The impact of systematic pre-screening of cancer patients on clinical trial accrual
Invasive Breast Cancer

Locoregional Treatment of Clinical Stage I, II A, or II B Disease or T3, N1, M0

- Radiation therapy to whole breast with or without boost\(^k\) (by photons, brachytherapy, or electron beam) to tumor bed and supraclavicular area (category 1). Consider radiation therapy to internal mammary nodes (category 3), radiation therapy may be given concurrent with CMF (category 2B) or follow chemotherapy when chemotherapy indicated.

- Radiation therapy to whole breast with or without boost (by photons, brachytherapy, or electron beam) to tumor bed (category 1). Consider radiation therapy to supravacular area (category 2B). Consider radiation therapy to internal mammary nodes (category 3). Radiation therapy may be given concurrent with CMF (category 2B) or follow chemotherapy when chemotherapy indicated.

- Radiation therapy to whole breast with or without boost (by photons, brachytherapy, or electron beam) to tumor bed. Radiation therapy may be given concurrent with CMF (category 2B) or follow chemotherapy when chemotherapy indicated.

See BINV-4

Lumpectomy with surgical axillary staging (category 1)\(^{46,5,6}\)

- 4 positive axillary nodes\(^k\)
- 1-3 positive axillary nodes
- Negative axillary nodes

Total mastectomy with surgical axillary staging (category 1)\(^{2,6}\) (convention)

or

If T2 or T3 and fulfills criteria for breast conserving therapy except for size\(^{5}\)

- See Surgical Axillary Staging (BINV-1)
- See Axillary Lymph Node Staging (BINV-2)
- See Axillary lymph Node Status in Infiltrating Carcinoma (BINV-2)
- See Special Considerations to Breast Conserving Therapy (BINV-2)
- See Principles of Reconstruction Following Surgery (BINV-4)
- Consideration may be given to additional staging including bone scan and abdominal CT (US/ MRI); chest CT (category 2B)
- See Principles of Radiation Therapy (BINV-3)

Radiation therapy should be given to the internal mammary lymph nodes if they are clinically or pathologically positive, otherwise the treatment to the internal mammary nodes is at the discretion of the treating radiation oncologist. CT planning treatment should be utilized in all cases where radiation is delivered to the internal mammary lymph nodes.

Breast irradiation may be omitted in those 70 y of age or older with estrogen-receptor positive, clinically node negative, T1 tumors who receive adjuvant endocrine therapy (category 1).

Note: All recommendations are category 2A unless otherwise indicated.

Clinical Trial: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.
Participation to clinical trials: The preferred treatment

<table>
<thead>
<tr>
<th>PR positive</th>
<th>ER-negative and PR-negative</th>
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<tbody>
<tr>
<td>Tubular</td>
<td></td>
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<tr>
<td>Colloid</td>
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</tbody>
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Note: All patients enrolled in a clinical trial should undergo biomarker testing to determine the best treatment approach.

Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial.
Breast Cancer is not one disease: Clinical subtypes

- **ER+**: 65%-75%
- **HER2+**: 15%-20%
- **TNBC**: 15%

Invasive Breast Cancer
2017 Accrual Ratios in all Disease Sites Across the RCN
2016 and 2017 Accrual Ratios in Breast Cancer Across the RCN
A Brief History of BR2 Project

June 2017
Project selected by breast co-leads Dr. Boileau and Dr. Meterissian

November 2017
Executive Committee approval

January 2018
Prescreening and flagging started

March 2018
Deployment of clinical trials buttons

August 2017
Coordinator training started

December 2017
Official approval from quality department at JGH and MUHC

December 2017
First patient accrued

April 2018
Identify procedures for flagging relapsed/progressed patients
<table>
<thead>
<tr>
<th>Prescreening procedure followed by coordinator</th>
<th>RCN Prescreening</th>
<th>Hospital Coordinator</th>
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<tr>
<td>Performance Status</td>
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<td>Hematology Analysis</td>
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<tr>
<td>Verifying tissue compatibility</td>
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<td>Previous Treatment</td>
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<td>Measurable Disease</td>
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<tr>
<td>Cardiac Function</td>
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<td>X</td>
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<tr>
<td>Locate regions of metastasis</td>
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</tbody>
</table>
Jewish General Hospital Current Prescreening Metrics

128 non-invasive events
103 patients

165 not eligible events
131 patients

Including 114 events with no trials across RCN
node negative HR
(largest patient population)
85 patients

382 prescreening events
279 patients

254 invasive events
182 patients

89 eligible events
(trials available within RCN)
61 patients

3 screen failures (3 patients)
20 enrolled (16 patients)
6 MD refused (5 patients)
15 patient refused (10 patients)
45 pending (26 patients)

N=279 patients
Selected for prescreening based on pathology or imaging results
Challenges

• Differences in Medical Records
  – OACIS vs. Endovault

• Clinical trial engagement
  • Patient and physician perception of trials
  • Transferring patients
  • Awareness

• Trial availability within the RCN

• Changing physician practice
  • Getting physicians on board with the project
Trial availability within the RCN

RCN Breast Treatment-based Trials accruing across all Hospital Sites (November 2018)
RCN Breast Cancer Patient Population  vs  RCN breast clinical trials

Histology

- IDC: N=980
- ILC: N=154
- Mixed IDC/ILC: N=107
- Other: N=69

Stage (New cases)

- Stage 1: N=541
- Stage 2: N=414
- Stage 3: N=97
- Stage 4: N=68
- Unknown: N=100

Stage

- Early stage: N=8
- Advanced/Metastatic: N=20

Molecular Subtype (New cases)

- ER+: N=939
- HER2+: N=154
- TNBC: N=105
- Unknown: N=112

Molecular Subtype

- ER+: N=11
- HER2+: N=3
- TNBC: N=190
- Any: N=6

N = 28 trials/year for IDC and ILC (as of November 2018)
Future of BR2…

• Promotional material
  – Poster
  – Pamphlets
  – Videos

• Flagging procedure for MUHC and SMHC needs to be identified
Thank you!