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

- **mitigate side effects**
- **improve quality of life**
- **allow continuation of a current 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 = 87%
  - 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: 83%
  - Side effects need to be discussed at every visit
  - Patients who reported being asked at every visit: 77%
  - Oncologists who indicated they ask at every visit: 100%

**How the PCDI is driving change**

**Catalyst for shifting the “one size fits all” paradigm**

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

- **Catalyst for shifting the “one size fits all” paradigm**
  - Patients experienced at least one bad treatment-related side effect
  - Oncologist-reported percent of patients who experienced a bad side effect

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

**PCDI’ers**

- Co-Founders: Maryam Lustberg, MD, MPH, Hope S. Rugo, MD, Anne Loeser, BS
- Advisory Board: Susan Love Research Institute, American Society of Clinical Oncology, American Society for Radiation Oncology, American Society for Breast Disease, American Society of Breast Surgeons, American Society for Therapeutic Radiology & Oncology, American Society for Clinical Oncology, American Society of Hematology, American Society for Radiation Oncology, American Society for Therapeutic Radiology & Oncology, American Society for Hematology

**ACR/BMI/ACR Net/MBC Alliance**

- The American Cancer Society, the American Society for Radiation Oncology, American Society of Clinical Oncology, American Society for Breast Disease, American Society for Therapeutic Radiology & Oncology, American Society of Hematology, American Society for Clinical Oncology, and American Society for Radiation Oncology, the American Society for Therapeutic Radiology & Oncology, American Society for Hematology, the American Society for Therapeutic Radiology & Oncology, American Society of Hematology, American Society for Therapeutic Radiology & Oncology, American Society of Hematology

**“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**

**References**

1. Lustberg, et al. ASCO Annual Worldwide Meeting, June 2021
2. Loeser, et all. ASCO Annual Worldwide Meeting, June 2021

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**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-provide collaboration

**Scan to learn more**

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