Informed Decision Making for Prenatal Tests: Is it Achievable?

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Today’s Talk

- Prenatal testing guidelines and decision making: A brief history
- Current ACOG recommendations
- Prenatal testing decision support tools
- Concluding thoughts

Disclosure

None

What percentage of the patients in your practice are currently making informed prenatal testing (screening and diagnosis) decisions?

A. <10%
B. 10-50%
C. 50-75%
D. >75%
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Prenatal Testing in the 1970's

**Will patient be ≥ 35 at the time of delivery??**

- **YES** Offer/encourage amniocentesis
- **NO** Nothing to discuss

Prenatal Testing in the 1980/90's

**How old will patient be at the time of delivery?**

- ≥35 Offer CVS/amniocentesis
  - Concerned about miscarriage risk ?? Suggest AFP test
- <35 Recommend AFP test
  - Screen positive results ?? Refer for amniocentesis
  - Maternal anxiety ?? **Maybe** offer amniocentesis

Rationale for Age/Risk-Based Guidelines

Need to limit access to invasive testing
- Inherent risk of procedure
- Limited availability of providers, laboratories
Age 35 selected as the threshold
- Cost/benefit considerations
- Threshold set where risks equal

Are these Equal Outcomes?

Risk of Miscarriage = Risk of Down Syndrome

*Implicit assumption: Women value these two outcomes equally*

- Procedure-related miscarriage
- Down-syndrome affected infant

Challenges to this Guideline

<table>
<thead>
<tr>
<th>Year</th>
<th>Authors</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>Druzin et al.</td>
<td>“Should all pregnant patients be offered prenatal diagnosis regardless of age?”</td>
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<td>1994</td>
<td>Pauker &amp; Pauker</td>
<td>“Prenatal diagnosis – Why is 35 a magic number?”</td>
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<tr>
<td>1999</td>
<td>Kuppermann et al.</td>
<td>“Who should be offered prenatal diagnosis? The 35-year-old question”</td>
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<td>2000</td>
<td>Kuppermann et al.</td>
<td>“Procedure-related miscarriages and Down syndrome-affected births: Implications for prenatal testing based on women’s preferences”</td>
</tr>
<tr>
<td>2005</td>
<td>Kuppermann &amp; Norton</td>
<td>“Prenatal testing guidelines: Time for a new approach?”</td>
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</tbody>
</table>

Generating Evidence on how Women Value Prenatal Testing Outcomes

- 1082 socioeconomically and age-diverse women
- English-, Spanish- or Chinese-speaking
- Interviewed <20 weeks pregnant
- Measured preferences (utilities)

On average, women do not equally weight the outcomes of procedure-related miscarriage and Down syndrome-affected birth

- Median value for procedure-related miscarriage = 0.86
- Median value for Down-syndrome affected infant = 0.73

P < 0.001 by Wilcoxon sign rank test

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ACOG Screening Guidelines

- All women, regardless of age, should have the option of invasive testing.
- A woman’s decision to have an amniocentesis or CVS is based on many factors, including:
  - Risk of chromosomal abnormality
  - Risk of pregnancy loss
  - Consequences of having an affected child.
- Women weigh these potential outcomes differently.
- The decision to offer invasive testing should take into account these preferences and should not be based solely on age.
- Maternal age of 35 years alone should no longer be used as a threshold to determine who is offered screening versus who is offered invasive testing.

ACOG Diagnostic Testing Guidelines

- Invasive diagnostic testing for aneuploidy should be available to all women, regardless of maternal age.
- Pretest counseling should include a discussion of:
  - Risk and benefits of invasive testing compared to screening tests
  - Screen positive rates
  - True positive (detection rates)
  - Detection rates for other aneuploidies
  - Type and prognosis of the aneuploidies likely to be missed by serum screening

Challenges to Informed Decision Making

- Patients vary substantially in their knowledge and awareness of Down syndrome
- Making informed screening decisions requires understanding that these tests are not risk-free
- Variations in literacy and numeracy make comprehension of information difficult
- Lack of time to discuss information
- Decisions about first trimester options need to be made early in pregnancy
- Values-based decision
- Partners, families


To what % of your patients were you able to convey all the ACOG recommended information and engage them in discussions of their values and preferences?

A. <10%
B. 10-50%
C. 50-75%
D. >75%

A. 45%
B. 23%
C. 21%
D. 11%

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Prenatal Testing Decision Tool RCT’s

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>N</th>
<th>Tool</th>
<th>Control</th>
<th>Findings</th>
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</thead>
<tbody>
<tr>
<td>UK</td>
<td>2000</td>
<td>876</td>
<td>Touch screen information system + leaflet</td>
<td>Leaflet only</td>
<td>Knowledge, Detailed anomaly scans, Anxiety</td>
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<tr>
<td>UK</td>
<td>2001</td>
<td>2000</td>
<td>Video + leaflet</td>
<td>Leaflet only</td>
<td>Knowledge, Prenatal test use, Anxiety</td>
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<tr>
<td>Hong Kong</td>
<td>2004</td>
<td>201</td>
<td>Interactive multimedia decision aid</td>
<td>Leaflet and video</td>
<td>Knowledge, Prenatal test use, Satisfaction</td>
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<tr>
<td>Australia</td>
<td>2008</td>
<td>339</td>
<td>24 page booklet (Ottawa decision framework)</td>
<td>Pamphlet</td>
<td>Knowledge, Prenatal test use, Decisional conflict, Anxiety</td>
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Prenatal Testing Decision Tool (PT Tool)

- Computerized and interactive
- Information on Down syndrome and other chromosomal disorders: tests and testing outcomes; and what it means to receive screen positive results
- Emphasizes all women have three legitimate options:
  - foregoing testing
  - starting with a screening test (“a starter test”) and what it means to receive screen positive results
- Provides tailored risk estimates and values clarification exercises
- Helps identify strategies that best reflect the viewer’s values and preferences
Information about Birth Defects

...most women give birth to healthy babies. However, about 3 to 4% of babies are born with a birth defect. For some of these conditions, there are prenatal tests that can tell you whether the fetus is affected.

Issues to Consider

The goal of this program is to give you the information you need to make informed decisions about prenatal testing that reflect your preferences.

Tailored Risk Presentation

What are the Chances that You are Carrying a Fetus Affected by Down Syndrome?

32 year old, 2/1000

Values Clarification

For me, knowing for sure whether or not my fetus has Down syndrome is...

- Absolutely crucial
- Very important
- Somewhat important
- Barely important
- Not important at all
Values Clarification

Which would be worse for you, having a miscarriage after diagnostic testing or giving birth to a baby with Down syndrome?

- Definitely giving birth to a baby with DS
- Probably giving birth to a baby with DS
- Both are about the same to me
- Probably having a miscarriage
- Definitely having a miscarriage

Randomized Trial of PT Tool

496 pregnant women (English or Spanish speaking)
Randomized to PT Tool or computerized State of California’s educational brochure
3 follow-up interviews throughout pregnancy
Focus on knowledge, risk comprehension, decisional conflict and test utilization


Knowledge

<table>
<thead>
<tr>
<th></th>
<th>Mean Score</th>
<th>P &lt; .0001</th>
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<tr>
<td>Immediately post viewing</td>
<td>PT Tool</td>
<td>Control</td>
</tr>
<tr>
<td>2 weeks later</td>
<td>PT Tool</td>
<td>Control</td>
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Correct Estimate of Down Syndrome Risk

<table>
<thead>
<tr>
<th></th>
<th>100%</th>
<th>50%</th>
<th>0%</th>
</tr>
</thead>
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<tr>
<td>Immediately post viewing</td>
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<td>Control</td>
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Correct Estimate of Miscarriage Risk


Decisional Conflict at 30 Weeks Gestation


Utilization of Invasive Testing by Baseline Testing Inclination, Age > 35 Years


PT Tool Conclusions

Compared to controls, PT Tool:

- Improves knowledge and risk comprehension
- Causes changes in testing behavior (in both directions)
- Results in less decisional conflict

Leads to more informed decisions that better reflect underlying preferences
Prenatal Testing: Exploring Your Options

Birthday & Due Date
Select the buttons below to enter your information.

Your Birthday
January 14, 1988
Age: 21

Your Due Date
November 30, 2010
First Trimester
10 Weeks, 4 Days along

Question 3
Knowing for sure whether or not your fetus has Down syndrome, trisomy 13 or 18, or a sex chromosome abnormality. How important is knowing for sure whether or not your fetus has a chromosome problem?

Most babies are born healthy, some have birth defects.

30 out of 1000
Concluding Thoughts

- Important to keep working toward a goal of informed prenatal testing decisions.
- Achieving that goal is challenging.
- Decision tools may be helpful.

Challenges:
- Disseminating tools and integrating them into clinical care
- Keeping tools updated with new tests and new evidence on their effectiveness
- Not all patients will be amenable to using tools
- Some patients will continue to prefer to have their providers make decisions for them

Is informed decision making for prenatal tests achievable?

A. Definitely
B. Probably
C. Probably not
D. Definitely not

Thanks!