NATIONAL ACADEMIES Sciences Engineering Medicine

Examining Clinical Guidelines for the Adoption of Genomic Testing: A Workshop

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Post-Workshop Survey

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Session II Highlights: Why Guidelines Matter for Genomic Testing

- Clinical Practice Guideline: document that focuses on a disease or condition, based on the *best available evidence*, to help clinicians and patients. (Temple-Smolkin)
- Guidelines are developed in a challenging landscape of changing technology and addressing equity and access issues. (Temple-Smolkin)
- When developing guidelines, must consider: **P**atient/population/problem; **I**ntervention; **C**omparison; and **O**utcome (PICO) (Temple-Smolkin)
- Value to patients in systematic reviews comes from public comments and expert panel input. (Temple-Smolkin)
- Clinical practice guidelines, consensus statements, and position papers are based on different processes but are all tools in a clinician's toolbox. (Temple-Smolkin)
- The field wants guidelines to develop faster; the future for some guidelines might be using living guidelines. (Temple-Smolkin)

Post-Workshop Survey

Session II Highlights, continued: Why Guidelines Matter for Genomic Testing

- Lives depend on high quality, objective, equitable, comprehensive guidelines. (Kapoor)
- Payers look at the same evidence and can come to different conclusions about which guideline to follow in coverage decisions. (Zetzsche)
- Patients and communities need to be included in the development process to ensure decisions are made *with* communities, not *for* them. (Arjunan)
- Non-genomics providers face barriers to ordering tests which can include a lack of confidence or knowledge, limited guidelines in primary care resources, and payor requirements. (Phillips)
- Can guidelines be written for genetic testing in general instead of by disease? (Leonard)
- Collaboration relies on communications across societies. (Arjunan)
- How can we move beyond society ownership and towards a more collaborative environment? (Wicklund)
- Collaboration makes a better product and organizations need to make the commitment to collaboration. (Temple-Smolkin)

Session III Highlights: Guidelines for Genomic Testing Today

- Incorporate equity considerations early and at every stage of development. (Lin)
- Develop actionable recommendations to mitigate health inequities which requires ensuring a wider perspective and representation; asking the “right” questions; and addressing upstream drivers of health and implementation of testing. (Lin)
- Seek solutions to address lack of resources, evidence, volunteers, patient engagement, equity, differences in recommendations, and dissemination surrounding guideline development. (Caudle)
- Streamline guideline development and their implementation into the clinic. (Meric-Bernstam)
- Consider implementation during guideline development as key for clinical utility once put into practice. (Rehm)
- Identify stable funding for guideline development and building the infrastructure is needed, particularly in living guidelines and reviews. (Lin)

Session IV Highlights: How Genomic Testing Guidelines Impact Payer Decisions

- Look for guideline deserts, areas in which guidelines have not been developed. (Hooker)
- Develop standards for the language used in guidelines. (Hooker)
- Follow the **T**ransparency, **R**edundancy, **U**tility, **E**fficiency (TRUE) framework for developing guidelines for payers. (Haywood)
- Use emerging technologies like AI, cloud based data storage, and a single EHR platform for more personalized care. (Agarwal)
- Shift to a care model away from a payment model. (Agarwal)

Session V Highlights: Clinical Care Implementation of Guidelines for Genomic Testing

- Implementation must be considered across the genomics care pathway along with how to balance general and case-specific care. (Chambers)
- Learning mindsets and systems can improve implementation. (Chambers)
- Educating the community, through innovative ways, can improve overall implementation. (Jonassaint)
- Inclusive clinical trials will lead to inclusive clinical guidelines which will ultimately improve genomic testing for underrepresented populations. (Jonassaint)
- Incorporate genomic testing within the clinical workflow to increase testing. (Pereira)
- Implementation of genomic testing requires institutional support and multidisciplinary teams involving clinicians, labs, informatics, and IT resources. (Pereira)
- Parents and patients should be incorporated in defining clinical utility. (Suwannarat)

Session VI Highlights: Guideline Development in a Rapidly Evolving Field - A Look Ahead

- Need to move faster from gene discovery to therapies. (Manickam)
- Improve diagnostic yield and treatable diagnosis. (Manickam)
- Increase the diversity of the genomic data available since genomics and AI are only as good as the information available. (Kondo)
- Systematic review evidence can include both published literature and grey literature. (Kondo)
- Living reviews are resource heavy but provide efficiency and to continuously address equity and implementation. (Kondo)
- The Living Guideline Model can help guidelines keep pace with evidence generation in genomics. (Lewis)
- Update the standards for guidelines and systematic reviews, particularly to incorporate emerging technologies. (Lewis)
- Need increased funding and funding mechanisms. (Lewis)

How Can Guideline Development Be Pushed Forward?

1. Provide clinicians with **information** about genetics and **how to read, understand how to interpret, and implement guidelines**. (Temple-Smolkin, Caudle, Meric-Bernstam)
2. Apply **standard approaches and collaborative models** across societies. (Kapoor, Zetzsche, Arjunan, Phillips, Agarwal)
3. **Include patients and communities** in all parts of decision making and guideline development. (Arjunan, Phillips, Jonassaint)
4. **Standardize implementation**. (Caudle)
5. **Build equity** into the guideline development process and **address health equity** in systematic review. (Lin, Kondo)
6. **Share data and evidence** for variants to enhance equity. (Rehm, Manickam)
7. **Conduct a 360 analysis of challenges within guidelines for payers** that can promote coverage policies for everyone. (Hooker)
8. **Incorporate genomic testing into multidisciplinary guidelines**, e.g., pre-surgery testing. (Agarwal)

How Can Guideline Development Be Pushed Forward? Continued

9. **Incorporate implementation outcomes when developing guidelines**. (Chambers)
10. **Increase diversity and representation in the data** for the benefit of all. (Jonassaint)
11. **Consider the level of evidence needed** to develop guidelines for genomic testing. (Pereira)
12. **Utilize Living Review (Kondo) and Living Guidelines models** and **move towards computable guidelines**. (Lewis)
13. **Fund research** and publish the results, both successes and failures. (Lewis)

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Thank you and Next steps

- Please complete our post-workshop survey
- If you had questions you didn't have a chance to ask, feel free to email them to genomics@nas.edu
- Slides and videos will be posted to the workshop webpage within a couple of weeks
- A proceedings-in-brief will be published in the coming months to capture the discussions here today
- Please leave your name badge holders either on your seat or at the registration table
- Thank you for participating with us!