Archives of Surgical Research | Original Research Communication

Appraisal Of Current Guidelines Regarding The Management Of Breast Cancer Using The Appraisal Of Guidelines Research And Evaluation (AGREE) Instrument: A Critical Review

Hadia Baig, Talat Waseem

ABSTRACT With rapid advancements in breast oncology, there is a growing need for high-quality, systematically developed clinical practice guidelines (CPGs) and consensus statements (CSs). This study aims to assess the quality of the current clinical practice guidelines and consensus statements related to the management of breast cancer employing the Appraisal of Guidelines Research and Evaluation (AGREE) II tool.

METHODS A systematic literature search of bibliographic databases (PubMed and Google Scholar) and 20 professional society websites was conducted from January 2019 onwards. Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument was used to evaluate the methodological quality of the included CPGs and CSs.

RESULTS The analysis of the AGREE II overall assessment of CPGs and CSs revealed a wide overall score range. The median overall score across the guidelines was 61%. The highest overall score was obtained by the American Society of Clinical Oncology (ASCO) guidelines, with scores ranging from 80-91%, followed by 5th ESO-ESMO ABC5 (77%), 4th ESO-ESMO BCY4 (76%) and V.4 NCCN (74%). Overall, CSs had a lower quality in the majority of the domains as compared to CPGs.

CONCLUSIONS The authors believe that the guidelines related to breast cancer management have a wide room for improvement. There is a growing need for CPGs/CSs that employ uniformly endorsed standards. Guideline development standards are the current state-of-the-art, and guideline developers must direct their efforts towards acknowledging and incorporating them into guidelines.

KEYWORDS breast cancer, management, AGREE II instrument, clinical practice guidelines, guidelines, consensus, quality of guidelines

HOW TO SITE Baig H, Waseem T. Appraisal Of Current Guidelines Regarding The Management Of Breast Cancer Using The Appraisal Of Guidelines Research And Evaluation (AGREE) Instrument: A Critical Review. *Archives of Surgical Research*. 2021, 2 (3):16-26. https://doi.org/10.48111/2021.03.03.

Critical Review

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https://doi.org/10.48111/2021.03.03

As of January 2021, breast cancer has transcended lung cancer, becoming the most prevalent cancer worldwide. As stated by the World Health Organization (WHO), during the year 2020, 2.3 million women were diagnosed with Breast Cancer, resulting in 685 000 deaths globally[1]. Healthcare systems worldwide utilize evidence-based guidelines to facilitate standardized, high-quality treatment decisions and patient care. Previous evaluations have shown profound variances in the quality of breast cancer management guidelines developed by organizations across the nations [2–4]. With an overwhelming volume of scientific evidence of uncertain value, now more than ever, critically appraised clinical practice guidelines (CPGs) and consensus statements (CSs) are a fundamental component of clinical practice. When rigorously developed, they have the potential to transform complex scientific research findings into guidelines of substantial quality that can be applied to target populations globally. It is crucial to analyze the variations in the recommendations made by different organizations, as conflicting and ambiguous statements can render clinicians feeling uncertain about which treatment plan to undertake, leading to adverse patient outcomes. Prior to guideline implementation, there are certain key factors that need to be appraised, including the guideline development process involving key stakeholders, the methodological strategy used, its applicability and the clarity of presentation. The Appraisal of Guidelines for Research and Evaluation (AGREE) II Instrument is a popular, internationally validated assessment tool developed by the AGREE Collaboration, that evaluates the methodological quality of CPGs/CSs. The AGREE Collaboration define the quality of guidelines as the "confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice"[5].

In this study, we carried out a systematic review of the recent CPGs and CSs related to breast cancer management and appraised their methodological quality by employing the AGREE II instrument.

METHODS

We performed a systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[6].

Data sources and searches: An independent systematic literature search was conducted by the two authors using PubMed and Google Scholar databases applying MeSH terms, "breast cancer", "breast neoplasms", "guidelines", "practice guidelines", "consensus", "management", "therapy", "treatment" and other alternative wordings, within a 2-year window, from January 2019 till present. The main ground for searching within this 2-year window was based on Vernooij et al.'s systematic review of methodological handbooks. They stated that "handbooks recommend a time frame between publishing a CPG and commencing an updating process, with two to three years being the most frequently recommended"[7]. The exclusion of obsolete guidelines allows us to focus on updated CPGs/CSs that have incorporated new evolving researches and developments in therapy. Only full-text English Language articles were selected. A search was also carried out across 20 professional society websites and bibliographies of well-known publications. The two authors gathered to compile the available information ensuring that there were no discrepancies and that no relevant material was missed.

Inclusion and exclusion criteria: This study includes CPGs and CSs related to breast cancer management developed by national and international professional organizations and societies.

We included CPGs and CSs if the following criteria were met:

1. Concerning any or all aspects of breast cancer management including, surgical (i.e., breast surgery, axillary surgery and breast reconstruction) and systemic management (i.e., neo- and adjuvant chemotherapy, radiotherapy and endocrine treatment).
2. Related to breast cancer in men and women.
3. Related to breast cancer management in Covid-19 Pandemic
4. Including early, locally advanced and metastatic breast cancer
5. Articles in the English Language
6. Full-text available
7. Published and unpublished guidelines

Our exclusion criteria were the following:

1. CPGs/CSs related to breast cancer risk assessment, screening, diagnosis and follow-up
2. Guidelines related to prevention and treatment of symptoms and adverse events induced by breast cancer therapies
3. Substituting obsolete guidelines for updates by the same organization
4. Randomized control trials, clinical trials, narrative reviews, discussion articles, survey papers, population-based studies and case reports

Guideline quality assessment: The authors appraised the quality of the included CPGs/CSs independently using the AGREE II tool. To avoid any discrepancies in the results, the appraisers carried out a discussion to reach a consensus.

The AGREE II tool is comprised of 23 items arranged into 6 domains, each domain highlighting a unique characteristic of guideline quality. These include domain 1 (Scope and Purpose), domain 2 (Stakeholder Involvement), domain 3 (Rigor of Development), domain 4 (Clarity and Presentation), domain 5 (Applicability) and domain 6 (Editorial Independence)[5].

Appraisers scored individual items on a 7-point scale, ranging between 1 or strongly disagree and 7 or strongly agree. The domain scores were calculated by adding together the appraisers' scores for each item and scaling it as a percentage of the maximum possible score by using the formula[5]:
Domain score = (obtained score-minimum possible score)/ (maximum possible score-minimum possible score)

An overall guideline assessment score was calculated by obtaining the mean score of the 6 domains. We then applied cut-off points to draw a distinction between high- and low-quality guidelines, with CPGs/CSs being 'recommended' if they had scores above 80%, 'recommended with modifications' if scores were between 50-80% and 'not recommended' if scores were below 50%8.

RESULTS

Study selection: A total of 555 records were obtained, out of which 537 were from online databases (PubMed and Google Scholar) and 18 from additional sources (professional society websites and bibliographies from well-known publications). Of these, 50 publications were duplicates and 460 did not fulfil the selection criteria. A sum of 45 articles (37 CPGs[9–45] and 8 CSs[46–53]) were identified for the final evaluation. This information has been laid out in a tabulated form in Table 1. The study selection process has been detailed in a PRISMA flow diagram provided in Figure 1. The ICCs of the appraisers for each CPG/CS ranged between 0.9-0.96 in AGREE II.

Table 1: CPGs and CSs included

Title	Abbreviated Name	Entity	Year	Country	Published in Journal
Guidance for the management of early breast cancer Recommendations and practice points	Australia Early BC	AG	2020	Australia	Not Published
AGO Recommendations for the Diagnosis and Treatment of Patients with Locally Advanced and Metastatic Breast Cancer: Update 2019	AGO LABC/MBC 2019	AGO	2020	Germany	Breast Care
AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2021	AGO Early BC 2021	AGO	2021	Germany	Breast Care
Systemic Therapy for Early Breast Cancer	AHS systemic for Early BC	AHS	2021	Canada	Not Published
Consensus Guideline on the Management of the Axilla in Patients With Invasive/In-Situ Breast Cancer	ASBrS Axilla Invasive BC	ASBrS	2019	USA	Not Published
Endocrine Treatment and Targeted Therapy for Hormone Receptor–Positive, Human Epidermal Growth Factor Receptor 2–Negative Metastatic Breast Cancer: ASCO Guideline Update	ASCO Endocrine & Targeted therapy for HR+/HER2- MBC	ASCO	2021	USA	JCO
Chemotherapy and Targeted Therapy for Patients With Human Epidermal Growth Factor Receptor 2–Negative Metastatic Breast Cancer That is Either Endocrine-Pretreated or Hormone Receptor–Negative: ASCO Guideline Update	ASCO Chemo- & Targeted therapy for HER2- MBC	ASCO	2021	USA	JCO
Selection of Optimal Adjuvant Chemotherapy and Targeted Therapy for Early Breast Cancer: ASCO Guideline Update	ASCO Chemo- & Targeted Therapy for Early BC	ASCO	2020	USA	JCO
Management of the Axilla in Early-Stage Breast Cancer: Ontario Health (Cancer Care Ontario) and ASCO Guideline	ASCO Axilla Early BC	ASCO	2021	USA	JCO
Management of Male Breast Cancer: ASCO Guideline	ASCO Male BC	ASCO	2020	USA	JCO
Adjuvant PARP Inhibitors in Patients With High-Risk Early-Stage HER2-Negative Breast Cancer and Germline BRCA Mutations: ASCO Hereditary Breast Cancer Guideline Rapid Recommendation Update	ASCO Hereditary BC	ASCO	2021	USA	JCO
Use of Endocrine Therapy for Breast Cancer Risk Reduction: ASCO Clinical Practice Guideline Update	ASCO BC Risk Reduction	ASCO	2019	USA	JCO
Neoadjuvant Chemotherapy, Endocrine Therapy, and Targeted Therapy for Breast Cancer: ASCO Guideline	ASCO Chemo-, Endo- & Targeted Therapy for BC	ASCO	2021	USA	JCO
Breast cancer management guidelines during COVID-19 pandemic	India Covid-19 BC	ASI	2020	India	IJS
Chinese Expert Consensus on the Clinical Diagnosis and Treatment of Advanced Breast Cancer (2018)	China Advanced BC	CACA	2020	China	ACS Journals
Clinical practice guidelines for modified radical mastectomy of breast cancer: Chinese Society of Breast Surgery (CSBrs) practice guidelines 2021	China MRM BC 2021	CSBrs	2021	China	CMJ
Clinical practice guidelines for diagnosis and treatment of invasive breast cancer: Chinese Society of Breast Surgery (CSBrS) practice guidelines 2021	China Invasive BC 2021	CSBrs	2021	China	CMJ
Clinical practice guidelines for breast cancer implantable intravenous infusion ports: Chinese Society of Breast Surgery practice guidelines 2021	China BC implantable ports	CSBrs	2021	China	CMJ
Clinical practice guideline for breast-conserving surgery in patients with early-stage breast cancer: Chinese Society of Breast Surgery (CSBrS) practice guidelines 2021	China BCS Early BC 2021	CSBrs	2021	China	CMJ
5th ESO-ESMO international consensus guidelines for advanced breast cancer (ABC 5)	5th ESO-ESMO ABC5	ESO, ESMO	2020	Europe	Annals Of Oncology
ESO-ESMO 4th International Consensus Guidelines for Breast Cancer in Young Women (BCY4)	4th ESO-ESMO BCY4	ESO, ESMO, EUSOMA	2020	Europe	Annals Of Oncology
Early breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up	ESMO Early BC	ESMO	2019	Europe	Annals Of Oncology
GEICAM Guidelines for the Management of Patients with Breast Cancer During Spain's COVID-19 Pandemic	GEICAM BC Covid-19	GEICAM	2020	Spain	The Oncologist

International multidisciplinary expert panel consensus on breast reconstruction and radiotherapy	IMEP BR & RT	IMEP	2019	Europe	BJS
The Japanese Breast Cancer Society clinical practice guidelines for surgical treatment of breast cancer	Japanese surgical BC	JBCS	2019	Japan	Breast Cancer
The Japanese Breast Cancer Society Clinical Practice Guidelines, 2018 edition: the tool for shared decision making between doctor and patient	Japanese SDM BC	JBCS	2019	Japan	Breast Cancer
The Japanese breast cancer society clinical practice guidelines for systemic treatment of breast cancer	Japanese systemic BC	JBCS	2020	Japan	Breast Cancer
Breast cancer management during the COVID 19 pandemic: French guidelines	France Covid-19 BC	Multiple groups	2020	France	Eur J Breast Health
NCA Breast Cancer Clinical Guidelines	NCA BC	NCA	2020	UK	Not Published
Breast cancer, version 4.2021 featured updates to the NCCN guidelines	V.4 NCCN	NCCN	2021	USA	JNCCN
Chinese guidelines for diagnosis and treatment of breast cancer 2018 (English version)	China BC diagnosis & treatment	NHCPRC	2019	China	CJCRCN
Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic breast cancer after 2 or more anti-HER2 therapies	NICE Trastuzumab deruxtecan	NICE	2021	UK	Not Published
Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	NICE Ribociclib & Fulvestrant	NICE	2021	UK	Not Published
Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer	NICE Atezolizumab & Nab-paclitaxel	NICE	2020	UK	Not Published
Trastuzumab emtansine for adjuvant treatment of HER2-positive early breast cancer	NICE trastuzumab emtansine	NICE	2020	UK	Not Published
Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer	NICE Palbociclib & Fulvestrant	NICE	2020	UK	Not Published
Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab	NICE Neratinib	NICE	2019	UK	Not Published
Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	NICE Abemaciclib & Fulvestrant	NICE	2019	UK	Not Published
Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer	NICE Pertuzumab	NICE	2019	UK	Not Published
Abemaciclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer	NICE Abemaciclib & Aromatase Inhibitor	NICE	2019	UK	Not Published
SEOM clinical guidelines in advanced and recurrent breast cancer (2018)	SEOM Advanced & Recurrent BC	SEOM	2019	Spain	CTO
Customizing Local and systemic therapies for women with early breast cancer: The St. Gallen International Consensus Guidelines for treatment of early breast cancer 2021	St. Gallen 2021	St. Gallen	2021	Europe	Annals Of Oncology
Guidelines on Management of the Patient with Breast Cancer	BC	UWI, UHWI, ASJ	2019	West Indies/ Jamaica	West Indian Med J
Evidence-based guidelines for managing patients with primary ER+ HER2− breast cancer deferred from surgery due to the COVID-19 pandemic	Primary ER+ deferred BC	---	2020	International	NPJ Breast Cancer
2020 consensus guideline for optimal approach to the diagnosis and treatment of HER2-positive breast cancer in Bosnia and Herzegovina	BiH HER2+ BC	---	2020	BiH	BJBMS

Table 1. ABBREVIATIONS: American Cancer Society, ACS; Arbeitsgemeinschaft Gynakologische Onkologie, AGO; Alberta Health Services, AHS; American Society of Breast Surgeons, ASBrS; American Society of Clinical Oncology, ASCO; Association of Surgeons of India, ASI; Association of Surgeons in Jamaica, ASJ; Australian Government, AG; Bosnia and Herzegovina, BiH; Breast Cancer, BC; Bosnian Journal of Basic Medical Sciences, BJBMS; British Journal of Surgery, BJS; Chinese Anti-Cancer Association, CACA; Chinese Society of Breast Surgery, CSBrs; Chinese Journal of Cancer Research, CJCRCN; CPG, Clinical practice guideline; Clinical and Translational Oncology, CTO; Consensus statement, CS; European School of Oncology, ESO; European Society for Medical Oncology, ESMO; European Society of Breast Cancer Specialists, EUSOMA; Indian Journal of Surgery, IJS; International multidisciplinary expert panel, IMEP; Journal of Clinical Oncology, JCO; Journal of the National Comprehensive Cancer Network, JNCCN; Breast Expert Advisory Group/ Northern Cancer Alliance, NCA; National Comprehensive Cancer Network, NCCN; National Health Commission of the People's Republic of China, NHCPRC; National Institute for Health and Care Excellent, NICE; Nature Portfolio journals, NPJ; Sociedad Espanola de Oncología Medica, SEOM; University of the West Indies, UWI; University Hospital of the West Indies, UHWI

Figure 1: PRISMA Flow Diagram of the Search Strategy

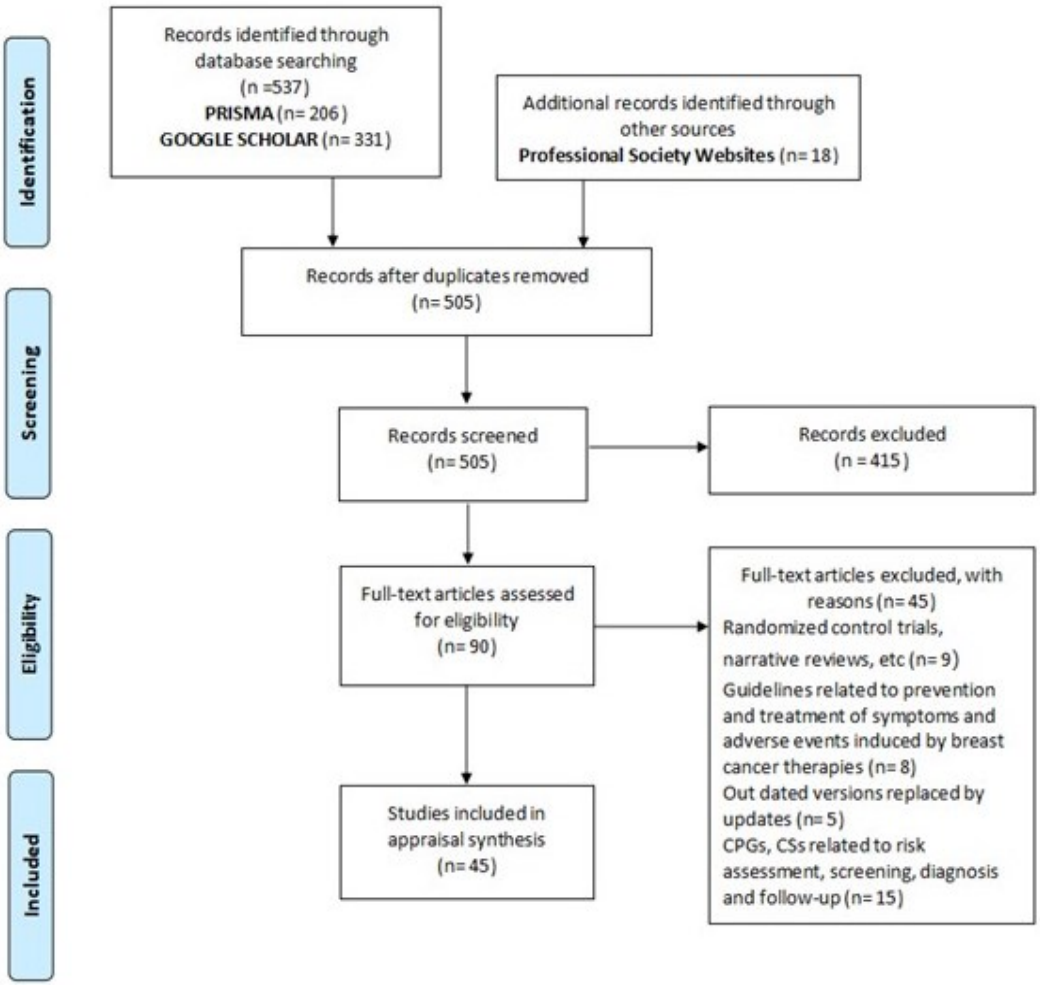

Fig. 1. The study selection process has been detailed in a PRISMA flow diagram.

GUIDELINES APPRAISAL

Overall Quality Assessment: The analysis of the AGREE II overall assessment of CPGs and CSs revealed scores over a wide spectrum (Figure 2). The median overall score across the guidelines was 61%. The highest overall score was obtained by the American Society of Clinical Oncology (ASCO)[13–20] guidelines, with scores ranging from 80-91%, followed by 5th ESO-ESMO ABC5[48] (77%), 4th ESO-ESMO BCY4[50] (76%) and V.4 NCCN[34] (74%). The lowest scores were obtained by French[28] guidelines (16%) and guidelines by NHCPRC[32] (17%). Only 8 out of 45 (18%) of CPGs/CSs were in the 'recommended' zone, 25 (56%) were in the 'recommended with modifications' zone and 12 (27%) were in the 'not recommended' zone.

Domain Assessment: There was a profound disparity in the quality across the domains (Figures 3a-f). Across the guidelines, we observed the highest mean score in Domain 1 (Scope and Purpose) (83.7%), followed by Domain 6 (Editorial Independence) (75.4%) and Domain 4 (Clarity and Presentation) (68.3%). The lowest mean scores were observed in Domain 5 (Applicability) (40.2%) and Domain 2 (Stakeholder Involvement) (49.1%). Figures 3a-f depict the assessments at a domain level.

CPGs vs. Consensus Statements: This study included 37 CPGs and 8 CSs. Overall, CSs had a lower quality in the majority of the domains as compared to CPGs. The median (range) in 'Scope and Purpose' was CPG 88% vs. CSs 85.5%, 'Stakeholder Involvement' CPG 54% vs. CSs 31.5%, 'Rigor of Development' CPG 53% vs. CSs 38% and 'Applicability' CPG 43% vs. CSs 41.5%.

The ASCO13–20 CPGs (80-91%) had the highest quality, whereas 5th ESO-ESMO ABC548 (77%) and 4th ESO-ESMO BCY450 (76%) had the highest quality in the CSs.

DISCUSSION

Main Findings: Our study demonstrated that the median overall quality (61%) of the guidelines was somewhat improved compared to M Maes-Carballo et al.'s[4] previous study (54%). 8 out of 45 guidelines were above 80%, in the 'recommended' zone and were considered of high-quality. It was found that ASCO[13–20], ESO-ESMO[26,48,50] , and NCCN[34] CPGs/CSs had the highest scoring overall assessments, whereas France[27], NHCPRC[32] and ASBrS[46] had the lowest. Our evaluation showed that CPGs had a better overall quality as compared to CSs.

We are aware that several factors are involved during the development of CPGs/CSs, including differing perspectives, conditions, available resources, and time-frames available to the organizations among others. The values and views of guideline developers and how they weigh evidence is reflected in their recommendations. Furthermore, we must therefore also consider that breast cancer management guidelines related to the Covid-19 pandemic were developed during these uncertain conditions with perhaps shorter time-frames involved.

Limitations: We included only full-text English Language articles within a 2-year window from January 2019 onwards. Therefore, we understand that several commendable guidelines by credible organizations would have been excluded. The guidelines included had differing themes. We did not distinctively weigh individual domains' relative importance, although some have a more pivotal role in generating practical, high-quality guidelines than others. The appraisal was based on each item's given information, but the inability to quantify this provided information made it a subjective process.

CONCLUSION

The authors believe that the guidelines related to breast cancer management have a wide room for improvement. There is a growing need for CPGs/CSs that employ uniformly endorsed standards. Guideline development standards are the current state-of-the-art, and guideline developers must direct their efforts towards acknowledging and incorporating them into guidelines. High-quality evidence and a standardized guideline development process are prerequisites for trustworthy, resource-stratified CPGs/CSs utilized in individual patient encounters.

Figure 2. AGREE II Overall Assessment Scores Of CPGs & CSs

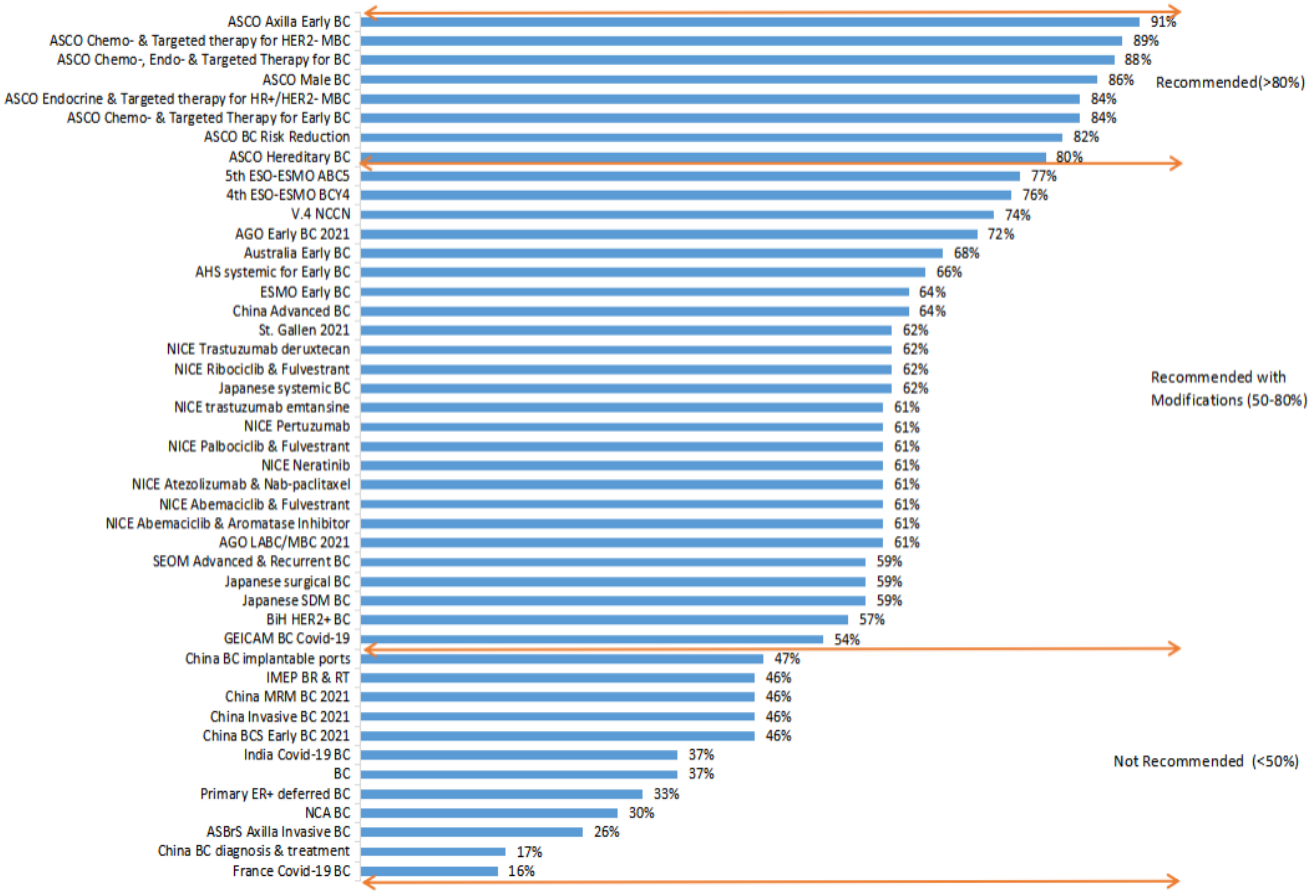

Figure 3a.

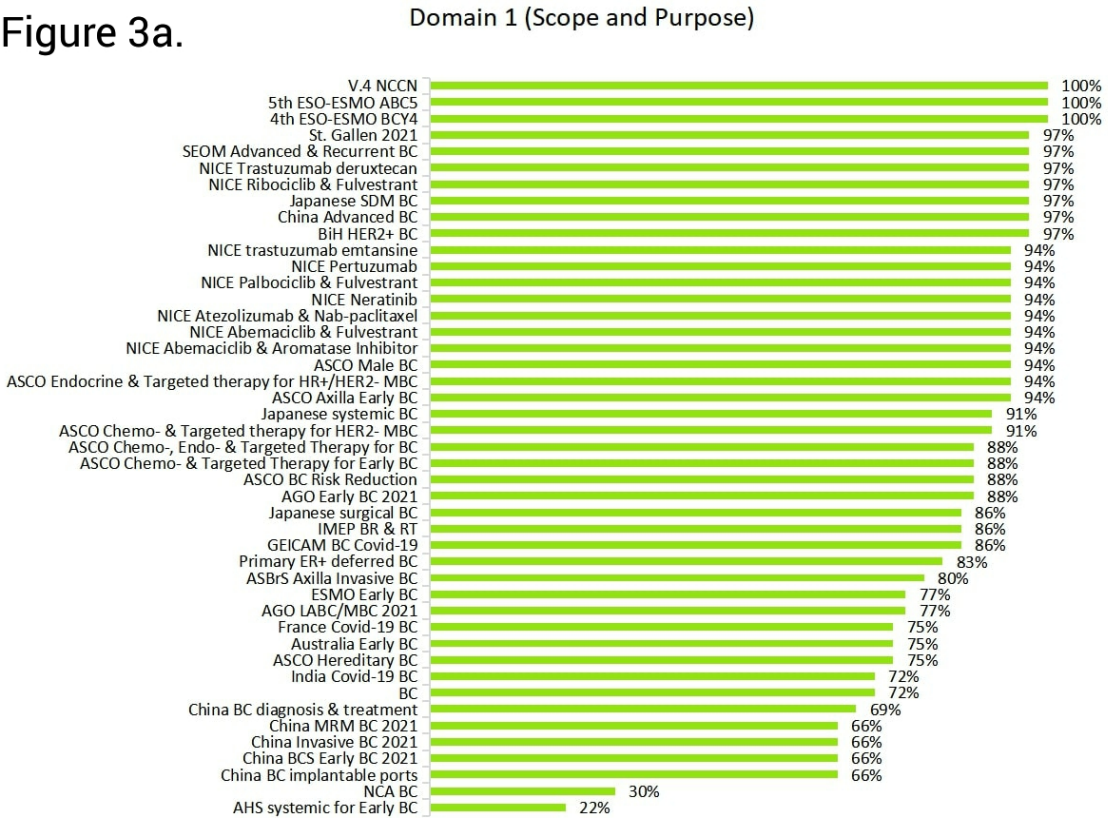

Figure 3b.

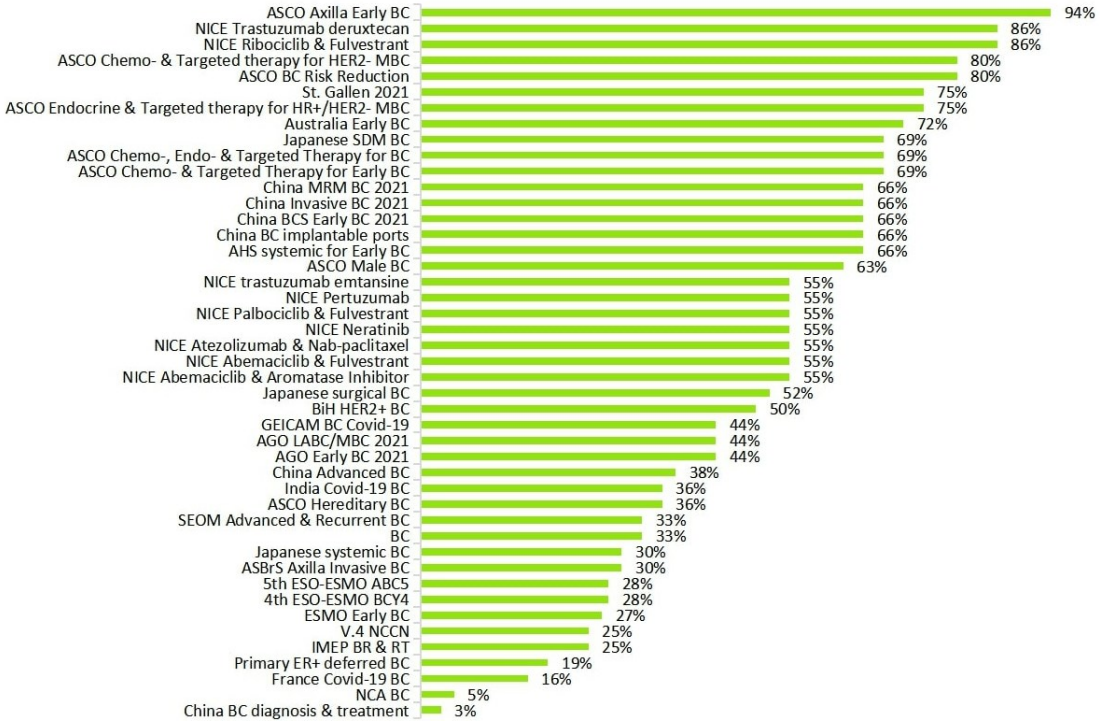

Figure 3c.

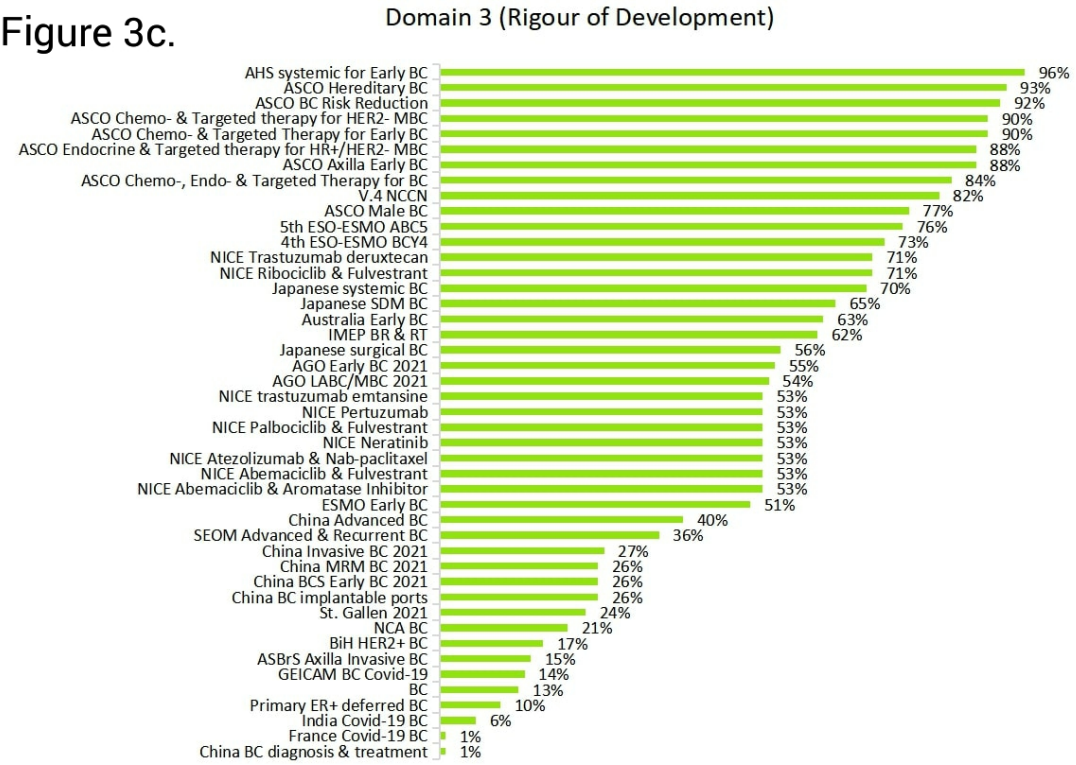

Figure 3d.

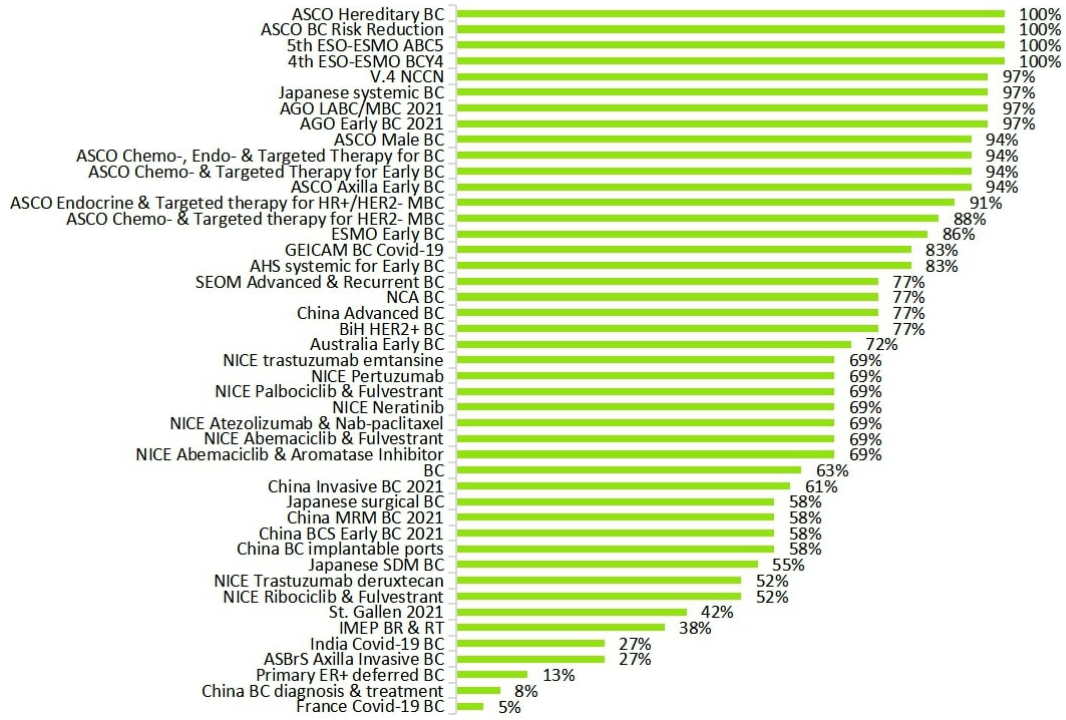

Figure 3e.

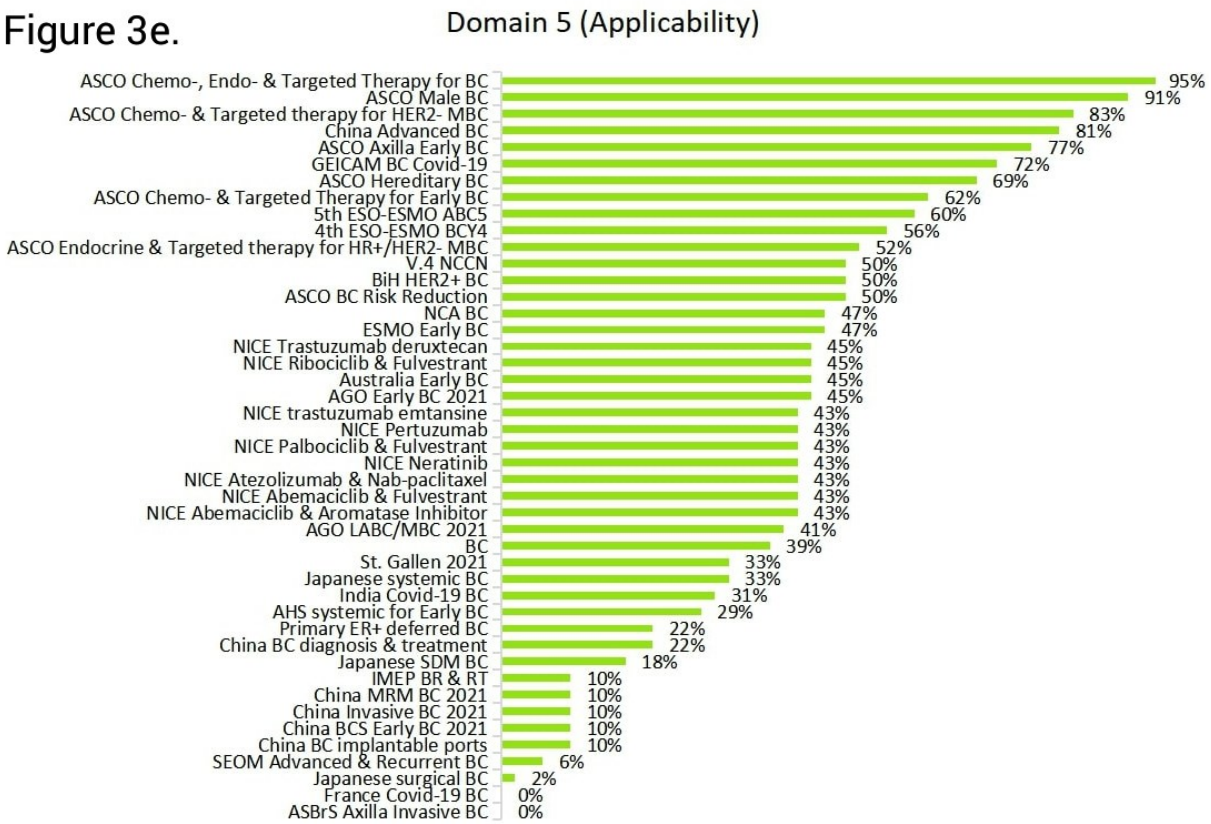

Figure 3f.

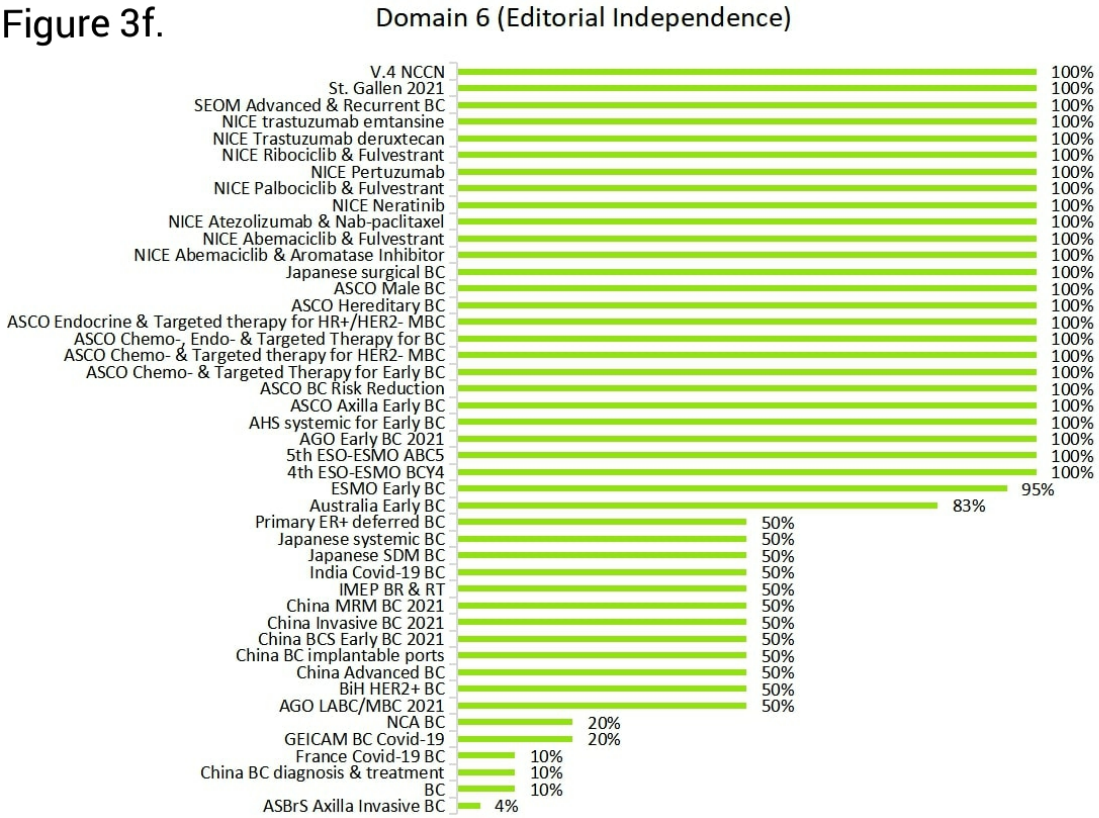

Figure 3 clearly depicts the assessment at domain level.

ARTICLE INFORMATION Accepted for Publication: September 24, 2021
Published Online: September 29, 2021.
https://doi.org/10.48111/2021.03.03

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Financial Support and Sponsorship: Nil.

Conflicts of Interest: There are no conflicts of interest.

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