The Pregnancy & Health Profile: A Screening and Risk Assessment Tool

Family History for Prenatal Providers

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Executive Director, NCHPEG

SACHDNC Meeting
Washington, D.C.
September 14, 2012
## Project Partners

<table>
<thead>
<tr>
<th>NCHPEG</th>
<th>Genetic Alliance</th>
<th>March of Dimes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joan Scott</td>
<td>James O’Leary</td>
<td>Siobhan Dolan</td>
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<tr>
<td>Emily Edelman</td>
<td>Vaughn Edelson</td>
<td>Bruce Lin</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Harvard Partners/NWH/MGH</th>
<th>HRSA</th>
<th>Evaluator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kevin Hughes</td>
<td>Sara Copeland</td>
<td>Teresa Doksum</td>
</tr>
<tr>
<td>Brian Drohan</td>
<td>Lisa Vasquez</td>
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<td></td>
<td>Alaina Harris</td>
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</tbody>
</table>

*Work presented is funded through HRSA cooperative agreement #U33MC12786*
Objectives

1. Describe the Pregnancy & Health Profile tool

2. Describe implementation in four clinical settings

3. Present data on patient and provider response and clinic outcomes

4. Discuss next steps
Advisory Committee

Eileen Beard, C.N.M., F.N.P.
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Alan Zuckerman, M.D.
Georgetown University Hospital
Historical Perspective

• Need identified through:
  • HRSA, SACHNC, ACOG Genetics Committee
• 2008 HRSA Funding Announcement: “Family History for Prenatal Providers”
  • Integrate genetics and NBS information into a health history
  • Assist genetic clinical decision-making
  • Educate the patient and the provider
  • Address the life-course of the female patient
Pregnancy & Health Profile: A Screening and Risk Assessment Tool

- Helps the busy primary care provider
  ➔ Translates family history data for clinical care
- Engages the patient as an active participant
- Provides a personalized clinical encounter
  ➔ Clinical decision support
  ➔ Provider and patient materials
- Freeware
Conditions with Decision Support

**Mendelian Congenital**
- Ashkenazi Jewish-associated diseases
- Cystic fibrosis
- Fragile X
- Sickle cell disease
- Spinal Muscular Atrophy
- Tay-Sachs
- Thalassemia

**Mendelian Pregnancy & Lifespan**
- Thrombophilia
- Hemophilia
- von Willebrand
- HBOC
- Lynch

**Complex Congenital**
- Consanguinity
- Hearing loss, congenital and early-onset (<40 y)
- Vision loss, congenital and early-onset (<40 y)
- Congenital heart defect
- Neural tube defect

**Complex Pregnancy & Lifespan**
- Cardiovascular Disease
- Diabetes
- Epilepsy
- Hypertension
- Mental Illness
- Osteoporosis
- Pre-term birth
- Recurrent pregnancy loss (2+)
- Sudden death
How it Works

**Waiting Room or Exam Room**
Patient completes e-form on Tablet, returns Tablet to front desk

---

**Clinician prints and reviews report and ed. materials**

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**Clinician discusses recs with pt.**

---

**Pt receives targeted educational materials**
Clinician documents encounter, uploads report into paper or e-record, orders tests/referrals

---

**Clinician makes updates to input data as needed**
Implementation & Evaluation
Clinical Implementation

Augusta & Fairfield, ME
- Maine-Dartmouth Family Medicine Residency
  - Family Medicine Practice, Academic

Bronx, NY
- Montefiore Medical Center
  - Comprehensive Family Care Center
  - Community Health Center, Academic

Asheville, NC
- Mountain Area Health Education Center
  - State Area Health Education Center, Academic

Indianapolis, IN
- Clearvista practice, Community Health Network
  - OB Practice, Community Hospital System
### Overview of Summative Evaluation Design

<table>
<thead>
<tr>
<th>Source of Data</th>
<th>Outcome</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrators</td>
<td>✓ Approach to integrating tool</td>
<td>Interview</td>
</tr>
<tr>
<td></td>
<td>✓ Challenges with implementation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Level of effort and resources needed for integration</td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td>✓ Time required for patients to use tool</td>
<td>Post-tool survey</td>
</tr>
<tr>
<td></td>
<td>✓ Patient satisfaction with tool</td>
<td></td>
</tr>
<tr>
<td>Providers</td>
<td>✓ Knowledge</td>
<td>Pre-tool survey</td>
</tr>
<tr>
<td></td>
<td>✓ Confidence using family history</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Satisfaction using tool, including efficiency</td>
<td>Post-tool survey</td>
</tr>
<tr>
<td></td>
<td>✓ Perceived usefulness of tool</td>
<td></td>
</tr>
<tr>
<td>Provider behavior</td>
<td>✓ Provider practices regarding guidelines for:</td>
<td>Chart audits</td>
</tr>
<tr>
<td></td>
<td>• discussion, counseling, education;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• referrals to specialists; and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• screening tests offered and ordered</td>
<td></td>
</tr>
</tbody>
</table>
Process & Implementation Evaluation

- Key steps, resources, and staff support needed
- Impact on clinic and provider work flow
- Barriers and successes in implementation and integration
- Changes needed to support future use

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Process & Implementation Evaluation

1. Pt. visits project website, learns about FHx (voluntary)

2. Scheduler/nurse hands pt. tablet and paper survey

3. Waiting room/other space: Patient completes e-form on Tablet

4. Study coordinator wheels tool system to proximity of pt. exam room


6. Data updated as needed

7. Pt. completes voluntary 3-minute paper survey, returns to nurse

8. Provider documents encounter, report filed into paper record/scanned into EHR

9. GC has access to record & pedigree

If referral is needed

Pt. receives targeted educational materials
Conclusions from Implementation Data

1. Customization is critical
   - Clinic flow, implementation, and installation plans
   - Continuous assessment and modification of clinic and work flow
   - Providers desire customizable tool

2. Clinical champion and IT support critical
Patients

Findings from Patient Feedback Survey
n=513/618 (83%) total across 4 sites

Unpublished Data: Confidential
## Patient Demographic Characteristics

<table>
<thead>
<tr>
<th></th>
<th>NC n=225</th>
<th>ME n=42</th>
<th>NY n=37</th>
<th>IN n=209</th>
<th>Total n = 513</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15-17 yrs</td>
<td>6%</td>
<td>11%</td>
<td>3%</td>
<td>0%</td>
<td>4%</td>
<td>***</td>
</tr>
<tr>
<td>18-24</td>
<td>37</td>
<td>36</td>
<td>31</td>
<td>16</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>25-34</td>
<td>45</td>
<td>48</td>
<td>51</td>
<td>68</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>35-46</td>
<td>12</td>
<td>5</td>
<td>11</td>
<td>15</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td><strong>Highest grade completed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>***</td>
</tr>
<tr>
<td>Less than high school</td>
<td>23</td>
<td>33</td>
<td>20</td>
<td>2</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>High school grad</td>
<td>22</td>
<td>31</td>
<td>14</td>
<td>7</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>27</td>
<td>21</td>
<td>43</td>
<td>22</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>College graduate</td>
<td>21</td>
<td>11</td>
<td>11</td>
<td>49</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Graduate school</td>
<td>7</td>
<td>3</td>
<td>9</td>
<td>19</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td><strong>First pregnancy</strong></td>
<td>29</td>
<td>31</td>
<td>22</td>
<td>42</td>
<td>34</td>
<td>*</td>
</tr>
<tr>
<td><strong>English 1st language</strong></td>
<td>97</td>
<td>97</td>
<td>72</td>
<td>94</td>
<td>94</td>
<td>***</td>
</tr>
<tr>
<td><strong>Very comfortable with computers</strong></td>
<td>83</td>
<td>76</td>
<td>92</td>
<td>94</td>
<td>88</td>
<td>**</td>
</tr>
</tbody>
</table>

Unpublished Data: Do not cite or share without permission from NCHPEG
# Patient Ethnicity/Race

<table>
<thead>
<tr>
<th>Race:</th>
<th>NC n=225</th>
<th>ME n=42</th>
<th>NY n=37</th>
<th>IN n=209</th>
<th>Total n = 513</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latina</td>
<td>6%</td>
<td>6%</td>
<td>65%</td>
<td>3%</td>
<td>9%</td>
<td>***</td>
</tr>
<tr>
<td>Caucasian or White</td>
<td>85</td>
<td>92</td>
<td>25</td>
<td>83</td>
<td>81</td>
<td>***</td>
</tr>
<tr>
<td>African-American / Black</td>
<td>10</td>
<td>0</td>
<td>42</td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Asian or Pacific Islander</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Native American</td>
<td>0.5</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Caribbean or West Indian</td>
<td>0.5</td>
<td>0</td>
<td>25</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Multi-racial</td>
<td>4</td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

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Patient Feedback

• Tool was easy to use 96%

• Questions were easy to understand 98%

• Not worried about confidentiality of information entered into the tool 96%
How willing would you be to provide your personal & family hx info to your provider via…(n=513 across 4 sites)

- Type into computer tool: 84%
- Provider ask questions: 83%
- Write on paper form: 68%
- Type into website at home: 64%
- Cell/smart phone: 47%
Conclusions from Patient Data

1. Tool tested in diverse patient population
2. Acceptability and usability high across populations
3. Patients comfortable entering personal and family history info into computer
4. Equally willing to provide info in computer tool as compared to verbally to provider
5. Computer tool more desirable than paper tool

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Providers

Findings from Provider Feedback Survey
n = 20 / 65 (30% response)

Unpublished Data: Confidential
Provider Characteristics (n = 20)

- **Provider type**
  - 10 Obstetricians (8 NC, 1 NY, 1 IN)
  - 6 Family Medicine Physicians (ME)
  - 2 Nurse Midwives (NC)
  - 2 Other (RD/OB Educator and Nurse at IN)

- **Patient Volume**
  - 47% saw 2 – 5 pts total
  - 41% saw 12 – 60 pts
  - 12% saw 200 – 275 pts
Knowledge & Confidence

Knowledge

• OB: No pre-post change (89.0% to 89.1% average scores)

• FM: 67.9% pre to 85.7% post average scores (p = 0.018)

Confidence

• Knowing when to refer and conduct follow-up for at-risk patients increased
Satisfaction & Usefulness: Impact on Clinic Flow

<table>
<thead>
<tr>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Made process of seeing new pt. faster, smoother</td>
<td>• Hindered productivity of visits</td>
</tr>
<tr>
<td>• Reduces time spent on taking high quality pt. family history</td>
<td>• Difficulty documenting more immediate pregnancy-related issues (e.g., physical abuse, blood type)</td>
</tr>
<tr>
<td>• Pre-formed questionnaire with all appropriate questions and info...allows me to focus on details that make every pregnancy different</td>
<td>• More time spent clarifying responses &amp; follow up with pt.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% who reported useful or very useful</th>
<th>FM (n=8)</th>
<th>OB (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient data pre-populated into form</td>
<td>57.1 (4/7)</td>
<td>53.9 (7/13)</td>
</tr>
<tr>
<td>Family history collection &amp; pedigree</td>
<td>37.5 (3/8)</td>
<td>61.5 (8/13)</td>
</tr>
<tr>
<td>Structure/organization of report</td>
<td>25 (2/8)</td>
<td>38.5 (5/13)</td>
</tr>
</tbody>
</table>
## Satisfaction & Usefulness: Patient Engagement

<table>
<thead>
<tr>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Made conversation of history easier for pt.</td>
<td>• Missed one-on-one interaction where I could clarify issues &amp; build rapport</td>
</tr>
<tr>
<td>• Engaged pt. to ask good questions about risk of passing conditions to newborn</td>
<td></td>
</tr>
<tr>
<td>• Allows pts. to open up about many different genetic issues</td>
<td></td>
</tr>
<tr>
<td>• Helped me give more educational info to pts.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% who reported useful or very useful</th>
<th>FM (n=8)</th>
<th>OBs (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient questionnaire</td>
<td>60 (3/5)</td>
<td>61.5 (8/13)</td>
</tr>
<tr>
<td>Patient fact sheets</td>
<td>60 (3/5)</td>
<td>44.4 (4/9)</td>
</tr>
</tbody>
</table>
Satisfaction & Usefulness: Clinical Decision Support

<table>
<thead>
<tr>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
</table>
| • Offering right screening tools  
  • Liked recommendations, referrals, teaching list and genogram | • Too lengthy, too much paper  
  • Unfamiliar report  
  • Hard to decide what to do with it all  
  • List made too many referrals not needed  
  • Many more ultrasound were ordered |

<table>
<thead>
<tr>
<th>% who reported helpful or very helpful</th>
<th>FMs (n=8)</th>
<th>OBs (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity-based risks (Example: Hemoglobinopathy)</td>
<td>57.1 (4/7)</td>
<td>57.1 (5/13)</td>
</tr>
<tr>
<td>Complex birth outcomes (Example: neural tube defect)</td>
<td>57.1 (4/7)</td>
<td>57.1 (5/13)</td>
</tr>
<tr>
<td>Non-genetic health conditions (Example: blood clots)</td>
<td>42.9 (3/7)</td>
<td>42.9 (3/13)</td>
</tr>
<tr>
<td>Conditions unrelated to pregnancy (Example: hereditary cancer)</td>
<td>28.6 (3/7)</td>
<td>28.6 (4/13)</td>
</tr>
</tbody>
</table>
Conclusions from Provider Data

1. Confidence in identifying & managing pts at-risk increased
2. Value in questionnaire and fact sheets for patient engagement, education
3. Mixed perceptions of impact on work flow and practice
4. Mixed perceptions of value of clinical decision support
5. Report needs to be shorter & tailored to meet providers’ needs
Performance Measures

Findings From Patient Medical Records & Tool
n = 522 total across 3 sites

Unpublished Data: Confidential
# Genetic Performance Measures

Assessed through pre- and post-chart audits

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>% of patients that have a documented 3-generation family history. 3-Generation Definition: At least one member of three generations documented. For example: the patient, her children, and her parents.</td>
<td>(ACOG. Obstet Gynecol. 2011;117:747-750)</td>
</tr>
<tr>
<td>2</td>
<td>% of patients and FOBs that have documented ethnicity and ancestry data.</td>
<td>(ACOG. Obstet Gynecol. 2011;117:747-750)</td>
</tr>
<tr>
<td>3</td>
<td>% of patients for whom there is documented discussion, counseling, or education about cystic fibrosis carrier screening.</td>
<td>(ACOG. Obstet Gynecol. 2011; 117:1028-31)</td>
</tr>
<tr>
<td>4</td>
<td>% of African-American patients for who there is documented discussion, counseling, or education about SCA carrier screening.</td>
<td>(ACOG. Obstet Gynecol. 2007; 109:229-37)</td>
</tr>
<tr>
<td>5</td>
<td>% of Asian-American patients for who there is documented discussion, counseling, or education about thalassemia carrier screening.</td>
<td>(ACOG. Obstet Gynecol. 2007; 109:229-37)</td>
</tr>
</tbody>
</table>
Conclusions from Performance Measures

1. Tool collects greater detail and higher quality family history information
   • Especially FOB and ancestry info
2. Cystic fibrosis screening rates similar pre and post or improved with tool
3. Additional analyses planned to further study outcomes
Summary

1. Clinical implementation
   - Identified process and recommendations for clinical implementation

2. Patient feedback
   - High patient satisfaction

3. Provider outcomes
   - Mixed provider feedback about decision support
   - Value patient engagement and education
   - Improvements in confidence

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Next Steps

1. Disseminate prenatal tool for free download
   http://www.hughesriskapps.net

2. Continue to study the impact of the tool in a prenatal population

3. Develop adaptations for additional clinical settings (e.g., pediatric, adult)

4. Develop web-based and non-English language versions

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Thank You

For more information contact:
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410-583-0600

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