Editorial

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On The Verge of a Breakthrough in Pediatrics Through the View of Personalized and Precision Healthcare Services

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1. Editorial

It is now clear that standard protocols for examining pediatric patients do not provide appropriate level of medical care. An upgraded approach to reshape tomorrow's healthcare whilst doing it today, resulted in a new global trend in the healthcare services, entitled as Personalized and Precision Medicine (PPM) to be used in pediatric practice, PPM-guided pediatrics, including pediatric oncology (Figure 1 A and B) [1-4].

PPM illustrates the integration of many sources of variability in patient response, including genetic and non-genetic sources, is a therapeutic approach that seems here to stay. While the implementation of PPM resources into clinical practice, progress in pediatrics has been slower, despite emerging evidence that PPM approaches can make drug therapy for children both more effective and safer. The successful implementation of PPM in Pediatrics offers considerable potential to enhance our ability to provide effective and safe drug therapy, including canonical, preventive, prophylactic and rehabilitative treatment, for the world's children.

Figure 1A: Personalized & Precision Medicine as applicable to Clinical Pediatrics.

PGx, pharmacogenomics; Pmetrics, a fast-growing platform dedicated to leveraging cutting-edge machine learning and

artificial intelligence techniques to revolutionize the fields of pharmacogenomics, pharmacokinetics and pharmacodynamics [5].

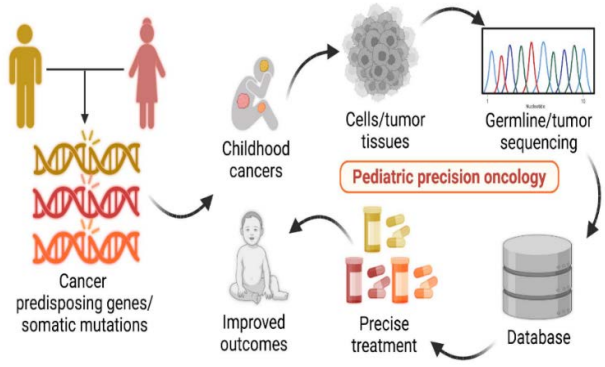

Figure 1B: Personalized & Precision Medicine in Pediatric Cancers.

The latest efforts to develop PPM for childhood malignancies and pediatric cancer-related clinical and subclinical oncology have led to the identification of genomic alterations and profiles of pediatric patients, which presents promising opportunities to study and to assess malignancies neoplasms, whilst providing perspectives on precise therapeutic strategies [6].

PPM and PPM-guided pediatrics as a unique entity demonstrating an integration of Fundamental, Healthcare & Life Sciences, Biodesign-driven BioTech, Translational ART and IT Armamentarium, are the new developmental strategy driven by Biomarkers- and Biotargeting-related biomachines.

Technological advances in OMICS evaluation and bioinformatics and artificial intelligence have made us rethink ways to improve patient outcomes. Collective quantification and characterization of biological data including genomics, metabolomics and proteomics is now feasible with rapid turnover. Significant advances in the integration methods of the multi-OMICS data sets by IT-driven tools and algorithms promise us a holistic view of disease pathogenesis and yield genomic, proteomic and metabolomics biomarkers for disease diagnosis and prognosis [7,8].

Essential questions that need to be addressed in applications of biomarker-driven precision therapeutic program include the applicability of the genetic testing, the significance of the mutation variant and the existence of an approved biomarker-based targeted therapy. Identifying the mutational signatures of, for instance, pediatric solid tumors will open opportunities for targeted therapeutic strategies. Those treatments could improve survival and reduce toxicity in pediatric patients and maximize therapeutic advantages when incorporated into standard care [9].

To understand PPM-guided pediatric philosophy and practice, we would have to understand the armamentarium and tools to exploit and practice PPM resources and genomics tools, in particular! In this sense, PPM and personalized and precision genomics as the major part of the latter are a new and exciting field with the potential to improve medical care for children. In general, three major types of genomic biomarkers are crucially important and valuable for PPM-related services: diagnostic, predictive and prognostic ones, to be used in most of genomic testing platforms (Figure 2A and B).

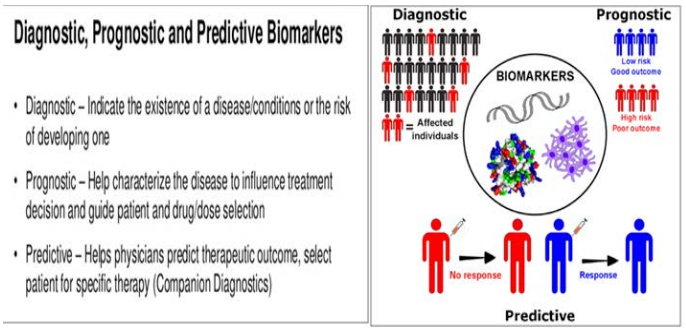

Figure 2A and B: Diagnostic, predictive and prognostic biomarkers.

Genetic, protein and cellular components can serve as diagnostic, prognostic and/or predictive biomarkers of cancer. Diagnostic biomarkers are used to identify and detect presence of cancer in individuals; prognostic biomarkers provide information on disease progression and expected outcomes and predictive biomarkers forecast the likely benefit of a specific treatment.

In terms of genomic biomarker-based testing, we would stress approaches depicted at (Figure 3).

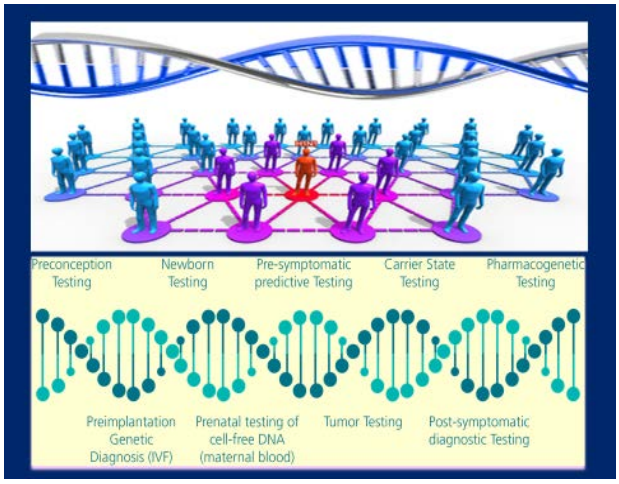

Figure 3: Types of genomic testing.

Genomic testing - finds changes in genes that can cause health problems and is mainly used to diagnose rare and inherited health conditions and some cancers. There are many different kinds of genomic tests. Newer tests and technologies have generally added to the testing options for pediatricians.

A genetic test can:

i. Help to diagnose a rare health condition in a child.
ii. Help you understand whether an inherited health condition may affect you, your child or another family member and help you decide whether to have children.
iii. Show if you are at higher risk of getting certain health conditions, including some types of cancer.
iv. Guide doctors in deciding what medicine or treatment to give you guide doctors on whether you're able to join a clinical trial [10].

Advances in understanding the genetic basis of disease through genomic technologies are refining diagnostic, predictive and prognostic capabilities, enabling tailored surveillance, offering new targeted and multi-targeted therapeutic options and optimizing treatment delivery [11].

Of particular interest, pharmacogenomic testing is now entering the realm of pediatric care, a development that offers great promise in providing evidence to guide therapy notably given the substantial increase in the use of multi-targeted drugs among children [12].

Pharmacogenomics testing is aimed at tailoring drug therapy at a dosage that is most appropriate for an individual patient, with the potential benefits of increasing the clinical efficacy and individualized safety (Figure 4A and B).

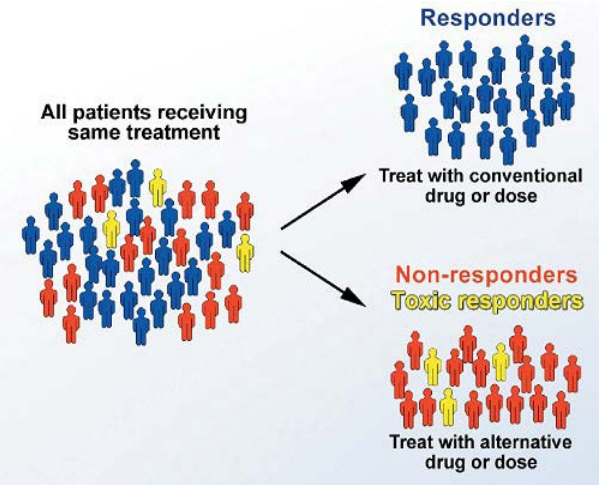

Figure 4A: Pharmacogenomic testing.

Pharmacogenomics relates to the study of genetic factors determining variability in drug response. Pharmacogenomics testing identifies individual differences in how well or badly people respond to particular drugs. Implementing the latter testing in pediatric patients can enhance drug safety, helping to improve drug efficacy or reduce the risk of toxicity [13,14].

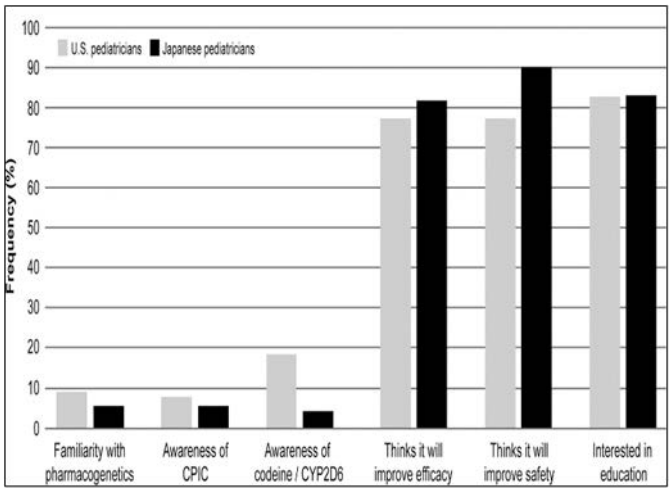

Figure 4B: Pediatrician knowledge and attitudes on pharmacogenomic testing.

In children with suspect genetic conditions that have high genetic heterogeneity, genome sequencing is becoming a first-tier test (i.e., a broad genetic differential diagnosis with many candidate genes or loci) instead of the second-tier approaches, utilizing so far. Pharmacogenomics testing provides the potential to unveil heritable and somatic genetic variations for guiding PPM-guided targeted therapy to reduce the risk of toxicity. A better understanding of pharmacogenomics will optimize the current treatment selection and dosing of immunotherapy. In this sense, the use of genome sequencing as a preventive health tool in seemingly healthy children or pre-illness persons-at-risk has tremendous potential in the future [15-17].

Moreover, microbial genomics, the diagnostic evaluation of undiagnosed disease and reproductive genetics/newborn screening exemplify the need for the practicing pediatrician to have competency in genomics, epigenomics and metagenomics. And, finally, individually tailored nutriogenomics-based interventions are also considered a promising frontier for personalized nutritional diets on the area of PPM-guided pediatric services [18-21].

Anyway, PPM-guided pediatric services have been at the forefront of genomic technology adoption! Effectively integrating genomics into routine pediatric care will demonstrate the efficacy of a new molecular diagnostic or targeted therapeutic in controlled settings.

Pediatricians have the unique and exhilarating responsibility to help ensure that young patients derive maximal benefit from genomics, which, in turn, will provide pediatricians new and often unexpected insights into the biological basis of health and disease and will afford new health care options requiring informed and sometimes challenging choices of physicians and patients. So, developing pediatrician competency in genomics is a daunting task, but one that the specialty can and must accomplish in the near future. Achieving such competency will provide effectively integrating genomics into pediatric practice, will improve pediatricians' effectiveness in caring for patients' current health concerns and will make pediatricians the guides to lifelong health.

Along with genomics, a myriad of challenges is faced when preparing to implement PPM-guided pediatric care into daily clinical practice. For children, who are still developing and have the most to gain, PPM is more than a bumper sticker. On the micro scale, pre-early (subclinical in most cases) genomic testing and large-scale OMICS-driven profiling - perhaps routinely, someday, in newborns - can help secure PPM-guided medical care, multi-targeted therapies and preventive strategies based on a child's genetic makeup. On a macro scale, big data from the larger population becomes a predictive tool, guiding medical decision supports that could be life-altering in a still-malleable child.

In this context, a combination of genomic and phenotypic biomarkers is becoming of great significance to be translated into the daily PPM-guided pediatric practice to predict risks of the chronification and disabling (Figure 5).

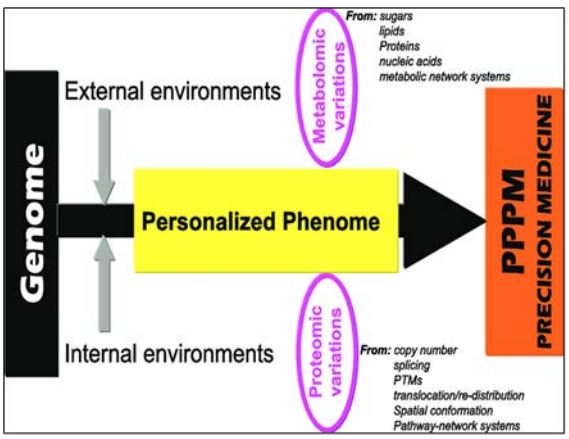

Figure 5: Biomarkers and their clinical implications through the view of genome and phenome.

The genetic and phenotypic abnormalities are used as diagnostic, prognostic and predictive biomarkers that play an important role in pre-early disease detection, more accurate risk stratification and treatment. Identification of new biomarkers and thus a greater understanding of their molecular basis, will lead to better monitoring of the course of the disease [22].

As a result, bioinformatics, Artificial Intelligence (AI), Machine Learning (ML) and biostatistics are becoming crucial in translating Big Data into useful applications, leading to improved diagnosis, evidence-based prediction, prognostication and treatment. Harmonizing data elements and linking together of longitudinal biobanks for generating outcomes based on genetic makeup and health determinants of pediatric population (Figure 6).

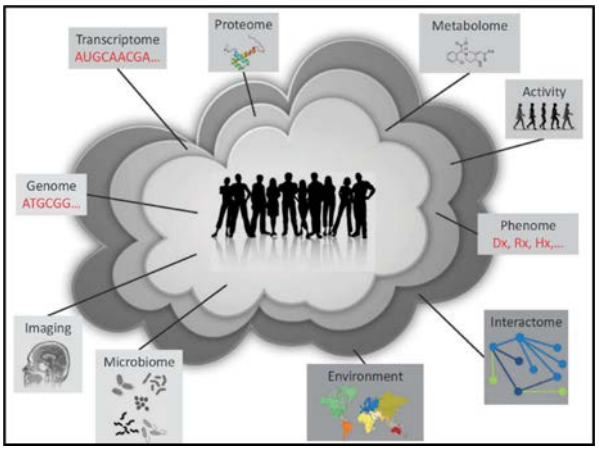

Figure 6: Medical information systems and tools.

PPM are enabled by individuals surrounded by a cloud of data. Layers of the cloud represent data varying between those directly affecting/quantifying the individual and those quantifying the environment and indirectly affecting the individual, i.e. levels of the exposome.

PPM-related subareas are becoming valuable in pediatric treatment. The initial efforts and pioneering steps are concentrated on providing answers to children with severe seizures and inborn conditions, including pre-illness persons-at-risk. Therefore, the clinical and translational applications into novel therapeutics will help enable children with previously debilitating and fatal genetic diseases via the usage of smart and targeted therapy treatments.

Despite the advances in cancer treatment outcomes, cancer remains the biggest cause of death from disease in children. Because the etiology and biology of cancers that occur in children differ dramatically from those that occur in adults, the immediate extrapolation of efficacy and safety of new cancer drugs to childhood cancer indications is not possible. We discuss factors that will play key roles in guiding pediatric oncologists as they select lines of research to pursue in their quest for more effective treatments for pediatric cancer. Recent studies exploring etiopathogenesis of cancer treatment-related late effects have provided important information that will assist in ongoing efforts to develop PPM-guided cancer care.

PPM-guided pediatric oncology has provided a greater understanding of the wide range of molecular alterations in difficult-to-treat or rare tumors with the aims of increasing survival as well as decreasing toxicity and morbidity from current cytotoxic therapies. Pediatric tumors have a different genetic make-up, with a fewer number of actionable targets than adult tumors (Figure 7).

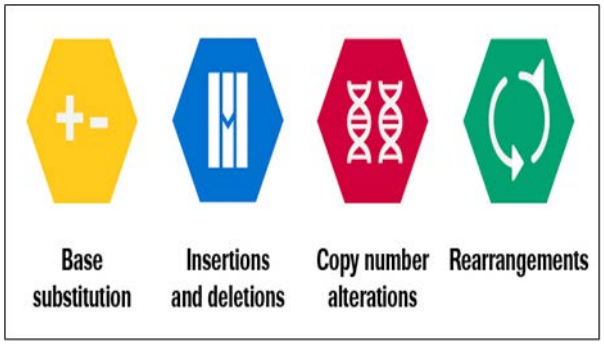

Figure 7: Four major types of genome changes that can cause cancer.

Meanwhile, the development of upgraded targeted treatments for these diseases has been hampered by two major factors. First, the extremely heterogeneous nature of the types of tumors encountered in this age group and their fundamental differences from common adult carcinomas, has made it hard to truly get a handle on the complexities of the underlying biology driving tumor growth. Second, a reluctance of the biopharma to develop products or trials for this population due to the relatively small size of the 'market' and a too-easy mechanism of obtaining waivers for pediatric development of common oncology drugs based on disease type rather than mechanism of action, led to significant difficulties in getting access to new drugs.

Meanwhile, PPM-guided oncology incorporates comprehensive genomic profiling into the individualized clinical care of pediatric cancer patients. The latter has led to the successful implementation of genomics-based pediatric trials and accelerated approval of novel targeted agents, resulting in molecular subclassification of myriad cancer types with subsequent tailoring of treatment intensity based on the patient's prognostic factors.

The introduction of PPM-related philosophy and armamentarium into clinical oncology practice, an approach that uses the understanding of molecular profiles of a disease to tailor treatment to a patient, has quickly started to change the diagnostic and therapeutic landscape of pediatric oncology. With its use, a better understanding of tumor biology, improved classification systems for various cancers and genetically and molecularly targeted therapeutic strategies have been developed. So PPM-based pediatric oncology is becoming an emerging approach for cancer treatment that has recently taken giant steps in daily pediatric practice. Recent advances in molecular diagnostics that can analyze the individual tumor's variability in genes have provided greater understanding and additional strategies to treat cancers or to prevent pre-cancer conditions. Nevertheless, PPM-guided pediatric oncology in the population has greatly improved the survival of patients with leukemia and solid tumors [23-31].

The other clinical area of PPM-guided pediatrics are congenital heart diseases, where advances have identified individual genetic and environmental factors that have helped understand variations in morbidity and mortality in PPM-guided pediatric cardiology and confirmed successful application of emerging technologies in genomics, proteomics, transcriptomics and bioinformatics to diagnostics and therapeutics of the child with heart disease. A focus on genomics and pharmacogenetics

has also been key to risk prediction and improvement in drug safety and efficacy in the pediatric population. With the rapidly evolving understanding of these individual factors, there also come challenges in implementation of personalized medicine into our health care model. This review outlines the key features of precision medicine in pediatric cardiology and highlights the clinical effects of these findings in patients with congenital heart disease [32-35].

In this context, PPM-driven pediatric approaches identify phenotypes of pediatric patients and/or pre-illness persons-at-risk with less-common responses to treatment or unique healthcare needs. Meanwhile, bioinformatics leverages sophisticated computation and inference to generate insights, enables the system to reason and learn and empowers clinician decision making through augmented intelligence. Therefore, it would be extremely useful to integrate data harvesting from different databanks for applications such as pre-early predictive diagnostics, precise prognostication and personalization of further treatment to provide more tailored measures for the diseased children and pre-illness persons-at-risk resulting in improved outcomes and more cost-effective use of the latest health care resources.

The latest advances in multi-OMICS technologies and bioinformatics allow creation of a fundamentally new integrated approach, which applies a 'predictive, preventive and personalized' model of care to pediatric practice. PPM successfully utilizes data obtained from an individual's genome sequencing. Moreover, Next Generation Sequencing (NGS) has shifted genetic research from the analysis of separate genes to the parallel studying of hundreds of genes and pathological ways of diseases. The technique provides breakthrough possibilities in OMICS-assisted molecular diagnostics such as a quick identification of causal mutations, comparative genomic analysis, ability to search for non-random associations between a disease and mutations and identification of new pathological pathways. The latter is becoming extremely useful for integrating data harvested from different databanks to secure prediction and personalization prior further treatment, providing more tailored measures for the patients resulting in improved 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.

The initial efforts will be concentrated on providing effective care to children with severe seizures and inborn conditions, i.e., pre-illness persons-at-risk. The research into novel therapeutics will help enable children with previously debilitating and fatal genetic diseases, with clinical trials testing gene and/or cell therapy treatments for rare, genetically pre-determined and inborn serious diseases. Results of such an approach will inevitably lead to a reduction of morbidity and mortality among children. However, the actual question is how to best integrate data obtained from genomics profiling, OMICS-driven testing and bioinformatics with the PPM-guide approach globally. This question directs us to bbioinformatics, in particular, which applies high-throughput modeling to support the clinical diagnosis and development of novel treatment strategies in PPM-guided pediatrics.

PPM and PPM-guided pediatric services are those of the most promising technologies for improving health care and health outcomes. The latter offers many advantages for PPM applications, including a size that matches the scale of the molecular substrates of PPM, an increased sensitivity in detecting and binding with target molecules and flexibility in the design and function of therapeutics and diagnostics. The above-mentioned areas being an integral part of PPM are really an interdisciplinary research field that has the potential to improve some canonical treatments, prevention, prophylaxis and rehabilitation within the frame of pediatric services.

The drug design and discovery of new types of therapeutics, such as targeted drugs, immune checkpoint inhibitors and immune cell therapies, as well as nucleic acid-based drugs for initiating and enhancing the anti-tumor response and development in biocompatible and cell type targeting nanocarriers, have facilitated both patients and doctors to fight with pediatric cancers. For instance, the treatment paradigms utilization of nucleic acids, including short interfering RNA (siRNA), antisense oligonucleotides (ASO) and messenger RNA (mRNA), can target specific protein expression to achieve the therapeutic effects in rare diseases and genetic diseases, as well as for cancers. For instance, miRNA expression is dysregulated in many diseases, making them appealing tools for novel therapeutic approaches and highlighting strategies for delivering miRNA agents, presenting viral, non-viral and exosomic delivery as therapeutic approaches for different cancer types [36-38].

Of special interest are biomarker-driven targeted therapies, which target specific features of cancer cells (affecting only the abnormal receptor) to stop the cancer growing and spreading.

In addition to the cancer type and subtype being identified, potential molecular targets are found by testing the tumor sample for overexpression of biomarkers or for mutations causing cells to multiply rapidly. Identifying those specific targets helps determine management options (Figure 8).

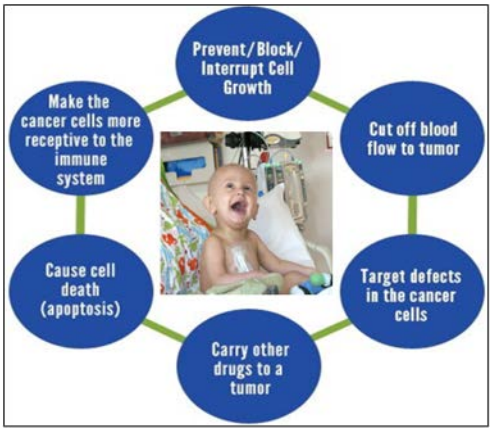

Figure 8: Targeted Therapy in Case of PPM-guided Pediatric Practice.

Depending on the specific molecular targets, targeted therapy can act on cell surface antigens, growth factors, receptors or signal transduction pathways that regulate cell cycle progression, cell death, metastasis and angiogenesis. While most targeted therapies are either monoclonal antibodies (MAbs) or small-molecule drugs, they are classified as hormone therapies, signal transduction inhibitors, gene expression modulators, apoptosis inducers, angiogenesis inhibitors, immunotherapies and toxin delivery molecules [39,40].

Given the rarity of cancer in children, developing targeted treatments for small numbers of children will be challenging, yet

these treatments are likely to improve outcomes and survival. The number of patients available can be highly limited for pediatric cancers and when evaluating molecular targets, only children who have already failed therapy might be considered for enrollment, further narrowing the pool.

The ability to reprogram virtually any cell of human origin to behave like embryonic or Pluripotent Stem Cells (PSCs) is a major breakthrough in stem cell biology. In this sense, Cancer Stem Cells (CSCs) are a subpopulation of tumor cells that have the ability to self-renew, initiate tumors in model systems and differentiate into non-cancer stem cells. Due to these properties, cancer stem CSCs contribute to tumor progression and recurrence and need to be inclusively targeted with therapeutic paradigms used in the clinical setting, including medulloblastoma, ependymoma, diffuse intrinsic pontine glioma and pediatric gliomas [41].

Patient-derived iPSCs provide an exciting opportunity for drug discovery and drug re-purposing for disorders with a known molecular basis including childhood onset heart disease, particularly cardiac genetic disorders. Issues that will need to be addressed for practice include scaling up of stem cell platforms for high-throughput drug screens, translating drug testing results to clinical applications in the paradigm of PPM-guided pediatric practice and improving both the efficiency and the safety of iPSC-derived lineages for future stem cell therapies.

Moreover, we will also consider within a concept of PPM-guided pediatric services the implications of the nanodiscipline for individual kids. The nature of research, diagnosis and screening in nanopediatrics will be illustrated in nanodiagnostics and nanotherapeutics via collaborative projects the combined use of diagnostics and therapeutics in a single nanodevice referred to as companion diagnostic or theranostics (……..). In this sense, for instance, multimodal genomic theranostic drug (Figure 9).

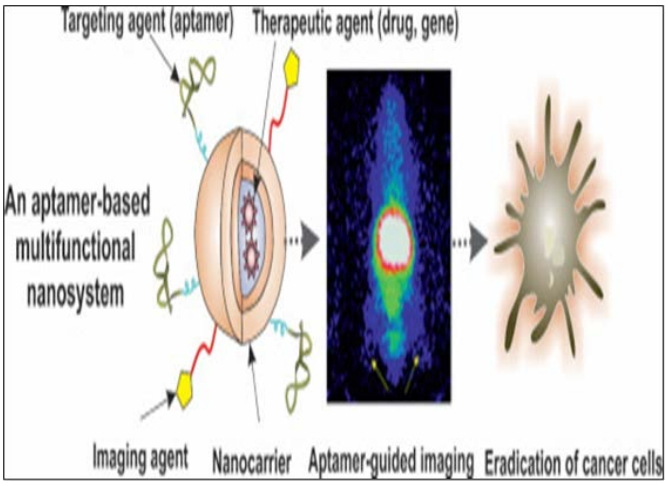

Figure 9: Multimodal genomic theranostic drug.

A systematic investigation of multimodal therapy with chemoradiotherapy, surgery, target agents and immunotherapy are paramount. And appropriate drug selection remains crucial in this evolving landscape to derive maximum benefit for the patients [42,43].

Companion diagnostics (theranostics) and AI-driven approaches may indeed become a key driver in harmonizing the needs of the various stakeholders by allowing cost-effective delivery and monitoring of drug efficiency and safety and close-meshed high-quality data collection.

The next step is the implementation of 3D printing technology, which has significantly propelled PPM-driven drug delivery and accommodated the precise requirements of pediatric drug dosages and the complexities of multiple drug combinations, improving drug safety and minimizing side effects PPM-guided pediatric practice [44-46].

A future field of implementation for 3D printing could be regenerative therapies, with the creation of human tissue for organ replacement. The technology may lead to better cost-efficiency within health-care systems by, for instance, cutting drug testing costs.

The field of PPM-guided health has emerged as part of this paradigm shift, where the integration of multi-OMICS technologies and IT-driven algorithms into medical management decisions promises to improve the quality of care for specific patient groups, including children and development of PPM-guided pediatric services of the next-step generation. Translating the latter into pediatric practice in an equitable and sustainable manner is the next challenge. The unique attributes of child health and illness have significant implications on the PPM-guided translational medicine pathway. We need

To develop PPM-guided health technology frameworks and principles for value assessment that attend to the unique needs of children and the distinct context of PPM;

To integrate PPM-related child health principles throughout the research translation process; and

To encourage cooperation between clinical hospitals, healthcare communities, medical and insurance agencies and key stakeholders to ensure that these checkpoints do not serve as a barrier to access.

The aim of pediatric PPM, we do believe, is to combine genetic variation with developmental stage and environmental exposure to provide a tailored preventive, diagnostic and therapeutic regimen. Current evidence suggests that the effect of genetic variation, proteomics- and metabolomics-related landscapes depends on the developmental stage of a child and environmental exposure such as infection, autoimmune and degenerative diseases or oncogene carrying during a specific stage. The complexities of this interdisciplinary OMICS-related interface have likely contributed to the widespread delays in the implementation of OMICS testing (Lauschke and Ingelman-Sundberg, Reference Lauschke and Ingelman-Sundberg2020).

Adaptive profiling strategies involving tissue- and liquid-based testing that account for the immense plasticity of pediatric cancer during the patient's journey and also include early detection approaches are already finding their way into clinical routine and will become paramount. A second major driver is the development of smart clinical trials and trial concepts which, complemented by real-world evidence, rapidly broaden the spectrum of therapeutic options. Tight coordination with professional clinical communities, regulatory agencies and health technology assessment bodies is crucial in this context. Multicentric networks operating nationally and internationally, are key in implementing precision oncology in clinical practice and support developing and improving the ecosystem and framework needed to turn invocation into benefits for patients [47,48].

Successful implementation of PPM-guided pediatric services along with OMICS portfolio and IT-related armamentarium also relies on a seamless interface with practitioners and colleagues in laboratories undertaking OMICS testing and other relevant members of a transdisciplinary team for PPM-guided pediatric services (Figure 10).

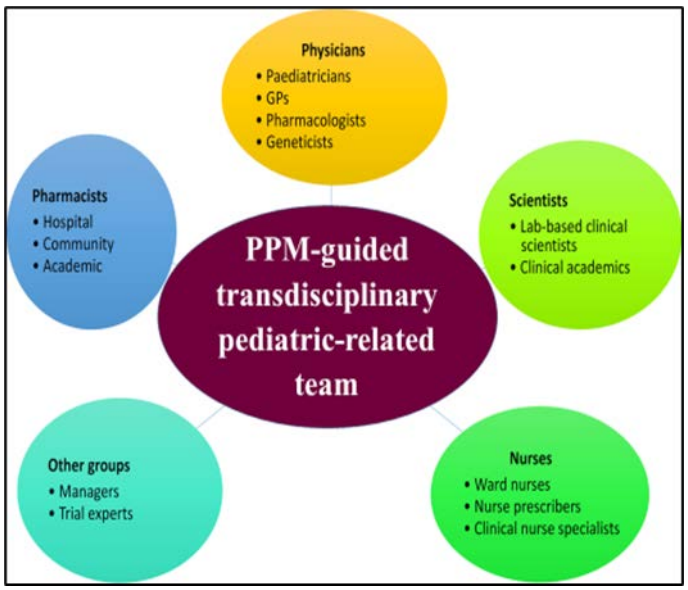

Figure 10: Healthcare partners for a trans-disciplinary team in PPM-guided pediatric practice.

PPM-guided cancer clinical practice is a trans-disciplinary team effort that requires involvement and commitment of many stakeholders including the society at large. Transdisciplinary team are widely recognized to benefit healthcare delivery in many different contexts and can be associated with improved healthcare outcomes in PPM-guided pediatric practice GP, general practitioner; PPM, personalized & precision medicine [49].

The above-mentioned approach to PPM-guided pediatric practice, designed as an all-states learning collaborative grounded in transdisciplinary team-science research. Such an approach would require consideration of the most common causes of infant morbidity, mortality and disabling (e.g., conditions related to prematurity; congenital malformations; heart disease; pre-cancer and cancer) and their root causes, including social factors, in order to be focused yet inclusive in taking collective action across states. This endeavor would benefit greatly from federal support for clinical care and research, using a national "moonshot" model commonly deployed to attack major children chronic disorders [50].

The professional and political boundaries between specialties and professions can be navigated by clear signposting of the diagnostic, predictive and targeted therapeutic tools lead for each team, respectively, prospective stakeholder engagement meetings and establishing clear routes of communication with the team responsible for implementing the PPM-driven clinical service.

Several advances have been made in the field of pediatric PPM, heralding a new chapter in the fight against pediatric chronic disorders including cancer. The next-step generation programs in PPM-guided pediatric services would sustain, strengthen and expand upon existing collaborative projects. The ultimate goals of the programs are to improve health care by promoting state-of-the-art translational research and applications, to drive scientific growth by facilitating improvements in the quality of scientific investigation and thereby enhance future competitiveness for external funding so that we may continue to make improvements in healthcare. The latter is the reason for developing global scientific, clinical, social and educational projects in the area of PPM and PPM-related pediatric care to elicit the content of the new branch. In short, PPM will transform the way doctors practice and will shake up the entire pharmaceutical value chain. The above-mentioned says that PPM introduces a new era in healthcare that tries to identify and predict optimum treatment outcomes for a patient, person-at-risk or a cohort, regarding pediatric services as well.

PPM is thus a new and exciting field with the potential to improve medical care for children and young and smart communities. Meanwhile, a lack of medical guidelines has been identified as the predominant barrier for adoption, indicating a need for the development of best practices and guidelines to support the implementation of PPM-related pediatric services!

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