A novel approach to lab-based clinical genetic counseling

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Disclosure

I am an Invitae employee and stockholder.

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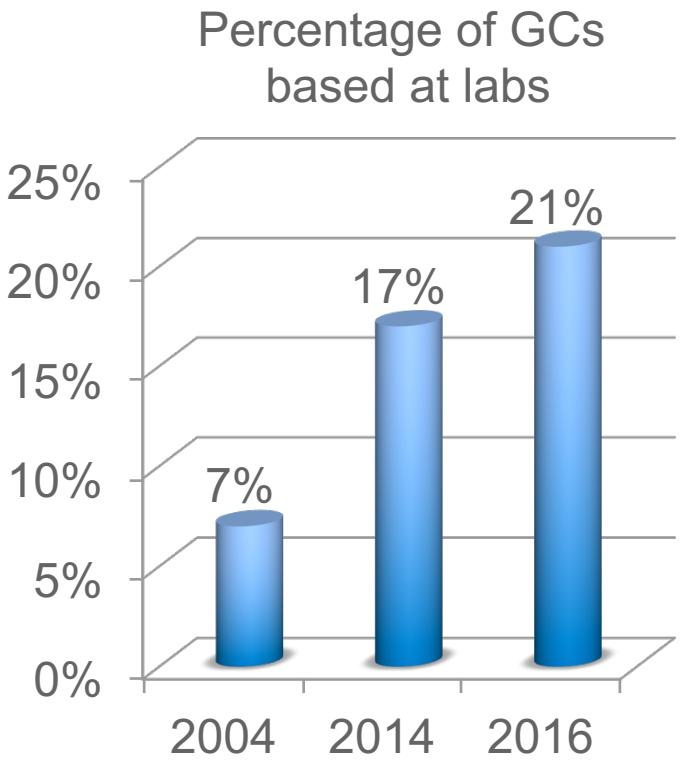
Genetic testing has changed

- Decreased cost of genetic testing combined with improvements in technology have led to an unprecedented era of multi-gene panel testing.
- Demand for GC services is escalating without a parallel increase in the number of genetic counselors.
- To fill this void, some commercial laboratories employ genetic counselors to provide genetic counseling directly to patients undergoing testing in their lab.
- This raises potential for conflict of interest.



NSGC Professional Status Survey: 2004, 2014, 2016

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Conflict of interest

- Realities
  - Demand for genetic counseling cannot be met with the current number of GCs.
  - Specialized clinics are mainly in urban areas and academic centers, which limits access.
  - COI is an issue for all GCs, regardless of their employment setting.[1]
- Concerns
  - Can laboratory GCs offer objective, unbiased information if employed by a company dependent upon test volume?[2]
  - Might genetic counselors steer patients to proceed with testing not clinically indicated?
  - Might they be incentivized to recommend more testing than necessary?
- Opportunities
  - Use of lab-based GCs may allow patients access who would not otherwise have been able to receive services.

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1 Groepper, D et al. (2015). JGC 24(4), 580-596.
2 Resta, R. Web blog post. The DNA Exchange, 15 Jan. 2012. Web. 16 May 2016.

Recommendations/guidelines

- No published recommendations or professional guidelines exist to direct lab-based GCs providing clinical services.
- NSGC Task Force was created this year to explore COI among genetic counselors.
- Labs must develop internal policies.

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- Invitae has made extensive efforts to demonstrate responsible and transparent genetic counseling services by defining a specific 5-point guideline for provision of patient care.

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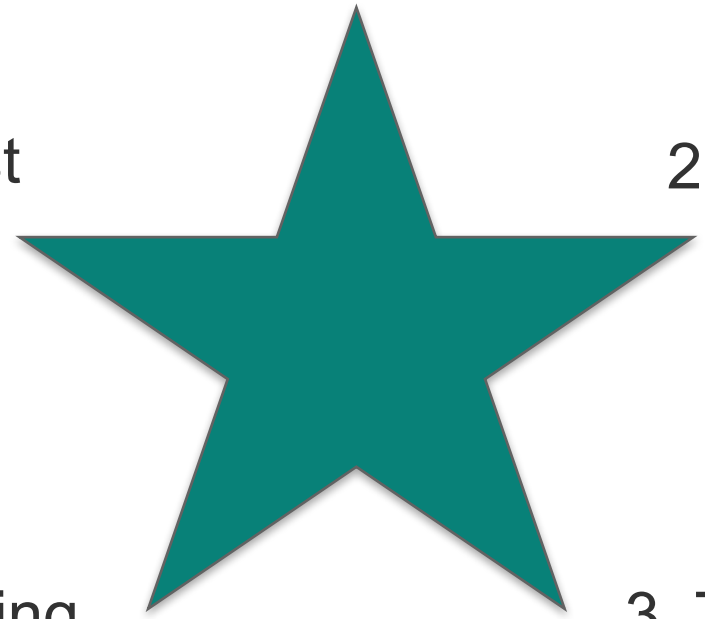
Invitae's guideline for provision of care is based on five core principles

1. Abide by NSGC Code of Ethics



2. No commission; no quotas

3. Transparency with patients

4. Genetic counseling provided post-requisition

5. No additional cost for adding clinically appropriate genes

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What does this look like in practice?

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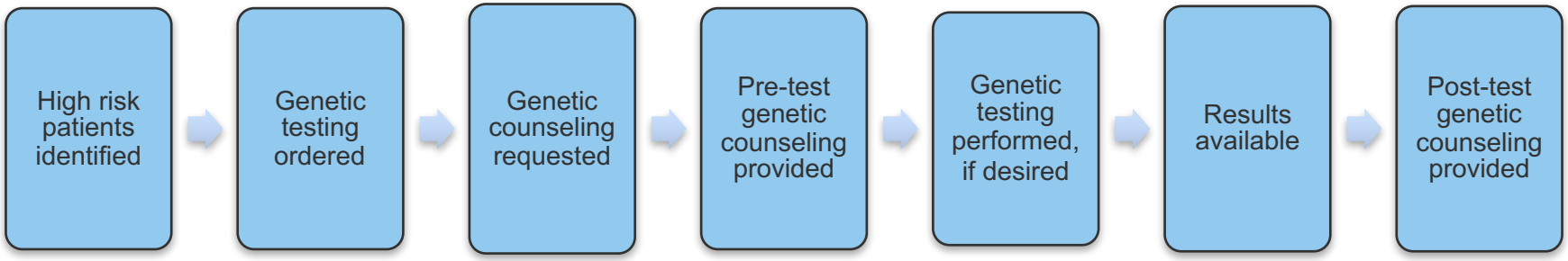
Pilot Study

- Three-way collaboration among Invitae, a large primary care practice, and a large private payer
- Primary care physicians were provided with referral criteria and a simple, streamlined process for referring patients for genetic testing and counseling.
- 129 referred patients underwent cancer genetic counseling during a 14-month period



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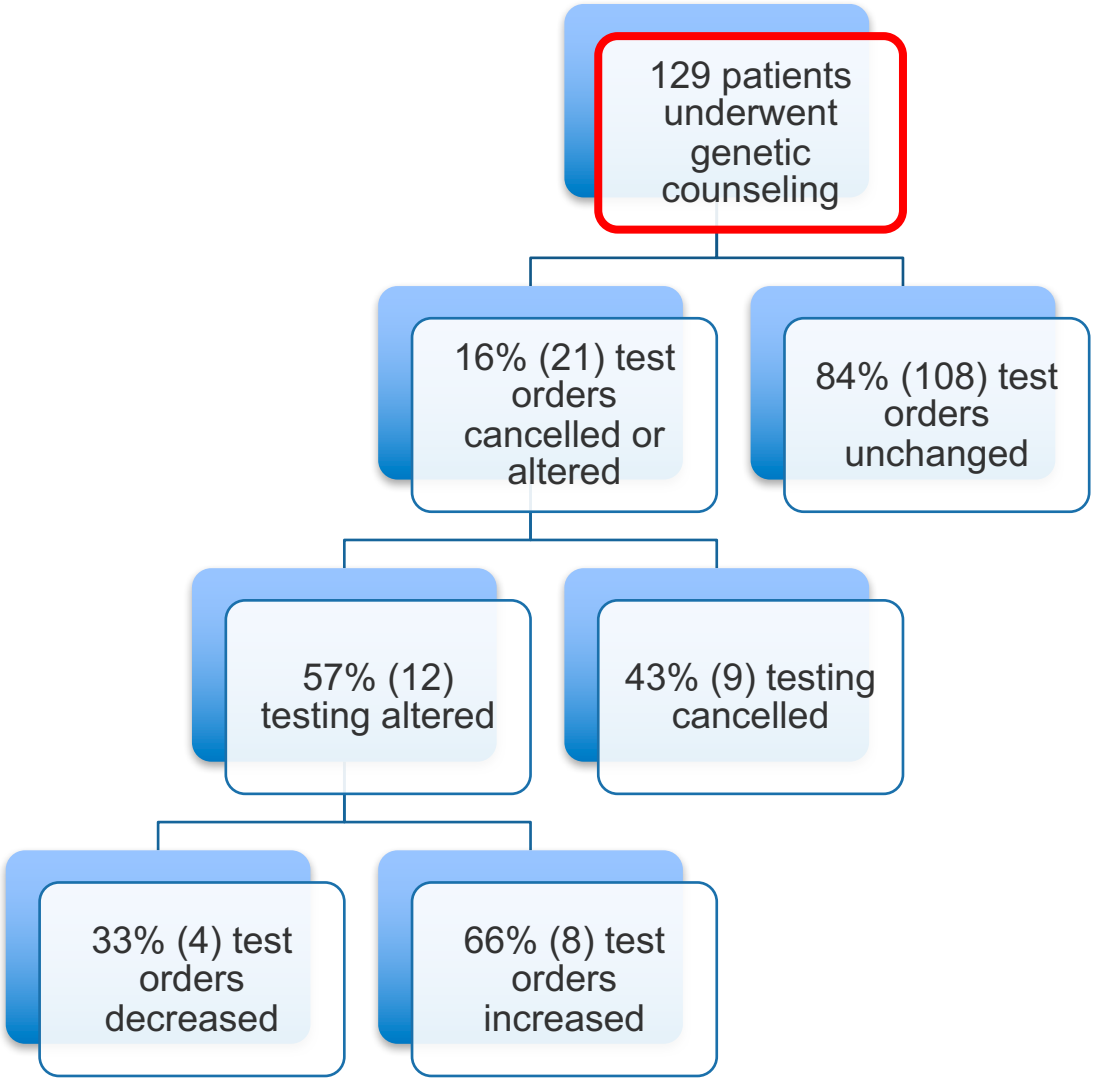
Outcomes of genetic counseling



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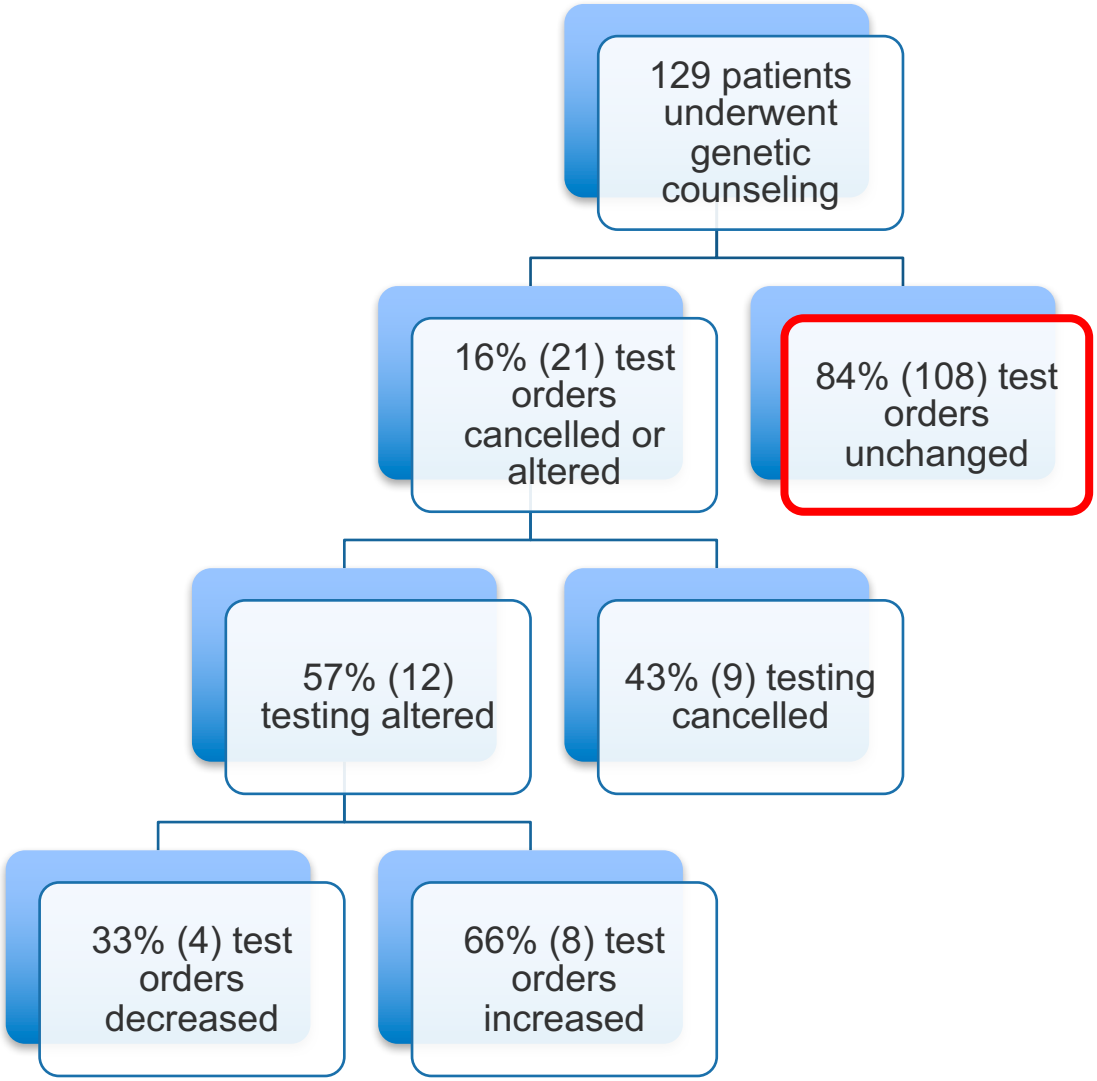
Outcomes of genetic counseling



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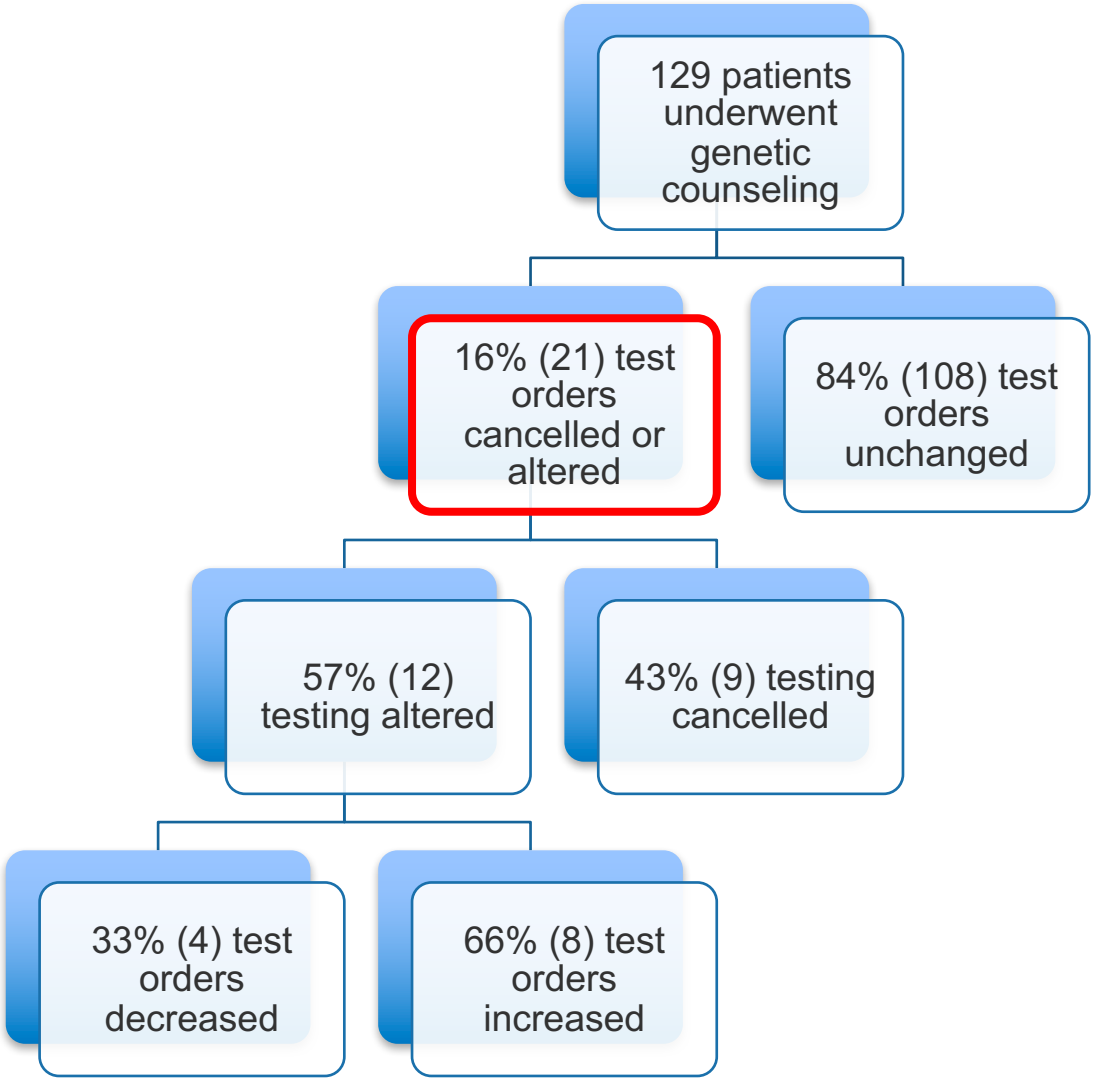
Outcomes of genetic counseling



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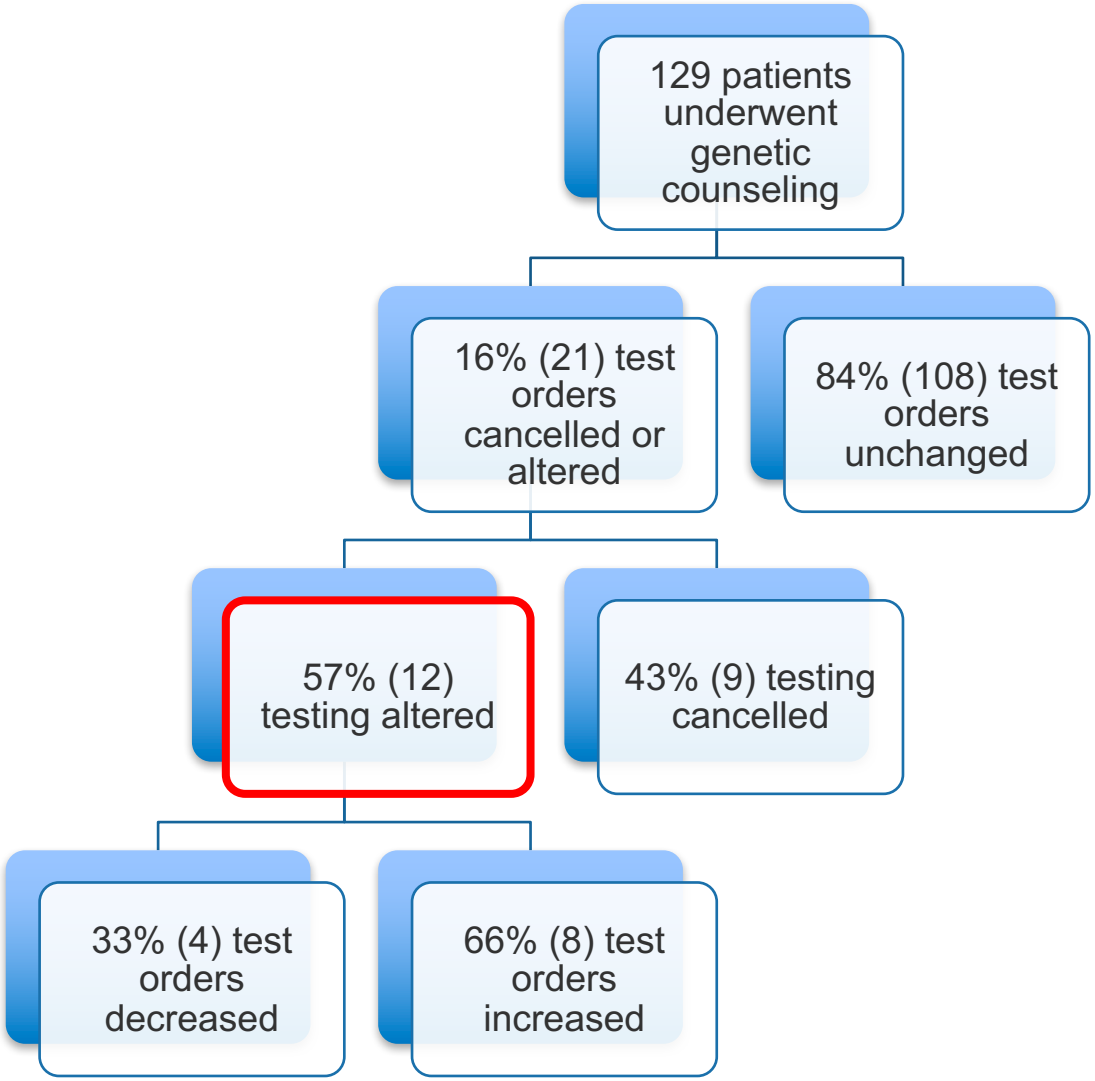
Outcomes of genetic counseling



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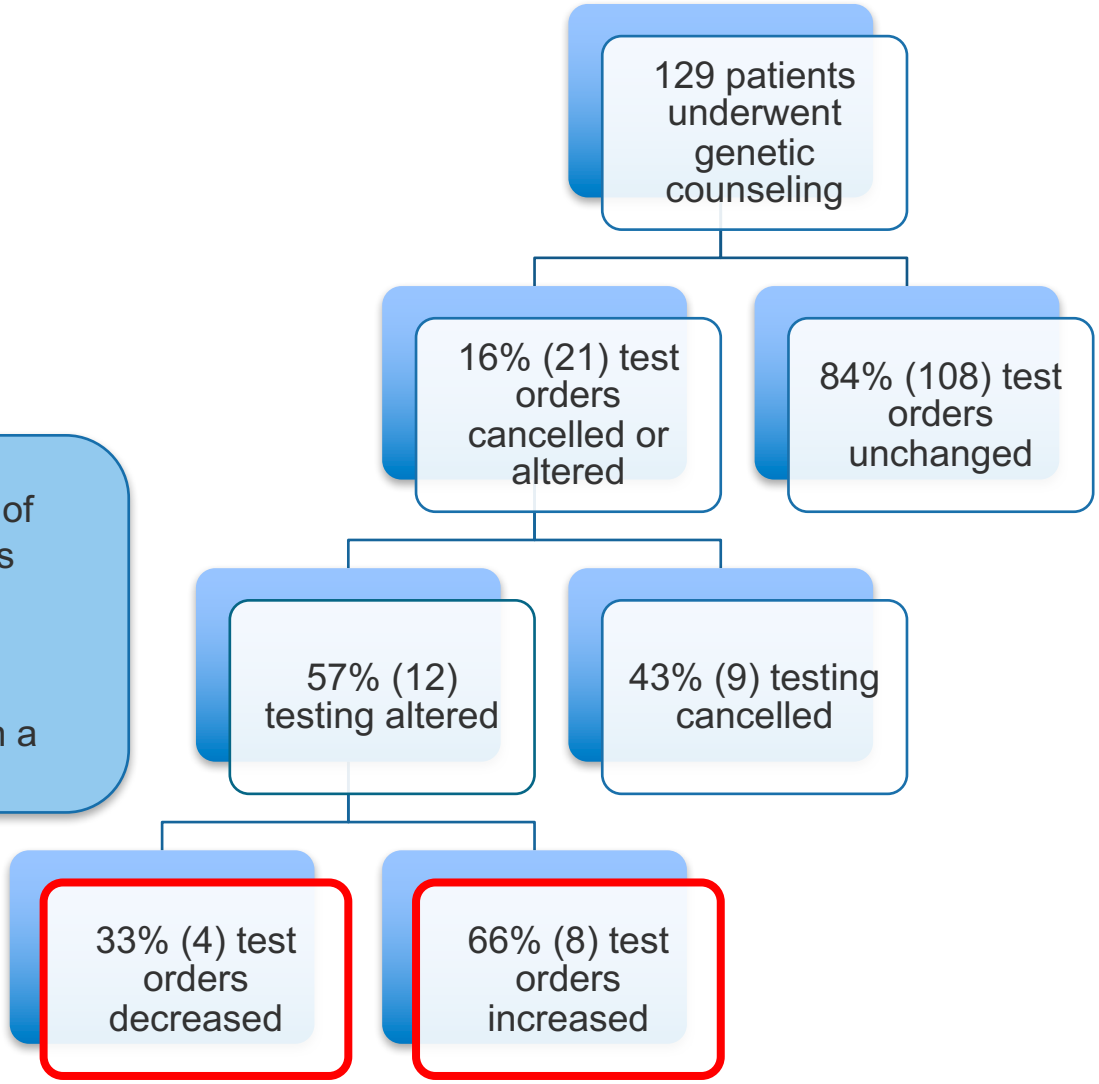
Outcomes of genetic counseling



Increase:
Due to identification of additional risk factors

Decrease:
Due to previously identified mutation in a family member

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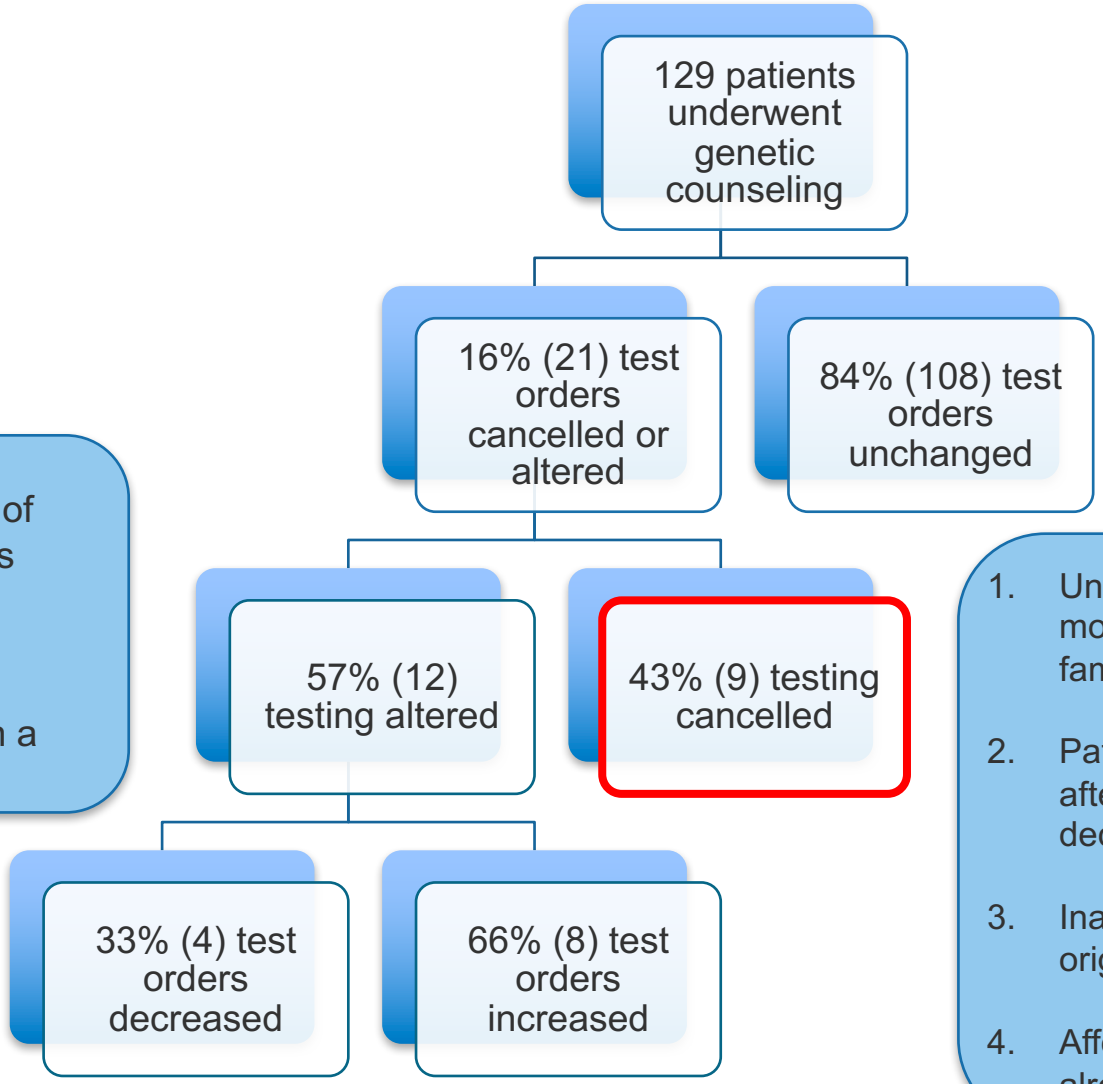
Outcomes of genetic counseling



Increase:
Due to identification of additional risk factors

Decrease:
Due to previously identified mutation in a family member

1. Unaffected patient with a more appropriate affected family member to test
2. Patient deemed low risk after genetic counseling; declined testing
3. Inappropriate testing originally ordered
4. Affected family member already tested negative

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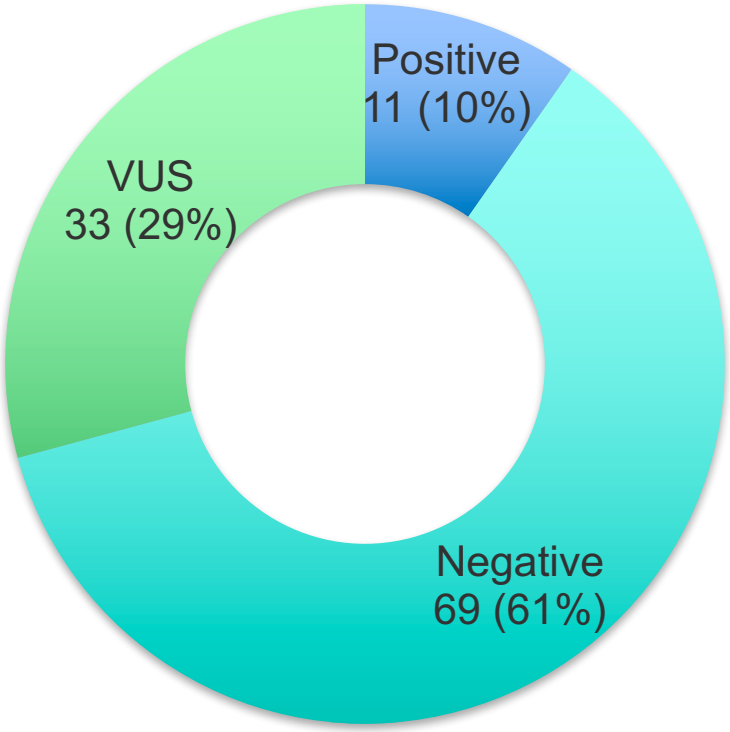
Outcomes of genetic testing

Test results for 113 patients



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Conclusions

- These data provide an example of a principled application of lab-based genetic counseling services.
- A substantial number of patients had their genetic testing altered or cancelled after genetic counseling.
- A significant proportion of patients had test results that altered their clinical management.
- This model provides an example of how lab-based GC services can ensure the most appropriate test will be provided and improve access for optimal patient care.

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Thank you!

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