

Setting the Standard for Cutaneous Melanoma Wide Local Excision: An Overview of the American College of Surgeons Commission on Cancer Standard 5.5

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The purpose of this article is to review the objectives of the American College of Surgeons Commission on Cancer Operative Standards with a specific focus on Standard 5.5, which pertains to curative intent wide local excision of primary cutaneous melanoma lesions. We review the details and rationale of the standard itself, including its requirement to include specific elements and responses in synoptic format in operative reports. (J Am Coll Surg 2023;236:424–428. © 2022 by the American College of Surgeons. Published by Wolters Kluwer Health, Inc. All rights reserved.)

The American College of Surgeons Commission on Cancer (CoC) created the Cancer Surgery Standards Program (CSSP) in 2020 as a quality improvement endeavor to improve cancer care. The *Operative Standards for Cancer Surgery* manuals focus on evidence-based best practices related to the critical elements of oncologic procedures, which, if adhered to, will improve outcomes.^{1–3} So far, the CoC has adopted operative standards from these manuals for breast cancer, melanoma, colon cancer, rectal cancer, and lung cancer among its standards for accreditation. This article discusses CoC Standard 5.5, which applies to curative intent wide local excision (WLE) of primary cutaneous melanoma. Our aim is to summarize the operative standard, including the requirement to include specific elements and responses in synoptic format in operative reports, and review the timeline for its implementation. We will discuss the rationale behind Standard 5.5 and evidence supporting the use of synoptic operative reporting.

COC OPERATIVE STANDARD 5.5

Standard 5.5 pertains to the operative conduct of curative intent WLE for primary cutaneous melanoma. Specifically,

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this standard outlines evidence-based recommendations for radial margin width based on Breslow depth of melanoma and also requires adherence to synoptic formatting for documentation of such procedures. Indications for sentinel lymph node biopsy and its role in melanoma staging and prognostication are not part of Standard 5.5 and are therefore not discussed in this review.

The CoC requires that each accredited cancer program fulfill the following compliance criteria related to Standard 5.5:⁴

1. WLEs for melanoma include the skin and all underlying subcutaneous tissue down to the fascia (for invasive melanoma) or subcutaneous fat (for in situ disease). Clinical margin width is measured from the edge of the primary lesion if present at time of surgery or edge of the biopsy scar. The standard clinical margins are based on the original Breslow depth:
 - a. Clinical margin width for WLE is 1 cm for invasive melanomas less than 1 mm thick.
 - b. Clinical margin width for WLE is 1 to 2 cm for invasive melanomas 1 to 2 mm thick.

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- c. Clinical margin width for WLE is 2 cm for invasive melanomas greater than 2 mm thick.
 - d. Clinical margin width for WLE is at least 5 mm for melanoma in situ.
 - e. In circumstances of deviation from the above standard margins based on Breslow thickness, the surgeon should document reasons, which may include anatomic constraints (eg lesions located on an anatomically constrained area) or when an operation is performed within a clinical trial.
2. Operative reports for WLEs of primary cutaneous melanoma must document the required elements in a synoptic format.

RATIONALE FOR STANDARD 5.5

Standard 5.5 pertains specifically to margin width based on Breslow thickness during curative intent WLE for primary cutaneous melanoma given the impact of margin width on local recurrence. For primary cutaneous melanoma, surgical resection removes the primary tumor and surrounding at-risk lymphatic tissue. Operative management requires balancing appropriate margin size with surgical morbidity. Recommendations guiding this practice are largely derived from prospective, randomized clinical trial data.⁵⁻⁹

In a randomized controlled trial of the WHO Melanoma Group published by Veronesi and colleagues, patients with invasive melanoma less than or equal to 2 mm in Breslow depth were randomized to resection with either 1 cm or 3 cm radial margins.¹⁰ At a mean follow-up of 55 months, the authors found no difference in disease-free survival or overall survival rates. Four patients developed a local recurrence during follow-up, all with melanomas 1.1 mm or greater in depth treated with narrow (1-cm) margins of excision. These data provided assurance that a narrower margin (1 cm) is safe for thin melanomas. The Swedish Melanoma Study Group compared a similar cohort (invasive melanoma, 0.8 to 2 mm Breslow depth) with 2-cm vs 5-cm margins, again demonstrating no disease-free or survival benefit with a wider margin.⁷ Therefore, for invasive melanomas up to 1 mm in Breslow depth, current evidence supports a margin of 1 cm given the extremely low likelihood of local recurrence in this cohort.⁹ For invasive melanomas that are between 1 and 2 mm in Breslow depth, local recurrence rates may be diminished with 2-cm vs 1-cm margins, but retrospective data suggest no survival benefit with a wider (2-cm) margin compared with a 1-cm margin.¹¹ Based on National Comprehensive Cancer Network (NCCN) guidelines, clinical discretion about factors such as anatomic location and type of closure should be taken into consideration when determining margins for 1-mm to 2-mm Breslow depth melanomas.

For melanomas greater than 2 mm in Breslow depth, the recommended margin width is 2 cm, based on data from several prospective randomized clinical trials. The Melanoma Intergroup Trial results showed no statistically significant differences in recurrence or 10-year overall survival in groups treated with 2-cm margins compared with 4-cm margins.¹²⁻¹⁴ However, the cohort with wider margins had a greater need for skin grafting and an increased length of hospital stay. This trial gave justification to limit the maximum margin to 2 cm no matter the depth of the melanoma. In a multicenter randomized trial of 900 patients using 1-cm vs 3-cm margins for greater than 2 mm Breslow depth melanomas, patients in the 1-cm margin group had significantly higher local recurrence rates.¹⁵ Based on these data, a 1-cm margin currently is considered inadequate for melanoma with Breslow depth 2 mm or greater; therefore, the recommended margin is 2 cm for these patients.

Finally, melanoma in situ recommendations of 5-mm margins are derived from expert consensus rather than trial data. The option within Standard 5.5 for surgeon documentation in circumstances of deviation allows for exceptions, because some advocate for a 1-cm margin of excision for melanoma in situ of particular subtypes.¹⁶

For all invasive melanomas, the required depth of excision is full-thickness skin and subcutaneous tissue to fascia. This requirement is supported by preclinical and clinical anatomic data as well as data from the margin trials referenced previously. The ongoing international, multicenter MelmarT Melanoma Margins Trial (NCT02385214), which randomizes clinical stage II primary cutaneous melanoma patients to 1-cm vs 2-cm margins, may change recommendations for future radial margins. This trial requires WLE be performed without undermining the biopsy and full thickness of all skin and subcutaneous tissue to fascia.

RECOMMENDATIONS FOR OPERATIVE TECHNIQUE AND EXCEPTIONS TO THE STANDARD

Specific recommendations on the technical conduct of melanoma surgery are detailed in *Operative Standards for Cancer Surgery* Volume 2.² The critical elements of WLE for melanoma include adequate depth of excision down to fascia and margin width as outlined above. Generally, it is recommended that excision margins should be measured from the edges of residual tumor or the biopsy scar in all directions. The excised specimen must be oriented so that pathology can make an accurate assessment of margins (ie superior, lateral). For extremity melanomas, the orientation of the incision should be longitudinal, and truncal tumors are

oriented with Langer's lines. If closing a wound primarily, a circular incision can be used to ensure appropriate margins are obtained circumferentially. The circle can then be made elliptical to allow for cosmetic closure (Figure 1).

These recommendations also apply to melanomas affecting the skin of the digits. However, it should be noted that subungual melanomas often require amputation of the distal phalanx given that an appropriate WLE and soft tissue loss would leave the digit nonfunctional. There are circumstances when a WLE with the standard margins may not be possible due to anatomic or functional constraints such as for melanomas of the face or distal to flexion creases. The CoC elements of Standard 5.5 allow variance in margin width for these reasons by selection of the choice "other: ___cm due to cosmetic/anatomic concerns."

SYNOPTIC OPERATIVE REPORTING

There are 2 parts to compliance with CoC Standards 5.3 to 5.6. In addition to performing the required elements of the standard for curative intent surgery, the critical elements of the cancer operation must be documented in synoptic format to be deemed compliant.¹⁷ Standards 5.3 through 5.6 represent the first time that documentation of critical aspects of an oncologic operation are required to be in the operative note. Operative reports are the critical piece of documentation associated with surgical procedures and are important for both patient safety and quality of care. Traditional narrative operative reports often have been found to be inaccurate and lacking in critical components. Synoptic operative reports, or standardized reports using predetermined and procedure-specific templates, have been shown to be more complete and timely when compared with narrative reports, reducing omission of the most critical data elements by as much as one third.^{18,19} In a comparison of narrative to synoptic colon cancer operative reports, Maniar and colleagues found synoptic reports

had significantly higher scores on quality indicators and a faster data extraction time.²⁰

A key aspect of Standard 5.5 is the requirement to document critical components of melanoma WLEs in synoptic format. There are 4 elements that require a response in the synoptic format, which must be included in the operative report. These elements are shown in Figure 2. The CSSP is currently developing comprehensive synoptic reporting templates for cancer surgery that are designed to be a stand-alone replacement for a traditional narrative or hybrid-type operative note.²¹ These synoptic operative reports include the elements currently required by the CoC for compliance with Standards 5.3 to 5.6 in addition to all data required to completely document a cancer operation.

TIMELINE

Compliance with CoC Standard 5.5 and other operative standards will be assessed at site visits by the American College of Surgeons, which occur every 3 years. Before site visits, it is highly recommended that sites perform internal audits to assess and improve compliance with these standards, particularly during the integration period. Standards 5.3 to 5.6, which apply to the performance of critical elements for specific cancer operations and documentation in operative reports, are being implemented in a phased approach that began in 2020. An overview of the timeline for implementation of Standards 5.3 to 5.6 is shown in Figure 3.

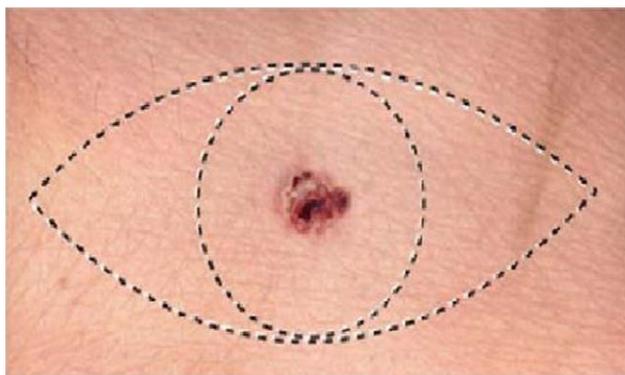


Figure 1. Incision marking for a wide local excision from *Operative Standards for Cancer Surgery, Vol. 2*,¹⁰ reprinted with permission from Wolters Kluwer.

Element	Response Options
Operation performed with curative intent	Yes; No.
Original Breslow thickness of the lesion	Melanoma in situ (MIS); _._ mm (to the tenth of a millimeter).
Clinical margin width (measured from the edge of the lesion or the prior excision scar)	0.5 cm; 1 cm; 2 cm; Other: ___ cm due to cosmetic/anatomic concerns; Other (with explanation).
Depth of excision	Full-thickness skin/ subcutaneous tissue down to fascia (melanoma); Only skin and superficial subcutaneous fat (melanoma in situ); Other (with explanation).

Figure 2. Required synoptic elements for CoC Standard 5.5 from *Optimal Resources for Cancer Care 2020*, updated February 2021.⁴ Reproduced with permission from the American College of Surgeons Commission on Cancer.

