InnoVationInfo

Scholarly Journal of Surgery

Scholarly J Surg 2018

Volume 1: 1

Beyond Personalized, Precision and Translational Medicine- Redesigning Health Care Services to Restore Value and Meaning for Patients and Providers

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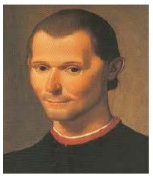

"There is nothing more difficult, than to take the lead in the introduction of a new order of things. For the reformer has enemies in all those who profit by the old order, and only lukewarm defenders in all those who would profit by the new order. This indifference arises partly from fear of their adversaries, and partly from the incredulity of mankind, who do not truly believe in anything new until they have had actual experience of it."

Niccol Machiavelli

Healthcare delivery is transitioning away from a volume-based reimbursement model to an efficiency-and-quality-oriented model. The balance between high quality, evidence-based and value-based care is posing a challenge for healthcare systems. Reducing the risk of patient harm during the process of healthcare delivery is at the forefront of policy and practice. The present health care model is in a political, financial and social crisis. Personalized and Precision Medicine (PPM) offers an opportunity to reframe and reassess the control over patient morbidity, mortality and disabling outcome rates as well as significantly optimize the cost and efficacy of treatment for those who have fallen ill. PPM is a new model of healthcare services that illustrates how we can apply new sets of thinking for the population, community, and individual citizen.

Implementing a PPM framework into the daily practice of a complex healthcare care delivery system requires a new strategy based upon subclinical and/or predictive recognition of biomarkers for the hidden imbalances and defects long before the illness manifests clinically. This prevention strategy offers an opportunity to implement preventive, prophylactic, therapeutic and rehabilitative measures to help drive care improvement and patient-centered outcomes while the reducing costs of care.

PPM can assist in forecasting, predicting and ultimately preventing diseases. PPM is rooted in the new sciences generated by the achievements of Systems Biology and Translational Medicine (TraMed) (Figure 1-3). PPM integrates and consolidates the platforms of OMICS

Article Information

Article Type: Short Communication

Article Number: SJS108

Received Date: 16 May, 2018

Accepted Date: 14 June, 2018

Published Date: 21 June, 2018

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Citation: Suchkov S, Marshall T, Antonova E, Barach P, Studneva M, et al (2018) Beyond Personalized, Precision and Translational Medicine- Redesigning Health Care Services to Restore Value and Meaning for Patients and Providers. J Surg. Vol: 1, Issu: 1 (44-46).

(basic) technologies and bioinformatics and utilizes in real-world artificial intelligence (AI).

The key objectives of PPM are:

1. Screening for subclinical imbalances and genetic defects with a pre-selection of suitable targets to secure the next steps of an applied PPM protocol, i.e., prevention, therapy and rehabilitation;
2. Repair of the imbalances and defects to restore the function and to prevent the clinical illness manifestation and/or to get defects and imbalances repaired.

For instance, genetic testing (including canonical diagnostic testing, gene carrier testing, prenatal testing, preimplantation testing, pre-symptomatic and predictive testing, etc.,) can provide information about a person's genes, their products, and chromosomes. Moreover, a subset of mutations may also be targeted for potential drugs, i.e., be potential biomarkers and targets for future therapeutic development. DNA and RNA sequencing technologies now allow whole-genome, exome, transcriptome and epigenome sequencing at rates that are dramatically faster, and much more productive and cheaper than traditional methods. Meanwhile, having access to genomic information will become increasingly important as healthcare providers become progressively receptive to incorporating genomics into their daily clinical practice.

Translational Innovations today are accompanied by the development of predominantly genomic-and proteomic-based technologies, in general, and diagnostics, in particular. Meanwhile, PPM will require the integration of clinical information, stable and dynamic genomics, and molecular phenotyping. (Figure 4)

Bioinformatics and its applications and tools are in huge demand by applying mathematical modeling to maintain unified biobanks and databanks necessary for personal health monitoring based on principles of genotyping and phenotyping.

Who will patients (and persons-at-risk) and their healthcare providers trust to store and interpret the data?: Healthcare information technology offers potential solutions to address these barriers since the patient or person-at-risk is a data carrier, while learning about possible risks of a disease, and physicians can reasonably select a kind of preventive and personalized protocol based on the predictive assays. (Figure 5)

It is becoming clear that further development of 1) molecular technologies; 2) risk prediction algorithms and 3) clinical decision support (CDS) are needed. PPM is an evolving field in which physicians use diagnostic and predictive tests to identify specific simple and combinatorial biomarkers that help determine which medical treatments and procedures will work best for each patient or person at risk. (Figure 6)

Individuals will be under regular monitoring that will detect pathological shifts at subclinical stages. This means that society could save more than US$20,000- 40,000 per person annually. At the community level, the annual savings

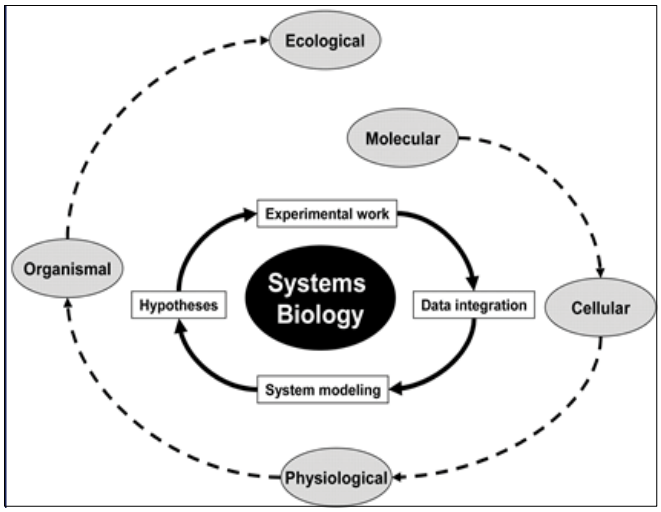

Figure 1: *Systems biology* is the computational and mathematical modeling of complex *biological systems*.

Figure 2: Translational medicine is a rapidly growing discipline in biomedical research and aims to expedite the discovery of new diagnostic tools and treatments by using a multi-disciplinary, highly collaborative, "bench-to-bedside" approach.

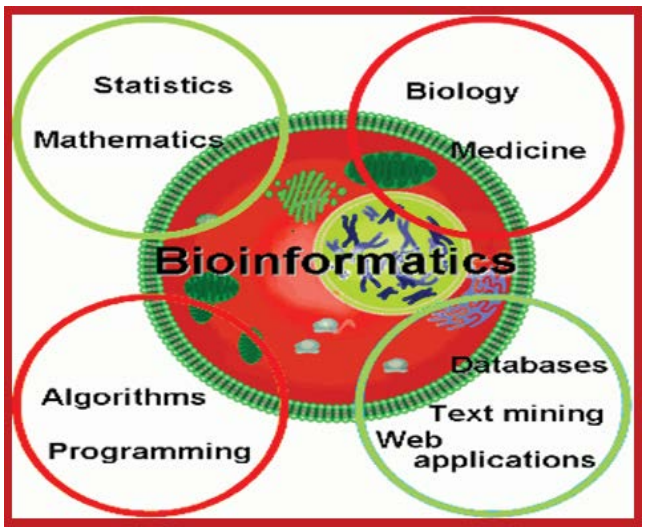

Figure 3: Bioinformatics is conceptualizing biology in terms of macromolecules (in the sense of physical-chemistry) and then applying "informatics" techniques to understand and organize the information associated with these molecules, on a large-scale.

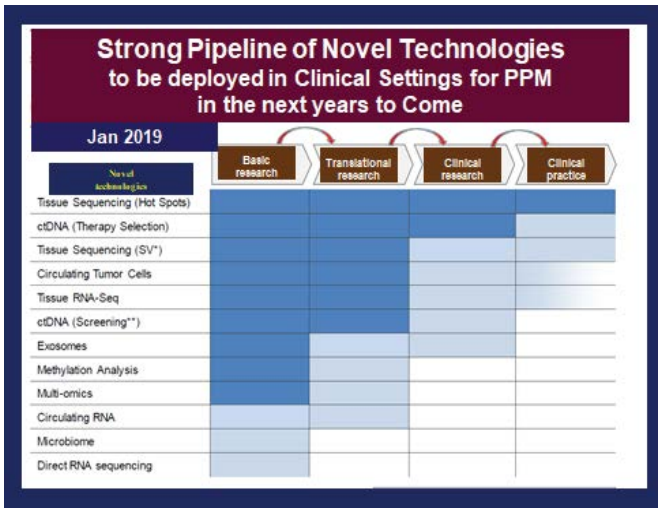

Figure 4: The promising future of new PPM technologies.

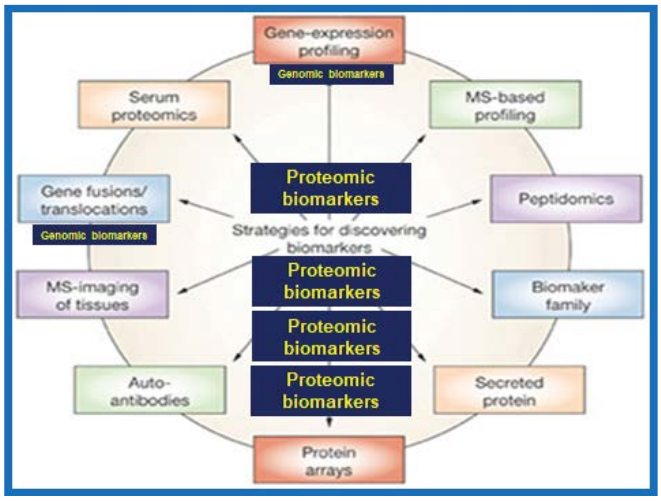

Figure 5: The wide range of proteomic biomarkers defined as "a molecule detected in body fluids or tissues that are associated with a special process (normal or abnormal), a condition or disease".

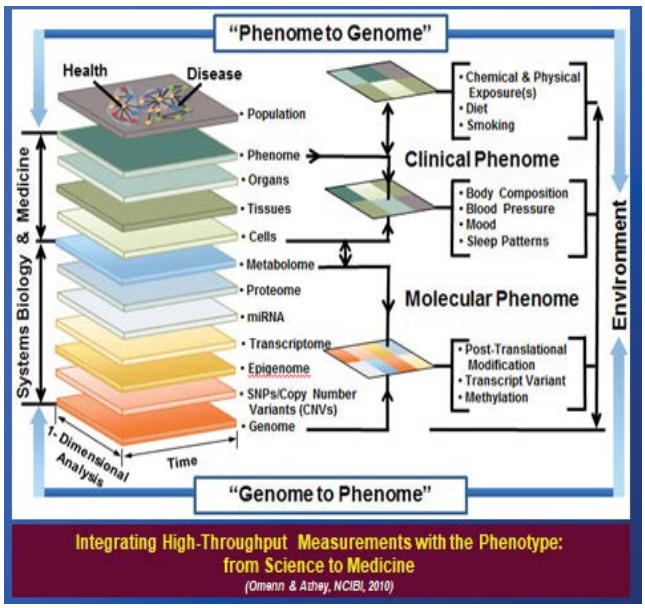

Figure 6: The journey from phenome to genome assessment.

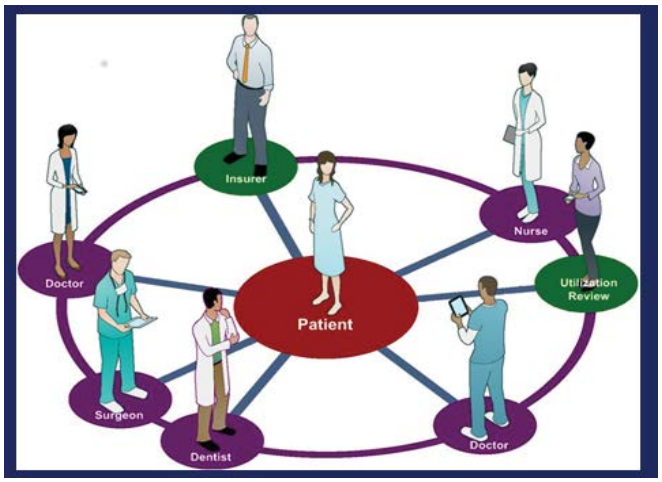

Figure 7: The future of patient care under PPM.

from each individual may vary from several thousand to several tens of thousands U.S. dollars.

All healthcare professionals will need to be educated to deliver patient-centric care (Figure 7) as members of interdisciplinary teams, emphasizing patient safety, evidence-based practice, risk management, quality improvement approaches and bioinformatics. The current model of the "physician-patient" dyad would have to be gradually displaced by a "medical advisor-healthy persons-at-risk" model. And thus the opportunities would exist at every stage of disease initiation and progression to develop a Personalized Health Plan (PHP) addressing lifestyle, risk modification and disease management, and later, Personalized Health Management & Wellness Program (PHMWP).

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