Hughes RiskApps™

Risk Clinic - Cancer Risk Assessment System for Personalized Screening and Prevention of Breast Cancer

Developed at Massachusetts General Hospital

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The Leader in Software for Cancer Risk Assessment

**Mission:** Identify High-Risk Patients for Screening and Prevention to Improve Patient Care and Outcomes

**Return on Investment:** $9 Billion in potential revenue is not being collected for clinically indicated breast MRI studies
About: Hughes RiskApps™

Hughes Risk Apps was developed in 2006 at Massachusetts General Hospital as a guidelines-based breast cancer risk assessment tool. More than $3 Million has been invested in product development to date.

In 2007 Newton Wellesley Hospital was the first site to install HRA. 70 facilities including teaching hospitals, genetic counselors, and mammography centers are live today.

The company was spun out of Massachusetts General Hospital in March of 2014.
Poor compliance with MRI Screening Guidelines

Screening MRI for Breast Cancer

• Established Practice Guidelines recommend MRI screening for high-risk women*
• 99% of eligible women do not get a screening MRI
• 75% of screening MRIs ordered DO NOT meet the guidelines
• Based on 40,000,000 mammograms per year in the US, 5,960,000 women are missing out on a potentially life saving MRI

David Euhus, MD: Dr. Euhus is a Professor of Surgery and Chief of Breast Surgery at the Johns Hopkins University School of Medicine in Baltimore, MD. He is the author of the popular cancer genetics software program, CancerGene, which has over 6000 users in more than 75 countries. He was on the faculty of the University of Texas Southwestern Medical Center at Dallas as an Assistant Professor of Surgery from 1996 to 2013. During his 17 years in Dallas he maintained a translational research laboratory focused on biological markers of breast cancer risk and developed one the nation’s largest Clinical Cancer Genetics programs. He completed his General and Oncologic Surgery training at UCLA in 1991 after which he served as a Surgical Oncologist in the US. Army.

Daniel B. Kopans, MD: Daniel B. Kopans, MD, FACR, is a Professor of Radiology at Harvard Medical School and founder of the Breast Imaging Division at the Massachusetts General Hospital. Dr. Kopans was among the first to recognize the value of Ultrasound, CT, and MRI in breast evaluation and developed the first "Breast Imaging" Division in the U.S. He pioneered innovations in early breast cancer detection, including tomosynthesis, a procedure that increases the accuracy of mammograms without significantly increasing radiation exposure, and the Kopans Wire, a tool that helps clinicians detect small breast tumors.

Marc E. Lippman, MD: Dr. Lippman is the Kathleen and Stanley Glaser Professor of Medicine at the University of Miami, Leonard M. Miller School of Medicine, and Chairman of the Department of Medicine. Previously, Dr. Lippman was John G. Searle Professor and Chair of Internal Medicine at the University of Michigan, Ann Arbor, and prior to that, Chair, Department of Oncology, at Georgetown University and Director of the Lombardi Cancer Center, Georgetown University Medical Center. Dr. Lippman also served as Head of the Medical Breast Cancer Section, Medicine Branch, at the National Institutes of Health. Dr. Lippman is widely known for his research in breast cancer.

Giovanni Parmigiani, PhD: Dr. Parmigiani is Professor of Biostatistics at Harvard School of Public Health and chair of the Department of Biostatistics and Computational Biology at Dana-Farber Cancer Institute. He is an Associate Director for Population Sciences at the Dana-Farber/Harvard Cancer Center. His research interests include models and software for predicting who is at risk of carrying genetic variants that confer susceptibility to cancer. He is the inventor of BayesMendel, a risk prediction software for Mendelian diseases, and one of the primary developers of BRCAPRO, a model and software for genetic counseling of families at high risk of breast and ovarian cancer.
The Background:
The Affordable Care Act (ACA) shifts reimbursement from treatment of disease to screening and prevention, Doctors are ill equipped to institute these changes.

The Facts:
• Screening and prevention guidelines exist for many diseases and conditions
• Many guidelines require the use of models that are difficult to use
• Doctors follow the guidelines only sporadically

The Solution:
HRA develops risk assessment tools for guideline-appropriate care while focusing on ROI for healthcare providers.
Workflow-integrated Clinical Decision Support

- Patient-entered family history and risk factors

- Risk calculations using standard models ⇒ Recommendations based on established guidelines

- ≥20% risk of breast cancer
  (Tyrer Cuzick, BRCAPRO, Claus)

- High-Risk Patients Receive Appropriate MRI Screening
Hughes RiskApps™: Return on Investment

- Reimbursement per MRI: $1,000
- # mammograms: 10,000
- 15% need MRIs: 1,500
- Uptake 1 in 3 agree: 500
- Total MRIs per year: 500

Annual MRI reimbursement: $500,000
Eligibility for MRI by NCCN and ACS Guidelines
(National Comprehensive Cancer Network and American Cancer Society)

Newton Wellesley Hospital without breast cancer: n=9972

Lifetime risk ≥20% risk scores from Tyrer Cuzick, BRCAPRO and/or Claus: 1,494 (14.98%)

For every 1,000 mammograms performed, we should be doing 150 breast MRIs
Utilization of MRIs in US

**Stout, New England:** multispecialty group practice
- 10,518 women
- Screening MRI 3.2 per 1000 women
- **79% did not meet the guidelines**

**Wernli, National:** 5 Breast Cancer Surveillance Consortium registries
- 1,288,924 screening mammograms
- 8931 breast MRIs and Screening MRIs
- 4.3 per 1000 women
- **75% did not meet the guidelines**

**Highest risk women are not being identified and are not getting the MRIs they need**

1. Polubriaginof F et al. Implications of following the guidelines for genetic testing and MRI use for breast cancer. ASCO 2014
Hughes RiskApps™: Guideline-based tests and procedures are recommended to the physician.
Hughes RiskApps™: High risk individuals receive letters and are tracked for compliance.
Att: Pre-Authorization
General Health Insurance Corp.
555 Main Street
Hartford, CT, 06101

ATTN: Pre-Authorization

Re: Cindy Test, – MRN: 99909011408 DOB: 01/11/1970

Dear Medical Director:

I am writing to request coverage for a breast MRI for Jane Doe. She is at a significantly increased risk as determined by the accepted models.

She meets the American Cancer Society Guidelines\(^1\) and the National Cancer Center Network (NCCN)\(^2\) guidelines for screening MRI of the breast. Both guidelines recommend MRI of the breast if the patient has a lifetime risk of breast cancer of 20% or greater.

This patient’s risk is elevated: **Tyrer Cuzick 34.00% lifetime risk**

Thus, she is considered at significantly increased risk to develop breast cancer as compared to other women her age. MRI would significantly increase the chance of finding breast cancer at an earlier, more treatable stage, and thus allow less aggressive treatment, and potentially to increase her chance of cure.

Please contact me if I can provide you with any additional information.

Sincerely,

John Smith, MD
Director of Breast Imaging
Sample Survey Screens

Cancer Risk Assessment

About what age were you when you had your first period?

If you do not know the age for certain, please give your best guess.
¿Aproximadamente qué edad tenía cuando tuvo su primera menstruación?

Si no está seguro de la edad, por favor proporcione la edad aproximada.
Sample Survey Screens: Continued

Cancer Risk Assessment

How many times have you been pregnant?

1 2 3
4 5 6
7 8 9
0 Clear

Back  Next
Sample Survey Screens: Continued

Cancer Risk Assessment

Please select what best describes your ethnicity.

- [ ] Caucasian or White
- [ ] African American or Black
- [ ] American Indian/Aleutian/Eskimo
- [ ] Asian or Pacific Islander
- [ ] Caribbean/West Indian
- [ ] Other

We ask this question because it helps us determine the risk of hereditary cancer.
Sample Survey Screens: Continued

Cancer Risk Assessment

Have any of your blood relatives had cancer?

Yes
No
Not sure
Clear

Back
Next
Sample Survey Screens: Continued

**Cancer Risk Assessment**

**Which cancers does your Sister have or has she had?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Cancer</td>
<td>Non-melanoma skin cancer</td>
</tr>
<tr>
<td>BREAST Cancer</td>
<td>Melanoma</td>
</tr>
<tr>
<td>Cervical Cancer</td>
<td>Ovarian Cancer</td>
</tr>
<tr>
<td>Colon or Rectal Cancer</td>
<td>Other</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Pancreatic Cancer</td>
</tr>
<tr>
<td>Kidney or Bladder Cancer</td>
<td>Sarcoma</td>
</tr>
<tr>
<td>Leukemia</td>
<td>Stomach Cancer</td>
</tr>
<tr>
<td>Liver Cancer</td>
<td>Thyroid Cancer</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>Uterine Cancer</td>
</tr>
</tbody>
</table>
Sample Survey Screens: Continued

<table>
<thead>
<tr>
<th>Avon Demo</th>
<th>Cancer Risk Assessment Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test, Standard1</td>
<td>DOB: 01/11/1970 Age: 44 Gender: F</td>
</tr>
<tr>
<td>Unit #: 05031401</td>
<td>Provider: HUGHES, KEVIN S 05/03/2014</td>
</tr>
</tbody>
</table>

![Family Tree Diagram]

- Test, 44 lymph 15
- Ov 29
- Br 59
- Ov 23
- Col 59
### Avon Demo

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The ACS* and the NCCN* suggests MRI screening should be considered in people with a 20% or greater lifetime risk of breast cancer by BRCAPRO, Tyrer-Cuzick or Claus.

The lifetime risk of breast cancer is 20% or greater by BRCAPro, Tyrer/Cuzick.

*ACS = American Cancer Society
*NCCN = National Cancer Centers Network

### DEMOGRAPHIC

- Age: **44**
- Height: **5' 5"**
Returning patient:
Data from previous appointment retrieved

Cancer Risk Assessment

A prior assessment survey has been found in the system.

Your answers from this prior survey will be loaded.

If an answer to a question has not changed please continue to the next question.

If an answer has changed, please take the time to make the appropriate changes so that we can update our records.

Thanks.

Back  Next
Women will finally have the screening and prevention they need to prevent needless cancer deaths

Contact Information:
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