Overcoming Barriers in the Implementation of Personalized Medicine into Clinical Practice

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KEY WORDS: personalized medicine (PM), translational medical research, decision support systems, health information technology, health economics, bioinformatics

IMAJ 2013; 15: 599–601

The overflow of scientific information has transformed the field of medicine. The new challenge for the medical system is therefore to translate the success obtained in molecular and genomic research and informatics into readily available tools that can be used in clinical practice. Physicians should be able to extract the relevant information for an individual patient during an office visit and use a decision support system to drive personalized medical care. The evolving scientific and technological innovations that enable the physician to tailor disease prediction, diagnosis and treatment to the individual patient constitute "Personalized Medicine." Turning knowledge into feasible action and implementing these abilities challenge patients, health care providers, policy makers and leaders [1,2].

This position paper is not a stand-alone manuscript and should be read and associated with the position statements regarding the assessment of PM technologies, their relation with and effect on health economy, and bioethical and legal aspects – all presented at the Israel National Institute for Health Policy Research international workshop held in September 2012.

PM technologies available for use should have undergone rigorous scientific evaluation to assess their proposed use, validity and reliability. Professionals in law, backed by ethical standards, should have given thought and generated limitations and barriers, to the best of their ability, so that society can incorporate these advancements. The economic market, either freely or after intervention, should be able to cope, and pathways to market failure should have been foreseen and blocked [3]. For example, exploring the care-delivery barrier in oncology, Weldon et al. [4] found that poor coordination of genomic tests relative to treatment decisions concomitant with reimbursement-related disincentives were the two major obstacles to implementing successful treatment in breast cancer patients.

In this monograph we describe the barriers to implementing personalized medicine into clinical practice and we propose a road map to guide the journey ahead.

KNOWLEDGE GAP OF PROFESSIONALS

PM promises to turn cutting edge knowledge into clinical reality. However, there is a knowledge barrier, namely, current practicing physicians have inadequate cutting edge knowledge. Most medical and surgical practitioners begin their clinical career in their third decade of life and practice for 30 to 40 years until retirement. Despite requirements for credited continuous medical education, this is not the case in all countries, Israel for example. Furthermore, CME most often provide updates in clinical practice and guidelines and less often disseminates basic science knowledge. In order to introduce PM technologies into clinical use and allow physicians and patients the opportunity to communicate and make informed decisions, knowledge needs to be disseminated to both practicing and training residents, medical students and patient communities [4]. One option raised was that use of PM technologies be limited only to specifically trained professionals, perhaps only in certain disciplines (e.g., genetic counselors, oncologists). However, this would limit the widespread availability of PM and, most importantly, is not expected to be realistic as more and more opportunities for PM in various medical and surgical fields become available.

RECOMMENDATIONS

- Introducing, updating and training practicing physicians regarding PM

PM = personalized medicine

CME = continuous medical education

- Medical schools should provide the necessary tools for medical graduates
- A disease-oriented knowledge and decision support system should be developed and updated with reliable data and practical recommendations, including financial considerations.

AVAILABILITY OF GENOMICS, PHARMCOGENETICS AND OTHER "-OMICS" TESTS

Drawing associations between clinical medicine, genetics and molecular mechanisms, pharmacogenomics, and metabolic profiling holds the promise of guiding therapy based on a multidimensional appreciation of disease pathogenesis and opportunities to intervene [5]. The choice of therapeutics also has the potential to be personalized using pharmacogenetics, acknowledging that patients react, respond, and metabolize medications in a varying and hopefully predictable manner. The access to and availability of all relevant tests should be kept in mind, and the concept of personalized medicine should not be limited to genetic profiling.

RECOMMENDATIONS

- Professional collaborations should convene to update standard practices and promote the use of all valid and available technology to improve our ability to tailor care to patient needs
- Active care should allow the myriad of technologies, once proven efficient, to enter the health care market
- The repository of 'approved' tests should be established and maintained according to established and transparent protocols.

ETHICAL CHALLENGES AND USE OF GENOMIC DATA

The availability of expensive technologies is always a public health issue of varying significance, depending on the characteristics of the cause of disease and the potential benefit that novel technologies have to offer. Direct-to-consumer advertising and services could lead to inadequate use of PM capabilities [6] and patient over-enthusiasm, and the potential disappointments could eventually direct public opinion away from the merits PM can indeed offer [7-9]. Genetic data repositories have evoked fears of data leaks, mainly to insurance companies [10,11]. Additionally, advancements in molecular technologies and reproduction science might pave the way for use of genetic material for ethically questionable purposes, similar to research in asexual mammalian reproduction [12]. These, and other concerns, limited only by the extent and breadth of human imagination, require that data and tissue be collected, stored and available only to approved people/organizations/institutions, be used for approved purposes, and not serve as commodities [13]. In order to optimize PM usage at the point of care, integrating genomic data into electronic health records and clinical decision systems is needed [14]. Indeed, the eMERGE network program is aiming toward this goal [15].

RECOMMENDATIONS

- Regulatory directives and legislation should define the appropriate use of human material and genetic information, and a licensing mechanism for such services should be offered
- Governing bodies should be wary of threats to the ethical and moral societal frameworks, and appropriate legislation or public committees should be encouraged to maintain social and moral security
- Rules should be defined for integrating "-Omics" data in electronic health records and decision support systems.

DATA DISPERSION, LACK OF COOPERATION AND SUBOPTIMAL ACHIEVEMENTS

Although current knowledge of the genomic framework, which shapes life, sickness and death, is greater today than it ever was, recent genomic deciphering has only revealed the vast complexity of the biological systems. There is increasing demand for more research in order to appreciate these endless actions and interactions [2]. In contrast to the fear of concentrated data-holding and control, another problem is that there is too much to know, and in the academic competitive arena sharing and mutual cooperation are not common enough [4,16,17].

RECOMMENDATIONS

- Establish a national bio-repository and databank
- Determine rules for shared access of bio-repository and databank
- Create financial incentives for data sharing
- Support collaborative national scientific network for analyzing, integrating and updating molecular and "Omics" data to be integrated in the electronic health records.

PM IS ALWAYS EVOLVING

We believe that integrating PM into our daily patient care practice holds significant promise for enhancing health care quality while reducing its cost. The recommendations of the convened panel reflect our current state of knowledge and hopes regarding the future. In order to maintain consistency and follow-up on previous thoughts and recommendations, a steering committee should convene on a regular basis.

While PM holds much promise, implementation could prove challenging with regard to differential reimbursement schemes, the expected need for rapid and reliable genomic information on acutely ill patients in hospital settings, and

the need for a framework to enable consistent and coherent communication of information between community health services and hospitals.

RECOMMENDATIONS

- The Ministry of Health should appoint a national multidisciplinary steering committee comprising scientists, clinicians, bioinformatics specialists and public health experts [3,18,19]
- The steering committee will provide recommendations to the Ministry of Health and relevant partners in order to:
  - define national priorities
  - assess national advances
  - conceive and assess ongoing projects
  - identify neglected areas of importance and direct relevant attention to them
  - coordinate and monitor the various PM implementation processes.

ADVANTAGES OF THE ISRAELI HEALTH CARE SERVICE STRUCTURE AND POPULATION

Panel members from various backgrounds and from abroad all expressed their enthusiasm with regard to the Israeli health care market and system, which is small enough to enable local cooperation and large enough for other health care systems to look upon and learn from [16]. The country's ability to implement new systemic solutions involving personalized approaches to health care and then study their outcomes for patients and for the health system, including costs, can be valuable for local decision-making as well as in the international arena where such concentrated efforts seldom materialize to cover and serve entire populations and health markets.

RECOMMENDATIONS

- Attention should focus on taking advantage of the unique features of the Israeli health care system (full coverage of all residents, few health care providers). Information already existing and being documented should be concentrated and shared to promote proof-of-concept studies and assess throughput and outcomes that PM generates
- Incorporation of PM capabilities and services into the health services market by the regulating offices should account for the variable nature of medical practice (community, hospital, long-term care facilities, prenatal settings, disaster medicine) and allocate relevant resources for optimal use of the available technologies.

CONCLUSIONS

Integrating and implementing personalized medicine in our daily patient care will not be easy and requires knowledge and multilayer efforts from health system stakeholders, industry, science, health care givers, and patients. However, we believe that implementing personalized medicine into our daily patient care practice holds significant promise for enhancing health care quality while reducing its cost.

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