Importance of Patient–Provider Discussions about Oncology Dose Optimization

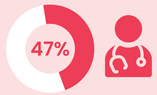
Patient-centered dosing for people living with metastatic breast cancer can:

- **mitigate side effects**
- **improve quality of life**
- **allow continuation of a current treatment**

More is not necessarily better

- People living with metastatic breast cancer (MBC) typically **remain on treatment indefinitely**
- Recommended starting doses for MBC treatments are often based on the **maximum tolerated dose** (MTD)
- Approved **lower doses may be just as effective** with less severe side effects
- High toxicity and related side effects negatively **affect quality of life** and may **reduce treatment options**
- The Patient-Centered Dosing Initiative (PCDI) surveyed **1,221 people living with MBC** and **119 oncologists** who treat MBC and found that **oncologists underestimated bad side effects**

Patients experienced at least one bad treatment-related side effect



Oncologist-reported percent of patients who experienced a bad side effect

- **Toxicity has serious impact:** Of the 86%, 1 in 5 patients visited the ER/hospital and 2 in 5 missed a scheduled treatment

What is patient-centered dosing?

Metastatic breast cancer drug dosages are personalized for each patient based on:

- **Frank conversation and informed discussion** between HCP and patient, before and during treatment
- Criteria developed by the **PCDI and its medical advisory board**, including personal wishes, age, health, availability of at-home care, history of side effects, and more

Patients should NEVER change anything about treatment on their own – they should always speak with their care team!

Why patient-centered dosing?

The PCDI surveys reveal opportunities to explore options, address side effects, and individualize care

- Patients *and* providers are **willing to discuss** flexible dosing options

Patients – 92%

Oncologists – 97%

- **80% of patients are aware** that many MBC therapies are available in multiple approved dosages
- Many patients and providers **do not believe** a higher dose is always more effective

- Dose reduction **improves quality of life**

Patients who reported feeling better when dosage was reduced

Oncologists who said patients given a dose reduction felt better and that efficacy was similar to the standard dose

- **Side effects need to be discussed at every visit**

Patients who reported being asked at every visit

Oncologists who indicated they ask at every visit

How the PCDI is driving change

Catalyst for shifting the "one size fits all" paradigm

- **FDA Project Optimus** supports identifying dosages in early clinical trials that maximize efficacy, safety, and tolerability rather than routinely leveraging the MTD
- **FDA Project Renewal** is reviewing approved therapies and updating indications for use, dosage, and administration
- **Increased discussion** among governmental agencies, pharmaceutical companies, and oncology organizations about the need for additional studies to validate multiple dosing options

"It's loud and clear from our patients that the drugs are too toxic… patients deserve a more tolerable dose."

— Dr. Atik Rahman, FDA Division Director, Friends of Cancer Research Annual Meeting 11/10/21

Actions

Communicate

- Initiate conversation with patients about side effects at every single visit
- Discuss ways to alleviate side effects, including patient-centered dosing

Personalize

- Understand each patient's unique needs and characteristics
- Educate patients about options
- Monitor quality of life and appropriateness of therapy and dose

Collaborate

- Engage in shared decision-making with patients about dosing, before and during treatment
- Use this PCDI-developed downloadable tool as a framework for patient-provider collaboration

Scan to learn more

therightdose.org

BACKGROUND/METHODS
The Patient-Centered Dosing Initiative (PCDI) sought to examine patient and medical oncologist experience, communication, and perspectives about treatment-related side effects and conducted 2 online surveys:
• MBC Patient Survey (2020), 1,221 responses
• Medical Oncologists Survey (2021), 119 eligible responses (oncologists who treat people living with MBC)

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PATIENT CENTERED DOSING INITIATIVE
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