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Personalized and Precision Medicine (PPM) as a Unique Healthcare Model of the Next Step Generation to be Set Up, and to Develop and Advance the Nursery Service Marketing: The Future of Nursing Services

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You might have heard the terms "precision medicine" and "precision health" and wondered how they relate to you. A new systems approach to diseased states and wellness result in a new branch in the healthcare services, namely, *personalized* and precision medicine (PPM) (Fig. 1A-C).

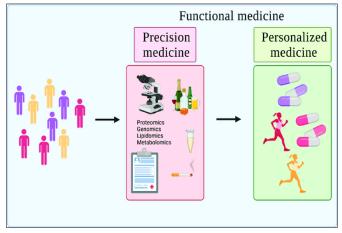


Fig. 1A. Personalized and precision medicine (PPM)

Precision medicine identifies differences in individuals, categorizing based on environmental, biological, and psychosocial factors:

Personalized medicine takes these differences and implements preventions/treatments tailored to the individual

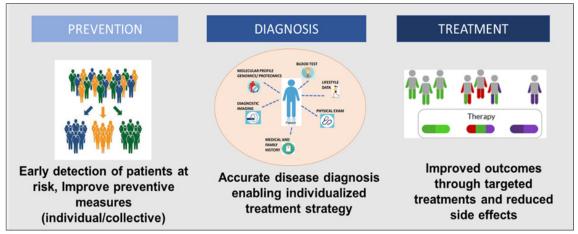


Fig. 1B. Personalized and precision medicine (PPM) through the View of Diagnostic, Preventive and Therapeutic manipulations

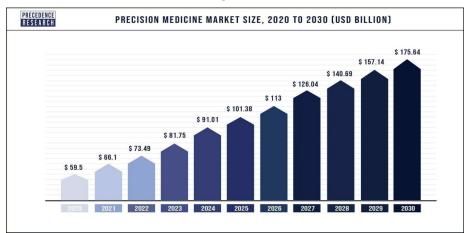


Fig. 1C. Personalized and precision medicine (PPM) through the View of the Global Worldwide Market

PPM as a Model of Healthcare Services of the Next-Step Generation is the Science and ART illustrating application of sets of the different Tools of the Model at the Population, Communities and Individuals *(Fig. 2)*.

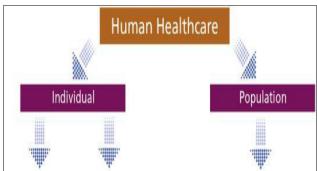


Fig 2. Individual and population-based medicine through the View of Personalized & Precision Healthcare Services

And exerting reliable control over morbidity, mortality and disabling rates as well as significantly optimizing the cost and efficacy of treatment for those who had fallen ill (*patients*) and for *persons-at-risk*.

This strategy would give a real opportunity to secure preventive, prophylactic, therapeutic and rehabilitative measures whose *personalization* could have a significantly positive influence on demographics (1-6,11,12,14,17,19,25,36,38,39,48,51,53).

PPM is a goal of healthcare, in which diagnostic and treatment decisions are informed by each person's unique clinical, basics ("OMICS") (Fig. 3)

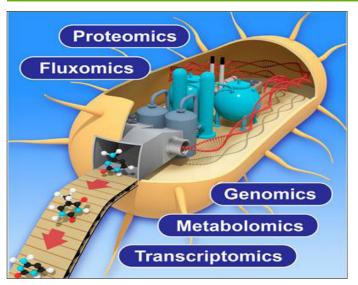


Fig 3. OMICS-technologies

And environmental (*exposomics*-related) (*Fig. 4*) information (1,2,7,8,10,16-18,20,30,31,37,49).

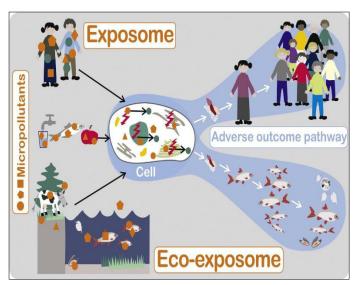


Fig 4. Microenvironment and the influence of exposomics-related factors on the population

Each decision-maker values the impact of their decision to use PPM on their own budget and well-being, which may not necessarily be optimal for society as a whole. To really understand PPM, we would have to understand the various fields of translational applications that provide the tools to exploit and practice PPM, and *genomics*-related tools, in particular (1,2,7,8,10,16,17,20,30,33,41,44,46,47,55,58)!

Having access to the deepest genomic information via unique genomic technologies and genomic testing and profiling, will become increasingly important as physicians are progressively receptive to incorporating genomics into clinical practice.

Meanwhile, *phenome (Fig 5)* is considered to be a bridge from genome, proteome and metabolome, which are two important elements of phenome.

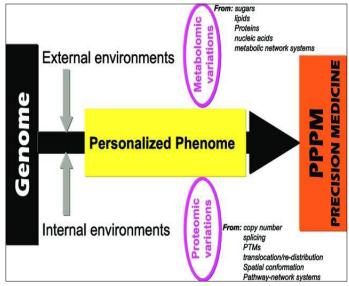


Fig 5. Phenome is a bridge from genome to PPM, and proteome and metabolome are two important elements of phenome

Proteomic variations are much more complicated than genomic and transcriptomic variations. Proteomic variations are the final form of genomic and transcriptomic variations. Proteins and metabolites are two main elements in the phenome. Phenome must be elucidated for real PPM. Clarification of proteomic and metabolomic variations will benefit the realization of the real PPM

PPM is understood as a medical approach in which patients and/or persons-at-risk are stratified based on their disease subtype, risk, prognosis, or treatment response using specialized diagnostic, predictive, prognostic and monitoring tests. The key idea is to base medical decisions on individual patient characteristics, including molecular and behavioral biomarkers (33,44), rather than on population averages.

PPM aims to empower clinicians to predict the most appropriate course of action for patients with complex (multifactorial) diseases like cancer, diabetes, cardiomyopathy, etc. With a progressive interpretation of the clinical, molecular, and genomic factors at play in diseases, more effective and PPM-driven treatments are anticipated for many disorders. Understanding patient's metabolomics and genetic make-up in conjunction with clinical data will significantly lead to determining predisposition, diagnostic, prognostic, and predictive biomarkers and paths ultimately providing optimal and personalized care for diverse, and targeted chronic and acute diseases. In clinical settings, we need to timely model clinical and multi-omics data to find statistical patterns across millions of features to identify underlying biologic pathways, modifiable risk factors, and actionable information that support early detection and prevention of complex disorders, and development of new therapies for better patient care.

The goal, today, is to facilitate implementation of mainstream PPM-related resources to improve the traditional symptom-driven practice of medicine, and allow earlier interventions using predictive diagnostics and tailoring better-personalized treatments.

PPM is deeply connected to and dependent on data science. While during recent years there has been a lot of enthusiasm about the potential of 'big data', there exist only few examples that impact current clinical practice. The lack of impact on clinical practice can largely be attributed to insufficient performance of predictive models, difficulties to interpret complex model predictions, and lack of validation via prospective clinical trials that demonstrate a clear benefit compared to the standard of care (1,2,4,9,15,19,25,28,48).

In the era of growing data volumes and ever shrinking costs for data generation, storage, and computation, PPM comes with high promises, which can only be realized with the help of advanced algorithms from data science, particularly artificial intelligence (AI) and machine learning (ML). Modern algorithms have the potential of integrating multiscale, multi-modal, and longitudinal patient data to make relatively accurate predictions, which, in some examples, may even exceed human performance. Large commercial players that are now entering the field of medicine underline the potential that is widely seen for computational solutions.

Let us stress that in the above-mentioned context, diagnostic, prognostic and predictive information technologies are used in the field of PPM and the relations between this use and how patients, persons-at-risk and disease are perceived. This might be examined in a qualitative case study of a PPMdriven cancer clinical trial, where oncologists made clinical decisions for each patient based on drug matchings and efficacy predictions produced by bioinformatic technologies and algorithms. We focus on PPM-related practice itself, as a postgenomic phenomenon, rather than on epistemic, ethical and institutional critiques. So, PPM aims to process molecular, clinical, environmental and social data into individually tailored decisions. In this case, however, the engagement of clinicians with data and digital artefacts that processed multiple information sources resulted in treatment choices that were paradoxically both immutable and uncertain. In contrast to the situatedness of the body in post-genomics, this practice subverted the PPM-driven approach while decontextualizing both cancer and patients.

Who will patients (or persons-at-risk) and their physicians trust to store and interpret the clinical and other multilevel data collected, harvested and mined to be used further for managing the personality? Health care IT does offer a potential solution to overcome those barriers (1,4,9,19,24,28,40,43,48) (Fig. 6A,B).



Fig 6A. Medical IT systems, tools and devices

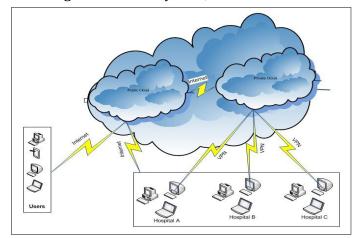


Fig 6b. Cloudy technologies

As a result, a patient or a person-at-risk becomes a data carrier (Fig. 7).

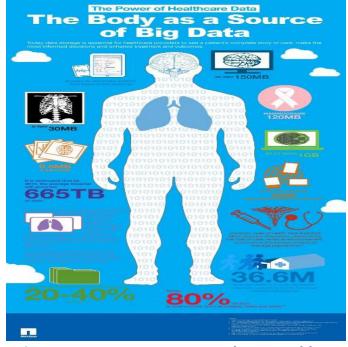


Fig 7. Human Big Data as Data routinely generated from patient records, research labs, pharmaceutical companies, and health insurance organizations

Human Big Data are now used to improve all Healthcare components. Prevention, diagnostics, treatment, and health system efficiency have all been revolutionized by big data's smart use.

The availability of massive amounts of data and computational methods associated with the Big Data paradigm has brought hope that such systems may soon be available in routine clinical practices, which is not the case today. Because diagnosis is essentially a classification task, we address the IT techniques with supervised and unsupervised classification, making a critical assessment of the progress already made in the medical field and the prospects for the near future.

Improved patient (or persons-at-risk) outcomes with the application of the biomarker tests must consider not only increased survival or quality of life, but also improved clinical decision support (CDS) & making leading to the avoidance of unnecessary therapy or toxicity captured within the rapid learning system. So, bioinformatics, artificial intelligence (AI), machine learning (ML) and biostatistics will be crucial in translating those Big Data into useful applications, leading to improved diagnosis, prediction, prognostication and treatment.

It would be extremely useful to integrate data harvesting from different databanks for applications such as prediction and personalization of further treatment to thus provide more tailored measures for the patients resulting in improved patient outcomes, reduced adverse events, and more cost effective use of the latest health care resources including diagnostic, prognostic, preventive and therapeutic (targeted) etc.

Each decision-maker values the impact of their decision to use PPM on their own budget and well-being, which may not necessarily be optimal for society as a whole. It would be extremely useful to integrate data harvesting from different databanks for applications such as prediction and personalization of further treatment to thus provide more tailored measures for the patients resulting in improved patient outcomes, reduced adverse events, and more cost effective use of the latest health care resources including diagnostic (companion ones), preventive and therapeutic (targeted molecular and cellular) etc. (1-6,11,12,51,53,55)

Putting PPM-tools in a public health perspective requires an apprehension of the current and future public health challenges. The principles of PPM and efforts to approaching the right health issues in a timely manner can be applied to population health. Doing so will, however, require a careful view and concerted effort to maintain the needs of population health at the forefront of all PPM discussions and investments.

PPM has drastically changed and is keeping on changing the landscape of healthcare (*Fig 8*).

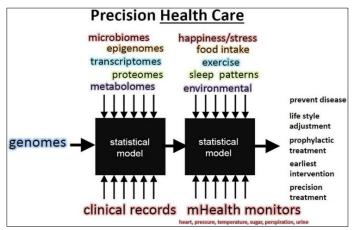


Fig 8. A biological computation view of 'The Holy Grail: Personalized & Precision Health Care'

(image by kind permission of Professor Alexander Hoffman, Institute for Quantitative and Computational Biosciences, UCLA, 2015: 17).

It would be extremely useful to integrate data harvesting from different datasets for the prediction and personalization of treatment resulting in improved patient outcomes, reduced adverse events, and more cost effective use of the latest health care resources including diagnostic, preventive and therapeutic, etc. Those advancements are also changing the scope of nursing care and practice.

The implementation of PPM requires major health systems changes, including the incorporation of IT resources to handle the data and introduce support tools for clinical use of the information. However, it also brings important implications for nursing to the forefront as nurses must have adequate preparation and knowledge of the ongoing evidence to care for patients using PPM-based strategies. As patient advocates, educators, and providers of direct care, nurses will be on the front lines of implementation of state of the science care (1-6,11,12,14,17,19,25,32, 38,39,48,51-53).

Despite the surge of interest and attention to precision health, most nurses are not well-versed in precision health or its implications for the nursing profession. Based on expert opinions, we might provide a viewpoint of precision health and the importance of engaging the nursing profession for its implementation *(Fig. 9)*.

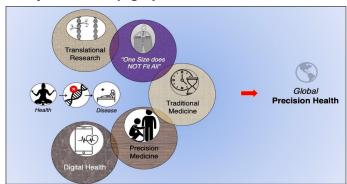


Fig 9. Global precision health

Healthcare is continuously undergoing fundamental changes, particularly with transformations in biomedical data, including genomics. In recent years, genomic sciences have served as an origin for the field of precision medicine, and the field is growing as a brighter entity known as *Precision Health*, where it accentuates on "transition from health to diseased state" rather than merely diseased state.

Precision health also involves more accurately predicting what type of care for a particular disease will work best, and in which populations of people, which is crucial to improve health outcomes for all. At the core, precision health is a model for customizing healthcare and medical decisions. Instead of a one-size-fits-all approach, it allows us to tailor treatment and prevention strategies to particular subgroups of patients by integrating information about their genes, environments, and lifestyles.

Precision health aims to prevent diseases based on the personalized genetic background that is a surrogate of the related populations' genomic structures. Precision Health aims to systemize monitoring and maintaining people's health in the first place and before getting sick by integrating big biomedical data, computational technology, and engineering.

The nursing profession is the largest sector and a significant component of PPM-driven health care delivery, which is the largest percentage of the practitioners. In PPM-driven healthcare practice, nurses perform a vital role in supporting, maintaining and improving health by coordinated treatment of patients, households, societies and populations. Nursing staff have encouraged, preserved and improved wellbeing through comprehensive assessment of OMICS-related and environmental influences, as well as social and economic factors to determine their effect on genetics in order to improve health precision. So, centering care around a patient's needs is the main task for a nurse coordinator, who is considered the core person for communication among all inter-professional care providers. Therefore, nurses, being at the frontline of provision of services across practice environments and communities, are well placed to become pioneers in providing reliable medical care.

In this context, nurses need to be prepared to assist patients in interpreting the results of consumer-based testing, and/or referring to the targeted specialists as needed. Nurses need to assess clinical risk factors; discuss and clarify patient values and priorities; provide information to enhance decision making around screenings or risk-reducing treatments; and provide support for family notification and testing as indicated.

For nursing services of the near future to come, the main challenge is the incorporation of the OMICS-technologies in training and professional practice, so that nurses can empower themselves to provide personalized care to individuals and families based on PPM-driven innovations (59).

For instance, the implications in global PPM and in personalized and precision cancer nursing care include interpretation and clinical use of novel and personalized information including genetic testing (Fig 10);

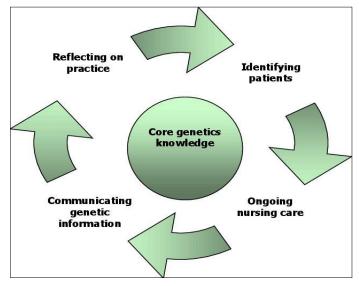


Fig 10. Applying genetics/genomics knowledge and skills in nursing practice

(This figure was uploaded from the permission of Maggie Kirk, PhD, BSc Hons, Dip N, RGN, Professor at University of South Wales, UK)

Patient advocacy and support throughout testing, anticipation of results and treatment; ongoing chronic monitoring; and support for patient decision-making. Attention must also be given to the family and ethical implications of a personalized approach to care. In particular, cancer nurses are important touchpoints in contact and communication with patients, since nurses complete comprehensive assessments, examine a patient's lifestyle, assess symptoms.

Given the nature of nursing practice in direct clinical care and in public health, nurses are ideally situated to advocate for and use genetic testing results. For example, nurses who collect and interpret personal and family health histories can identify high-risk individuals and groups who should be offered genetic screening. Collaborating with genetic services can help ensure that pretest counselling and formal risk assessments are conducted. Nurses are involved in patient and family education that can be individualized to genetic risks and administer prescribed treatments based on precision medicine. Additionally, nurses can advocate for and participate in health-system planning that includes programs related to disease prevention and health promotion based on genetic findings.

To meet the new demands for care, these advances need to be incorporated into professional nursing practice and, above all, into nursing care. In order for patients and their

families to fully benefit from the explosion of genomic knowledge, healthcare professionals, especially nurses, need to grasp the underlying principles of genomics that have been shaping all healthcare practice and care. Therefore, the necessary emphasis on the professional training of nurses based on genomics will become an important requirement as the omics sciences will become part of routine care, no longer being exclusively an area of specialization (8,10,13,20,23,27,40,43,46,50,57,58, 64,65,67).

The spotlight on genomics within health care is fueled by the shift toward precision and personalized health - whereone's genetic profile informs the risk of developing disease, recommended screening and prevention strategies, and treatment decisions. Patients and families increasingly recognize the value of understanding their genomic profile and are highly motivated to participate in genetic testing and profiling. Nurses who have foundational knowledge in genomics can support patients after they receive results (e.g., incidental findings from genome sequencing), helping them interpret the findings and make decisions (8,10,13,20,41,46).

Given the nature of nursing practice in direct clinical care and in public health, nurses are ideally situated to advocate for and use genetic testing results. For example, nurses who collect and interpret personal and family health histories can identify high-risk individuals and groups who should be offered genetic screening. Collaborating with genetic services can help ensure that pretest counselling and formal risk assessments are conducted. Nurses are involved in patient and family education that can be individualized to genetic risks and administer prescribed treatments based on PPM. Additionally, nurses can advocate for and participate in health-system planning that includes programs related to disease prevention and health promotion based on genetic findings.

In this sense, health care professionals, including medical nurses, face educational challenges related to the acquisition of competencies to perform their professional practice optimally and efficiently in this new environment. The definition of competencies for health care professionals provides a clear guide on the level of knowledge, skills, and attitudes required to adequately carry out their professional practice. In this context, this acquisition of competencies by health care professionals can be defined as a dynamic and longitudinal process by which they use knowledge, skills, attitudes, and good judgment associated with their profession to develop it effectively in all situations corresponding to their field of practice.

In the academic setting, nursing faculty have an opportunity to develop curricula that include stand-alone mandatory courses in genomic health, as well as threading genomics into the broader curriculum to ensure that students gain experience with applying this knowledge (10). Faculty who have the necessary expertise and training to develop curricula in both undergraduate and graduate nursing programs are needed (10). Faculty members can collaborate with institutional and community partners to champion clinical placements with a genetics and genomics focus, as well as create global opportunities for students to participate in research and policy development in this area (8). Additionally, inter-professional learning opportunities, such as collaborative partnerships between nursing and colleagues in the medical genetics field and genetic counsellors, can be fostered as part of clinical education. The evidence supports the need for early integration of genomics within nursing academic programs, with ongoing professional development opportunities within the workplace (8,59,60,61).

Nurses can play a pivotal role in bringing the benefits of genomics and precision and personalized health care to fruition. To optimize nurses' impact in genetics and genomics, a concerted effort to develop infrastructure that supports genomic literacy is required. Specifically, given the rapid uptake of genetics and genomics in clinical care, additional nursing knowledge and skills are required to support patients in their health-related decisions, optimize patient care and contribute to inter-professional care. Collaboration between nurses in point of care, policy, administration, education and translational research and applications - and with other health professionals - will ensure that nurses develop competencies, knowledge and clinical skills and practice in genetics and genomics (Fig. 11).

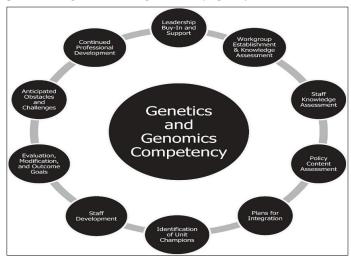


Fig 11. Method of Introducing a New (Genetics & Genomics)

Competency model into Nursing Practice

(*Reprinted with permission from* Jenkins J, Calzone K, Caskey A, Culp S, Weiner M, Badzek L. Methods of genomic competency integration in practice. J Nurs Scholarsh. 2015:47:200-210.13)

Nurses face increasing challenges and opportunities in communication, support, and advocacy for patients given the availability of advanced testing, care and treatment in PPM. Meanwhile, the current curricula for training nurses often

fail to give them the knowledge they need to deliver precision care and thus do need to understand PPM in some depth. So, nursing education and continuing education, clinical decision support, and health systems changes will be necessary to provide personalized multidisciplinary care to patients, in which nurses play a key role. And getting education and

collaboration right for PPM-driven resources could be just a first step towards a more universal involvement of nurses in precision health! (8,10,13,20,23,27,40,43,46,50,57,58,62).

Meanwhile, personalized aims and objectives exist at every stage of disease initiation and progression to develop a *Personalized Health Plan (PHP) (Fig 12A,B)*

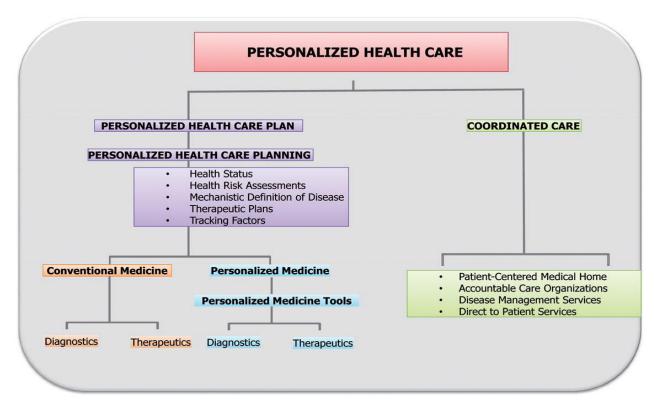


Fig 12A. Primary Care Personalized Health Plan Responsibilities

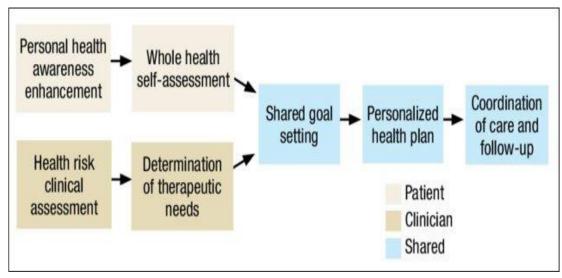


Fig 12B. Primary Care Personalized Health Plan Responsibilities

"Personalized Health Care" utilizes personalized health planning in conjunction with coordinated delivery systems to deliver personalized, predictive, preventive, and participatory care. This strategic approach to care is built on the concepts of systems biology and enables personalized medicine to be applied broadly to health care delivery

Addressing lifestyle, risk modification and disease management, and later, *Personalized Health & Wellness Management Program (PHWMaP) (Fig. 13A,B)* (14,22,38,51,53,54)



Fig 13A. Personal Health & Wellness Coaching Programs for Individuals



Fig 13B. Personal Health & Wellness Coaching Programs for Individuals

Every patient or a person-at-risk is different, they vary in age and capabilities, they suffer from different ailments, they require different treatment depending on the severity of their condition and they require different degrees of attention and explanation. We first understand the patient as a person, then understand the disease and treatment regime in depth to offer personalized care.

And a lack of medical guidelines has been identified by responders as the predominant barrier for adoption, indicating a need for the development of best practices and guidelines to support the implementation of PPM! And activating the nursing role in PPM-driven health thus enhances the provision of community health where personalized genetically oriented health campaigns can be organized and lead by highly knowledgeable nurses. This will

imply the need for revising the definition of nursing practice by nurse leaders and managers. Nursing practice therefore will be guided by a new perspective on health and wellbeing, where tasks and procedures might be altered and applied differently. Such modifications might even entail various financial enhancements for nursing staff as well as might lead to cost effective healthcare services of higher quality.

Those advancements are also changing the scope of nursing care and practice. Nurses need to assess clinical risk factors; discuss and clarify patient values and priorities; provide information to enhance decision making around screenings or risk-reducing treatments; and provide support for family notification and testing as indicated.

In reality, a new buzzword has crept into the health sciences lexicon: **PPM-based public health (Fig 14)**.

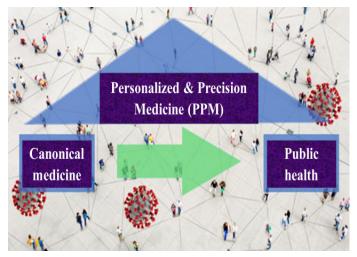


Fig 14. PPM and precision public health

PPM and precision public health are emerging fields that use genomics and other big data technologies to provide more targeted interventions at the individual and population levels. PPM can be thought of as delivering the right intervention to the right individual at the right time, while precision public health can be simply viewed as delivering the right intervention to the right population at the right time. Precision public health is deeply rooted in addressing health disparities and is "about using the best available data to target more effectively and efficiently interventions of all kinds to those most in need

The initial drive toward PPM-based public health is occurring, but much more work lies ahead to develop a robust evidentiary foundation for use. PPM and PPM-based Public Health calls for a *transdisciplinary* approach *(Fig.15)*

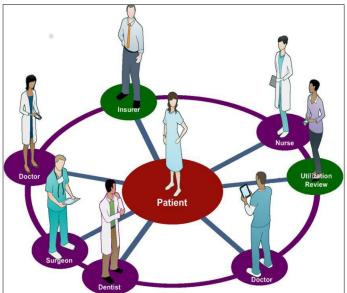


Fig 15 Key Members of the Transdisciplinary Clinical Healthcare Service Team

All healthcare professionals of the future should be educated to deliver patient-centric care as members of transdisciplinary teams

To support safe and effective deployment of the new enabling diagnostic and therapeutic technologies stressing: **not to treat but to get cured!!!**

And thus the latter would need for novel training since the society is in bad need of large-scale dissemination of novel systemic thinking and minding. And upon construction of the new educational platforms in the rational proportions, there would be not a primitive physician created but a *medical artist*, and not a canonical nurse from the deepest past but of the high quality Doctor's Assistant, to be able both to enrich flow-through medical standards with creative elements to gift for a patient a genuine hope to survive but, in turn, for a person-at-risk – a trust for being no diseased. This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM to elicit the content of the new branch (61,62).

Specific to oncology, there is an ever-increasing complexity to and utilization of genetic testing in clinical care. Nurses in oncology have witnessed increased utility of genomic analysis for individualized tumor analysis and the evolution of targeted drugs for blocking more specific biochemical pathways. Those advancements are also changing the scope of nursing care and practice, as nurses address patient implications of PPM (63,64).

Nurses need to be at the forefront of patient care with a multidisciplinary team to truly deliver PPM-based care. Nurses need to be prepared to assist patients in interpreting the results of clinical genetic testing, as well as commercially available consumer-based testing, and/or referring to genetic specialists as needed. It is likely that these activities will be in concert with a genetic counselor; however, nurses are anticipated to fill the increasing gap in services related to genetic counseling that are consistent with the scope of nursing practice. Nurses need to assess other clinical risk factors; discuss and clarify patient values and priorities; provide information to enhance decision making around screenings or risk-reducing treatments; and provide support for family notification and testing as indicated.

The implications in PPM-based cancer nursing care include interpretation and clinical use of novel and personalized information including support for patient decision-making mentioned above. Cancer nurses are important touchpoints in contact and communication with patients and even with pre-cancer persons-at-risk. They complete comprehensive assessments, examine a patient's lifestyle, assess symptoms. This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM to elicit the content of the new branch. So, nursing education and continuing education, clinical decision support, and health systems changes will be necessary to provide personalized multidisciplinary care to patients, in which nurses play a key role.

As a member of the transdisciplinary health care team, nurses must be prepared to move ahead with the advances in PPM and PPM-related services, and to facilitate their use in clinical practice. This will require nursing education, patient education, health systems changes, and the engagement of a multidisciplinary team in oncology care. The improved and personalized care provided to patients should lead to continued improvements in patient outcomes, as long as nurses and other health care professionals

Moreover, as the largest clinical body of healthcare providers, the *nursing* profession can serve as a unifying and ubiquitous presence in the ethical and safe clinical translation, dissemination of *OMICS* (presumably, *genomics*!) *(Fig 16)* advances in this new era of precision health, across the globe.



Fig 16. The Role of Nurses in Healthcare Team in Genomic Era

The implications in PPM-based nursing care include interpretation and clinical use of novel and personalized information including support for patient decision-making mentioned above. Nurses face increasing challenges and opportunities in communication, support, and advocacy for patients given the availability of advanced testing, care and treatment in PPM (66).

Meanwhile, a lack of medical guidelines has been identified by responders as the predominant barrier for adoption, indicating a need for the development of best nursing practices and guidelines to support the implementation of PPM! This is the reason for developing global scientific, clinical, social, and educational projects in the area of PPM to elicit the content of the new branch. So, nursing education and continuing education, clinical decision support, and health systems changes will be necessary to provide personalized multidisciplinary care to patients, in which nursing personnel play an important role since they are consulting, educating, and providing care to patients whose needs often needs to be individualized (personalized nursing care).

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