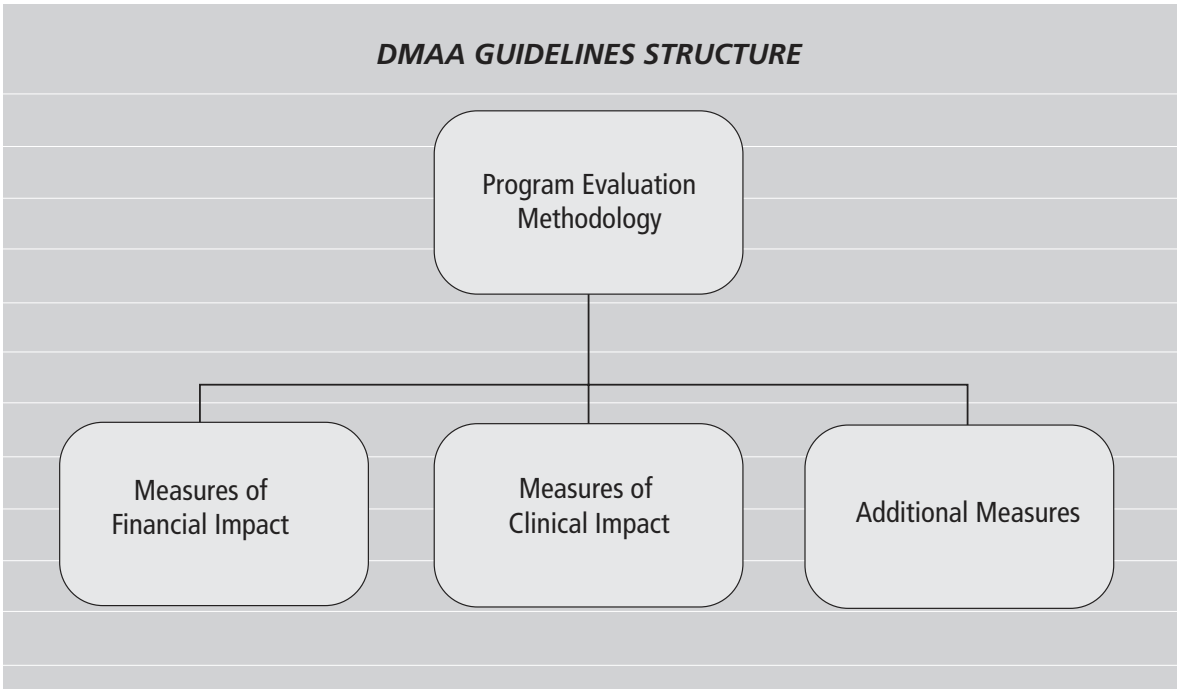
Evaluation Guidelines Summary

The Outcomes Steering Committee agreed to several assumptions and operating principles to be used throughout the guidelines development process:

- The guidelines developed in Phase I apply to traditional disease management programs that use a total population approach to patient identification and use an intention-to-treat evaluation methodology.
- Although the guidelines may be applicable to other conditions, they were designed to apply to evaluation of programs targeting diabetes, asthma, chronic obstructive pulmonary disease (COPD), coronary artery disease (CAD), and heart failure.
- The guidelines developed needed to strike a balance between *suitability* (rigorous methods, strong equivalence, controlling all bias and confounders, establishing causality) and *acceptability* (transparency, convenience, ease of implementation and understanding).
- The guidelines should promote transparency of evaluation methodologies used and the potential impact of choices on the interpretation of the results.

The guidelines include four sections: the foundation of an evaluation methodology; measures of financial impact; measures of clinical impact; and measures that represent areas beyond both financial and clinical. The Outcomes Guidelines are listed in Table 2 and are followed by a detailed narrative for each.



Evaluation Guidelines Summary (continued)

TABLE 2: TOPLINE GUIDELINES

EVALUATION METHODS
Evaluation design: DMAA recommends the use of a pre-post study design that incorporates an equivalent concurrent comparison group. DMAA recognizes, however, that a comparison group that is both equivalent and concurrent may not always be available in applied settings. Accordingly, DMAA recommends that evaluations using a pre-post study design make explicit efforts to control potential biases and error introduced by the design, and that the potential impact of the design on the interpretation of the findings be made clear.
Identification of study and comparison groups: DMAA recommends that the methods for program identification, qualification for evaluation, and Trend incorporate the principle of equivalence between baseline and intervention groups. Both Annual Qualification and Prospective Identification methodologies are considered to be acceptable methods for identifying groups for the purpose of program evaluation. The attributes and definitions of both annual qualification and prospective identification are included in the detailed description that follows.
Measurement period: DMAA recommends one year for baseline and subsequent years.
Criteria for inclusion in measurement: DMAA recommends that the member population be enrolled with the commercial buyer for six or more member months and with Medicaid TANF for one member month or more.
Look-back period: DMAA recommends 12 months of measurement period, as well as at least 12 months of the preceding period for the purpose of program evaluation.
Defining a member month: DMAA recommends that a member month be defined as members enrolled on the 15th of the month for commercial and Medicare populations, when possible.
Claims run-out period: DMAA recommends three months with completion or six months with no completion, contingent upon consistent payment patterns.

Table 2: Topline Guidelines (continued)

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FINANCIAL MEASURES
Financial metric: DMAA recommends using health care cost outcomes as the metric for assessing the financial impact of the program. Health care cost outcomes would be measured using medical and pharmacy claims (where available) to calculate changes in total dollars, and also expressed as per-member-per-month charges.
Which costs to use: DMAA recommends using paid and/or allowed costs.
Trend: DMAA recommends the use of a non-chronic population to calculate Trend. For this purpose, the non-chronic population is defined as those members not identified as having any of the following "common chronic" conditions: diabetes, CAD, heart failure, asthma, and COPD. In addition, when warranted and mutually agreed upon by the parties, members with certain other conditions may be excluded from the non-chronic population if these conditions also are being managed by another disease management program outside of the five common chronic conditions listed previously.
Risk adjustment: DMAA recommends that parties must agree on a mutually acceptable risk adjustment method, ideally a commercially available tool.
Dealing with small sample sizes: DMAA advises that as population size drops below a certain level, calculated disease management financial outcomes begin to lose credibility and reliability. (This level exists on a continuum, is empirically determined, and can be estimated using common actuarial practices or statistical power methods.) The further the population falls below this level, the more that random variation will influence results and interfere with the credibility and reliability of the calculated outcome. As mutually agreed upon, parties may prefer to avoid this concern by choosing not to calculate financial outcomes for such small populations, or may elect to mitigate this concern by using a credibility factor approach to blend their smaller population result with some larger (typically, comparable "book of business") population to increase the credibility of this result.

Table 2: Topline Guidelines (continued)

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CLINICAL MEASURES

Clinical Measures: DMAA has incorporated, as a starting point, the series of ICD-9 codes established in the latest version of the DMAA "Dictionary of Disease Management Terminology." The complete coding list is given in Appendix 1, at the end of this report.

In 2007, DMAA will develop standardized identification criteria for defining both the numerator and the denominator for an agreed-upon list of disease-specific clinical measures for the purpose of program evaluation.

Exclusions: DMAA recommends that there should be three types of exclusions from the evaluation for financial and utilization measures:

- Patients with conditions such as:
  - ESRD
  - HIV/AIDS
  - Transplants
  - Non-skin cancers with evidence in claims of active treatment
  - Hemophilia
- Claims for diagnoses such as: (but not the person with these claims)
  - Trauma with hospitalization
  - Skin cancers
- Stop-loss at member level; such as removing claims above $100,000 annually, indexed to grow at future years concurrent with an appropriate Trend.

ADDITIONAL MEASURES

Consider use of one of the short-form (SF) health surveys (e.g., SF-8, SF-12, SF-36) to measure general mental and physical health status.

Consider assessing participant satisfaction using the DMAA Standardized Participant Satisfaction Survey.

Consider inclusion of standardized measures in the behavioral category of lifestyle behaviors.

Consider inclusion of standardized measures in the behavioral category of medication adherence.