Statement on Metastatic Breast Cancer + Clinical Trials

MBC RESEARCH POSITION PAPER

rethink BREAST CANCER

BACKGROUND

Metastatic Breast Cancer (MBC)[1] is the most advanced form of breast cancer, when the cancer that originated in the breast has spread to other parts of the body, most commonly (but not limited to) the bones, liver, lungs and brain. Metastasis can occur at the time of a breast cancer diagnosis (called de novo) or anytime after an early stage diagnosis (called metastatic recurrence). MBC can be treated locally and/or systemically. The goal of treatment of MBC is to provide the person with good quality prolonged survival. Psychological supports are important to achieving this goal.

People with MBC can be as varied as the general population, affecting people of all ages, races, genders and abilities. The inclusion of people at all stages of the breast cancer experience strengthens evidence-based care through the continuum of the disease.

Clinical trials help to determine the safety and effectiveness of potential new treatments, and existing treatments being used in different ways. They provide an important route for people with MBC to potentially access new treatments, services, or resources. Clinical trials offer the greatest hope in terms of improving both prognosis and quality of life. It may take many years before new treatment options in clinical trials become part of standard breast cancer care.

Major advances in MBC treatment - and in turn improving the clinical outcomes and quality of life of people living with MBC - occur because the effectiveness of new therapies is demonstrated in clinical trials.

1 The term Metastatic Breast Cancer is interchangeable with Advanced Breast Cancer or Secondary Breast Cancer.

RETHINK MBC ADVISORY BOARD'S POSITION STATEMENT

Patient Involvement

Trained and supported people with MBC should be engaged at every step of the research process, including:

- design of trials
- development of protocols
- preparation of informed consent material
- monitoring and reporting of trials

Rationale: Patient participation, engagement and involvement can all add value to research in different ways; it can improve the quality and relevance of the research, highlight the benefits that the research can have for those living with MBC, and facilitate patient recruitment in the trial.

Clinical Trial Development

Developers establishing clinical trials should be familiar with the current MBC landscape (disease progression, treatments, prognosis) before creating trials or establishing study criteria to ensure that eligibility criteria are not overly restrictive nor exclude people living with MBC based on previous lines of treatment or perceptions of what a person living with MBC can do.

Rationale: Heavily pre-treated people with MBC are often excluded from trials, limiting treatment options and stalling progress for those who've been living with the disease for longer periods of time. Innovative trials can be inclusive while still meeting goals in this changing landscape. Improving overall survival requires additional treatment lines in pre-treated patients.

Information

Clinical trial information should be easily accessible to both patients and healthcare professionals to ensure patients are better informed and increase participation in health research. An easy-to-use database and search engine should be made available to patients to help them find and match to clinical trials, both Canadian and worldwide, and be widely promoted to patients and healthcare professionals.

Clinical trial information that will be shared with patients should be in lay terms and avoid jargon. Utilize alternative solutions to overcome language barriers (e.g. translators, providing information in multiple languages, alternative media for those with hearing or vision impairments).

Rationale: People with MBC have difficulty finding clinical trials for which they may be eligible for a number of reasons, such as: a rapidly changing research landscape, disjointed systems to document open research studies, language barriers, lack of understanding of medical terminology.

Clinical Trial Access

Patients should have access to and be included in clinical trials that could improve their outcomes and quality of life. Those establishing clinical trials should support people with MBC to encourage clinical trial participation, such as:

- eligibility criteria that consider people with MBC as individuals with a spectrum of needs and abilities
- monitoring procedures that do not put those living in rural and remote areas at a disadvantage in participating
- financial aid to patients accessing the clinical trial (e.g. travel support, childcare)

Rationale: Clinical trials are inaccessible to many patients due to geography and related expenses. Clinical trials may require repetitive, invasive and expensive pre-screening; a treament-free period; restrictive eligibility criteria based on inaccurate perceptions of what a person living with MBC can do; and/or monitoring procedures that must be done at a research center rather than the patient's local hospital or treatment facility.

Patient Recruitment

Developers establishing clinical trials should:

- work with industry partners to facilitate recruitment
- consider clinical trial navigators to support patients and healthcare professionals
- develop a strategy to meet accrual goals
- review progress and if possible, adjust as required to ensure that accrual strategies are met
- establish representation criteria during trial development to ensure that people of colour and all genders will be recruited
- meet ethics approval requirements for including MBC patients

Rationale: Many clinical trials do not reach end points because accrual goals are not met, resulting in wasted time, money and resources.

RETHINK MBC ADVISORY BOARD'S POSITION STATEMENT (CONTINUED)

Patient Representation

Developers establishing clinical trials should establish appropriate representation criteria during trial development and consider outreach strategies to ensure that people of colour and all genders will be recruited and adequately represented in clinical trials for people with MBC.

Rationale: There is a lack of representation of people of colour and all genders in clinical trials and research study populations.

Informed Research

Accurate data of people with MBC, such as recurrence information, should be collected and analyzed to better understand MBC. Access to accurate data could also inform and increase the number of MBC clinical trials.

Real world evidence and translational research should be adequately supported and funded.

To increase the number of clinical trials offered in Canada, databases that could increase access to clinical trials in Canada should be developed (e.g. patient registries).

Rationale: Most cancer registries around the world collect information about initial cancer diagnosis and mortality but do not document recurrences, which represent the majority of MBC cases. We don't know how many people receive a MBC diagnosis each year because the data is not being collected. Real world evidence and translational research is the basis for advancing MBC knowledge and MBC treatments in an accelerated fashion, leading to well thought out research plans and clinical trials.

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(234 breast cancer trials in Canada)

https://www.cancer.gov/about-cancer/treatment/clinical-trials/disease/breast-cancer/treatment
(550 treatment clinical trials for breast cancer in the US)

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