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Need and Essentiality of Genetic Counselling in India: a Systematic Review of Research Evidence

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Abstract: *Genetic counselling is viewed as a therapeutic interrelationship between genetic counsellors and their clients. The process involves pre-test counselling as well as post-test counselling to enable the individuals to face the situation and take appropriate decisions with the right frame of mind. Genetic counselling is an expanding field in the era of genomic medicine. This unique medical speciality provides clinical health care, education, and emotional support to individuals and families facing genetic and inherited diseases. The profession of genetic counselling has undergone many transitions since its inception over 60 years ago. Genetic disorders is a serious health problem in India. Genetic counselling is a one intervention which is done before marriage or during antenatal if there is already case of genetic disorders. This review was conducted to describe the effectiveness and need of genetic counselling in Indian clinical genetics settings and Experimental studies (N=25) published between 1998 and 2015 were synthesized. The advent of genetic tests has had a tremendous effect on clinical diagnosis. Diseases, which were difficult to diagnose earlier, are now aided by genetic screening tests. These tests are new and not very well known among clinicians. More importantly, the implications of the results must be explained to the patient and relatives in a professional manner, since most of the times, the results have an immense emotional impact on families. The education and counselling accompanying genetic testing is provided by genetic counsellors in all developed countries as this is essential for the decision-making process regarding testing and dealing with test outcomes.*

INTRODUCTION

Genetics is probably one of the most exciting lessons in biology. At the same time, it can be a bit confusing because sometimes it is difficult to imagine what the bare eyes cannot see. Genetics is the science of studying how living things pass on characteristics (or traits) and its variations in their cell make up from one generation to the other. Simply, it is the study of how living things inherit features like eye colour, nose and even behaviour from their parents. Genes are made up of DNA molecules, which are the building blocks of heredity. They're grouped together in specific patterns within a person's chromosomes, forming the unique "blueprint" for every physical and biological characteristic of that person. Current science suggests that every human has about 25,000 genes per cell. An error in just one gene (and in some instances, even the alteration of a single piece of DNA) can sometimes be the cause for a serious medical condition.

"To counsel" means to advice, to recommend, to advocate, to exhort, to suggest, to urge‟ (Oxford Dictionary1996:131). However, counselling as a concept, as observed by Miller and Bor (1991) has many interpretations. Whatever its goals, counselling is directed towards Assisting people to take decisions, to effect a change, to prevent problems or crises or to Manage them when they arise.

The word "counselling" refers to information-giving or communication as opposed to psychotherapy or psychology thus *doing* genetic counselling means communicating genetic information in a meaningful way to patients. But it does not just mean having a conversation that happens to involve genetic information; it goes much further than that. Genetic counselling provides an individual or family with information and support regarding health concerns which run in their family. Genetic counselling may involve the diagnosis of a genetic condition, the provision of information and supportive counselling (advice and guidance) by a team of health professionals, so that families and individuals may be better able to adjust to diagnosis. Genetic counselling is "the process of helping people understand and adapt to the medical, psychological, and familial implications of genetic contributions to disease." Traditionally, this process includes collecting and interpreting the family and medical history, risk assessment, a comprehensive educational process

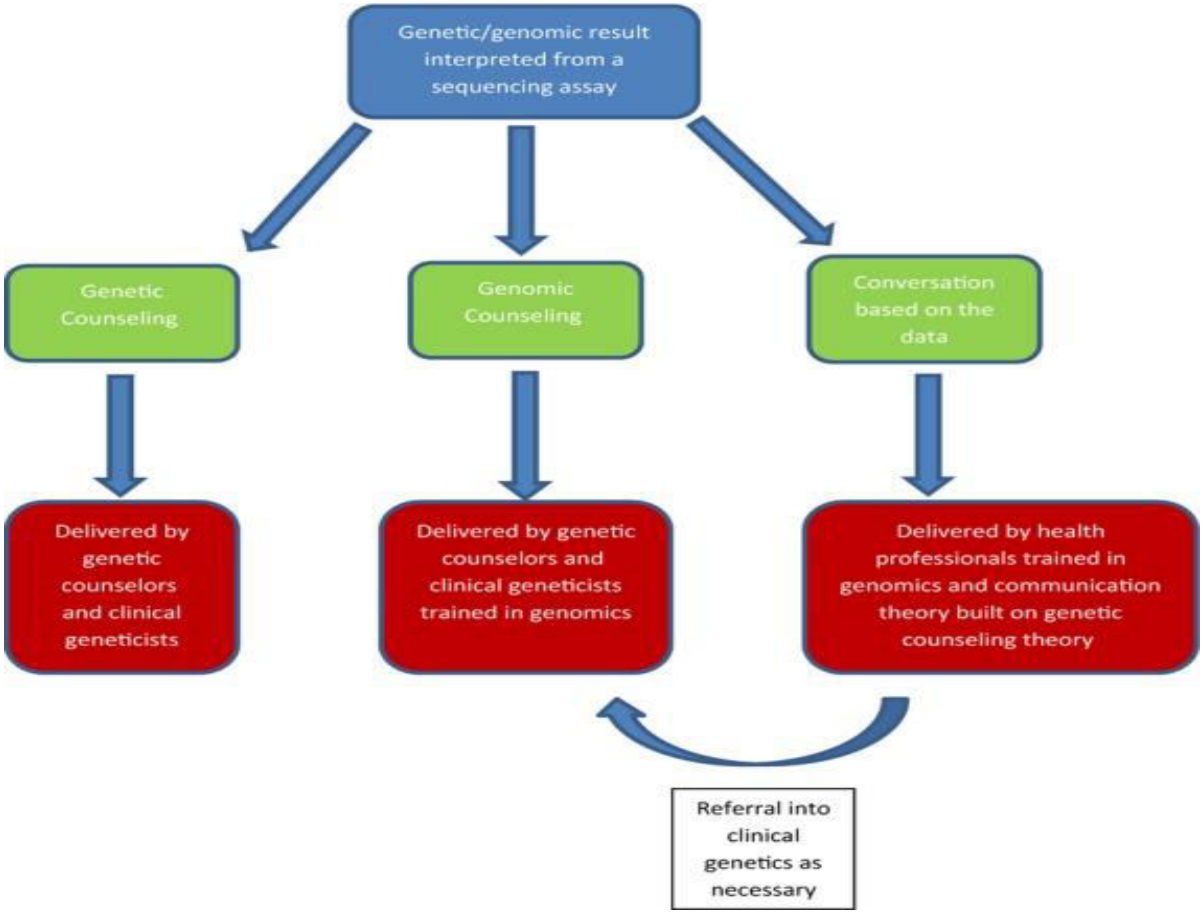
for potential genetic testing, informed consent, and psychosocial assessment and support (National Society of Genetic Counsellor's Definition Task Force et al. 2006). Although the term 'genetic counselling' was coined by Sheldon Reed in 1947.Genetic counselling is an educational process that aims to inform and advise patients and relatives at risk of a genetic condition about the nature of the disorder, the probability of developing it and the risk of passing it on to future generations.

Genetic counselling is the process of:

- evaluating family history and medical records
- ordering genetic tests
- evaluating the results of this investigation
- helping parents understand and reach decisions about what to do next

In general, a genetic counselling session aims to:

- Increase the family understands about a genetic disease(s), the risks and benefits of genetic testing and disease management, and available options.
- Identify with the individual and family the psychosocial tools required to adjust to potential outcomes.
- Reduce the family's anxiety.



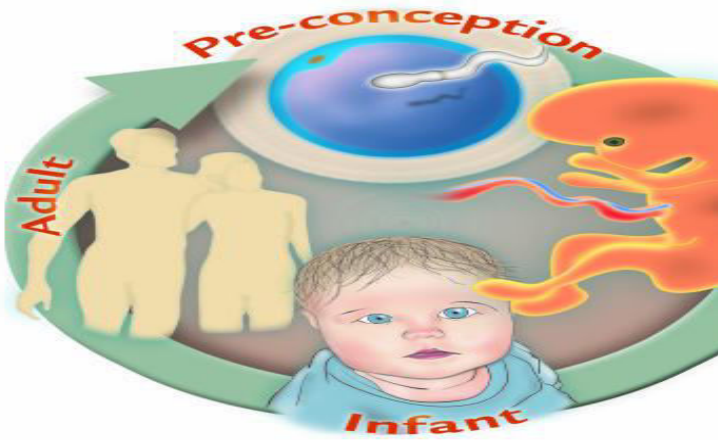
Genetic Counselling session structure

The goals of genetic counselling are to increase understanding of genetic diseases, discuss disease management options, and explain the risks and benefits of testing. Counselling sessions focus on giving vital, unbiased information and non-directive assistance in the patient's decision-making process. Seymour Kessler, in 1979, first categorized sessions in five phases: an intake phase, an initial contact phase, the encounter phase, the summary phase, and a follow-up phase. The intake and follow-up phases occur outside of the actual counselling session. The initial contact phase is when the counsellor and families meet and build rapport. The encounter phase includes dialogue between the counsellor and the client about the nature of screening and diagnostic tests. The summary phase provides all the options and

decisions available for the next step. If counselees wish to go ahead with testing, an appointment is organized and the genetic counsellor acts as the person to communicate the results. The traditional approach to genetic counselling for single-gene disorders is highly education focused, and genetic counselling sessions can last 30–90 min or more. A recent practice analysis suggests typical genetic counselling sessions can include (but are not limited to): a review of general genetic principles, modes of inheritance, family/individual specific risk assessment, an in depth discussion of the diagnosis and natural history, potential testing options, and case management for the condition occurring within the family or for which they are at risk (Hampel et al. 2009). Ideally, in a genetic counselling session, a psych educational and person-centred approach allows the information to be tailored to the person's understanding level, culture, and personal context. Genetic counselling is frequently an emotional process (McCarthy Veach et al. 2003a); the patient may come for genetic counselling at one of the most vulnerable moments in their life, an event caused by a faulty gene may result in grief, loss or crippling fear. Helping patients in that moment, and being emotionally congruent (McCarthy Veach et al. 2003b), as they discuss the impact of the genetic event, is at the heart of what genetic counsellors do. In the context of a family history, genetic counsellors traditionally have worked from the phenotype back to the genotype and defined, through genetic analysis, whether there is a single gene fault that is responsible for the family condition. The emotional connection to a particular condition, which is provided by the lived-experience of it, helps to guide the patient in their decisions, for example, to give informed consent for genetic testing. This is strikingly different from a patient who (seemingly) has no family history of a particular condition who is then faced with a genome-based test and subsequent result (Middleton 2012). Taking informed consent for such testing and supporting patients with the results (as emotionally challenging they may or may not be) is likely to be at the forefront of genomic counselling. It is not unusual for multiple genetic counselling sessions to occur and, at a minimum, include a pre-testing and post-testing session. During the initial genetic counselling visit, the genetic counsellor will determine why the patient/family is seeking genetic counselling, identify what information they wish to obtain from the session, collect and record a family history, and assess and record the psychosocial history of the patient.

WHO REQUIRES GENETIC COUNSELLING?

The best time to seek genetic counselling is before becoming pregnant, when a counsellor can help assess your risk factors. But even after you become pregnant, a meeting with a genetic counsellor can still be helpful. A genetic counsellor can help determine what testing is appropriate for your pregnancy. Experts recommend that all pregnant women, regardless of age or circumstance, be offered genetic counselling and testing to screen for Down syndrome. Every mother wants to give birth to a healthy baby. To rule out any chances of birth defects and complications, genetic testing is done. Genetic testing is not a norm for all pregnancy cases. It is done only in certain cases or those with a family history of certain diseases. Genetic testing improves the chances of giving birth to a healthy baby. Genetic tests are carried out during different stages of pregnancy. Genetic counselling helps expecting parents to understand the family traits that can be passed to the baby.



It's especially important to consider genetic counselling if any of the following risk factors apply:

- a standard prenatal screening test (such as the alpha fetoprotein test) yields an abnormal result
- an amniocentesis yields an unexpected result (such as a chromosomal defect in the unborn baby)
- either parent or a close relative has an inherited disease or birth defect
- either parent already has children with birth defects, intellectual disabilities, or genetic disorders

- the mother-to-be has had two or more miscarriages or babies that died in infancy
- The mother-to-be will be 35 or older when the baby is born. Chances of having a child with Down syndrome increase with the mother's age: a woman has about a 1 in 350 chance of conceiving a child with Down syndrome at age 35, a 1 in 110 chance at age 40, and a 1 in 30 chance at age 45.
- either parent is concerned about the effects of exposures they have had to radiation, medications, illegal drugs, infections, or chemicals

Genetic Diseases: Indian Scenario

A genetic disorder is a disease that is caused by a change, or mutation, in an individual's DNA sequence. Some diseases, such as Huntington's disease (a degenerative nerve disease) and Marfan syndrome (a connective tissue disorder), can be inherited from just one parent. But most disorders, including cystic fibrosis, sickle cell anaemia, and Tay-Sachs disease, cannot occur unless both the mother and father pass along the gene.

Other genetic conditions, such as Down syndrome, are usually not inherited. In general, they result from an error (mutation) in the cell division process during conception or Fetal development. Still others, such as achondroplasia (the most common form of dwarfism), may either be inherited or the result of a genetic mutation.

The load of genetic diseases varies widely between different populations depending on its structure, reproductive practices and other factors.

The Indian represent one-sixth of the world population and India consists of ethnically, geographically and genetically diverse populations with several thousand endogamous groups with strong potential for excess of recessive diseases

Globally, at least 7.6 million children are born annually with severe genetic or congenital malformations; 90% of these are born in mid and low income countries. Precise prevalence data are difficult to collect, especially in developing countries, owing to great diversity of conditions and also because many cases remain undiagnosed. The genetic and congenital disorder is the second most common cause of infant and childhood mortality and occurs with a prevalence of 25-60 per 1000 births. The higher prevalence of genetic diseases in a particular community may, however, be due to some social or cultural factors. Such factors include tradition of consanguineous marriage, which results in a higher rate of autosomal recessive conditions including congenital malformations, stillbirths, or mental retardation. Furthermore, maternal age greater than 35 years is associated with higher frequencies of chromosomal abnormalities in the offspring (WHO 2005). Genetic diseases can vary in severity, from being fatal before birth to requiring continuous management; their onset covers all life stages from infancy to old age. Those presenting at birth are particularly burdensome, and may cause early death or life-long chronic morbidity. In India's urban areas, congenital malformations and genetic disorders are the third most common cause of mortality in new-borns .In March 2006, research carried by the March of Dimes Birth Defect Foundation reported the birth defect pervasiveness in India as 64.4 over 1000 live births. Rao and Ghosh(2005) states, 1 out of every 20 newborns admitted to the hospital carries a genetic disease that eventually account for nearly 1 out of 10 infant mortality.

Most Common Genetic Disorders in Indian ethnicity

Table-1

Genetic Disease	Pattern	Signs	Statistics of Occurrence
Cystic Fibrosis(CF)	Autosomal recessive Pattern. Presence of mutations in both copies of the gene for CFTR(cystic fibrosis trans membrane conductance regulator)protein	Persistent Lung Infections, Digestive and Reproductive Issues	1 in every 25 live births suffer from CF or 1 in every 10000
Sickle Cell Anaemia(SCA)	Autosomal Recessive Pattern. Abnormality in Haemoglobin(oxygen carrying protein).Inheritance of two abnormal copies of the haemoglobin gene	RBC becomes Misshapen & break down	1 in every 150 live births
Spinal Muscular Atrophy(SMA)	Autosomal Recessive Pattern. Mutation in the Survival	Loss of Motor neurons. Progressive muscle	1 in 10000 babies and 1 in every 50 live

	Motor Neuron Gene1(SMN1)	wasting,Fasciculations(twitching) of the tongue	births is a genetic carrier.
Haemophilia A	Inherited as an X-linked recessive trait.	Blood doesn't clot normally. Unexplained bleeding and blood in urine or stool	1 in 5000 live births
Beta-Thalassemia	Autosomal recessive Pattern. Two genes for beta thalassemia. Mutations in Beta globin genes.	Reduce the production of haemoglobin and make abnormal form of haemoglobin. Enlarged Spleen	1.2 in 1000 live births

Who are Genetic Counsellors?

Genetic tests don't yield easy-to-understand results. They can reveal the presence, absence, or malformation of genes or chromosomes. Deciphering what these complex tests mean is where a genetic counsellor comes in. Genetic counsellors are health professionals with specialized training and experience in the areas of medical genetics and counselling. Genetic counsellors work as members of a healthcare team, providing individuals and families with information on the nature, inheritance, and implications of genetic disorders to help them make informed medical and personal decisions. Genetic counsellors identify individuals and/or families who may have or be at risk for a genetic condition, investigate the problem present in the family, interpret information about the disorder, analyse inheritance patterns and risks of occurrence or recurrence, and review available options with the individual/family in a manner that promotes informed choice. Genetic Counsellors help people understand and adapt to the medical, psychological, and familial implications of how genetics contributes to disease. In addition to the roles described above genetic counsellors guide individuals/families in discussions about test result interpretation, prevention, medical management and options for prenatal diagnosis. One thing that separates genetic counsellors from other health professionals with expertise in genetics is their stated focus on the psychosocial adaption to genetic conditions or genetic risk (Biesecker and Peters 2001).

ROLE OF A GENETIC COUNSELLOR

- A genetic counsellor must not only convey information about diseases or problems they harbour to individuals and their families but also the consequences of testing and the potential for therapeutic intervention.
- They Collect, select, interpret and analyse information (including family and medical history, pedigree, laboratory results and literature) relevant to the delivery of genetic counselling for individuals or families
- Genetic counsellor must enumerate the risks to other family members both in present and future generations and identify the needs of the individual or family and use an empathic client-centred approach to the provision of genetic counselling
- Genetic counsellors play a key role in educating about inheritance, testing, management, prevention, resources and research to relevant individuals or families and healthcare providers and assist in establishing standards of practice.
- They promotes informed choices and psychological adaptation to the condition or risk of the condition
- Trained genetic counsellors liaise with healthcare professionals, diagnostic labs and patients.
- They also communicate with policy makers, media and the public about new and emerging medical-genetic technologies and services.

Methods

Conducting a systematic review enables the evidence on a particular topic to be gathered, analysed and synthesised.In order to conduct complete search and syntheses of results, we searched two biomedical journal data bases, medline and pubmed and two humanities journal data bases,open edition and PubPsych. The authors read the full text of the 37 papers. After reading the full texts 12 papers were excluded from the analysis because topics were not relevant, simulated genetic counselling, were assessing genetic risks only, or were a combination of genetic counselling and testing. Finally a total 25 articles were reviewed.

Discussion

Genetic counselling is an important clinical practice since it assists patients in choosing preventive screening test, adopting healthy behaviours, and making decisions about having genetic tests and preventive measures. Communicating accurate genetic risk levels effectively is the core process of genetic counselling. However, due to the complicated nature of the genetic risk, conducting such communication is challenging in clinical settings. The studies that we reviewed were less diverse in terms of the target diseases and the population thus may not represent the genetic counselling domain in general. Among the various information topics covered by the studies, detailed knowledge on hereditary disease was the most frequently appearing topic. However, despite their importance, topics of various preventive options, screening test, therapy options, and cultural beliefs/values were less frequently found in the studies. Considering that people responded more proactively to the risks that they can mitigate, specific risk mitigation options should be the topic regularly covered during the counselling.

Sixteen of twenty five (64%) studies compared the effectiveness of a specific counselling method or aid to the traditional genetic counselling alone. Outcome variables were common across studies, mostly looking into cognitive (risk perception and knowledge), psychological well-being (decision conflict, cancer worries, depression, and distress), attitude or behaviour change (intention to and/or actual uptake of screening test or preventive measures), and overall satisfaction with the interventions provided. Findings also varied across studies. Similar interventions did not necessarily yield similar outcomes. As noted in previous reviews, the intervention effects were less prominent in many studies and even contradictory across certain studies. One plausible reason might be the fact that personalized risk information was not communicated routinely during counselling even if communicating risk information was the central part of intervention. When an intervention is constructed in a way that personalized risk information can be delivered to the patient effectively, the intervention effects may increase consistently.

Two of twenty five (8%) studies followed up on the actual behaviour change. More studies evaluated the intervention effects on the intention related to health behaviour but only one of them followed up on the actual behaviour change. Therefore, it is not clear if the intention can be a reliable proxy for behaviour change. Although longer term follow-up can be a challenge, more evaluation is needed to better understand the effects of various genetic counselling interventions on the actual behaviour outcome.

The studies investigated in this review show that a large amount of information is communicated with patients during limited counselling time. Also, the study findings suggest that any formats of decision aids can benefit both counsellors and counselees in terms of time saving, streamlining the counselling process by providing readily available comprehensive information. Regardless of its format, however, the studies that used decision aids commonly showed increased knowledge, decreased decision conflicts, and increased satisfaction with counselling interventions. This implies that decision aids could serve as an essential tool in genetic counselling.

However, interventions that incorporated information technologies (computer programs, and video/audio tapes) were not necessarily more effective than their controls in all outcome measures. Although computer programs are able to support the customization of information based on individual's needs, two studies implemented the tailoring functionality in their decision aids. Studies shows that utilized decision aids provide canned information to patients. It is clear that information technologies can provide additional benefits by supporting information tailoring and allowing users to take an active role in information seeking and decision making. Although intervention effect of using a computerized decision aid has not been proved widely, a computerized tool has potential to improve outcomes of genetic counselling because it provides a systematic way to customize risk and its mitigation information according to saliency of a patient. Such computerized decision aids can also present various educational topics such as risk level, disease related knowledge, family heredity, genetic testing, and screening options according to literacy of a patient, incorporating various presentation formats such as graphics and numbers.

Conclusions

The primary objective of this review was to describe the today's need and essentiality of genetic counselling in India and to also describe various methods employed to improve patient outcomes including health behaviours, psychological well-being, and enhanced decision makings by genetic counselling and their effects. It is stated that there was a need for genetic counsellors to be utilised to provide care because the number of patients seeking genetic healthcare was growing rapidly and the numbers of available medical geneticists could not cope with the demand. the increased demand for genetic counsellors was also related to increase in the

complexity of cases and the number of laboratory test that were available, for which informed consent was necessary. Related to this point, Kromberg et al suggested that the role of the genetic counsellor would expand further, as pre and post-test counselling was essential to accompany the increasing number of tests available, particularly for pre-symptomatic tests. It was claimed that genetic counsellors had more available clinical time than medical geneticists and consultations with genetic counsellors were therefore less pressured. . Powell et al stated that the skills of the genetic counsellor were useful in public health settings, the control of genetic diseases/chromosomal disorders should be based on an integrated and comprehensive strategy combining best possible treatment and prevention through community education, population screening, genetic counselling and the availability of early diagnosis. Congenital and hereditary genetic diseases are becoming a significant health burden in India and hence there is a need for adequate and effective genetic testing and counselling services. Factors contributing to high prevalence of Genetic Diseases including consanguineous marriages, high birth rate, improved diagnostic facilities and a lack of expertise in genetic counselling. Nevertheless, it is crucial to prevent the birth of a child with genetic disorder thus reducing the risk. The importance of genetic counselling is increasing with the advancement in the field of genetics. The genetic counselling can help families to cope with emotional, psychological and medical consequences of genetic diseases. There are insufficient data currently available on the epidemiology of genetic disorders, the demand for genetic services and the quality, use and outcomes of genetic services in India. The efficient registries, databases and continued investment in genetic research are key to successful public health interventions. A critical mass of trained genetic counsellor who have understanding of the ethical issues and its appropriate handling with the required sensitivity is needed in India. It has been found that the principal obstacles to the effective use of genetic counselling are emotional conflicts, and lack of knowledge of genetics and biology. Trained counsellors are expected to provide the service in the genetic clinics. Genetic counsellors relay important genetic and reproductive information to families at risk and to the public, they often play an important role in the way the relevant ethical issues are understood and acted upon.

The methods and outcome variables evaluated varied across studies. We found that no single method was consistently reported bringing positive outcomes, partly due to the relatively small scale of the review. Various risk communication methods should be developed and outcomes of each method are measured in randomized clinical trial studies. As more such experimental studies accumulate in this domain, a more comprehensive review needs to follow in the future.

Since genetics and genomics knowledge are influenced in health care, demand for genetic counselling has increased. During genetic counselling sessions, vast amount of information is communicated between a counsellor and a counselee. After or before genetic counselling, counselees and their families may feel comfortable sharing concerns and questions with nurses who are more familiar with them than other healthcare providers. Effective communication of the information on risk levels and potential benefits of preventive measures to individuals and their family members is one key element of realizing the benefits of genetic counselling. Genetic counsellors also provide supportive counselling to individuals/families with sensitivity to ethnic and cultural diversity and they address potential ethical issues. Genetic counsellors serve as educators and resource people for other healthcare professionals and for the general public. Increasingly, genetic counsellors are working in non-traditional roles within both public and private health related institutions. The unique skills and roles of genetic counsellors will become even more paramount, and genetic counselling will evolve in ways that preserve the central tenets of values-based decision making for patients while also promoting patient health outcomes. Genetic counsellors are trained in patient education and will continue to find roles in developing interactive educational content across many of these venues. I encourage research on the effectiveness of these approaches, and clinicians may need to have multiple educational approaches available to address the varied learning styles of patients.

This role will become increasingly relevant for all genetic counsellors, whether they work directly with patients or not, and our training and continuing education processes will need to ensure that all genetic counsellors are proficient in variant interpretation and understand the laboratory and bioinformatics processes.

Conflict of Interest: the authors declare no conflict of interest.

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