International Society of Nurses in Genetics

Position Statement:

Informed Decision-Making and Consent Related to Genetic Testing (Clinical and Research): The Role of Nursing

Brief Statement of Need/Importance

Genetic and genomic technology, such as molecular genetic testing and multi-gene panels, can now be integrated across the healthcare continuum, including risk assessment, screening, diagnosis, and precision medicine. Benefits of genetic testing include improved risk identification, individualized screening and risk-reduction. Consumers of genetic technologies may also value the psychological and social benefit of knowing their genetic status as well as appreciate the potential societal benefits of future genomic advancements. Potential adverse effects of clinical or research-based genetic testing include: psychosocial distress, altered family functioning, incidental findings, misunderstanding of meaning of the results, discrimination, and unnecessary healthcare resource use. Nurses have a central role in assessing capacity and providing sufficient and accurate information and support to clients in the multiphase process of informed consent. With knowledge of both genetics and informed consent practices, nurses can advocate for, educate, counsel and support clients during their decision-making process.

It is the Position of ISONG that nurses be responsible for:

- Establishing pre-consultation/counseling rapport with clients considering the complexity of the genetic testing process and the need for trust between service providers and clients.

- Outlining the counseling process and the possibility of physical examination, thereby addressing concerns that clients may have towards the nature and conduct of the testing.

- Assessing status/criteria of the visit/referral i.e. whether the client has a genetic condition or is concerned about the possibility of being a carrier.

- Gathering of patient-family pedigree information and identifying other necessary investigative documents such as previously performed tests.

- Alerting clients before genetic testing of their right to make an informed decision.

- Advocating for autonomy, comprehension, privacy, security and confidentiality in the informed decision-making process (U.S. Department of Health & Human Services, Office for Human Research Protections, 2016; Council for International Organizations of Medical Sciences [CIOMS] & World Health Organization [WHO0, 2016).

- Ensuring that the informed decision-making process involves discussion of benefits and risks and if possible, time for reflection (U.S. Department of Health & Human Services, Office for Human Research Protections, 2016).

- Being aware of the clinical and personal utility of genetic testing, such as positive predictive value, penetrance rates, background populations and affected percentages and advising clients of the meaning of the testing and results

- Advising clients on the difference between research versus clinical use of genetic testing, return of results, clinical utility and defining the status of a specific test for that individual.

- Integrating into their practice the guidelines for practice (e.g. privacy and confidentiality, truth telling and disclosure, and non-discrimination) identified by national nursing organizations within their own country, such as the American Nurses Association and British Nursing association, and international organizations, such as the International Council of Nurses.

- Augmenting the informed decision-making process by assisting clients in the context of clients' specific circumstances of genetic literacy, family, culture, and community life.

- Acquiring appropriate education in preparation for providing genetic services that includes knowledge of the implications and complexities of genetic testing and research, ability to interpret results, and knowledge of the ethical, legal, social, cultural and psychological implications of genetic testing and research.

- Being aware of genetic health professionals and services with whom they can collaborate to maximize the ability of clients to make an informed decision.

- Ensuring that the informed decision-making process for genetic research includes possible implication (i.e. future unknown use to allow potential study participants to agree to researchers using their identifiable genetic information or bio specimens and related data, originally obtained for other purposes, including clinical care or genetic testing, for future, unknown research studies with unknown benefits and risks). Also making clients aware of the possible timeframes that their identifiable information will be stored and the associated storage sites (U.S. Department of Health & Human Services, Office for Human Research Protections, 2016).

- Being aware of national, governmental, and institutional regulations or guidelines for the ethical conduct of genetic testing and genetic research.

- Educating clients to the possible implications that personal test results may have on family members, including the possibly that knowledge of the diagnosis of a genetic condition could affect family members in terms of disclosure prior to applying for health insurance (U.S. Department of Health & Human Services, 2009; U.S. Department of Health & Human Services, 2015).

Summary

ISONG supports a collaborative process of genetic testing with an emphasis on the informed decision-making authority of clients to choose to accept or to reject testing. Pivotal to accomplishing this process is a dialogue between clients and the providers in a joint endeavor to facilitate informed decision-making through open discussion and an honest exchange of relevant information at the level of language comprehensible and genomic literacy of clients. The dialogue includes encouraging clients to seek information and identify concerns before undergoing genetic testing. The informed consent process can be universally utilized to assist clients contemplating any type of genetic testing and to ascertain whether essential information is understood and is part of the decision-making process. This position statement applies to the use of clinical and research-based genetic testing within the healthcare context. Direct to consumer and other forms of genetic testing are beyond the intended scope of this statement.

References

Council for International Organizations of Medical Sciences (CIOMS) & World Health Organization (WHO, 2016). International ethical guidelines for health-related research involving humans. Retrieved from https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

U.S. Department of Health & Human Services. (2009, December 24). Affordable Care Act. Retrieved from https://www.hhs.gov/sites/default/files/patient-protection.pdf

U.S. Department of Health & Human Services. (2015, April 15). The HIPAA Privacy Rule. Retrieved from https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

U.S. Department of Health & Human Services, Office for Human Research Protections. (2016, March 15). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Original position statement prepared by the Ethics and Public Policy Committee and approved by the ISONG Board on September 30, 2000. Revised April 2005, August 2011.
Revised 2018 by Lisa Aiello-Laws, Jennifer Sanner, Caroline Benjamin, Simbarashe Kamba and Laura Beamer
Approved by ISONG Board December 6, 2018.