



White Paper 23-20

Standards of evidence for health and wellness recommendations

Authors:

Becca Krock, PhD (bkrock@23andme.com)

Chelsea Robertson, PhD

Olivia Valenti, RN, BSN, MS

Jeffrey Pollard, MD

Adrienne Stone, PhD

Shirley Wu, PhD

Created: June 2019

Introduction

Direct-to-consumer (DTC) genetic testing has created the opportunity for millions of individuals to access new information about health risks. This consumer interest has the potential to shift public and individual consciousness around health towards prevention, through broad education about population-level recommendations, but also through increasing personalization of health risk information. Accordingly, a priority for 23andMe is ensuring that customers understand the best next steps to take after receiving their genetic results. In providing personalized health and wellness recommendations to 23andMe customers, we aim to promote appropriate clinical follow-up on important genetic results, as well as to increase awareness of health actions and services that may be appropriate for individuals based on standard non-genetic factors, such as obtaining age-specific health screenings or adopting healthy lifestyle habits.

This document outlines 23andMe's standards and process for developing health and wellness recommendations.

Clinical and scientific criteria for health and wellness recommendations

A "recommendation" is an imperative statement directed at an individual.¹ Examples of recommendations include: "Get at least 150 minutes of physical activity per week", "Consider talking to a doctor about the hepatitis B vaccine", and "Share this result with a healthcare professional." Health and wellness recommendations concern actions or health services with value for lowering or managing the risk of disease, symptoms, or complications, or for maintaining good health. These can include actions or health services that must be mediated by a healthcare professional, such as screenings and vaccinations, as well as those that individuals can perform independently, such as healthy lifestyle choices. Recommendations may be targeted to individuals based on genetic and/or non-genetic factors, such as age and sex, as supported by the clinical guidelines² and scientific evidence outlined below.

To be eligible to be presented to customers as a recommendation, an action or health service must either be supported by clinical guidelines, or meet all of the following criteria:

- there are two or more high-quality, peer-reviewed scientific studies supporting the value of the action or service,
- there is no strong contradictory evidence, and
- the action or service presents low risk to the individual.

Content regarding actions or services that do not meet the above requirements may still be provided to customers as long as those actions or services present low risk to the individual, are presented clearly as preliminary or exploratory in nature with appropriate qualifications, and are supported by a moderate level of scientific evidence from peer-reviewed publications, for example a single high-quality study, multiple moderate-quality studies, or large observational or correlational studies lacking causal evidence.

Evaluation of clinical guidelines

Each health and wellness recommendation included in 23andMe's reports and features is developed taking into account relevant clinical guidelines from public health organizations, healthcare professional organizations, and/or patient advocacy organizations. For example, the United States Preventive Services Task Force (USPSTF) regularly publishes clinical guidelines that describe which individuals should receive certain health screenings, immunizations, and other preventive health services.

When there are multiple clinical guidelines pertaining to a single health action or service, they may differ on topics such as the age to initiate health screenings, the appropriate frequency of health screenings, or which populations should receive a given service. A lack of consensus may reflect differing opinions among healthcare professional organizations on the appropriate way to balance benefits and potential

¹ Factual statements describing recommendations made by others are not defined as recommendations for the purpose of this document. For example, "Certain vaccinations are sometimes recommended for people with these genetic variants" would not be considered a recommendation.

² Clinical guidelines are evidence-based statements published by governmental public health agencies, healthcare professional organizations, and patient advocacy groups that are generally used by the clinical community to determine appropriate health actions for individuals based on factors such as age, sex, and/or genetic testing results.

harms of a given action or service, or may indicate that evidence around an action or service is rapidly evolving or unsettled.

After evaluating the level of consensus among identified clinical guidelines, we may determine that it is appropriate to provide customers with a summary of the range of available guidelines and a description of the decision-making process an individual might engage in with their healthcare provider to determine whether the action or service is appropriate for them. Alternatively, we may choose to emphasize certain guideline(s) based on considerations such as the risks and benefits to the individual of taking action, while providing appropriate indication that guidelines from different organizations may vary.

Communicating recommendations to customers

Our scientific and medical teams aim to present recommendations in language that is appropriate for lay audiences but also reflects important complexities and limitations. Considerations around the wording of health and wellness recommendations take into account factors such as:

- whether the action or service should be mediated by a healthcare professional,
- the level of consensus among guidelines and any differences between guidelines,
- the strength of evidence supporting a particular action or service (e.g., for USPSTF guidelines, "A", "B", and "C" ratings),
- potential risks and benefits to the individual of taking action or not taking action,
- potential contraindications, and
- risk factors that may modify the recommendation for certain individuals.

Recommendation language includes a statement that individuals should speak with a healthcare professional when clinician judgment is required or beneficial, such as in the following situations:

- there are multiple conflicting guidelines,
- the individual may or may not qualify for a given service, or
- there is uncertainty around the risks and benefits of taking the action or undergoing the service.

Review process

Health and wellness recommendations within the 23andMe service undergo extensive internal review by our scientific and medical teams to ascertain that they accurately reflect current scientific evidence and appropriate clinical guidelines. These recommendations are regularly reviewed, checked for accuracy based on current literature, and updated when warranted by new evidence or updated guidelines.

Acknowledgements

We thank Stacey Detweiler and Ruth Tennen for their insightful feedback on this white paper.