Moving Genomics to the Clinic Project Scoping

Workshop Summary

27 February 2020 - San Francisco, CA USA

Summary

The World Economic Forum hosted a workshop on 27 February 2020 on Moving Genomics to the Clinic Project Launch, to begin building a project community, develop a shared understanding of the barriers to moving genetic testing into clinical practice, and formulate solutions to the barriers to coverage of genetic tests. Twenty-five thought leaders, including payers, technologists, researchers, policy-makers, physicians, clinical geneticists and patient advocates, focused on how to address the gaps leading to the low and inconsistent levels of coverage of genetic testing in the clinical setting.

Lack of evidence on the clinical utility and clinical efficacy of genetic testing was identified as a consistent and ongoing challenge. Workshop participants brainstormed on incentives and/or pilot projects that the Forum and the Moving Genomics to the Clinic project community could scope to address the issue of evidence of clinical utility and clinical efficacy.

Background

The Moving Genomics to the Clinic project will address a foundational element of precision medicine: our ability to effectively deploy genetic screening and testing into routine clinical care.

Many experts and innovators argue that genetic testing should become a routine part of clinical care given its ability to accelerate how we identify and treat diseases as well as proactively stratify populations to identify risk mitigation or management strategies. However, many healthcare organizations and physicians are not incorporating genetic tests into routine practice.

After a scoping exercise in late 2019, the Forum's Precision Medicine team found that the most significant barrier to moving genetic testing into clinical practice is the **lack of coverage**. One example of this lack of coverage is a physician or healthcare institution not meeting reimbursement requirements for the process of ordering and returning the results of a genetic test. The workshop focused on understanding the issue and finding solutions to improve coverage of such tests.

Workshop agenda

The workshop was based on user-centred design principles to build connections between constituents, generate an understanding of the topic, and find solutions to address roadblocks or challenges.

Time	Workshop Agenda
09.00 - 09.20	Welcome and Overview
09.20 - 10.00	Activity with Participant Introductions
10.00 - 10.15	Project Background and Workshop Overview
10.15 - 10.45	Briefing on Barriers to Moving Genomics to the Clinic
11.00 - 12.00	Breakout 1: Identifying Barriers to Coverage
12.00 - 12.30	Plenary: Sharing Identified Barriers
13.30 - 14.15	Plenary: Explore Use Cases of Genetic Testing
14.15 - 15.15	Breakout 2: Identify Solutions to Use Cases
15.30 - 16.45	'Shark Tank' Plenary: Interactive Presentations on Possible Solutions
16.45 - 17.00	Summary and Closing

Workshop insights

Participants identified a variety of well-known barriers to coverage of genetic testing:

- Lack of uniform framework for proof of clinical utility or clinical efficacy leading to uncertainty about what evidence payers need
- Different values across the ecosystem applied to how we understand and calculate genetic testing; additionally, the benefits of a genetic test may only be realized years later after a person has moved to a different payer or provider
- Hesitancy to cover genetic testing because of blurred lines between whether test results are for research or clinical use
- Complexities of coding system dissuade clinicians from ordering tests and associated services

Participants raised some thorny questions:

- Are payers trying to fit the evaluation of the utility and efficacy of genetic tests into the model of other diagnostic tools, and does this framing work?
- Is there a higher evidence bar for genetic testing vs other types of medical testing? Is there an actual need to treat genetic testing differently?Does this reflect a disconnect between diagnostic companies and payers?
- Is the volume and novelty of genetic testing outpacing the ability of payers and health systems to validate clinical utility and efficacy?

Participants brainstormed potential solutions to address the lack of evidence of clinical utility and efficacy of certain genetic tests:

- Develop an agreed set of standards with all key stakeholders; once a test meets all evidentiary standards, it is given a “seal of approval”, which would enable payers to be comfortable covering the test; such a seal of approval would make it more straightforward for physicians and other health-care providers to order high-quality tests
- Develop a cost-sharing model between diagnostics companies and payers, and between healthcare organizations and diagnostic companies; these models would fund studies that provide sufficient proof of clinical utility and efficacy of specific genetic testing use cases where evidence needs strengthening or additional validation (e.g. population-level screening)
- Work with payers in a multistakeholder collaboration to identify healthcare conditions with the highest spend and poorest outcomes where a genetic test diagnostic tool could change the clinical course of action, improve outcomes and mitigate costs; then, use this scenario to develop a set of clinical-outcome requirements that meet the threshold for payers to cover testing as a new diagnostic approach

Project next steps

The Forum is analysing the participants’ contributions to the workshop and developing a project plan that includes completing targeted research, building a project and expert community, choosing a use case of genetic testing, and collaborating with anchor partners to leverage existing or new efforts to tackle barriers to coverage of genetic testing.

The Forum will take the following steps by June 2020:

- Create a list of targeted questions for key workshop participants, schedule interviews and identify anchor partners committed to providing resources to actions that improve coverage of genetic testing
- Host a webinar on Thursday 23 April 2020 with the project community
- Develop concept notes (proposals for areas of focus and initial actions to be taken) based on insight gathered from the workshop, interviews and additional research
- Choose use case of genetic testing (e.g. somatic, population-level, rare disease) around which to anchor and focus potential pilot activities
- Launch pilot project activities with two or more anchor partners co-leading project activities and objectives

The Moving Genomics to the Clinic project is part of the Forum’s Shaping the Future of Health and Healthcare Platform.

Contact

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