Cancer Biol Med 2026. doi: 10.20892/j.issn.2095-3941.2025.0674

EDITORIAL

Balancing global standards and regional nuances in breast cancer care: the role of guidelines, clinical research, precision medicine, and artificial intelligence in advancing quality of care for patients worldwide

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Breast cancer remains a global health challenge with greater than 2.3 million new cases diagnosed annually 1, according to the World Health Organization[1]. Management of breast cancer is shaped by a complex interplay of international guidelines, regional adaptations, and the rapidly evolving fields of precision medicine and artificial intelligence (AI). International guidelines and consensus statements, such as those from the National Comprehensive Cancer Network (NCCN)[2], the European Society for Medical Oncology (ESMO)[3,4], and the St. Gallen International Breast Cancer Conference[5], provide a framework for standardized care. However, these frameworks must accommodate clinical heterogeneity across diverse populations, while integrating cutting-edge advances in precision medicine and AI to achieve what is termed "intelligent standardization." This editorial explores how global guidelines inform region-specific practices, the transformative impact of precision medicine through molecular subtyping and biomarker-driven therapies, and the emerging role of AI in enhancing diagnostic accuracy, treatment decision-making, and patient stratification.

International guidelines and region-specific standardization

International guidelines serve as a cornerstone for breast cancer management, the aim of which is to standardize care to ensure equitable, evidence-based treatment worldwide. For example, the NCCN guidelines offer detailed algorithms for diagnosis, staging, and treatment, covering surgical, systemic, and radiation therapies. Similarly, the ESMO provides comprehensive recommendations tailored to early, locally advanced, and metastatic breast cancer with an emphasis on risk stratification and multidisciplinary care[3]. The St. Gallen consensus statements, which are updated biennially, integrate expert opinions to address contentious issues, such as the role of adjuvant therapies in early-stage disease[5].

Despite the global reach, these guidelines must be adapted to regional contexts due to variations in healthcare infrastructure, resource availability, and patient demographics[6,7]. For example, in high-income countries with advanced healthcare systems, such as the United States or Western Europe, guidelines are often implemented with access to cutting-edge diagnostics (e.g., MRI and genetic testing) and novel therapies (e.g., CDK4/6 inhibitors). In contrast, low- and middle-income countries (LMICs) face challenges, such as limited access to mammography, pathology services, or expensive targeted therapies[8]. The Breast Health Global Initiative (BHGI) addresses these challenges by providing resource-stratified guidelines, which categorize recommendations into basic, limited, enhanced, and maximal resource levels[9]. However, these regional differences are also used as a justification for not adhering to evidence-based modern standards of care. While we need to respect regional differences, the goal must be to provide the optimal level of care to every breast cancer patient[10]. International collaborative research and educational projects that include as many regions, disciplines, and caregiver professions as possible are an appropriate strategy to overcome global disparity in breast cancer therapy[11].

For example, mastectomy may be prioritized over breast-conserving surgery in a basic-resource setting due to the lack of radiotherapy facilities. This practice is *eo ipso* unacceptable because it is well-known that breast-conserving surgery is the standard surgical method for the treatment of breast cancer[12], but we need to accept the reality and strive to make progress. In addition to a lack of resources, "cultural" reasons, outdated treatment traditions, and a lack of knowledge are important causes for suboptimal treatment in some regions of the world[13].

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Received October 30, 2025; accepted November 19, 2025.
Available at www.cancerbiomed.org
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There is clearly a fine line between patronizing and educating. The optimal method to harmonize treatment standards globally involves a constant exchange of information and collaboration among experts and caregivers worldwide[5].

Another example is the subject of genetic testing and determination of molecular disease alterations[14], for which indications have recently been broadened[15]. However, this creates new questions and controversies about the subject[16], not only because of resource issues but also because not all testing results in actionable results[17].

In addition to regional differences, clinical heterogeneity further complicates standardization. Breast cancer is not a single disease but a spectrum of subtypes with distinct biological behaviors and treatment responses[18-20]. Factors, such as age, menopausal status, tumor stage, and comorbidities, also influence treatment decisions. For example, young women with breast cancer in Asia often present with more aggressive, triple-negative subtypes compared to their Western counterparts, which necessitates tailored approaches. Similarly, cultural preferences, such as a higher preference for mastectomy over breast conservation, or different approaches to side effect management in some Asian countries[21], influence guideline implementation. International guidelines must accommodate this heterogeneity by providing flexible decision trees, allowing clinicians to pragmatically adapt recommendations based on local epidemiology and patient preferences[14] without compromising the ultimate goal of equal care worldwide.

Precision medicine: refining treatment through molecular subtyping and biomarkers

Precision medicine has revolutionized breast cancer care by shifting the focus from "one size fits all" approaches to individualized treatment based on molecular subtyping and biomarker-driven therapies[22]. Breast cancer is classified into molecular subtypes (luminal A, luminal B, HER2-enriched, and triple-negative) based on gene expression profiles and immunohistochemical markers, like estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2)[23]. These subtypes guide prognosis and treatment. For example, luminal A tumors, which are ER-positive and low-grade, often respond well to endocrine therapies, like tamoxifen or aromatase inhibitors, while HER2-enriched tumors benefit from targeted therapies, like trastuzumab or pertuzumab[22,24]. Further subtyping suggests that even within these established categories, several new subtypes may exist and may be responsive to completely different treatment approaches[20].

Biomarker-driven therapies have further refined treatment protocols[25]. For example, the identification of BRCA1/2 mutations has led to the use of PARP inhibitors, like olaparib, in patients with metastatic breast cancer, which offers a targeted approach for those with DNA repair deficiencies[26]. Similarly, multi-genomic assays predict recurrence risk in early-stage ER-positive breast cancer, which helps clinicians decide whether chemotherapy can be safely omitted[27-32]. The TAILORx trial demonstrated that women with intermediate Oncotype DX scores could often avoid chemotherapy without compromising outcomes, highlighting the power of biomarkers in reducing overtreatment[33,34].

Precision medicine also addresses resistance mechanisms. For example, ESR1 mutations[35], which confer resistance to aromatase inhibitors in metastatic breast cancer, can be detected through liquid biopsies, offering alternative therapies, like fulvestrant or oral Selective estrogen receptor degraders (SERDs)[36-41]. Similarly, PIK3CA mutations, which are present in approximately 40% of ER-positive breast cancers, have led to the use of PI3K inhibitors, such as alpelisib[42] and inavolisib[43], in combination with endocrine therapy. Likewise, capivasertib can target alterations in ER-related growth signaling pathways, such as AKT[44,45]. Most of these alterations will be determined *via* liquid biopsy in the future, thus sparing patients multiple organ biopsies but determining the clonal evolution of the disease from plasma[45]. These advances underscore how precision medicine integrates with international guidelines, refining standardized protocols to account for molecular heterogeneity, while maintaining a structured approach to care whenever possible[46-48].

However, challenges remain, especially in LMICs, where access to genomic testing and targeted therapies is limited. International guidelines must balance the inclusion of precision medicine with feasibility, ensuring that recommendations remain actionable across diverse settings. For example, while HER2 testing using *in situ* hybridization techniques is standard in high-resource settings, immunohistochemistry may be the only feasible option in resource-constrained environments, somewhat limiting access to trastuzumab. Also, global guidelines may consider defining a "second-best" treatment approach in addition to the most innovative and often very expensive strategy[9,49].

Role of AI in advancing intelligent standardization

Artificial intelligence is poised to transform breast cancer care by enhancing diagnostic accuracy, optimizing treatment decision-making and improving patient stratification, while integrated with existing guidelines to achieve "intelligent standardization."[50] AI leverages machine learning, deep learning, and natural language processing to analyze vast datasets, including imaging, genomic profiles[51], and electronic health records, to provide actionable insights.

AI has shown remarkable promise in improving mammography diagnostics interpretation. Studies have demonstrated that AI algorithms can outperform radiologists in detecting breast cancer from mammograms with higher sensitivity and specificity[52]. For example, the Google Health AI model reduced false-negatives by 9.4% compared to human readers. Such tools can assist radiologists in high-volume settings, especially in LMICs where radiologist shortages are common, ensuring that guideline-recommended screening protocols are more effectively implemented.

AI also enhances treatment decision-making by integrating clinical and molecular data to predict outcomes and recommend therapies. For example, the IBM Watson for Oncology analyzes patient data against NCCN guidelines and clinical trial data to suggest personalized treatment plans. While early iterations faced challenges in generalizability[53], newer models are being trained on diverse, region-specific datasets to improve applicability. AI-driven decision support tools can help clinicians navigate the complexity of guidelines, particularly in cases of clinical heterogeneity, by providing tailored recommendations based on patient-specific factors.

Patient stratification is another area in which AI excels. Machine learning models can identify high-risk patients by analyzing patterns in genomic, clinical, and lifestyle data. For example, AI algorithms have been developed to predict the risk of recurrence in early-stage breast cancer by integrating tumor characteristics, patient demographics, and social determinants of health[54]. These models can refine risk stratification beyond traditional tools, like the Nottingham Prognostic Index, enabling more precise adherence to guideline-recommended adjuvant therapies[55].

AI integration with existing guidelines is critical for achieving intelligent standardization. By embedding AI tools within electronic health record systems, clinicians can receive real-time, guideline-compliant recommendations tailored to individual patients. For example, an AI system could flag a patient with a high Oncotype DX score for chemotherapy, while ensuring compliance with NCCN or ESMO protocols. Moreover, AI can bridge gaps in resource-limited settings by prioritizing patients for scarce resources, such as radiotherapy, based on predicted outcomes.

However, the adoption of AI faces challenges, including data privacy concerns, algorithmic bias, and the need for validation across diverse populations. For example, AI models trained on datasets from high-income countries may underperform in LMICs due to differences in tumor biology or imaging quality. International guidelines must incorporate standards for AI development, such as the standards proposed in the World Health Organization 2021 AI Ethics Report, to ensure equitable and transparent use.

Pivotal role of translational and clinical research

The crucial role of research must not be underestimated in all these situations. Both translational and clinical research is *eo ipso* communicating, critically reviewing and discussing, globally connecting, and at least in principle promoting equal access as well as diversity[56]. The role of translational research in transforming inventions and discoveries from basic sciences to actual benefit for mankind is of critical importance in addition to the education and development of the young with high potential to future academic leaders in the field[57]. In the past clinical research was left to pharmaceutical companies. We should recognize that academically sponsored clinical trials allow for more "relevance" in selecting the subjects that are of actual importance for those suffering from a disease[58]. Patient-reported-outcomes (PROs) have become an important endpoint in breast cancer clinical research[59] and global connection of successful academic societies and clinical trial groups are imperative[56]. AI can also assist in optimizing clinical trial designs, taking into account all the abovementioned aspects[60].

Conclusion: toward intelligent standardization

The management of breast cancer exemplifies the delicate balance between standardization and personalization in multidisciplinary oncology[11]. International guidelines provide a robust framework for ensuring consistent and evidence-based care, while regional adaptations address clinical and logistical heterogeneity[61,62]. Precision medicine, through molecular subtyping and biomarker-driven therapies, refines these guidelines by tailoring treatments to individual tumor biology, improving outcomes while reducing unnecessary interventions. AI can further enhance this paradigm by improving diagnostic accuracy, optimizing treatment decisions, and enabling precise patient stratification, all while being aligned with established guidelines.

The future of breast cancer care lies in "intelligent standardization," a dynamic approach that integrates global standards with regional realities, cutting-edge technologies, and facilitated access to clinical trials. To achieve this goal, all global stakeholders must address disparities not only of access to care but specifically to precision medicine and AI, particularly in LMICs, while ensuring that these tools are ethically developed and validated. International guidelines should evolve to incorporate AI-driven decision support and

precision medicine as standard components[63] with clear recommendations for use in diverse settings[64]. By harmonizing these advances we can move toward a future where every breast cancer patient receives care that is both standardized and uniquely tailored, maximizing outcomes across the globe, which remains the ultimate goal.

Conflict of interest statement

No potential conflicts of interest are disclosed.

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Cite this article as: Gnant M. Balancing global standards and regional nuances in breast cancer care: the role of guidelines, clinical research, precision medicine, and artificial intelligence in advancing quality of care for patients worldwide. Cancer Biol Med. 2026; 23: 314-319. doi: 10.20892/j.issn.2095-3941.2025.0674