Detection and Mitigation of Medical Errors

Ted Schenberg, CEO

International Symposium on
Forensic Science Error Management

July 21, 2015

About Strand Diagnostics, LLC

- Formed in ‘05 as Forensic DNA crime lab
- FQS accredited to FBI QA Standards to process crime samples
- States of NY, PA and CLIA-accredited to process medical samples
- Located in Indianapolis, IN
- Privately held
- Major forensic clients include Phoenix, Philadelphia, South Carolina

Fox News Medical Exposé (*2008*)

***NO CANCER FOUND AFTER RADICAL PROSTECTOMY*!**

An “Ah-Ha” Moment !

What Happened Next

- Contacted prominent Urologist who confirmed the problem of switching errors in urology
- Obtained medical accreditations: CLIA, NY, etc.
- Validated our forensic DNA identity test for medical use
- Dubbed it: DNA SPECIMEN PROVENANCE ASSAY

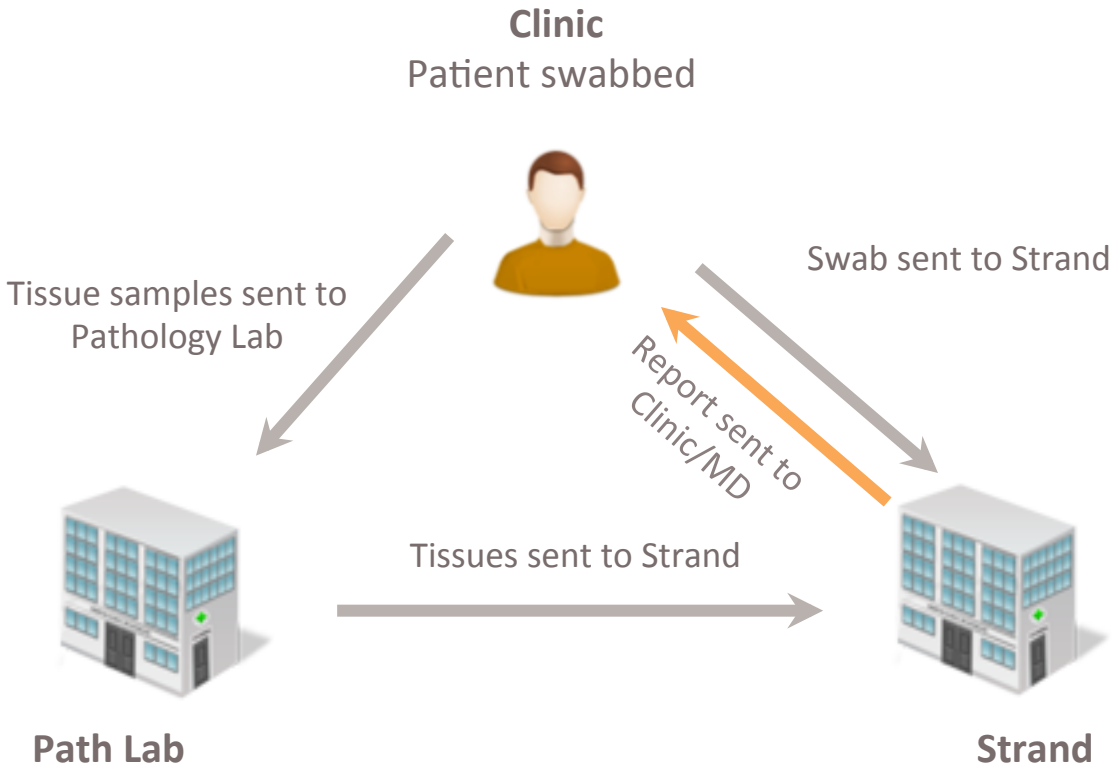
"DSPA"

- Developed the KnowError® system for prostate biopsies – Launched '09 – Filed for patent

Know Error® System (Patented)

- **Collection kit with bar codes and forensic chain-of-custody procedures to reduce errors**
- **Includes DSPA to establish specimen provenance**
  - **DSPA** increases specificity of histopathology *(eliminates false positives resulting from occult switching errors)*
  - Arms MDs with information to complete the diagnosis and ensure appropriate treatment

The Know Error® Process



2 to 3 Day Turn Around Time

At Strand's Laboratory

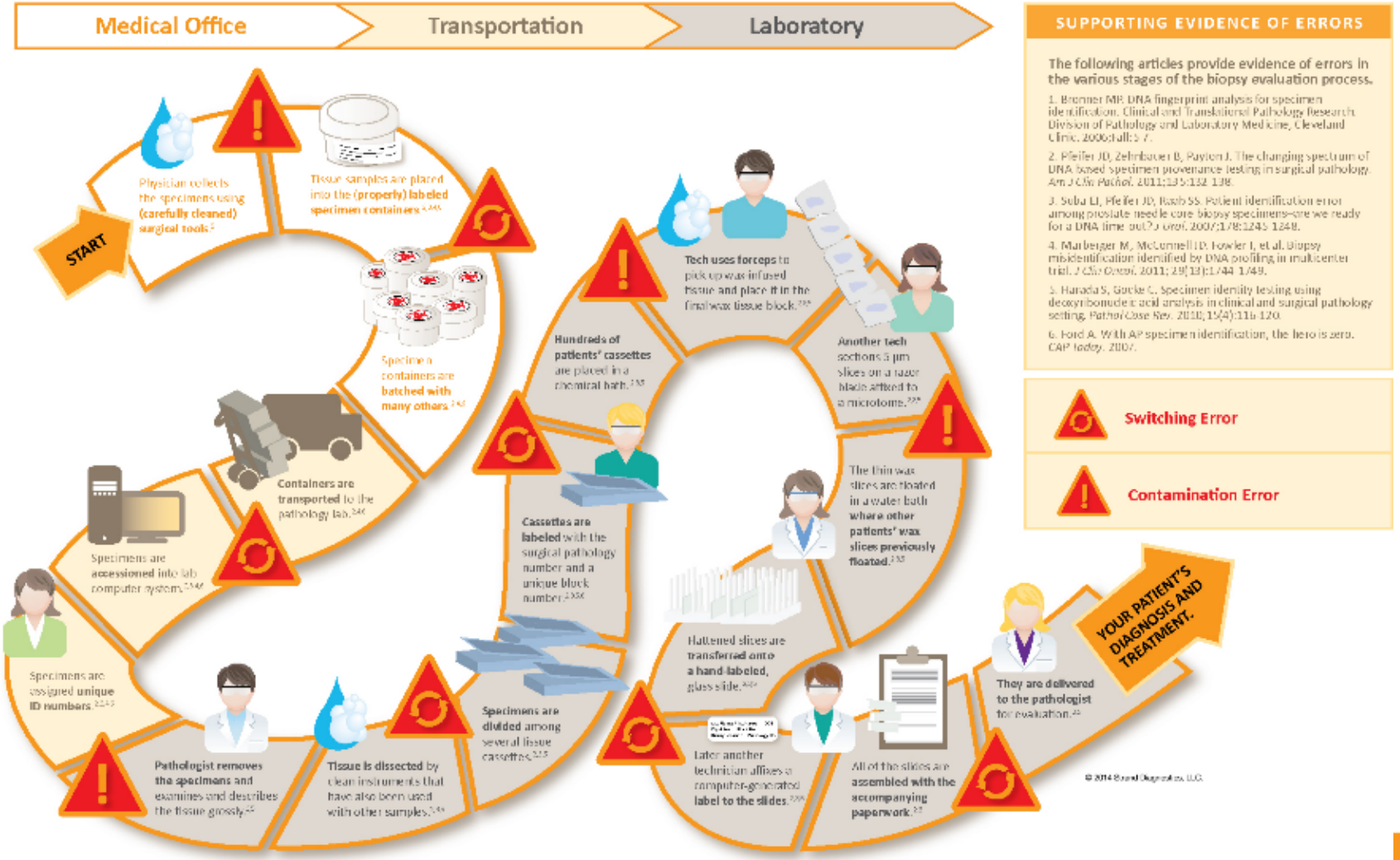
- **Medical samples and forensic samples processed in separate labs**
- **Medical samples given same import as forensic samples**
  - Samples photographed
  - Sample tracking protocols followed
- **Extracted samples stored in vault**
- **HIPPA requirements impose extra steps**

Errors We've Caught

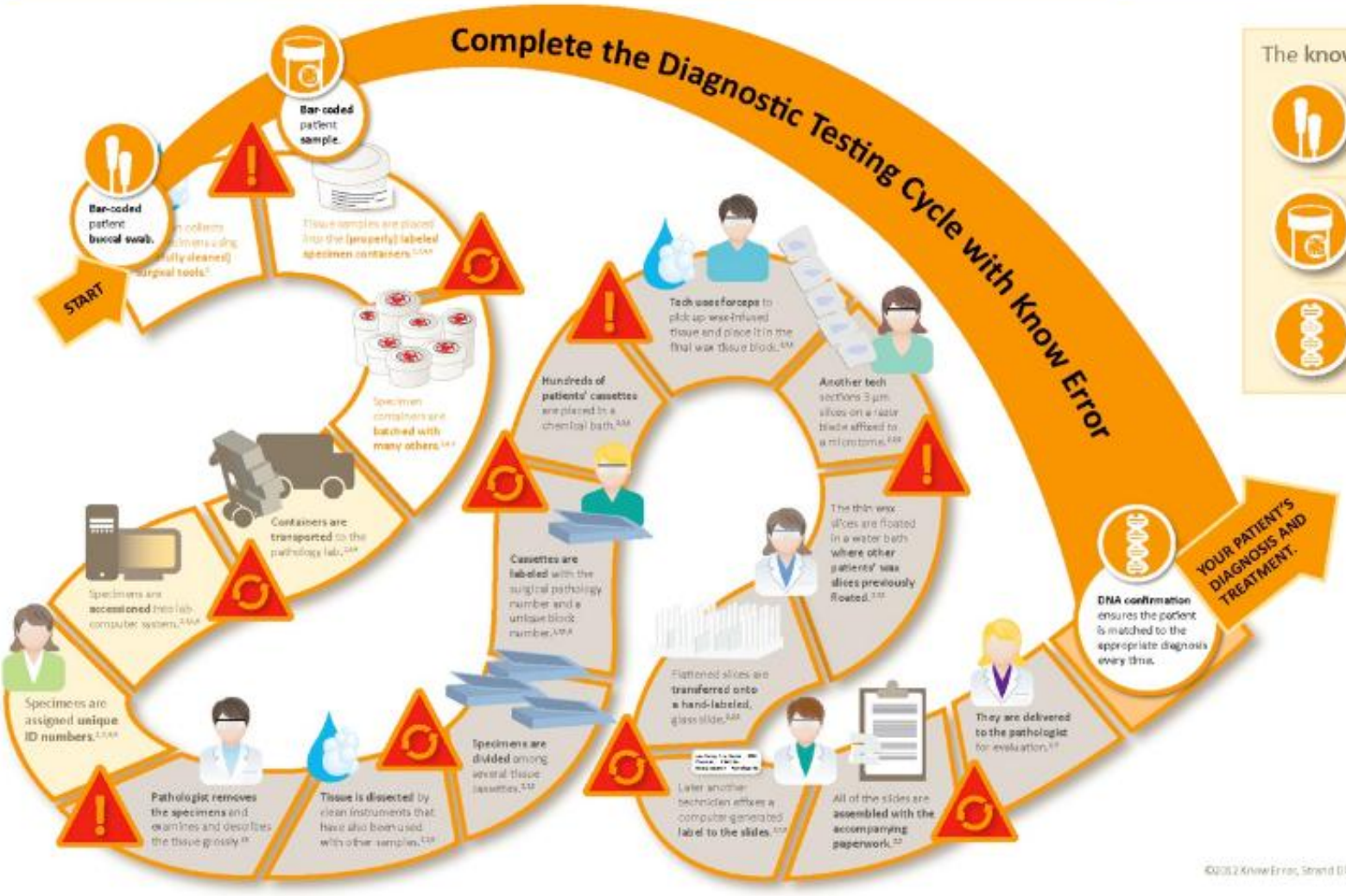
- **Error rate remains steady at 1%**
  - Transpositions: 0.25%
  - Admixtures (contaminations): 0.75%
- **Over 1,000 procedures halted *(DNA Timeout called)***
- **Medical community has taken notice**

NBC *(LA)* News Story

Clinical Biopsy Workflow:
18 Opportunities For a Switching Error!



Medical Office | Transportation | Laboratory | Know Error



Medical Mistakes In The News

"What You Don't Know Could Kill You"

Newsweek 9/17/12

"How to Stop Hospitals From Killing Us"

Wall Street Journal 9/22/12

98,000 deaths/ year due to medical mistakes

(4 jumbo jets full of patients/ week)

6th leading cause of death in the U.S.

White House Opens Hotline for Consumers to Report Medical Mistakes

New York Times 9/23/12

Medical Mistakes

"Vanishing Prostate Cancer"
Dr. Jonathon Epstein's,
Johns Hopkins – 2005

Little or No Residual Prostate Cancer at Radical Prostatectomy: Vanishing Cancer or Switched Specimen?

A Microsatellite Analysis of Specimen Identity

Dengfeng Cao, MD, PhD, Mike Hafez, MS,* Karin Berg, MD,‡ Kathleen Murphy, PhD,* and Jonathan I. Epstein, MD*†*

Abstract: With more vigilant screening for prostate cancer, there has been an associated increase in patients with little or no residual cancer at radical prostatectomy after an initial diagnosis of minute cancer on needle biopsy. This raises a critical question as to whether the biopsy and subsequent radical prostatectomy in these patients are from the same patient. We used PCR-based microsatellite marker analysis to perform identity test in 46 men (35 with minute cancer and 11 with no residual cancer). Of them, 41 were interpretable, including 31 with minute cancer and 10 with no residual cancer. All 31 interpretable cases with minute cancer showed match between the initial biopsy and radical prostatectomy specimens. Nine of the 10 interpretable cases with no residual cancer showed match and 1 showed mismatch. The remaining 5 cases (4 with minute cancer and 1 with no residual cancer) were considered uninterpretable due to technical problems. The initial biopsy of the mismatched case had better diagnostic criteria to improve the recognition of minimal carcinoma on needle biopsy.[8,10,13,14] Correspondingly, there have been more cases with little or no residual cancer at radical prostatectomy. DiGiuseppe et al[12] reported that the annual incidence of minimal residual cancer at radical prostatectomy increased from 0.5% in 1988 to 3% to 4% in 1993 to 1995. In a subsequent study from our institution, 2.8% of the radical prostatectomy specimens contained only a minute amount of cancer following the needle biopsy diagnosis of a minute focus of cancer.[2] Occasionally, no residual cancer may be identified in the entirely submitted radical prostatectomy specimen.[12,16] Such cancers have been referred to as the "vanishing cancer phenomenon."[16] These cases have raised the question as to whether the initial biopsy and the following radical prostatectomy specimens come from the same patients.

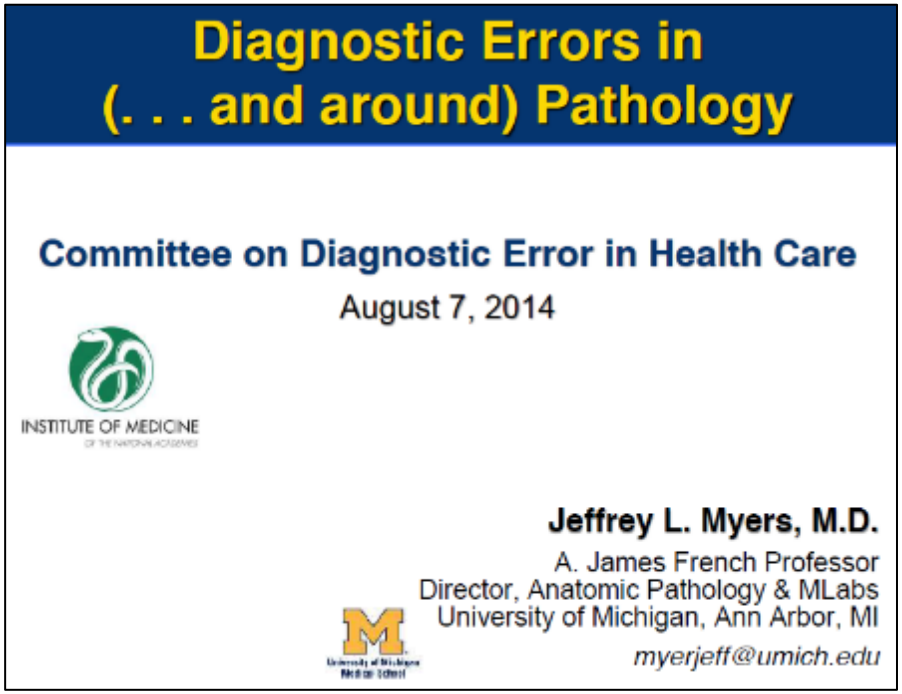
Darie Eason – NBC News - 2007
Mastectomy after Lab Mix-Up

Medical Mistakes: Feds Take Notice

Institute of Medicine

"Diagnostic Errors in Health Care"

Conference Aug 7-8, 2014



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Committee on Diagnostic Error in Health Care

MEETING 2 AGENDA

The Keck Center of the National Academies
500 Fifth Street, NW
Washington, DC 20001

August 7, 2014
Room 100

BEGIN OPEN SESSION

7:30 am	**Breakfast and Registration**
8:00 am	**Welcome and Opening Remarks** John Ball, Committee Chair
8:15 am	**Addressing Institutional Culture and Patient-Centeredness in Diagnosis** *Co-Moderators: Carolyn Clancy, Veterans Administration* *Mark Graber, RTI International* A patient's perspective on the diagnostic journey • Heidi Julavits, Columbia University Institutional culture, quality improvement, and patient-centeredness • Tejal Gandhi, National Patient Safety Foundation • Gordon Schiff, Brigham and Women's Hospital Discussion (45 minutes)
9:45 am	**Teams in Diagnosis: Interprofessional Culture and Education** *Moderator: George Thibault, The Josiah Macy Jr. Foundation* • Eduardo Salas, University of Central Florida • Barbara Brandt, National Center for Interprofessional Practice and Education Discussion (30 minutes)
10:45 am	**Break**
11:00 am	**Measurement, Reporting, and Feedback on Diagnostic Error** *Moderator: Elizabeth McGlynn, Kaiser Permanente* • Hardeep Singh, Houston VA Health Services Research Center for Innovations • Michael Kantor, Kaiser Permanente • Robert Trowbridge, Maine Medical Center

Medical Mistakes: Feds Take Notice

The Joint Commission

National Patient Safety Goals Effective January 1, 2015

Hospital Accreditation Program

Goal 1

Improve the Accuracy of Patient Identification

NPSG.01.01.01

Use at least two patient identifiers when providing care, treatment, and services.

--Rationale for NPSG.01.01.01--

Wrong-patient errors occur in virtually all stages of diagnosis and treatment. The intent for this goal is two-fold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Acceptable identifiers may be the individual's identification number, telephone number, ...

Wrong-patient errors occur in virtually all stages of diagnosis and treatment.

Much attention given to **REPORTING** of medical mistakes, but less attention to **PREVENTING** them.

Publications: *Error Rate*

1 in 200 Prostate Biopsy Patients affected by undetected (occult) specimen provenance complications

(switching or contamination errors)

*Wojno, K.; Hornberger, J.; Schellhammer, P.; Dai, M.; Morgan, T. The Clinical and Economic Implications of Specimen Provenance Complications in Diagnostic Prostate Biopsies, **The Journal of Urology**® (2014), doi: 10.1016/j.juro.2014.11.019.*

Occult Error Rate of 0.8 to 3.5 % in Surgical Biopsies (Washington University Study)

*Pfeifer JD, Liu J. Rate of Occult Specimen Provenance Complications in Routine Clinical Practice. **Am J Clin Path**. 2013;139(1):93-100.*

Clinical trial –Avodart®: 13.3% of specimens contaminated with foreign sources of DNA

*Marberger, McConnell, Fowler, Andriole, Bostwick, Somerville, & Rittmaster: **JCO** Vol.29: Number 13, May 1, 2011.*

Significance of Undetected *Specimen Provenance Errors*

- **Transposition Errors** (*switching*)
  - Inappropriate treatment of patient (and the complementary patient)
- **Admixture Errors** *(contamination)*
  - Histopathology maybe compromised
  - Biomarker test results can be confounded *(DNA and/or mRNA examination at nucleotide level is "blind" to issues of cross-contamination)*

Market Acceptance of the KnowError® system

- 180,000+ patients treated using the KnowError® system *(breast and prostate)* since '09
- 1,500 ordering physicians; 250+ participating path labs
- 4,300 DSPA tests per month
- 6% of prostate market; 1% of breast market
- 30% of the largest Urology practices utilize KnowError®
- Hundreds of labs/doctors have contacted us to sort-out suspected switching errors *(non-KnowError® clients)*

Cost To HealthCare

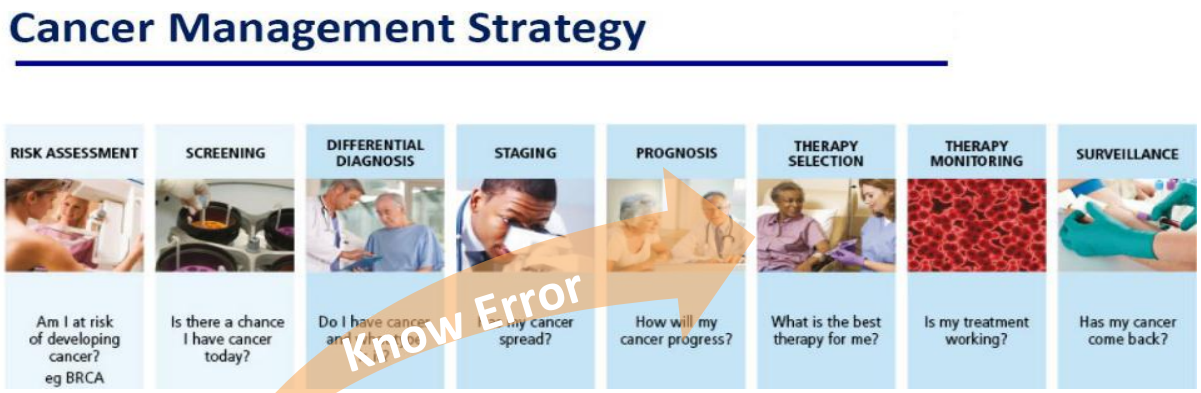
2 major studies conclude:

Proactive/prospective DSPA testing *(to rule out specimen switching errors)* makes economic sense

- ***Value in Health*** (‘12) – DSPA is cost effective
- ***Journal of Urology*** (‘14) – DSPA saves healthcare $880,000,000 annually *(prostate patients)*!

Future of Provenance Testing

- **Growth of personalized medicine/NextGen sequencing and biomarker testing**
  - **Increases importance of establishing provenance**
  - **Increases importance of ruling-out contaminations**
  - **Be DNA certain who is the *Person in Personalized* medicine**
- **College of American Pathologists (CAP) taking notice - will drive adoption as Standard of Care**



Our Mission For the Future…

For More Information

Contact:

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Or visit:

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www.Strandlabs.com

THANK YOU