The History & Future of Consumer Genomics Utilization

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Exploring the Current Landscape of Consumer Genomics – A Workshop
Roundtable on Genomics and Precision Health, Board on Health Sciences Policy
The National Academies of Sciences, Engineering & Medicine
October 29, 2019
A DATE WITH DNA

K. C. Dustin and his wife, Debra Netschert, give saliva samples.

Michael Nagle for The New York Times
Overview

• History of consumer engagement with DTC genomic tests

• Review of consumer utilization and impacts

• Speculation on future trends
Key Takeaways

1) **Limited Data** – Major existing studies a decade old, little or no public data on recent consumers

2) **Consistent Motivations for Testing & Few Health Behavior Impacts** – Snapshot from available studies

3) **Significant Physician Impact** – 1/3 of consumers bring results to at least one healthcare provider

4) **Upward Trajectory** – Recent increases in consumer purchasing are likely to continue
History of DTC Genomics Uptake

2003  Human Genome Project complete
2006  **23andMe founded, controversy and debate about pros/cons**
2007  Navigenics founded
2008  TIME names retail DNA test (23andMe) invention of the year
2009  30 companies offering DTC tests
2010  **Estimated ~$10 million market**
2010  Pathway announces Walgreens partnership to sell in stores
2010  GAO report released on July 22
2011  AMA letter to FDA suggesting all genetic testing involve a physician
2013  FDA issues notice to cease and desist
2015  FDA approves 23andMe Bloom Syndrome test
2016  Beginning of DTC genetic test inflection point
2017  **Estimated ~$600 million global market value**
2017  23andMe claims > 2 million consumers
2017  April 6, FDA approves 23andMe risk test for 10 diseases/conditions
2017  Among leading companies, total consumers > 12 million
2018  FDA grants 23andMe marketing authorization for BRCA tests
2018  GlaxoSmithKline invests $300 million in 23andMe for drug dev
2018  **Estimated ~$830 million global market value for DTC genetics**
2019  Total number of consumers projected at > 26 million
2021  MIT Tech Review predicts ~100 million customers
2025  Global DTC genetics market predicted at > $2.5 billion
Rapid Review
DTC Genetic Health Risk Tests

- Conducted rapid review
  - Keyword search in PubMed, Web of Science

- Augmented two prior reviews
  - Stewart et al. 2018
  - Covolo et al. 2015

- Impacts of testing
  - Motivations
  - Behavioral
  - Psychological
  - Medical utilization

**Example Risk Results**

<table>
<thead>
<tr>
<th>Disease Risks (116)</th>
<th>Your Risk</th>
<th>Average Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary Heart Disease</td>
<td>38.5%</td>
<td>24.4%</td>
</tr>
<tr>
<td>Gallstones</td>
<td>21.7%</td>
<td>14.3%</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>1.0%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Ulcerative Colitis</td>
<td>0.7%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Scleroderma (Limited Cutaneous Type)</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

**Drug Response (20)**

- Clopidogrel (Plavix®) Efficacy | Reduced
- Response to Hepatitis C Treatment | Reduced
- Warfarin (Coumadin®) Sensitivity | Increased
- Abacavir Hypersensitivity | Typical
- Alcohol Consumption, Smoking and Risk of Esophageal Cancer | Typical
Results

- 69 total articles, 18 new (from 2017-present)
- Mix of standard methodological approaches
- Few unique cohorts (~50% of all studies based on only 3 cohorts)
  - Impact of Personal Genomics (PGen)
  - Scripps Genomic Health Initiative (SGHI)
  - Multiplex Initiative
- Participants early adopters (recruited ~ decade ago)
Characteristics & Motivations

- Participants in cohort studies to date mostly White and high SES

- Primary motivations for seeking testing are (consistent finding):
  - Ancestry
  - Health
  - Curiosity
  - Family Health History

- Few studies on differences in motivations and outcomes as a function of demographic diversity

- Landry et al. (2017, PGen) found few differences in motivations as a function of race (small N)
Health Behavior Changes

• When asked directly, less than 1/4 people self-report any health behavior change
  • Exercise
  • Diet
  • Smoking behavior
  • Vitamin/medication use

• Objective/validated measures of behavior find few or no changes

• In studies where changes have been observed, difficult to ascertain:
  • Size of effects
  • Whether (positive) changes are maintained and appropriate
Psychological Impacts

- Critics have raised concern for adverse psychological responses, such as anxiety and depression
- Currently little evidence for statistically significant adverse psychological changes among groups of consumers in existing studies
- Although percentages of people with adverse responses appear low, consequences when it does happen may be significant
- Resources should be available
• Estimates that about a third share with at least one HCP (range 25-46%), usually PCP

• Findings inconsistent regarding characteristics of sharers

• Outcomes of sharing vary
  • In general, provision of reassurance more common than change in management

• Consumers express belief in right to access without physician

• But also that physicians should be available and able to provide counsel for these tests (that they did not order)
Future Trends
At start of 2019, > 26 million consumers tested by four leading companies

MIT Tech estimated > 100 million people within 24 months
**Key Implication**: Advertising (with low cost) will drive purchasing until market saturation
Adoption Curve

Moved from early adopter to early majority phase

Consumers differ by phase

- **Key Implication**: Existing studies may not accurately inform utilization and impacts on current consumers (need new studies with new approaches)
Broad & Shifting Consumer Health Landscape

- **Key Implication:** Consumers will increasingly seek after-the-fact physician guidance regarding genomic and other health tests purchased DTC.
Takeaways & Recommendations

1) **Limited Data** – Need studies of recent consumers (that leverage new approaches, e.g., social media studies), studies that assess influence of demographic factors, impact of emerging issues

2) **Consistent Motivations & Few Health Behavior Impacts** – Monitor for later stage adopters, make resources available to address adverse psychological impacts when they occur

3) **Significant Physician Impact** - Current US consumer base estimates suggest ~3.6 million instances of sharing with a physician (juxtaposed with only 850k practicing in US)
   
   • Learn about phenomena, develop/teach ways to approach these interactions in shifting heath care landscape, treat as an opportunity

4) **Upward Trajectory** – More people tested outside vs. inside medical model, part of broader trend of consumer interest in DTC health products and devices and likely to continue
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