Society for Immunotherapy of Cancer (SITC) published consensus recommendations in December 2016 on the role of immunotherapy in the treatment of hematological malignancies.[22] Since 2016, however, rapid advances in the field have brought about a wider array of immunotherapy-based treatment options for each of the individual disease states discussed in the original guidelines: acute leukemia, lymphoma, and multiple myeloma. Thus, the SITC Cancer Immunotherapy Guidelines—Hematologic Malignancies Subcommittee determined that stand-alone guidelines are needed. To form up-to-date recommendations on the use of immunotherapy for the treatment of patients with acute leukemia, SITC convened a panel of experts to develop a new clinical practice guideline. This publication represents an update to the previously published consensus statement based on a more recent assessment of the peer-reviewed literature and the clinical experience of expert panel participants. These recommendations are not intended to supplant sound clinical judgment but rather to provide clinicians with the most current thinking on how experts integrate immunotherapy into the treatment of patients with acute leukemia.

METHODS

SITC Acute Leukemia Immunotherapy Guideline Expert Panel

The SITC Acute Leukemia Guideline Expert Panel consisted of 17 participants, including medical oncologists, hematologists, a hematopathologist, a leukemia research nurse, and a patient advocate. Every clinical Expert Panel member reported previous experience/knowledge regarding the use of immunotherapy for the treatment of patients with leukemia. The panel members met in person and communicated regularly via email and teleconference. In addition, they completed a survey (see online supplementary file 1) addressing clinical topics concerning the use of cancer immunotherapy for the treatment of patients with acute leukemia, which helped form the basis for these recommendations.

Consensus statement policy

The Institute of Medicine's (IOM) Standards for Developing Trustworthy Clinical Practice Guidelines were used as a model to develop the consensus recommendations in this manuscript. IOM standards dictate that guideline development be led by a multidisciplinary team using a transparent process where both funding sources and conflicts of interest are readily reported. Recommendations are based on literature evidence, where possible, and clinical experience, where appropriate.[23] For transparency, a draft of this consensus statement was made publicly available for comment after journal submission. All comments were considered for inclusion into the final manuscript. This consensus statement is intended to provide guidance and is not a substitute for the professional judgment of individual treating physicians.

Evidence and consensus ratings

Recommendations were derived from evidence within the published literature along with responses to a clinical questionnaire that addressed current practices in the use or recommendation for use of immunotherapy agents (online supplementary file 1). SITC Cancer Immunotherapy Guidelines provide recommendations based on peer-reviewed literature and consensus within the expert panel. Consensus was defined as ≥75% agreement among expert panel members.

Conflicts of interest policy

As per SITC policy, expert panel members managed potential competing interests through disclosure of all financial relationships that might result in actual, potential, or perceived conflicts of interest. No commercial funding was provided to support the expert panel, literature review, or the preparation of this manuscript.

Literature review process

The MEDLINE database was used to search the scientific literature for current therapies related to acute leukemia and immunotherapy, including clinical trials, meta-analyses, practice guidelines, and research in humans.

The search terms included among others "acute lymphoblastic leukemia," "acute myeloid leukemia," "blinatumomab," "inotuzumab ozogamicin," "tisagenlecleucel," "CAR T AND leukemia," "gemtuzumab ozogamicin," "immunotherapy AND leukemia," and "immunotherapy toxicity." Manuscripts retrieved by the search were screened to include only papers with clinically accurate and relevant information and to remove duplicate articles from independent searches. The reference library was supplemented with additional articles identified by the panel as appropriate and necessary for a comprehensive literature review, resulting in a final bibliography of 141 manuscripts.

DIAGNOSTICS PRIOR TO IMMUNOTHERAPY FOR NEWLY DIAGNOSED PATIENTS WITH ACUTE LEUKEMIA

A number of clinical guidelines have been developed for the workup and diagnosis of acute leukemia. Initial workup provides disease classification, risk stratification, and a better understanding of both disease biology and potential treatment options.[1 5 6 24–26] Selection of appropriate diagnostics to initiate immunotherapies is under investigation. Only in a select few situations has consensus been achieved on how to determine whether a patient is a strong candidate for immunotherapy. Further, if a patient is eligible for two different immunotherapies, it is challenging to identify the treatment option that will provide maximal benefit. Potential diagnostic evaluations for patients with acute leukemia being considered for immunotherapy are discussed below.

A number of diagnostics are available for the initial workup of a patient suspected to have acute leukemia. Workup typically includes history and physical