What’s New in BCCCNBP and in Breast and Cervical Cancer Screening

E. J. Siegl, OCN, MA, CBCN
Project Director
Breast and Cervical Cancer Control Navigation Program
Objectives

Discuss:

- Data showing decline in some cervical cancers since start of HPV vaccination
- Efficacy of MRI and mammograms in breast cancer screening for women at increased risk
- BCCCNP eligibility guidelines in providing breast and cervical cancer screening services
HPV Vaccine and Cervical Cancer Trends
• Since 2010, **new cases** of cervical cancer have **decreased** by **11.6%** and **deaths** from cervical cancer have **decreased** by **9.8%**.

• **Hispanic** women are diagnosed with cervical cancer more than other races.

• The overall **five-year survival** rate for cervical cancer patients is **66.2%**.

• Women aged 21 to 65 should be screened for cervical cancer. Since 2012, the percent of women receiving an appropriately timed **pap test** has **decreased** by **9%**.

• **Black (78%), Hispanic (78%), and Arab (64%)** women are significantly less likely to have **EVER** had a **pap test** compared to **White women (91%)**.

• Women who belong to the **LGBT** community also are significantly less likely to have ever had a **pap test (75%)**.

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**Cervical Cancer Stats**

**Cervical Cancer Incidence and Mortality Rates by Race, 2011-2015**

<table>
<thead>
<tr>
<th>Race</th>
<th>Incidence</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>7.5</td>
<td>~</td>
</tr>
<tr>
<td>Michigan</td>
<td>6.7</td>
<td>~</td>
</tr>
<tr>
<td>White</td>
<td>6.6</td>
<td>~</td>
</tr>
<tr>
<td>Black</td>
<td>7.4</td>
<td>~</td>
</tr>
<tr>
<td>Hispanic</td>
<td>9.4</td>
<td>~</td>
</tr>
<tr>
<td>Native American</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>Asian</td>
<td>4.3</td>
<td>~</td>
</tr>
</tbody>
</table>

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**Stage at Diagnosis for Cervical Cancer, 2015**

- **In Situ**, 82.9%
- **Regional**, 5.4%
- **Localized**, 8.4%
- **Distant**, 2.6%
- **Unknown**, 0.7%

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Source: Michigan Cancer Surveillance Program, Division of Vital Records and Health Statistics
Persistent infections with high-risk HPV types can lead to cell changes that, if left untreated, may progress to cancer.

About 1,400 new cases of cancer in Michigan can be attributed to HPV each year.

Vaccines are the best way to protect men and women from the most common types of HPV and are most effective when given at age 11 or 12.

As of June 2017, 46.1% of females, and 39.2% of males had completed the vaccination series for HPV.
Trends in HPV 16/18 in cervical precancers from 2008-2014

CDC Report: HPV Vaccine Impact Monitoring Project (HPV-IMPACT)

- 2008-2014: incidence of HPV precancerous cervical lesions declined significantly, as did the HPV strains that cause most cervical cancers
- 10,206 specimens analyzed from women ages 18-39 containing CIN2/3 or AIS associated with HPV16/18
- Proportion of HPV16/18-positive CIN2+ cases declined from 52.7% in 2008 to 44.1% in 2014
- Declines were observed in vaccinated (55.2% to 33.3%) and unvaccinated women (51.0% to 47.3%)
Declines in rates of HPV 16/18 specimens by age group, diagnosis, race, and ethnicity.

<table>
<thead>
<tr>
<th>Subgroup Analysis</th>
<th>2008</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ages 18-20</td>
<td>47.7%</td>
<td>18.8%</td>
</tr>
<tr>
<td>Ages 21-24</td>
<td>53.8%</td>
<td>44%</td>
</tr>
<tr>
<td>Ages 25-29</td>
<td>56.9%</td>
<td>42.4%</td>
</tr>
<tr>
<td>Ages 30-34</td>
<td>49.8%</td>
<td>45.8%</td>
</tr>
<tr>
<td>CIN 2</td>
<td>40.8%</td>
<td>29.9%</td>
</tr>
<tr>
<td>CIN 2/3</td>
<td>61.8%</td>
<td>46.2%</td>
</tr>
<tr>
<td>Non-Hispanic Whites</td>
<td>59.5%</td>
<td>47.9%</td>
</tr>
<tr>
<td>Non-Hispanic Blacks</td>
<td>40.7%</td>
<td>26.5%</td>
</tr>
</tbody>
</table>
Impact study showed HPV vaccination leads to "herd protection," rates of HPV16/18 CIN2+ specimens declined in both vaccinated and unvaccinated individuals.

Vaccinated individuals protect themselves and their community. (Community Immunity)

When enough people are vaccinated against a disease germs can’t travel as easily from person to person—entire community is less likely to get the disease

So, people who can’t get vaccinated will have some protection from getting sick
US² trends in cervical cancer incidence rates by: age, race/ethnicity, histologic subtype, and stage at diagnosis

- Declining incidence rates of cervical squamous cell carcinoma (SCC) have stabilized in non-Hispanic whites
- Cervical SCC rates have also stabilized or the pace of declines has slowed in some age groups among Hispanics
- Overall cervical adenocarcinoma incidence rate is increasing among non-Hispanic whites, driven by increases in ages 40–59
- Cervical adenocarcinoma rates are generally stable in ages <50 but decreasing in older ages in other race/ethnicities
- Rates of distant stage cervical SCC and adenocarcinoma are increasing in several age groups among non-Hispanic whites

Study objective: Determine an "elimination threshold" for cervical cancer, estimated from projected effects of "scaled-up" screening and HPV vaccinations

2020-2069: Estimated 44.4 million cases of cervical cancer would be diagnosed worldwide, most in low/medium resource countries, in absence of changes in the current status of surveillance and vaccination

Authors projection: Rapid scale-up of surveillance/vaccination (80%-100% global coverage) programs beginning in 2020 would avert 6-7 million cases over the same period
Lancet Oncology study cont.

Rapid scale-up of prevention programs could reduce the incidence of cervical cancer to 4 cases/100,000 by:

- 2059 for VERY highly developed countries
- 2069 for HIGHLY developed countries
- 2079 for MEDIUM developed countries
- 2100 or > for LOW developed countries

Scientists conclusion:
Cervical cancer could be eradicated in most of the world by 2099 with widespread adoption of HPV vaccine and cervical cancer screening programs.
What’s on the horizon?

New ASCCP risk-based guidelines

• Patient’s current test results and past history
• Risk matrix is used to calculate her risk of CIN2/3
• Computer program generates risk score
• Recommends next step in management
Why revise the management component of the guidelines?
Timeline for new guidelines
Efficacy of MRI and mammograms in breast cancer screening for women at increased risk
BCCCNP can reimburse for both screening and diagnostic MRI’s

• Screening MRI’s reimbursed for women at high-risk for breast cancer, **not** for average risk women.
Factors that determine eligibility for Screening MRIs in High Risk Patients

1. Personal/family history of BRCA or other gene mutation
2. Personal/family history of genetic syndromes known to predispose to a high risk of breast cancer (E.g. Li-Fraumeni, Cowden’s Disease, etc.)
3. Radiation treatment to the chest between ages 10-30
4. History of atypical hyperplasia/Lobular Carcinoma In Situ
5. Personal lifetime risk of 20-25% or > of breast cancer based on family history models (i.e. Claus, BRCAPRO, BOADICEA, and Tyer-Cuzick) or NCI Risk assessment model of > 1.7%/5 years
Efficacy of MRI/Mammograms compared to Mammograms alone in BRCA 1-2 mutation carriers\textsuperscript{9,10}

<table>
<thead>
<tr>
<th>MRI/mammogram SENSITIVITY higher than mammography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening trials results showed the % of breast cancers detected:</td>
</tr>
<tr>
<td>- 89-100% with the combination of mammography and MRI,</td>
</tr>
<tr>
<td>- 33-50% with mammography alone</td>
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</table>

<table>
<thead>
<tr>
<th>MRI/mammogram SPECIFICITY lower than mammography:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 73-80% for mammography and MRI</td>
</tr>
<tr>
<td>- 91-99% for mammography alone\textsuperscript{5}</td>
</tr>
</tbody>
</table>

MRI identifies “false-positive” results: detects masses that may appear cancerous when they are benign

More false positives = more biopsies = increased costs and potential negative impact on QOL for screening participants
Screening MRI or Mammography?

What is more cost effective?

Quality-Adjusted Life-Years (QALY) Comparison Over 25 Years of Screening

- Breast MRI provided 14.1 QALY at a cost of $18,167
- Mammography provided 14.0 QALYs at a cost of $4,760

Cost of Screening High Risk Women

Relative to screening with mammography alone, the cost per QALY gained by adding MRI from ages 35 to 54 years

- $55,420/QALY and $69,125/QALY for BRCA1 carriers,
- $130,695/QALY BRCA2 carriers, and
- $179,599/QALY for women with >15% lifetime risk
<table>
<thead>
<tr>
<th>Screening MRI and Mammography</th>
<th>Screening MRI used in <em>addition</em> to screening mammography, not in place of mammography(^{12,18})</th>
</tr>
</thead>
<tbody>
<tr>
<td>For HIGH Risk Women</td>
<td>Inconclusive evidence on performing MRI same time as mammogram or 6 months apart</td>
</tr>
<tr>
<td></td>
<td>Screening MRI’s NOT recommended with genetic variant of unknown significance (VUS) without other indications for high risk screening(^9)</td>
</tr>
</tbody>
</table>
Should Breast Cancer Survivors Receive Screening MRI’s?\(^7,13\)

- Breast MRI screening is good at detecting small tumors; unclear of benefit in women with a history of breast cancer\(^7\).
- Study conducted among 13,000 breast cancer survivors screened for breast cancer between 2005 -2012. Survivors received nearly 34,000 mammograms and about 2,500 MRI screenings.

**Results**

- Overall, MRI caught more tumors (11 per 1,000 exams) compared to mammography (8 per 1,000 exams).
- To achieve that rate, the MRI group had to undergo more biopsies: 10% of MRI screenings led to a biopsy, compared to 4% of mammograms.
Should Breast Cancer Survivors Receive Screening MRI’s?

The question remains what is the ultimate benefit?

MRI detected more early tumors but the rate of "interval" cancers – (cancer diagnosed in between screenings) was the same in the mammography-only and MRI groups.

Conclusion: mammography did as well as MRI in detecting tumors that were "clinically important" -- small tumors that would progress enough to produce symptoms (like a lump) in the next year.

The decision comes down to women discussing the pros and cons of MRI screening with their doctors, the experts said.
Diagnostic MRI’s reimbursed for further work-up for an abnormal mammogram or US result to determine if biopsy is needed

Diagnostic breast MRI is not recommended until after clinical breast examination and breast imaging are performed and interpreted unless being performed as part of a standard screening program

False-positive findings on breast MRI are common - histologic confirmation of suspicious indeterminate MRI findings is necessary
<table>
<thead>
<tr>
<th>Breast Condition</th>
<th>American Society of Breast Surgeons (ASBrS)/NCCN Recommendation</th>
<th>BCCCNP Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implants</td>
<td>Routine MRI screening in asymptomatic patients with silicone or saline implants not recommended</td>
<td>No and cannot reimburse to evaluate implant rupture</td>
</tr>
<tr>
<td>High Risk Lesions identified post biopsy</td>
<td>ASBrS: recommends physician discretion regarding MRI in patients with high risk lesions based on history and existing conventional imaging. NCCN: Do NOT recommend MRI after breast biopsy that identifies LCIS, ADH or other lesions referred to as “high risk.”</td>
<td>No</td>
</tr>
<tr>
<td>Inflammatory Skin Changes</td>
<td>NCCN: consider breast MRI for patients with suspicious skin changes consistent with inflammatory breast cancer IF imaging and biopsies performed and are negative for malignancy</td>
<td>Yes</td>
</tr>
<tr>
<td>Breast Condition</td>
<td>ASBrS/NCCN Recommendation</td>
<td>BCCCNP Reimbursement</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Nipple Discharge</td>
<td>NCCN: consider diagnostic MRI in patients with spontaneous unilateral nipple discharge who have normal conventional imaging studies and no palpable mass. MRI sensitivity and specificity to detect or exclude cancer in the setting of nipple discharge is not well described. Routine use is NOT recommended</td>
<td>Maybe – depends on the discharge and underlying pathology</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>NCCN Guidelines and the ASBrS do not recommend breast MRI for evaluation of breast pain</td>
<td>No</td>
</tr>
</tbody>
</table>
Nipple Discharge\textsuperscript{14}

Presenting symptom for 3-9\% of patients seen in the breast cancer clinics

Isolated nipple discharge is not usually a sign of breast cancer.

Majority of patients have benign disease

A period of watchful waiting may prevent patients undergoing unnecessary surgery
Types of Normal Nipple Discharge

- Usually a thin, cloudy, whitish, or almost clear fluid that is not sticky
- Can also be other colors such as gray, green, yellow, or brown
- During pregnancy or breastfeeding – can be clear, light white, or milky. Slightly bloody discharge sometimes occurs.
Causes of Nipple Discharge

1. Hormonal imbalance due to sexual stimulation
2. Medications (E.g. birth control pills, tranquilizers, antidepressants, blood pressure medications)
3. Imbalance in hormone prolactin (cause milk secretion)
4. Squeezing or stimulating the breast or nipple
5. Vigorous physical exercise or jogging; stimulation in breasts due to the bra

“Normal” Causes of Nipple Discharge
Benign Nipple Discharge - Not related to breast cancer

- **Galactorrhea**: secreting milk even after stopping breast-feeding. Causes: hypothyroidism, marijuana, herbs like star anise, pituitary gland tumors

- **Breast infection or abscess**: Pus oozing from nipple due to infection (mastitis). Occurs in breast-feeding women, resulting in redness and soreness of nipples
Benign Nipple Discharge - Not related to breast cancer

- **Fibrocystic Breast Changes**: Fibrocystic means lumpy due to the presence of fibrous tissues or cysts. In addition to pain and itching, the breasts may discharge fluid.

- **Mammary Duct Ectasia**: occurs in menopausal women, resulting in blockage of ducts in lower part of nipple; can cause a greenish discharge.

- **Intraductal Papilloma**: noncancerous growth in ducts of the breast that can cause discharge of blood or fluid that is sticky in texture.
Abnormal Nipple Discharge: Suspicious for breast cancer

In non-breastfeeding women aged 40 or older

- Unilateral, spontaneous (one breast, no stimulation) discharge is bloody or pink
- Discharge accompanied by other abnormalities, (dimpled skin, swelling, redness, crusting, sores, and a retracted nipple).

- Any color breast discharge if accompanied by lump in breast should be treated as suspicious for cancer.

Breast Cancers that may result in nipple discharge:
Intraductal carcinoma
Paget’s disease
Clinician Assessment

Breast lump upon palpation?

Nipple changes (such as crusting or color change?)

Pain present in one breast or both?

Nipple Discharge
Color? When did the discharge start? Discharge present in one breast or both? Spontaneous or non-spontaneous?

What other symptoms do you have?

What medications do you take?

Are you pregnant or breastfeeding?
Breast Pain
(Mastalgia)

Common condition; categorized as cyclical or noncyclical.

Cyclical pain: Pain linked with the menstrual cycle

Noncyclical pain:
- Pain from breast injury or referred pain from surrounding muscles or tissues
- Can vary in intensity – sharp, jabbing pain to mild tingling.
- Not usually linked to breast cancer
Causes of Breast Pain

- Hormone Fluctuations
- Breast cysts
- Mastitis
- Over exertion due to physical activity
- Breast size – referred pain in neck and shoulders.
- Breast surgery
- Medications (antidepressants, hormone therapy, etc.)
- Smoking
- High Fat/Refined Carb Diet

Smoking

High Fat/Refined Carb Diet
Questions
BCCCNP Eligibility for Breast and Cervical Cancer Services
What’s New?
• Screening MRIs for High Risk Women
• Interval Pap/HPV tests for High Risk Women
• Screening Pap and/or HPV tests for women age 21-39

No change in reimbursement for:
• Diagnostic MRIs
• Breast diagnostic procedures for women age 21-39 with abnormal CBE
• Cervical diagnostic procedures for women age 21-39 with abnormal Pap or HPV test
Screening MRI Eligibility Criteria

High Risk Women (ages 25-64) with one or more risk factors

- Personal history/family member with BRCA/other gene mutation
- Personal lifetime risk of:
  - > 20-25% based on risk assessment models
  - OR
  - > 1.7 % per 5 years (NCI Risk model)
- Radiation treatment to the chest between ages 10-30
- History of atypical hyperplasia or Lobular carcinoma in situ
- Personal/family history of genetic syndromes (Li-Fraumeni syndrome, etc.)

Annual Mammogram and Screening MRI Reimbursed by BCCCNP
Patient Name: ________________________________  Enrollment Date: ________________________

**MEDICAL HISTORY** *(Clinician must Review this Section with Client)*

<table>
<thead>
<tr>
<th>Previous Mammogram?</th>
<th>Previous Clinical Breast Exam (CBE)?</th>
<th>Previous Breast Biopsy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ No</td>
<td>□ No</td>
<td>□ No</td>
</tr>
<tr>
<td>□ Yes: Date: / / /</td>
<td>□ Yes: Date: / / /</td>
<td>□ Yes: Date: / / /</td>
</tr>
</tbody>
</table>

**BREAST EXAM HISTORY**

<table>
<thead>
<tr>
<th>Client DOB: / / /</th>
</tr>
</thead>
</table>

**BREAST CANCER RISK**

Client at **High Risk** for BREAST cancer if any of the following is checked:
- □ Personal history/Family Member with BRCA/another gene mutation
- □ Personal lifetime risk of ≥ 20-25% or > 1.7 % (Gail model) based on risk assessment models
- □ Radiation treatment to the chest between ages 10-30
- □ History of atypical hyperplasia or Lobular carcinoma in situ
- □ Personal/family history of genetic syndromes (Li-Fraumeni syndrome)
- □ Other: ________________________________

Client at high risk for BREAST cancer?
- □ YES => **High / Increased Risk** (Screening mammogram & Screening MRI – preapproval required)
- □ NO => **Average** (Mammogram Only)
- □ * Unknown (Mammogram Only)
- □ Not Assessed (Mammogram Only)
Pre-approval for BOTH screening and diagnostic MRI’s must be obtained PRIOR to ordering

Contact E.J. Siegl (siegle@michigan.gov) or Danielle Hamilton (HamiltonD1@Michigan.gov) directly and BCCCNP Coordinator with the following information:

Type of MRI and reason for order

- Screening MRI – list client risk factors
- Diagnostic – reason for MRI (I.e. abn mammogram/US result)
BCCCNP Approval Process for Screening and Diagnostic MRI’s

POST MRI – notify E.J. or Danielle directly and BCCCNP Coordinator

- Client MBCIS # (if known)
- MRI Date of Service
- Facility where MRI Performed
- BI-RADS Result and if further f/u needed

- E.J. or Danielle will enter the information in BCCCNP database (MBCIS) for payment
Clients at High Risk for Cervical Cancer

- Prior history of CIN 2, CIN 3, or cervical cancer
- Prior DES exposure
- Immunosuppression for other causes
- HIV/AIDS infection
- Organ transplantation

Pap test (ALONE) annually x 3 years
If normal, Pap/HPV Co-test every 3 years
# Cervical Cancer Risk

Client at **High Risk** for Cervical cancer if any of the following is checked:

- Prior history of CIN 2, CIN 3, or cervical cancer
- Prior DES exposure
- Immunosuppression for other causes
- HIV/AIDS infection
- Organ transplantation
- Other __________________________

Client at high risk for Cervical cancer?

- **YES** ⇒ **High / Increased Risk**
  (Pap test (alone) annually for 3 years. If normal, then Pap/HPV Co-test every 3 yrs)
- **NO** ⇒ **Average** (Regular screening)
- **Unknown** (Regular screening)
  *Risk was assessed, but client answers “I don’t know”*
- **Not Assessed** (Regular screening)
Family Planning Clients Eligibility for BCCCNP Medicaid Treatment Program

- Age 21-64 and current MI resident
- Income $\leq 250\%$ Federal Poverty Level (FPL) (Family of 2 $< $42,275)
- Current Michigan resident
- US citizen/legal resident, registered alien or refugee as defined by MDHHS
- Insurance Requirements depends on type of insurance and amount of deductible (Call EJ or BCCCNP coordinator to discuss)
- **Diagnosed** with a NEW or RECURRING breast or cervical cancer or cervical pre-cancerous lesion (CIN 2, CIN 3/ CIS) requiring treatment
BCCCNP Reimbursement Screening Pap and/or HPV tests for women age 21-39

Clients Age 21-29
• Screening Pap test ONLY every 3 years (HPV test will NOT be reimbursed for women in this age group)

Clients age 30-64
• Screening Pap test ONLY every 3 years OR
• HPV-HR Test ONLY every 5 years OR
• Co-test Pap and HPV every 5 years
FP agencies who jointly enroll FP and BCCCNP clients at clinics

Eligible uninsured Family Planning clients can be enrolled in BCCCNP for reimbursement of their office visit and Pap/HPV test(s)

Complete:
BCCCNP Enrollment form and Agreement for Program Participation Consent Form

Send to BCCCNP agency:
All BCCCNP paperwork and results of Pap/HPV tests
Enrolling the client in BCCCNP does not affect Family Planning data collection

Data collected for BCCCNP can also be collected for Family Planning reports

BCCCNP Reimbursement:
Partial office visit and Pap/HPV test(s)

Family Planning Reimbursement:
Additional Family Planning charges for the client should be billed to Family Planning, not BCCCNP
<table>
<thead>
<tr>
<th>Breast Cancer Screening Services</th>
<th>Cervical Cancer Screening Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clients Age 40-64 (Average Risk)</td>
<td>Clients Age 25-64 (Increased Risk for Breast Cancer*)</td>
</tr>
<tr>
<td>Mammogram</td>
<td>SCREENING Pap test ONLY every 3 years</td>
</tr>
<tr>
<td>Ultrasound, Mammogram and/or MRI (based on age)</td>
<td>• Screening Pap test ONLY every 3 years OR</td>
</tr>
<tr>
<td><strong>MDHHS Nurse Consultant pre-approval required for all MRIs and is based on risk factors</strong></td>
<td>• HPV-HR Test ONLY every 5 years OR</td>
</tr>
<tr>
<td></td>
<td>• Co-test Pap and HPV every 5 years</td>
</tr>
</tbody>
</table>

### Summary of BCCCNCP Reimbursement Services

- **Breast Cancer Screening Services**
  - Clients Age 40-64 (Average Risk)
  - Mammogram
  - Ultrasound, Mammogram and/or MRI (based on age)
  - **MDHHS Nurse Consultant pre-approval required for all MRIs and is based on risk factors**

- **Cervical Cancer Screening Services**
  - Clients Age 25-64 (Increased Risk for Breast Cancer*)
  - SCREENING Pap test ONLY every 3 years
  - • Screening Pap test ONLY every 3 years OR
  - • HPV-HR Test ONLY every 5 years OR
  - • Co-test Pap and HPV every 5 years
References


Questions???

Contact Information
E.J. Siegl, BSN, RN, OCN, CBCN
BCCCNP Director
siegle@michigan.gov
517-335-8814