

Nano Clinical Challenges : Policy options

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ABSTRACT

Nanomedicine will challenge established norms and practices in the physician-patient relationship and resultantly in the clinical setting. Nanotechnology initiatives are facilitating the development of new tools that enable genomics. The incremental shift from micro to nano is indicative of the direction of development of many of these innovations. A variety of forms of nanotechnology diagnostics allowing for increased sensitivity and accuracy will pave the way for extraordinary advances in medical care. For instance, emerging nano-enabled technologies aim to instantaneously present multiple and comprehensive results. As such, it is important for us to consider the policy challenges such diagnostics create in the clinical setting. The potential challenges encountered could arguably affect the process of commercialization. In describing the technology, legal issues such as consent and confidentiality are considered.

Keywords : clinical, chip , physician, commercialization

1 INTRODUCTION

Particular to this discussion, are “lab on a chip” technologies, specifically those that utilize nanotechnology. One application of nanotechnology currently utilized at the University of Alberta is in the form of a chip that will eventually allow multiple tests per chip, giving instantaneous, standardized results. Such chips under development for use in a clinical setting have been described as “fast, accurate, sensitive, inexpensive, portable, Internet-enabled and easy-to-use”[1]. Similar to the advances in biotechnology, these nanotech innovations could be deemed “transformative” in methods of “prevention, detection and treatment of disease and disability”[2].

Important to consider, are the policy challenges such diagnostics may create in the clinical setting. A key premise for policy change in the clinical setting is the instantaneous and comprehensive nature of the results. Due to these improvements, one can hypothesize that previous challenges in the clinic will promise to continue in an amplified form. Understandably, legal and ethical issues already present in genetic testing are now magnified via aforementioned nano-enabled technologies.

In forming a framework for consideration of these issues, this paper gives a brief overview of some of the imminent policy challenges. Throughout the discussion it becomes obvious that the pairing of nanotechnology and genetics will create notable shifts and broad consideration of present policies. There are also a number of ethical and social concerns associated with the availability of genetic information that persist in this nano scenario but are not the focus of this discussion. Thus in examining the pertinent and imminent issues relative to technology and the law, one should surmise how these scenarios may play out in future litigation. Such examinations will give strength to campaigns for productive policy change.

2 CONSENT

The Supreme Court Case of *Reibl v Hughes* [3] remains an important decision that deemed the standard of disclosure as being information that the “reasonable patient” would want to know and adopted a modified objective test of causation, (“would a reasonable person in the plaintiff’s position have declined (or delayed) the treatment if properly informed?”[4] The court in *Riebl v Hughes* termed the information that must be conveyed as any “material, special, or unusual risk”[5]. The duty to disclose has become more onerous than in *Reibl v Hughes*[6]. It includes any information that a reasonable person in the patients position would want to know.

Key to this discussion is the type of information that will be deemed material. How will a physician determine what is material information in the case of an instantaneous test, garnering uncertain, unknown, and comprehensive results? With the instantaneous results that nanotechnology can produce, how do doctors properly and immediately convey the risks and the results while adhering to all the ethical and legal responsibilities that they have as a physician? Issues that have been noted include which tests would require counseling and whether patients would feel increased pressure to get the test because of the speed and accessibility[7]. If time and effort must go into an adequate consent process, it is questionable how adequate consent will be achieved in a short doctor’s visit, usually a matter of minutes given the potential of such testing.

One aspect of the consent process that warrants consideration is causation. In determining causation, one must consider the modified objective test. As per recent informed consent cases, the physician must consider if a reasonable person would “decline or delay” the proposed treatment if provided with all material information (including risks). As has been illustrated before, many genetic tests convey different types of information. Much of the past debate about consent in the context of genetic testing dealt with tests where there was a delay between testing and results. Previously results took time and laboratory results could take weeks before they were conveyed to the doctor. Also the test often took place at a specific genetic clinic (or research facility). This allowed for the implementation of specific “genetic” consent procedures including genetic counseling.

It is arguable that a reasonable person would absolutely decline or delay, given the technical complexity of a multiplexing, instantaneous test. Seemingly, if properly informed a reasonable patient should be able to comprehend the seriousness of the test they are about to undertake. Resultantly, at a minimum the reasonable patient would always delay if: (i) properly informed of the vast amount of complex information the test could potentially reveal; as well as (ii) the radiating effects that this instantaneous test could create. There are a variety of potential effects; for instance, in such testing nanotechnology could “custom tailor” treatments for cancer, while testing could also pinpoint individuals as patients by identifying a “pre-existing condition”[8]. The latter consideration could potentially affect insurability and employability. As such, it is important to make preliminary observations regarding the proper implementation of the causation standard in such unique circumstances. It is questionable how the traditional format will play out in such circumstances.

Resultantly, the instantaneous and comprehensive nature of results warrants a reconsideration of informed consent standards. Primarily, suggestions should be made for a mandatory genetic counseling session regardless of how quickly the test can be proposed and completed. Second to this is a reconsideration of informed consent principles. The instantaneous and probabilistic nature of these tests will not be adequately managed by current frameworks. This testing differs from diagnostic procedures that are prescribed, discussed and performed, with a delay offering ample opportunity for careful consideration, discussion and research. Similar issues are likely commonplace with respect to other diagnostic procedures that are quickly delivered. For instance, emergency rooms lend themselves to “instantaneous”, non threatening situations on a daily basis. There is an

emergency exception to consent. However, not all situations in an emergency room are life-threatening. It is commonplace to uncover an unexpected and unanticipated result based on unrelated symptoms. A logical suggestion for instantaneous procedures could be framed as the “Instantaneous Judgement” Model of Informed Consent”. This means that even though a procedure can be performed instantaneously the consent procedure may take longer.

3 DUTY TO REFER

Novel policy questions about expertise will arise in cases of duty to refer. Are doctors prepared to take on the genetic counseling themselves for tests that can produce such rapid, comprehensive results? For example, in deciphering multifactorial disease risk, the job of any genetic counselor is challenging because of the difficulty in determining if the disease is linked to contributions by genetic factors, environmental factors, or both [9].The instantaneous, comprehensive nature of such nano testing is a complex hurdle for policy makers in this area. As such, pressing challenges to be addressed in this discourse include the clarification of the acceptable level of expertise/knowledge for administering any given test. For example, the question of when a geneticist must be consulted should be clarified. Due to the complexity of results garnered through such testing, these questions are of utmost importance.

4 CONFIDENTIALITY

Increasingly important in this era of emerging technologies is how a physician views and conveys personal medical information. There are also issues regarding whether our family members are adequately protected in the upholding of confidentiality rules. In Canada the duty to warn third parties is a source of continuing debate. Novel technologies amplify the already controversial discussion. Again, the instantaneous, complex and uncertain nature of the results will affect the practices currently used to moderate such situations. As such, procedures on how these types of information are handled must be clarified. Seemingly, physicians need identifiable categories of harm or risk to aid them in classifying the cases they see. The key difference that may arise from nanotechnology is that some of the risks/harms are not known or definable. Therefore, new limits as to what exactly a physician is responsible for communicating may have to be discussed. There are many disease possibilities and the resources to handle these situations limited.

REFERENCES

5 POLICY OPTIONS

- (i) The instantaneous and comprehensive nature of clinical results warrants a reconsideration of informed consent standards - A logical suggestion for instantaneous procedures could be framed as the “Instantaneous Judgement” Model of Informed Consent”, that is, a longer consent process for a instantaneous procedure where circumstances warrant;
- (ii) A reconsideration of the causation standard in informed consent, for instance should the test be narrowed in the case of an instantaneous testing situation;
- (iii) Clarify the acceptable level of physician expertise/knowledge for any given test;
- (iv) Clarify proper circumstances in which to consult a geneticist;
- (v) Create identifiable categories of harm or risk to aid physicians in classifying the cases they see.

6 CONCLUSION

Such preliminary observations should aid in forming a dialogue regarding potential change within existing frameworks. The ramifications of positive testing, the probabilistic nature of predictions, and the sensitive nature of the information are legitimate quandaries when viewed from ethical, social and legal viewpoints. How a physician, counselor and patient view and convey information is problematic in both the case of informed consent and confidentiality given the uncertainty surrounding genetic information. Also noteworthy for further research is the use of such tests outside of a clinical testing situation. It is unfortunate to realize that these issues probably will not come to the forefront until someone litigates the issue as a result of a detrimental loss or a devastating result that was not adequately conveyed in their specific situation.

- [1]See L. Pilarski, Photonics. Microsystems for Bioscience: Progress in (20 September , 2004) Online: <<http://www.cmc.ca/news/events/mrdcan2004/highlights/highlights2004.html>> Last Accessed: January 14, 2006.
- [2]Canadian Biotechnology Advisory Committee, *Biotechnology and Health Innovation: Opportunities and Challenges* (March 2004).
- [3]Reibl v Hughes(1980), 114D.L.R.(3d) 1 (SCC)
- [4]Gerald B Robertson, “Informed Consent 20 Years Later” (2003) *Health Law Journal Special Edition* 153 at 154.
- [5]Bernard M. Dickens “Informed Consent” in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds. *Health Law & Policy* (Markham:Butterworths, May 2002) at 131.
- [6] *Supra* note 4 at 155.
- [7]Linda M. Pilarski et. al. , “Microsystems and Nanoscience for Biomedical Applications: A View to the Future” (2004)24 *Bulletin of Science Technology & Society* 40 at 43.
- [8]Bev Betkowski, “Nanotechnology sparks ethical questions” *Express News*, University of Alberta (28 November 2003).
- [9]Sheila McLean & John Kenyon Mason, *Legal & Ethical Aspects of Healthcare*, (London: Greenwich Medical) at 149.