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A Case of Mistaken Identity: Biomarkers for High Risk Premalignant Breast Lesions

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A case of mistaken identity ---
Biomarkers for high risk premalignant breast lesions

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Karl Simin, UMass Medical
May 8th, 2013
Estimated costs: $20,000 to $100,000/patient.

Campbell JD, Ramsey SD. Pharmacoeconomics. 2009;27(3):199-209. PMID: 19354340
Atypical hyperplasias

Progression to invasive cancer

50,000 new cases annually

Expect 10,000 new cases annually

Up to $1B to treat

Atypical hyperplasias
Progression to invasive cancer
Developing biomarkers of high risk premalignant breast lesions

Subtypes of Atypical Hyperplasias

- ADH
- LN

Subtypes of lesions with malignant potential
Bioanalyzer electropherograms

Intact RNA

FFPE RNA
Patient Population:
Diagnosis of Breast Cancer or Benign Breast Disease

IRB-approved Registry
Patient consent
Assign study ID

Patient Registry
Survey data
Clinical data
Archived tissues

Data Manager
• Collate data
• Provides summary data
• Extract data from clinical records
• Coded data for IRB-approved projects

Data/Tissue With Study ID

IRB-approved projects

Project 1
Project 2
Project 3
Project 4
Atypical hyperplasia (UMMS 1999-2003)

2833 breast core biopsies
120 with primary diagnosis of ADH

Upstaging upon re-excision
Summary

• Value of diagnostic test
  – Large interobserver variability in diagnosing premalignant lesions (Jain et al., 2011. PMID 21532546)
  – Identify subgroups to benefit from preventive therapies.
  – Identify molecular pathways to provide appropriate preventive treatments

• Technical challenges
  – Minute amounts of tissue
  – Fragmentation of RNA in FFPE tissues
  – Amplification and labeling for robust detection