
- Biopsy Costs
- Economic Studies and Models

PSA Screening Reduce PCa Mortality



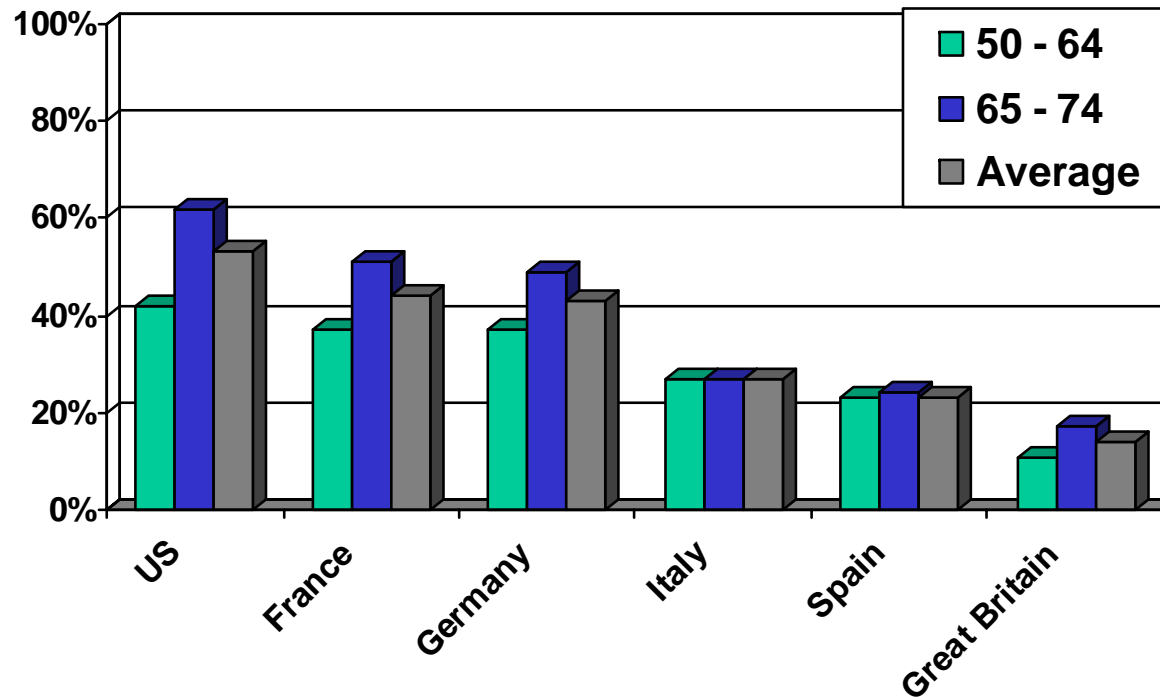
- 20 - 30%* reduction in PCa mortality
- Risk of over diagnosis and over treatment
- New biomarkers with increased specificity needed

Schroder et al. N Engl J Med 2009;360:1320-8

* Roobol et al. EurJUrol 2009;56:584-91

Prostate Cancer Screening

PSA Screening Rates^{1,2}



- U.S. National Health Policy calls for PSA screening yet it is underutilized
- Europe lacks established screening programs

1. Grubb RL et. al., Mortality Results from a Randomized Prostate-Cancer Screening Trial, NEJM, 360;12, March 26,2009.

2. Howard, David H. Cancer Screening and Age in the United States and Europe. Health Affairs 28;6, November/December 2009

Prostate Biopsies

- tPSA – Typically high sensitivity but lacks specificity
 - ✓ Schroeder et. al. reported ~ 75% of biopsies in first round of screening are negative³
 - ✓ Catalona et al. reported ~ 77% of biopsies in men are negative⁴
- ϕ 's[†] value:
 - ✓ Demonstrated improved specificity⁵
 - ✓ Ability to reduce negative biopsies and costs

3. Schröder FH, et. al. Eleven-year Outcome of Patients with Prostate Cancers Diagnosed During Screening After Initial Negative Sextant Biopsies. *European Urology*, 57(2010)

4. Catalona WJ, Richie JP, Ahmann FR, et al. Comparison of digital rectal examination and serum prostate specific antigen in the early detection of prostate cancer: results of a multicenter clinical trial of 6,630 men. *J Urol*. May 1994;151(5):1283-1290

5. Catalona, WJ et al *Journal of Urology* May 2011, Beckman Coulter Hybritech p2PSA Label. Approved for use in Europe 2009.

[†]Not Available in the United States

Cost of Prostate Cancer Diagnosis

- Current diagnostic strategy creates economic burden due to a large number of negative biopsies

Cost \ Country	U.S. ⁶	France ⁷	U.K. ⁸
Office Exam & Blood Tests	\$183 (€128)	€210	£62 (€70)
Biopsy	\$562 (€393)	€700	£307 (€350)
Anatomic Pathology	\$1540 (€1080)	€75-90	n/a
Total	\$2285 (€1600)	€985-1000	£369+Pathology (€420+Pathology)

- Nichol et al. Budget Impact Analysis of a New Prostate Cancer Risk Index for Prostate Cancer Detection. Prostate Cancer and Prostatic Diseases (2011) DOI: 10.1038/pcan.2011.16
- Le dépistage et le traitement du cancer de la prostate. Rapport n° 318 (2008-2009) de M. Bernard DEBRÉ, député, fait au nom de l'Office parlementaire d'évaluation des politiques de santé, déposé le 2 avril 2009
- Chilcott et al. Option appraisal: screening for prostate cancer. Report to the UK National Screening Committee. Version 2.0 May 2010. [SchARR]

phi Health Economic Research

- Conducted studies in the U.S. and EU to assess *phi*'s effect on prostate cancer detection and biopsies
 - ✓ Short term: within a 1 year budget cycle
 - ✓ Long term: within a lifetime model
- The studies assessed various metrics
 - ✓ Negative Biopsies
 - ✓ Total Costs

U.S. Budget Impact Model⁶

- Evaluated the health economic impact of introducing *phi* in a private health plan
- A one-year time frame
- Applied two different tPSA ranges
 - ✓ 2 -10 ng/mL
 - ✓ 4 -10 ng/mL
- Males 50 to 75 years old
 - ✓ 32% of eligible men screened annually
- Pathology Service Payment \$125
 - ✓ (tPSA + fPSA + p2PSA)

6. Nichol et al. Budget Impact Analysis of a New Prostate Cancer Risk Index for Prostate Cancer Detection. Prostate Cancer and Prostatic Diseases (2011) DOI: 10.1038/pcan.2011.16

U.S. Budget Impact Model⁶

Published Results

Utilization of <i>phi</i>	tPSA 2-10 ng/mL		tPSA 4-10 ng/mL	
	Negative Biopsy Reduction	Total Costs Reduction	Negative Biopsy Reduction	Total Costs Reduction
10%	-3%	-1.7%	-3%	-1.2%
50%	-14%	-8.3%	-14%	-6.7%
100%	-29%	-17%	-27%	-12%

6. Nichol et al. Budget Impact Analysis of a New Prostate Cancer Risk Index for Prostate Cancer Detection. Prostate Cancer and Prostatic Diseases (2011) DOI: 10.1038/pcan.2011.16

Beckman Internal Study (EU Data)

- Evaluated the impact of *phi* in European prostate cancer screening practices
 - ✓ Simulated cost-effectiveness model
- A life-time model projection
- Applied to a tPSA range of 3-10 ng/mL
- Males 50 to 75 years old
 - ✓ 80% of eligible men screened every 4th year
- Pathology Service Payment €100
 - ✓ (tPSA + fPSA + p2PSA)

Beckman Internal Study (EU Data)

Unpublished Results

Assumes 100% utilization of *phi* for eligible subjects

Screening Metrics	1-Year Interval	4-Year Interval
Negative biopsy reduction	-47%	-29%
Diagnosis cost reduction	-36%	-21%
Gain in cost-effectiveness	+7%	+12%

Conclusion

In multiple healthcare settings where
tPSA testing is utilized
for Prostate Cancer detection,
***phi* has the ability to reduce
negative biopsies**

Thank You

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