Patient-Centered Dosing Initiative (PCDI)

MBC Patient-Centered Dosing Survey Results, 08/20

“Designed by Patients, for Patients”

*** With Appreciation from the PCDI Team! ***
Patient-Centered Dosing Initiative (PCDI) Introduction
LAUNCHED BY A TEAM OF METASTATIC BREAST CANCER (MBC) PATIENT ADVOCATES WORKING WITH HEALTHCARE PROFESSIONALS TO IMPROVE PATIENTS’ QUALITY OF LIFE VIA TREATMENT-RELATED ADAPTATIONS

Rationale:
➢ While MBC is considered incurable, it can be treatable for years, or in rare cases, decades

➢ Cancer drug development normally focuses on the maximum tolerated dose (MTD), even though patients can rarely tolerate the MTD for extended periods

➢ As a consequence of toxicity-related side effects, patients with MBC have been known to require emergency medical assistance, stop a working treatment prematurely, or be rendered incapable of receiving their treatment on schedule

➢ Although more data is needed, recent evidence suggests that approved lower doses of some MBC cancer therapies may be just as effective as the MTD with less severe side effects, and may allow patients to remain on therapy for a longer period of time

Mission: To enhance quality of life, while maintaining therapy effectiveness, by enabling patients with MBC and their physicians to identify the optimal approved dosage of treatment based upon each patient’s unique physical, circumstantial, and psychological factors. Learn more at www.therightdose.org

Patients should never reduce their dosage or change anything regarding their treatment without speaking with their doctor!
Meet the PCDI Team!

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To the 1,221 People Who Took the Survey...
About the MBC Patient-Centered Dosing Survey

The PCDI sought to obtain a greater understanding about MBC treatment-related side effects and the approaches used to manage them - in lieu of making assumptions

✓ Questions pertained to treatment-related experiences, quality of patient-physician communication, and level of support provided by physicians whose patients experience treatment-related side effects

✓ Responses are enabling the 9-member PCDI patient advocate team and the medical professionals supporting this initiative to identify opportunities for future improvements regarding side effect mitigation
Survey Methods

Previously launched a limited “Beta Pilot Survey” to obtain key learnings

Reviewed the survey with the PCDI’s Advisory Board of Medical Oncologists

Attempted via Voluntary Consent verbiage to restrict responses to US-only due to varying data privacy and protection laws

Advertised participation via social media, online support groups, email lists, and organizational newsletters

Encouraged participation from minority groups via photos of African-American and Hispanic-American PCDI members accompanying the flyers; translated into Spanish
Similarities to Results from Other Studies

Most common side effects were fatigue (78%), nausea (53%), and low blood counts (53%). *(The MBCA Landscape Analysis reported fatigue as the most common side effect at 80%)*

All 7 males reported having hormone receptor (HR) positive disease - consistent with the 97% HR+ rate reported for male breast cancer

62% of survey respondents reported having recurrent breast cancer; 38% presented as de novo

- de novo disease normally represents 6% of all MBC cases
- The MBC Project indicated that 36% of patients reported de novo disease

7% of respondents were diagnosed > 10 years ago, similar to the MBC Project’s 6%

Disease by subtype reporting is likewise consistent with that of the MBC Project

<table>
<thead>
<tr>
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<th>PCDI</th>
<th>MBC Project</th>
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<tbody>
<tr>
<td>Hormone Receptor Positive</td>
<td>77%</td>
<td>81%</td>
</tr>
<tr>
<td>HER2 Positive</td>
<td>30%</td>
<td>32%</td>
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<tr>
<td>TNBC</td>
<td>10%</td>
<td>11%</td>
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Surprises and Key Learnings

22% of patients reported being diagnosed with MBC more than 5 years ago. (Normally the > 5 year survival rate is 27%).

16% of participants had 5 or more lines of treatment

86% reported experiencing one or more bad side effects from treatment

- 20% visited the Emergency Room/hospital
- More than 2 of 5 patients (43%) missed at least one treatment
- 98% reported discussing their side effects with their physician (in contrast to a study mentioned in the MBCA Landscape Analysis whereby only 65% of patients seen in comprehensive cancer centers and 50% of patients seen in community oncology practices told their physicians of these issues)
- 82% of these patients received assistance from their doctors
Surprises and Key Learnings, (Cont’d)

Of the patients who experienced treatment-related side effects and reported these to their physicians, 66% were prescribed a reduced treatment dosage

• 83% of patients whose dosage was reduced reported feeling better, at least initially
• 64% of these patients required only one dosage reduction to feel better
• 28% needed two dosage reductions
• 8% required 3 dosage reductions

80% of patients reported being aware that most MBC therapies are available in multiple approved dosages

53% of patients felt that a higher dose of a cancer drug is not necessarily more effective than a lower dose, whereas 20% hold the opposite belief (27% were undecided)

The vast majority of patients (92%) would be willing to discuss approved MBC drug dosing options with their physician based upon their unique characteristics
Gender Identification

- Female: 1,213, 99%
- Male: 7, 1%
- Transgender: 1, 0%

Total: 1,221
Age Group

- Prefer not to say, 3, 0%
- ≤ 35 yrs., 30, 3%
- 36 - 50 yrs., 416, 34%
- 51 - 65 yrs., 562, 46%
- > 65 yrs., 210, 17%

T=1,221
Racial Group

- **Caucasian**, 1,075, 88%
- **African-American**, 51, 4%
- **Asian-American**, 25, 2%
- **Hispanic-American**, 37, 3%
- **Multi-racial**, 25, 2%
- **Pacific Islander**, 1, 0%
- **Prefer not to say**, 7, 1%

T=1,221
Was Patient Previously Diagnosed with Early Stage BC?

- Yes, 754, 62%
- No, 465, 38%
- Don’t know, 2, 0%

Total: 1,221
Years Since MBC Diagnosis

- < 1 yr: 170, 14%
- 1 - 2 yrs: 394, 32%
- 3 - 5 yrs: 383, 31%
- 6 - 10 yrs: 192, 16%
- 11 - 15 yrs: 54, 4%
- 16 - 20 yrs: 20, 2%
- > 20 yrs: 20, 2%
- Don't know: 1, 0%
- T=1,221
MBC Subtype

- HR+, HER2+, 206, 17%
- TNBC, 121, 10%
- HER2+, HR-, 166, 13%
- HR+, HER2-, 728, 60%
- HER2+, HR-, 166, 13%
- TNBC, 121, 10%
- HR+, HER2+, 206, 17%

T=1,221
Nr. Sequential Treatments/Lines of Therapy

- 1 line: 486, 40%
- 2 lines: 252, 21%
- 3 lines: 170, 14%
- 4 lines: 105, 8%
- ≥ 5 lines: 192, 16%
- Don't know: 16, 1%

Total: 1,221
Types of Treatment (check all that apply, add other)

- Targeted: 997
- Hormonal: 936
- Chemotherapy: 674
- Radiation Therapy: 593
- Surgery: 341
- ADC: 160
- Immunotherapy: 110
- PARP Inhibitor: 38
- Other: Bone-directed therapy: 27
- Other: Ovarian Suppression: 6

Total: 1,221
Frequency of Physician Inquiry Regarding Side Effects

- Every visit: 944, 77%
- Every other visit: 22, 2%
- Occasionally: 129, 11%
- Rarely: 86, 7%
- Never: 40, 3%

Total = 1,221
Has Patient Experienced a Bad Treatment-Related Side Effect?

Yes, 1,051, 86%
No, 170, 14%
T=1,221
Did Side Effect Result in Emergency Room/Hospital Visit?

- Yes, 213, 20%
- No, 835, 80%
- Can’t remember, 3, 0%

n=1,051
Did Patient Miss Treatment Due to Side Effect?

- Yes: 454, 43%
- No: 584, 56%
- Can't remember: 13, 1%

n=1,051
Treatment-Related Side Effects

(check all that apply, add other)

- Fatigue
- Nausea
- Low blood counts
- Diarrhea
- Neuropathy
- Mouth sores/Gum issues
- Constipation
- Cognitive issues
- Change in appetite
- Hand Foot Syndrome/skin...
- Rash
- High glucose levels
- Cardiac (heart)
- Lung inflammation
- Osteonecrosis of the jaw/tooth issues
- Other (alopecia, eye issues, GI issues, ...)

N=1,051
Did Patient Inform Physician About Side Effects?

- Yes, 1,026 (98%)
- No, 20 (2%)
- Can't remember, 5 (0%)

n=1,051
Why Didn’t Patient Inform Physician About Side Effects? (check all that apply, add other)

- Side effects weren’t important enough: 13
- Concern that treatment would be changed: 3
- Other: Researched own options/no chance to discuss: 3
- Concern that physician would become angry: 2
- Patient was embarrassed: 1

n=20
Did Physician Assist Patient With Side Effects?

Yes, 838, 82%

No, 180, 17%

Can't remember, 8, 1%

T=1,221
Pts. w side effects: 1,051
Pts. who informed physician about side effects: 1,026

n=1,026
Patients’ Reactions When Physician Helped with Side Effects (check all that apply)

- Gratitude for physician’s help
- Felt that physician was listening to them as a person, not just a patient
- Confirmed expectations about physician’s willingness to help
- Increased trust in physician
- Feel more comfortable about future discussions with physician
- Patient liked physician more than before
- N/A - No reaction/none of the above

Pts. who informed physician about side effects: 1,026
Pts. whose physicians tried to help: 838

n=838
Did Physician Lower the Dosage?

- Yes, 556, 66%
- No, 272, 33%
- Can't remember, 10, 1%

n=838
Patients’ Responses to Lower Dosage

- Felt better, 393, 71%
- Felt the same, 87, 15%
- Felt better at first, then felt the same, 66, 12%
- Felt worse, 4, 1%
- Can’t remember, 6, 1%

Pts. whose physicians tried to help: 838
Pts. given a lower dosage: 556
Number of Dose Reductions Required to Feel Better

- One dose reduction, 293, 64%
- Two dose reductions, 128, 28%
- Three or more dose reductions, 38, 8%

Pts. given a lower dosage: 556
Pts. who felt better on a lower dosage: 393 + 66 = 459

n=459
Other Measures Taken by Physician to Alleviate Patients’ Side Effects
(check all that apply, add other)

- Pts. who informed physician about side effects: 1,026
- Pts. whose physicians tried to help: 838
Patients’ Reactions When Physician Didn’t Try to Relieve Side Effects
(check all that apply)

- Patient began doing own research: 87
- Patient felt physician wasn’t listening: 40
- Patient felt disappointed: 30
- Patient didn’t trust physician as much as before: 23
- Patient felt angry: 22
- Patient went to a different physician: 14
- None of these/no reaction: 59

Pts. who informed physician about side effects: 1,026
Pts. whose physician didn’t try to help: 180
Patient Aware that Lower Doses May be an Option to Relieve Side Effects?

- Yes: 982 (80%)
- No: 239 (20%)

Total: 1,221
Patient Believes the Highest Approved Drug Dose is Always More Effective than a Lower Approved Drug Dose?

- Yes: 237, 20%
- No: 651, 53%
- Don't know: 333, 27%

T=1,221
Patient Willing to Discuss Approved Drug Dosing Options with Physician
Based on Patient’s Unique Characteristics?

- Yes: 1,127 (92%)
- No: 11 (1%)
- Don’t know: 83 (7%)

T=1,221
Reason Patient is Unwilling to Discuss Approved Drug Dosing Options with Physician Based on Patient’s Unique Characteristics

(check all that apply, add other)

- Lack confidence in lower dose efficacy: 6
- Prefer to leave decision with physician: 3
- Physician doesn’t have time/isn’t easy to approach: 2

n=11
Summary

✓ Most patients (86%) experienced a bad treatment-related side effect

✓ 1 out of 5 (20%) patients visited the Emergency Room/hospital due to side effects

✓ 2 out of 5 (43%) patients missed treatment due to side effects

✓ 83% of patients given a lower dose reported feeling better

✓ Vast majority of patients (92%) would be willing to discuss dosage options with their physicians based on their unique characteristics
Find out more at www.therightdose.org

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