The Role of Diagnostics in Protecting and Promoting Women’s Health

December 12, 2012
Speakers

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• **Bonnie Rib**, Vice President and General Manager of Women’s Health and Cancer, BD

• **Lisa Hill**, Breast Cancer Survivor

• **Jennie McGihon**, Ovarian and Uterine Cancer Survivor
AdvaMedDx

- Founded in 2010 as a division of AdvaMed, the medical technology manufacturers association, to represent manufacturers of medical diagnostic tests.

- AdvaMedDx functions as an “association within an association”, with over 65 member companies – from global industry leaders to early stage test test developers.

- Diagnostic tests provide critical insights at every stage of medical care.

- The Improving Diagnostics Innovations Act, HR 6446 (Roskam), would reform the Medicare diagnostics payment system to reflect value of diagnostic tests to patient care and the healthcare system.
AdvaMedDx improves patient and public health by advancing the use of innovative, safe and effective medical diagnostic tests.

A Policy Primer on Diagnostics

Click here to learn about the diagnostics industry and key policies affecting patient care.
The Role of Diagnostics in Protecting and Promoting Women’s Health
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Carl Hull, SVP and General Manager of Diagnostics, Hologic | Gen-Probe
Mission: To improve the lives of the patients we serve by providing the products and services necessary for:

- Accurate and efficient screening
- Compassionate and less invasive diagnostics
- Therapies and treatments for today and far into the future
What are diagnostic tests?

• Tests performed on samples taken on and from the body
  – Also referred to as “in vitro diagnostics” or IVDs

• Test results aid patients, physicians, and caregivers in reaching medical treatment decisions for a particular patient at a given time
  – i.e. is a disease present, has it progressed, or has the disease changed course?
Where are diagnostic tests performed?

- Centralized laboratory
- Hospital
- Physician’s office
- Clinic
- Home (i.e. pregnancy test)
What is the value of Diagnostics?

• Least expensive component of the healthcare system
  – Comprise less than 5% of hospital costs
  – 1.6% of all Medicare costs
  – Individual tests cost as little as a few dollars to $50 per test

• Influence more than 70% of health care decisions

• Tests are designed to match the “right patient with the right treatment at the right time”
Sexually Transmitted Disease (STD) Testing
Estimated Annual Incidence of Leading Sexually Transmitted Diseases

- Syphilis (45,000)
- HIV (48,000)
- Hepatitis B (73,000)
- Gonorrhea (300,000)
- Herpes (750,000)
- Chlamydia (2.8 million)
- HPV (6.2 million)
- Trichomoniasis (7-8 million)

American Social Health Association (ASHA), 2011
**Chlamydia** is one of the most common, and easily curable, STD’s in the U.S.

- Over 2.8 million cases reported in 2011
- Largest number reported to the Centers for Disease Control (CDC) for any disease
- 426 cases per 100,000
- Up 5.1% from 2009

**Chlamydia — Rates by Age and Sex, United States, 2010**

<table>
<thead>
<tr>
<th>Age</th>
<th>Men</th>
<th>Rate (per 100,000 population)</th>
<th>Women</th>
<th>Rate (per 100,000 population)</th>
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<tr>
<td>Total</td>
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<td></td>
<td>3,700</td>
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</table>
Chlamydia is a significant public health problem

- Up to 29% of sexually active adolescent females are infected with Chlamydia\(^1\)
- 60% to 70% of infected women do not have symptoms\(^2\)
- Infection increases pre-term birth 2-3 fold\(^3\)
- Infection also increases risk of HIV transmission and acquisition 3-5 fold\(^4\)

4. CDC. Tracking the Hidden Epidemics: Trends in STDs in the United States 2000
Chlamydia is curable, once detected in screening programs

- Easily treated with antibiotics, but not easily diagnosed unless active screening is conducted
- Failure to diagnose and treat can lead to serious complications:
  - Pelvic inflammatory Disease (PID) – 40%
  - Infertility – 20%
  - Ectopic pregnancy – 9%
- 50% to 75% of babies born to infected mothers develop Neonatal pneumonia or eye infections

^CDC. Chlamydia in the United States. April 2001
Centers for Disease Control

Chlamydia Screening Guidelines

• The CDC recommends **annual** Chlamydia screening for:
  – All sexually active females aged less than 25 years
  – Sexually active females greater than 25 years with risk factors (e.g., new sex partner or multiple sex partners)

• Amplified Nucleic Acid Tests are the most sensitive and are the only method suitable for screening

• Re-test 3 months after treatment, to prove that the patient is cured

Centers for Disease Control. Sexually Transmitted Diseases in the United States, 2010
Chlamydia Screening is a universally accepted practice

- HEDIS, AMA, & American College of Preventative Medicine also recommend screening sexual active adolescents under 25 annually

- U.S. Preventive Services Task Force (USPSTF) and ACOG recommend, in addition to above guidelines, screening all pregnant women

- Per the Affordable Care Act (ACA), there is no co-pay associated with getting screened for Chlamydia because the USPSTF gave it a grade of A
How do we Prevent *Chlamydia* Infections?

- **Adults**
  - Public health education
  - Barrier contraceptives
  - Routine screening
  - Treat gonorrhea infections for coexisting *chlamydia*
  - Follow-up testing and treatment of sex partners

- **Infants**
  - Screening & treatment of expectant mothers
Gonorrhea

- Second most common bacterial STD
- Increasing drug resistance and incidence
- Asymptomatic carrier state is a particular challenge
  - Infections often do not produce symptoms until after complications have occurred

CDC. Sexual Transmitted Disease Guidelines. MMWR 2006
Gonorrhea consequences are similar to those of Chlamydia

- Sequelae of untreated infections include:
  - Pelvic Inflammatory Disease
  - Ectopic pregnancy
  - Infertility
  - Chronic pelvic pain
Gonorrhea U.S. Annual Incidence

- Over 300,000 cases reported in 2011
- 100.8 cases per 100,000 (1 in 1000)
- 2.8% increase from 2009

Centers for Disease Control. Sexually Transmitted Diseases in the United States, 2010
Consequences of Untreated Chlamydia and Gonorrhea Infections

- Infectious complications
  - Neonatal pneumonia or eye infections in 60-70% of infants born to untreated mothers
  - At least 2-5 fold increased risk of HIV infection
The cost-effectiveness of STD screening is well established

- Treating *Chlamydia* and its consequences costs over $3.5 billion per year in the United States.\(^1\)
- *Chlamydia* Screening reduces PID by 60%\(^2\)
- Every dollar spent on Chlamydia testing and treatment saves $12 in complications arising from untreated Chlamydia\(^1\)
- The higher sensitivity of nucleic acid tests is more cost-effective as a screening tool, despite higher assay costs

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1. The State of Health Care Quality, NCQA/HEDIS; 2005
Screening for only one infection is a missed opportunity

- Up to 50% of patients infected with Gonorrhea also have a *Chlamydia* infection*
- Similar symptoms
- Different specific treatments

Trichomonas vaginalis
Trichomonas Infections

- The most common, curable STD
  - although not yet a reportable disease
- Trichomonas infection may be asymptomatic in as many as 50% of women\(^1\)
- A recent study found that 72% of male partners of women infected with Trich were also infected, but the vast majority were asymptomatic\(^1\)
- May persist from several months to years

Issues with Trichomonas?

- Often misdiagnosed
  - Can be part of a mixed infection
- Current non-amplified methodologies aren’t sensitive enough for effective screening\(^1\)
- Unlike *Chlamydia*, no mandate for annual screening
  - Physicians have previously tested only when patients present with symptoms
  - Highly sensitive screening tests were just released in 2011

\(^1\) Chapin, Expert Rev. Mol. (2011)
Centers for Disease Control
Trichomonas Screening Guidelines

• Diagnostic testing for Trichomonas should be performed in women seeking care for vaginal discharge

• Screening for Trichomonas can be considered in those at high risk for infection
Trichomonas is the most widespread STD

- 7.4 million estimated new cases occur annually in the U.S.
- Trichomonas is more common than HPV infections (6.2 million), Chlamydia infections (2.8 million), herpes infections (750,000), and Gonorrhea infections (300,000)\(^1\)
- In a recent U.S. study, including both asymptomatic and symptomatic women, prevalence was 12.7\(\%\)\(^2\)
- Some studies show prevalence as high as 32\(\%\)\(^3\)

1. ASHA, 2011
2. Schwebke, J Clin Micro 2011
3. Freeman, Sex Transm Dis 2010
Trichomonas persists because women are not screened and treated.

New prevalence study: Trich prevalence is high and increases in populations of older women.

Prevalence of Trichomonas, *Chlamydia*, and Gonorrhea Infections in a subset of females in the US (N=7,593)

Trichomonas infection negatively impacts reproductive health

- Associated with female infertility and Pelvic Inflammatory Disease\textsuperscript{1,2}
- Responsible for premature births and low birth weight\textsuperscript{3,4}
- Linked to significant decreases in sperm motility and viability\textsuperscript{5}
- Risk factor for intellectual disability in children born to infected mothers\textsuperscript{6}

2. Fichorova JRI 2009
3. Cotch Sex Trans Dis 1997
5. Gopalkrishnan JIVFET 1990
6. Mann AEP 2009
Trich is an appropriate public health concern

- Trichomonas also is associated with other sexually transmitted infections
  - Prevalence of Chlamydia, gonorrhea, Herpes, syphilis, and HIV are all higher in Trichomonas-positive populations
    - Increases risk for HIV transmission and acquisition

- Trichomonas infections may increase risk for development of certain types of cancer
  - Increases time to clear HPV infection
  - Risk factor for cervical neoplasia
  - Increases prostate cancer risk

References:
1. Allsworth Sex Trans Dis 2009
2. CDC STD Treatment Guidelines 2010
3. Shafir CMR 2009
4. Kissinger Sex Trans Dis 2009
8. Sutcliff Future Oncol 2010
The Role of Diagnostics in Protecting and Promoting Women’s Health
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Bonnie Rib, Vice-President / General Manager
BD Diagnostics - Women's Health and Cancer
Leading global medical technology company that develops, manufactures and sells medical devices, instrument systems and reagents

Focused on improving drug delivery, enhancing the quality and speed of diagnosing infectious diseases and cancers, and advancing research, discovery and production of new drugs and vaccines

Founded in 1897, employs nearly 30,000 associates in more than 50 countries

“Helping all people live healthy lives.”
Herpes Simplex Virus (HSV)

• After initial infection the virus remains latent
  – Can be reactivated by: stress, sun exposure and compromised immunity

• Two major types: HSV 1  HSV 2

• Sites affected: skin, lips, oral cavity, eyes, genital tract and central nervous system
Genital Herpes (HSV 1 & 2) is more common than you might think

- As many as 1 in 5 US adults has genital herpes
- Most individuals have no or only minimal signs or symptoms
- When symptoms occur, they can include:
  - painful, itchy or tingling lesions
  - flu-like symptoms
  - painful burning during urination
HSV: A Significant Public Health Issue

- Associated with increased risk of HIV infection
- Co-factor in development of cervical cancer
- Risk of neonatal transmission
- No cure. Antiviral therapy can reduce the magnitude
- Lifelong infections
Testing for Cervical Cancer
What is Cervical Cancer?

• Cervical cancer is caused by persistent infection of the human papillomavirus ("HPV")
• HPV is a group of more than 100 related viruses
• Infection is common
  – especially women in mid-20s & 30s.
• Most HPV infections clear themselves
• But certain high-risk types of the HPV virus are strongly linked to cancer, including cancer of the cervix
• If left undetected and untreated, these high-risk types can cause cancer
Technologies to screen for Cervical Cancer

• **The Pap Test** uses the science of cytology to check the cervix for abnormal cells that could turn into cervical cancer if they are not treated properly. Liquid-based cytology has largely replaced the Pap “smear”

• **The HPV Test** uses the science of molecular biology to check the cervix for the virus (HPV) types that can cause abnormal cells and cervical cancer
Benefits of Regular Screening

• Cervical cancer was once one of the most common causes of cancer death in American women

• Between 1955 - 1992, cervical cancer deaths declined by more than 70%

• Why? Pap test invented by Dr. George Papanicolaou in 1943

• Pap test screens for pre-cancerous cells which can be treated and removed, stopping cervical cancer before it starts

• 12,000 women in US still develop cervical cancer
What Does the Pap Test Find?

ASC-US -
Atypical Squamous Cell - Undetermined Significance

LSIL or HSIL
Low-grade or High-grade squamous intraepithelial lesion

CYTOLOGY
Certain Types of HPV Cause Cancer

• *Persistent* infection of these types is the direct cause of cervical cancer

• HPV-16 & HPV-18 are the most widespread types associated with cancer
  – Account for approximately 70-80% of cervical cancer worldwide

• HPV-6 & HPV-11 are examples of “low-risk” types, however they cause genital warts
Cervical Cancer burden in US

• Over 12,000 women will be diagnosed with invasive cervical cancer in 2012
  - Most not screened in past 3 years
  - Median age at diagnosis is 48
  - Over $300 million annually in medical costs

• Overall screening rates differ by type of coverage:
  Private insurance 82%  Medicaid 76%  Uninsured 65%
New US Screening Guidelines

- Begin screening at age 21
- Women aged 21-29 should have a Pap test every 3 years
  - HPV test only for abnormalities
- Women aged 30 and older should be screened with Pap and HPV tests (“co-testing”) every 5 years or with Pap only every 3 years
- Women who have had the HPV vaccine should still follow the screening recommendations for their age group.

Source: American Cancer Society, March 2012
US Cervical Cancer Statistics by Race/Ethnicity

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Incidence&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Mortality&lt;sup&gt;1&lt;/sup&gt;</th>
<th>% Screened&lt;sup&gt;2&lt;/sup&gt;</th>
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<tr>
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<td>American Indian/Alaska Native</td>
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<tr>
<td>Hispanic</td>
<td>11.8</td>
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<td>78.7</td>
</tr>
</tbody>
</table>

<sup>1</sup>Per 100,000 women per year 2005-2009.

<sup>2</sup>% > 18 years of age who reported having had a Pap test between 2007 and 2010.
Cervical Cancer Is a Global Epidemic

• 2nd most common type of cancer among women worldwide
• In 2005, there were over 500,000 new cases
• 80% of these cases were in developing countries
• Nearly 300,000 women died of the disease
• Without urgent action, deaths due to cervical cancer are projected to rise by almost 25% over the next 10 years
Public-private partnerships to tackle Cervical Cancer

• Pink Ribbon, Red Ribbon, a public-private partnership to expand screening, treatment women in PEPFAR-funded countries
  - BD is providing education and training for laboratory staff and healthcare workers

• BD collaborating with National Cancer Coalition to screen and treat 75,000 women in the remote, mountainous region of Cusco, Peru
Cervical cancer screening can prevent needless deaths

- In the US, screening is covered by private plans, Medicaid and Affordable Care Act
- Yet, many women still do not know about the importance of screening
  - Education and outreach programs are critical
- CDC works with states, non-profits to provide education and free screenings to uninsured

www.cdc.gov
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