



Complete Summary

GUIDELINE TITLE

American Society of Clinical Oncology Technology Assessment: chemotherapy sensitivity and resistance assays.

BIBLIOGRAPHIC SOURCE(S)

Schrag D, Garewal HS, Burstein HJ, Samson DJ, Von Hoff DD, Somerfield MR. American Society of Clinical Oncology Technology Assessment: chemotherapy sensitivity and resistance assays. J Clin Oncol 2004 Sep 1;22(17):3631-8. [17 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Cancer

GUIDELINE CATEGORY

Technology Assessment

CLINICAL SPECIALTY

Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To summarize the evidence on the use of chemotherapy sensitivity and resistance assays (CSRAs) and offer recommendations for clinical practice regarding the utility of this technology

TARGET POPULATION

Patients with cancer who require chemotherapy

INTERVENTIONS AND PRACTICES CONSIDERED

Use of chemotherapy sensitivity and resistance assays in the selection of chemotherapeutic agents in order to inform individual patient treatment regimens

Note: Guideline developers considered but did not recommend any of the following chemotherapy sensitivity and resistance assays:

- Subrenal capsule assay (SRCA)
- Human tumor cloning assay (HTCA)
- Capillary cloning system (CCS)
- Differential staining cytotoxicity (DiSC)
- Methyl thiazolyl-diphenyl-tetrazolium bromide (MTT)
- Adenosine triphosphate bioluminescence (ATP)
- Extreme drug resistance assay (EDR)

MAJOR OUTCOMES CONSIDERED

- Clinical utility of chemotherapy sensitivity and resistance assays (ASCOs)
- Survival
- Tumor response

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Health Services Committee of the American Society of Clinical Oncology (ASCO) negotiated a collaborative relationship with the Blue Cross and Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) through which ASCO was granted access to the systematic review conducted by BCBSA on the topic of chemotherapy sensitivity and resistance assays (CSRAs) under contract to the Health Care Financing Administration. The ASCO Working Group used the BCBSA

systematic review analysis as a template, but reviewed the method used to identify additional relevant sources of information and to review independently the articles selected for inclusion in the BCBSA systematic review. The BCBSA method included a search of the MEDLINE database using the Medical Subject Heading (MeSH) term, "drug screening assays, antitumor." Text words were also included in the search strategy, including the following truncated forms, all linked with the MeSH term, "neoplasms": chemosens *, chemo-sens*, chemoresist*, chemo-resist*, drug sens*, drug-sens*, drug resist* and drug-resist*. The search was limited to English-language references and studies using human subjects. The dates covered by this systematic review included references entered between January 1966 and August 2002. This search was supplemented with articles identified by the ASCO Working Group, which used the same search strategy and covered references appearing through January 2004. Reference lists of key articles were also searched for additional citations.

In order to be reviewed, articles had to meet all of the following criteria: the study was of prospective design; the article compared outcomes for patients treated by both assay-guided therapy and empiric therapy; the patients receiving empiric treatment were contemporaneous to patients receiving assay-guided treatment (historical controls were excluded); the study had to include a total of 20 or more patients per group.

One Working Group member and an ASCO staff member reviewed the abstracts identified by the comprehensive literature search. Seventeen abstracts met inclusion criteria. The full text of each article was reviewed by the steering committee of the Working Group and 11 articles were selected including two reports not previously identified in the BCBSA review.

In order to identify additional articles, the Working Group contacted firms that market these products commercially and requested relevant literature. An additional 20 abstracts or articles were provided and reviewed by two members of the Working Group. One of these studies met inclusion criteria.

NUMBER OF SOURCE DOCUMENTS

12 articles (eight identified by the original Blue Cross Blue Shield Association [BCBSA], one provided by industry, and three identified by the American Society of Clinical Oncology [ASCO] updated literature review)

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Working Group developed a structured data abstraction tool to facilitate review of selected manuscripts. Three Working Group members independently extracted data from each manuscript to create summary evidence tables.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Summary evidence tables were circulated to the Working Group for use in developing recommendation and consensus on the final manuscript.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The use of chemotherapy sensitivity and resistance assays to select chemotherapeutic agents for individual patients is not recommended outside of the clinical trial setting. Oncologists should make chemotherapy treatment recommendations on the basis of published reports of clinical trials and a patient's health status and treatment preferences. Selection of chemotherapeutic agents on the basis of results of chemotherapy sensitivity and resistance assays (CSRAs) is not warranted based on the current body of evidence. Because the in vitro analytic strategy has potential importance, participation in clinical trials evaluating these technologies remains a priority.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is not specifically stated. The recommendations are based on a critical review of the current scientific and clinical information.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The information provided from published reports of clinical trials will assist oncologists in making decisions regarding the use of chemotherapy sensitivity and resistance assays as a tool in recommending chemotherapy treatment regimens.

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Aug 2 (published online ahead of print)

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology (ASCO)

GUIDELINE COMMITTEE

American Society of Clinical Oncology Working Group on Chemotherapy Sensitivity and Resistance Assays

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Deborah Schrag; Harinder S. Garewal; Harold J. Burstein; David J. Samson; Daniel D. Von Hoff; Mark R. Somerfield

Working Group Members: Deborah Schrag, MD (Co-chair), Memorial Sloan-Kettering Cancer Center; Daniel D. Von Hoff, MD (Co-chair), Arizona Cancer Center; Jaffer Ajani, MD, UT M.D. Anderson Cancer Center; Al B. Benson III, MD, Northwestern University Feinberg School of Medicine; Harold J. Burstein, MD, PhD, Dana-Farber Cancer Institute; Rowan T. Chlebowski, MD, PhD, Harbor UCLA Medical Center; Harinder S. Garewal, MD, PhD, Arizona Cancer Center; Anne Hamburger, PhD, Cancer Center-University of Maryland; Axel Hanauske, MD, PhD, Sections Medical Oncology, Germany; Lawrence B. Holt Jr, MD, FACP, Coastal Cancer Center; Samir N. Khleif, MD, NCI Naval Hospital Bethesda; Gary H. Lyman, MD, University of Rochester Medical Center; Cheryl Perkins, Susan G. Komen Foundation; John Sandbach, MD, Texas Oncology Cancer Center; James A. Talcott, MD, Massachusetts General Hospital; Peter H. Wiernik, MD, OLM Cancer Center; David J. Samson (Ex-Officio), Blue Cross Blue Shield Association

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All Working Group members complied with the American Society of Clinical Oncology (ASCO) policy on conflict of interest, which required disclosure of any interest (financial or otherwise) that might be construed as constituting an actual, potential, or apparent conflict. Members completed ASCO's disclosure form and

were asked at the face-to-face meeting to report ties to companies developing products that might be affected by promulgation of the technology assessment report. Information was requested regarding employment, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees. One member of the original Working Group chose to resign based on self-identified perceived conflict. No other limiting conflicts were identified among the Working Group members.

The following contributors have indicated a financial interest. No conflict exists for drugs or devices used in a study if they are not being evaluated as part of the investigation. Acted as a consultant within the last 2 years: Axel Hanauske, Eli Lilly & Co, Hoffman-La Roche, iOnGen; Rowan T. Chlebowski, AstraZeneca, Novartis, Aventis, Eli Lilly & Co. Performed contract work within the last 2 years: Axel Hanauske, Eli Lilly & Co, Hoffman-La Roche. Served as an officer or member of the Board of a company: Anne Hamburger, Biocell, Analytical Biosystems Corp. Received more than \$2,000 a year from a company for either of the last 2 years: Axel Hanauske, Eli Lilly & Co; Jaffer Ajani, Novartis, Aventis, Sanofi, Taiho; Rowan T. Chlebowski, AstraZeneca, Novartis, Aventis, Eli Lilly & Co.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Society of Clinical Oncology \(ASCO\) Web site](#).

Print copies: Available from American Society of Clinical Oncology (ASCO), Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Samson DJ, Seidenfeld J, Ziegler K, Aronson N. Chemotherapy sensitivity and resistance assays: a systematic review. *J Clin Oncol*. 2004 Sep 1; 22(17):1-13.

Electronic copies available from the [American Society of Clinical Oncology \(ASCO\) Web site](#).

Print copies: Available from ASCO, Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

Guidelines are available for Personal Digital Assistant (PDA) download from the [ASCO Web site](#).

PATIENT RESOURCES

The following is available:

- ASCO patient guide: technology assessment: chemotherapy sensitivity and resistance assays. 2004 Jul. Available from the [Cancer.Net Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on September 24, 2004. The information was verified by the guideline developer on September 24, 2004.

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