A Guide To Genetic Consenting

Module 3:
How is genetic consenting performed?

Prof. Christian Singer

This information has been organised and fully funded by AstraZeneca and MSD in collaboration with the Central European Cooperative Oncology Group (CECOG).
The views expressed in this publication reflect the experience and opinions of the authors and not necessarily that of MSD / AstraZeneca / CECOG.

Z4-45906
Date of preparation: July 2022

Learning objectives

The primary purpose of this learning module is to inform and educate non-genetics HCPs on genetic consenting.

This module will enable HCPs to:

- Be aware of the essential criteria to carry out a genetic test
- Understand how genetic consenting should be delivered and recorded
- Be aware of the traditional approach to genetic consenting as well as its' challenges

HCP=healthcare professional

Information requirements for genetic testing

- The type of sample required
  - A gene mutation test is undertaken by examining the patient's DNA in the specific regions of the gene
  - DNA tests can be performed on any sample from which sufficient DNA can be extracted
  - In practice, blood is usually taken and DNA is extracted from the white cells
    - However, a sample of buccal cells from the inside of the cheek may also be used

- Information about how the sample will be securely stored and the usual time period for the result to be available should be obtained from the laboratory doing the test and conveyed to the patient

- The fact that the results are confidential and will only be shared with other health professionals or other relatives with the patient's permission

Essential criteria to provide informed consent

- In order for a patient to give informed consent, three criteria must be satisfied:
  - The patient must have sufficient information about the test and the implications of the result. He or she must have received sufficient information in an accessible format to allow them to make an informed decision
  - The patient must have the capacity to make a decision about the test
  - The patient must be able to communicate his or her decision in a clear manner, free from coercion

How should genetic consenting be recorded?

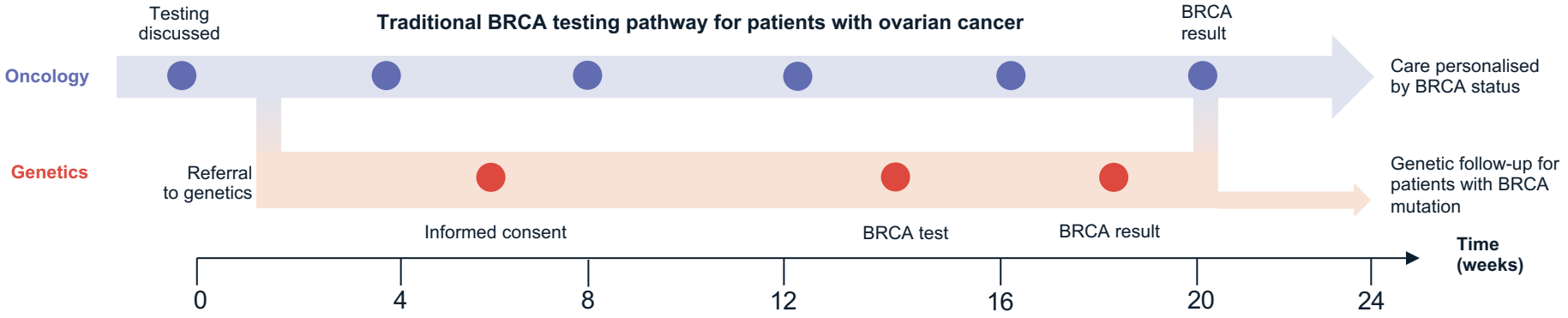
- Consent is a dynamic process
- It is essential to ensure that the information is given, is understood and the consent is given without any coercion. This can be recorded by hand in the notes or via a formal consent form
- It can be done with varying degrees of formality
  - In some centres, a formal consent form is used. This can help to ensure that all aspects of the information giving and consent are recorded
- Consent for the test, for storage of the sample and for disclosure of information about the results to other relatives and health professionals should all be recorded

The traditional approach to genetic consent and counselling involves referral to a genetic counsellor following in-person oncological assessment

In the traditional, genetics-led model, patients receive genetic counselling from a trained genetic counsellor following referral from an oncologist

The traditional BRCA testing pathway involves two genetic appointments for testing following initial discussions with an oncologist

Although patients benefit from in person discussions with genetic counsellors, the traditional approach can be associated with limited resources and time delays

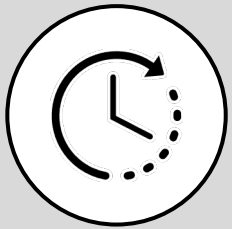


George A, et al. *Sci Rep.* 2016;6:26506

The traditional, genetics-led model can be optimised by embedding genetic counsellors in oncology clinics

Genetic counsellors are embedded into multidisciplinary teams in oncology clinics[1,2]

Genetic counsellors provide pre- and post-test genetic counselling and obtain consent for testing during visits to the oncology clinic[1,2]



Providing cancer genetics services on-site in oncology clinics significantly increases referral to cancer genetics and timely completion of genetics consultation[1]

1. Senter L, et al. *Gynceol Oncol.* 2017;147:110–114; 2. Rana HQ, et al. *Gynecol Oncol.* 2021;160:457–463

Challenges observed

- Limited number of trained doctors to provide counselling
- Complex access to testing
- Lack of streamlined process
- Lack of administrative staff

Informed consent / withholding information	Organisational constraints	Attaining / maintaining proficiency	Other constraints
• **What information could we provide to patients** so they could make an autonomous decision while not being overburdened or directive	• **Language** barriers • **Lack of space** for uninterrupted counselling • Missing written **information material** for patients	• Challenge **in keeping up with genetic information** and maintaining proficiency	• **Insufficient experience**, lack of training as a psychotherapist • Too much **time and effort** for non-medical organisational tasks • **Deficient cooperation** between institutes • A **lack of up-to-date data**

1. Gschmeidler B and Flatscher-Thoeni M. *J Genet Couns.* 2013;22:741–752

Increasing numbers of patients are being referred for genetic testing and/or counselling, but there is a shortage of genetic counsellors

The capacity of genetic counsellors is rate limiting and presents a potential barrier to the implementation of BRCA testing for patients with or at high-risk for BRCA-associated cancers.[1]

It is expected that the current restriction of counselling to clinical geneticists in several countries will lead to a shortage in counselling slots and to a prolongation of already long waiting times.[3]

The increase in referrals and the desire to meet the demand for genetic counselling has already led some providers to implement innovative service delivery models.[4]

With the increasing availability of high-throughput testing platforms and the growing number of indications for PARP inhibitors, the number of patients requiring genetic counselling is expected to continue to increase.[2,3]

"… the number of patients that are being referred is increasing, and… our biggest hurdle is that it's… impossible and unsustainable to hire the number of genetic counsellors that are needed to keep our wait times low in doing a fairly traditional service delivery model"[4]
Genetic counsellor

1. Colombo N et al. *J Clin Oncol.* 2018:36:1300–1307; 2. Neviere Z, et al. *Ther Adv Med Oncol.* 2020;12:1–16; 3. Singer C, et al. *Eur J Cancer.* 2019;106:54–60; 4. Khan A, et al. *J Genet Couns.* 2021;30:319–328

Summary

- A gene mutation test is undertaken by examining the patient's DNA in the specific regions of the gene[1]
- DNA tests can be performed on any sample from which sufficient DNA can be extracted[1]

- Genetic consent for the test, for storage of the sample and for disclosure of information about the results to other relatives and health professionals should all be recorded[1]

- The traditional approach to genetic consent and counselling involves referral to a genetic counsellor following in-person oncological assessment. However, there are challenges with this model[2,3]

1. Speaker communication; 2. George A, et al. *Sci Rep.* 2016;6:26506; 3. Gschmeidler B and Flatscher-Thoeni M. *J Genet Couns.* 2013;22:741–752.