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A Systematic Approach to Optimize the Implementation of Precision Oncology in Clinical Practice: A Meeting Proceeding

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INTRODUCTION

Although precision medicine offers a great opportunity to improve cancer care, there are many challenges to maximizing its use in practice. This article presents expert recommendations and best practices on how to overcome these challenges to build an effective precision oncology (PO) program. A multidisciplinary panel of experts convened to address the topic at the Precision Oncology Forum on March 11, 2023. The panel included medical oncologists (ARJ, ARC, ML), hematologists (EC, RK), an advanced oncology nurse practitioner (AG), an oncology nurse (SH), a pharmacogenomic pharmacist (NER), a genetic counselor (KMH), a research coordinator (JJC), information technology (IT) staff (LV), a precision medicine operation manager (JG), a financial advisor (SCO), and a scientist (BCB). The panelists were asked to address the following questions: What are the challenges encountered by PO programs? What are the potential practical recommendations to help implement PO in practice? What are the essential components and best practices of an effective PO program?

Panelists discussed different challenges and suggested recommendations to address them by providing a description of the best practices and the structure of a PO program. Although PO programs may cover a broader range of topics than the issues addressed in the article, we focused on the topics presented. This article is a compilation of the points discussed by the panelists, citing relevant and updated references to support the issues presented.

The panel listed challenges to implementing PO in practice and classified them into different categories with examples of these challenges. Potential solutions were listed for each of the challenges (Table 1).

REQUIREMENTS AND STRUCTURE OF A PRECISION ONCOLOGY PROGRAM

Staffing

It is critical for the PO program to include a multidisciplinary team of experts with different roles and functions including the following individuals: physicians and advanced practice providers from multiple disciplines (hematology, oncology, pathology, radiology, surgery, and others), genetic counselors, genetic counselor assistants, pharmacogenomic pharmacists, patient navigators, administration and operation staff, research staff, advocacy staff,

Table 1. Challenges and potential solutions for implementation of precision oncology (PO) into the practice

Type of Challenges	• Examples	• Potential Solutions
Rapid innovation advances	• Many companies with different testing platforms • New tests and technologies • Variability in FDA approval • Multiple technical assessment requirements • Many new biomarkers and therapeutic agents • Multiple aberrations and difficulty interpreting the results. • Lack of real-time clinical decision support in standard workflow • Difficulty in integrating many of these platforms with EHR	• Selecting the platforms that provide more comprehensive services efficiently • Starting with one platform first and then work with others • Identifying strong lab partners for EHR integration • Investing in IT resources to support integration in the EHR
Personnel shortage	• Shortage of genetic counselors, pharmacists with pharmacogenomic training, oncology nurses, IT technical teams with knowledge of EHR integration, and others • Personnel in various specialties within one system are siloed in their application of PO system-wide • Efforts are spent on tedious tasks that could be automated	• Training more genetic counselors, pharmacogenetic pharmacists, and IT resources • More efficient use of the personnel • Automation of tedious time-consuming tasks by harnessing AI or application of automatic alerts in EHR • Using existing resources provided by the testing companies • Using MTB to further education, awareness, and clinical decision-making • Using algorithm and processes • Training other staff to do some of the work that does not require in-depth expertise (calling negative germline testing) • Using telehealth
Access to testing	• Test availability at facility • Copayment • Lack of awareness about testing components • Disparities in ordering the tests due to implicit bias	• Education about indications • Raising awareness of financial access programs provided by testing companies that can eliminate financial toxicity for patients • Educating leadership, third-party payers, and healthcare leadership on the value of precision medicine • Automating the process for test ordering • Educating patients on their options for copayments, coinsurance, and deductibles for precision medicine and help estimate testing costs in advance
Access to treatment	• Having actionable targets with inability to get the treatment • Having mutation with no available biomarker-guided treatment • Lack of access to clinical trials • Inability to efficiently apply test results for trial eligibility	• Advocacy for patient access • Patient financial assistance program and payment plans • Innovative clinical trial design with real-time matching by biomarker and local access • Drug repurposing • Off-label use
Patients' perception and expectation	• High unrealistic expectation of testing results, difficulty in interpreting results • Refusal to participate in trial to access new treatment • Resistance to testing due to perceived cost	• Proper counseling and education before testing • Adequate explaining of the findings • Access to results through myChart or similar • Transparency in billing and financial access, education about EOB
Logistics issues	• Lack of leadership support • Long turnaround time • Accessing the results • Lack of standards and clear process • Siloed workflow across system	• Assurance of C-suite support with consideration of downstream revenues and benefits • Working on process improvement • Interfacing with EHR • Providing results when needed and within clinical workflow • Establishing clear process and guideline to incorporate PO in workflow
Technology issues	• Having accessible results on EHR • Updating EHR orderables and results as tests constantly expand offerings • Lack of clinical decision support within the clinical workflow	• Interfacing results with EHR • Creating database to capture findings • Including clinical input from oncologists, genetic counselors, pharmacists for integration building • Implementing robust clinical decision support tools (AI driven)

Table 1 continues on next page

Table 1. Continued

Type of Challenges	• Examples	• Potential Solutions
Providers' issues	• Slow adoption of testing • Resistance to change • Difficulty accessing the results • Understanding the results • Busy clinicians with conflicting priority	• Doing reflex testing • Interfacing platform with EHR • Using MTB with regular cadence • Using other experts in the team • Using application of PO as performance indicator for QA • Using expertise available through labs • Using consolidated knowledge bases and guidelines. • Using decision support systems • Using innovative approach such as AI • Involving other specialties in ordering tests such as pathology, pulmonary, surgery.
Specimen availability	• QNS: tissue quantity or quality not sufficient • Many competing tests for specimen • Underutilization of liquid biopsy • Difficulty of re-biopsy	• Updating tissue management plan • Notifying interventionalist that biopsy specimen is needed for NGS and requires adequate tissue • Creating workflows that default from QNS to liquid biopsy • Prioritizing order of testing when tissue is scarce • Updating associated therapies and trials based on existing DNA findings • Prioritizing testing based on the effect on the care • Using MTB and MDT
Financial aspects	• Test and treatment cost reimbursement and copay • Effect of cost on underserved and/or uninsured patients • Misconception that NGS is not covered by insurance or has financial toxicity for patients. • Cost of infrastructure • Cost of IT implementations	• Advocacy • Early preauthorizing • Using existing patient assistance programs • Exploring innovative collaborative agreement • Creating customized appeals using guidelines and metrics • Creating a standard technical assessment to meet requirements
Ethical and legal issues	• No access to the test • Disparities in ordering the test • No access to treatment of actionable targets • Participating in innovative trials • Carrier of inherited cancer gene and effect on family, insurability, employability, others	• Exploring methods to assess health equity and increase equitable testing • Genetic counseling for patients with germline mutations and education on family cascade testing, GINA law • Upfront patient counseling and education

AI: artificial intelligence; EHR: electronic health record; EOB: explanation of benefits; FDA: Food and Drug Agency; GINA: Genetic Information Nondiscrimination Act; IT: information technology; MDT: multidisciplinary tumor board; MTB: molecular tumor board; NGS: next-generation sequencing; QA: Quality assurance; QNS: quantity not sufficient

financial counselors, IT staff, electronic health record (EHR) engineers, and phlebotomists. Other team members can be added, based on the practice setting, such as basic scientists, bioinformatics experts, and others (Table 2).

Program structure

While every healthcare provider in the system will have a role in practicing precision medicine, it is important to have a structured program with dedicated staff to assure coordinated efforts to implement PO in a systemic way. The program should have direct and strong support from the C-suite and clearly define the functions and responsibilities of different team members (Fig. 1).

Adequate expertise

Given the shortages of specialists in PO, it is crucial to ensure that each specialist practices at the top of their license and that more tedious and routine tasks are automated or left to support staff. To give an example of the need for adequate expertise, there are approximately 5000 genetic counselors in practice in the United States today according to the National Society of Genetic Counselors, although the cancer burden in the United States is far greater. American Board of Genetic Counseling certification and state licensure is required to practice as a genetic counselor. To ensure that patients with cancer and their families receive adequate genetic counseling, clinician extenders can be applied. This might include using artificial intelligence (AI) or chatbots to screen patient populations, automating genetic testing, and incorporating support of genetic counseling assistants and streamlined workflow within the EHR, thus allowing genetic counselors to focus time on patients with the most complex genetic findings and in need of high-risk management. The incorporation of clinical decision support such as best practice alerts that guide referral for high-risk care can also support clinicians system-wide when a new germline mutation is

Table 2. Precision oncology team members and their essential roles

Staff	Roles
Hematologists Oncologists	• Select and order the tests • Counsel patients about the test results and implications for therapy or clinical trials • Select and administer treatment • Evaluate for clinical trials • Monitor disease with markers of recurrence, MRD, liquid biopsy • Re-evaluate therapy options based on new clonal drivers or resistance biomarkers
Pathologists	• Manage specimen process • Review solid tissue specimen for adequate tumor content • Order testing for diagnostic and prognostic • Correlate between various lab results • Order reflex testing for therapy when indicated • Verify reports and help interpret the results[19]
Genetic counselor	• Work at the intersection of somatic and germline testing, supporting the identification of incidental germline mutations on tumor profile tests and the elevation of relevant germline results for use in therapeutic decision-making • Identify patients who meet guidelines for germline testing and identify the appropriate test and modality (e.g., DNA, RNA) • Advise patients regarding the need for and implications of germline testing. Counsel patients about limits, benefits, implications for patient • Initiate and coordinate family cascade testing • Coordinate and refer for specialized high-risk care, based on risk stratification and testing outcomes. Coordinate multidisciplinary efforts for coordinated care and support the clinical team in vetting new genomic tests and technology • Provide insight for molecular tumor boards on germline testing • Participate in paired somatic-germline protocols • Counsel patients about test implications, financial aspects, and test results
Pharmacogenomic pharmacist	• Advise about the need for testing[20] • Advise on treatment selection and treatment adjustment • Counsel patients on post pharmacogenetics results[21,22]
Genetic counselor assistant	• Support blood, buccal, saliva collection for matched tumor normal and germline testing • Coordinate necessary information for testing orders, support consistent resulting process • Provide proactive testing recommendations and referrals • Deliver results to patients • Prepare to apply for Genetic Counseling Program
Financial counselor	• Counsel patients about the financial implications of testing • Explore solutions to defray out-of-pocket costs to patients
Research staff	• Screen patients for clinical trials, based on tumor profile, germline mutations, medication selections, others • Update clinical trials when testing is updated or new trials become available • Screen and review new research proposals
Information technology staff	• Interface the vendors platform with EHR • Fix the technical bugs to facilitate providers' access to results • Partner with clinical team to enhance usability and interface • Support reporting and QA • Implement robust clinical decision support tools
Administration and operation staff	• Organize and coordinate various functions and activities of the PO teams • Ensure adequate FTEs from each specialty • Liaise between the institutions and vendors • Support system-wide consistency and collaboration

EHRelectronic health records; FTEs: full-time equivalents; MRD: molecular residual disease; QA: quality assurance.

identified. Additional training and education in genetics can allow other types of providers to extend the reach of genetic counseling, including advanced nurse practitioners, nurses, and others trained to perform pretest counseling.

Similarly, most practicing pharmacists do not receive formal training in pharmacogenomics and may need additional continuing education to support the complex clinical decision-making that accompanies genomic and pharmacogenomic tests. The addition of best practice

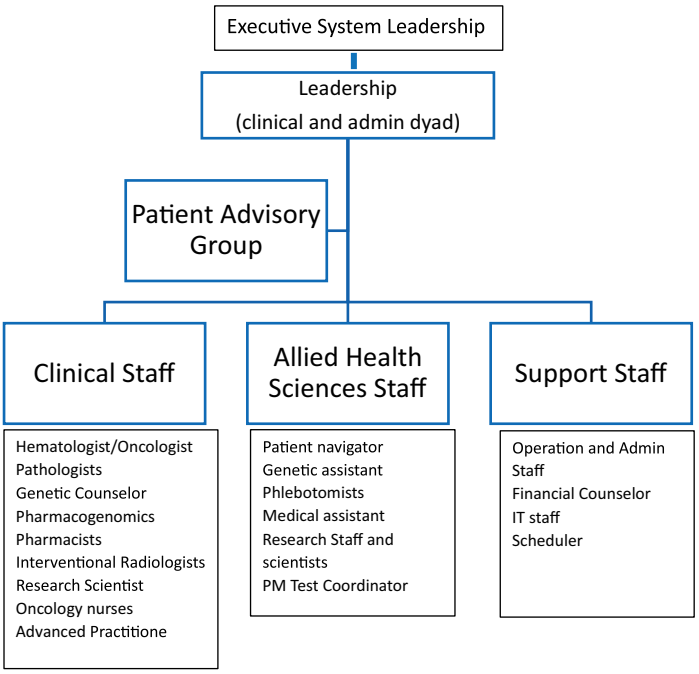

Figure 1. Precision Oncology Program structure.

IT: information technology.

alerts that fire within the EHR can direct patient care and provide the opportunity for consultation with a pharmacist trained in pharmacogenomics.

Increasing the number and caliber of formally trained geneticists and pharmacogenetic trainees should coincide with the advancement of clinical decision algorithms. Trained pharmacogenomic pharmacists and genetic counselors are crucial to educating clinicians and patients, building clinical decision support tools, and in interpreting the genomic data. Patients should be educated and counseled about the purpose of testing, the financial implications, the interpretation of the results, and available interventions based on the results. Resource extenders such as accessible chatbot technology, AI, and genetic assistants can also help to maximize genetic resources. In addition, novel care pathways such as EHR-driven referrals and telehealth visits were cited as important in ensuring the communication of incidental findings by genetic counselors and to facilitate cascade screening of families.

Infrastructure support

The support and buy-in from C-suite leaders is critical as is the service line leadership.

Frequent meetings with providers and staff are important to raise awareness regarding the implementation of PO. The need for dedicated IT support professionals cannot be overemphasized to implement and maintain interfaces with external laboratories as well as clinical decision support tools.

Clear process and workflow

The development of a consistent, efficient workflow and protocol is critical to have clear delineation of the work process, including required tasks and responsible individuals. A multidisciplinary team is needed to determine when and how patients are tested, ownership of test ordering, and processes for results that lead to shared decision-making. The availability of genomic results system-wide and how to act on these results are additional quality measures for the delivery of a comprehensive PO program.

Technical Support

Information technology and informatics resources

Heterogeneity in laboratory offerings results in a lack of standardization with regard to the genes and variants tested, how results are reported, and the delivery of the results in a user-friendly language. The role of the technical informatician is crucial to address the challenges associated with a constantly evolving testing platform and the rapid evolution of PO applications. The many challenges in increasing the use of PO within the context of the current rapid trajectory of testing and drug development have been described in the literature.[1] The volume of data generated with each tumor profile test emphasizes the critical importance of processing and interpreting the data while ensuring its availability to clinicians. It is crucial to have dedicated resources that can adapt to a highly dynamic field and its fast-growing technologies. PO data are complex and there are challenges in translating genomic information into clinic applications.[2] Having a novel EHR tool like Epic Genomics Modules, which can be integrated within the EHR, can serve as a backbone for customizations and house the information from external laboratories. Additionally, housing genomics data in an easily retrievable place within the EHR can facilitate therapy decision-making at the time of patient-oncologist encounter. The broad landscape of PO is constantly changing with rapidly evolving tests and technologies and updated clinical evidence, which makes it hard for clinicians to remember how, when, and which test to order. Having a dedicated space within the EHR that houses the data feed from multiple tests and laboratories, with guidance to clinicians on how to order them, is extremely important.

Clinical decision support systems and novel tools

Lack of education, awareness, and training among clinicians and oncologists is a barrier to implementation, as is the rapid progress that is being made in PO with new tests and treatments. Integrated clinical decision support tools and best practice alerts are needed to inform the busy clinician and are crucial for a successful adoption of PO. Precision medicine was premised on integrating patient's specific clinical data, genomics data, and demographic and socioeconomic factors; therefore, advanced AI and machine learning tools should be embedded within the EHRs to integrate patients' data and tumor genomics in order to generate easily interpretable information to guide therapy plans.[3–6] The use of AI and machine learning tools as a key component of clinical decision support was

proposed as a solution to overcome the increasing volume and complexity of genomics and clinical data.

Enhance clinician adoption of testing

Despite many guidelines for testing actionable mutations, compliance with ordering the tests is lagging. In general, data suggest that real-world testing remains low.[7,8] Robert et al noted that less than 50% of patients in a national community oncology network were tested for 5 key biomarkers. Bruno et al[8] further described that among those being tested, there was a double-digit discrepancy in testing Black versus White patients. When looking at the demographics of patients enrolled in clinical trials in general, but also in PO pharmaceuticals, it is not uncommon to see that most trials enroll White subjects as compared to other races. Certain interventions may enhance the physician's adoption of testing, such as education, reflex testing, having easily accessible and interpretable data, EHR-integrated and AI-driven clinical decision support tools, and having support for coverage and patient counseling.

Access to Research and Clinical Trials

Despite the availability of multiple therapeutic options for actionable targets, many targets do not have approved treatment, and therefore it is very critical to have a robust research program to facilitate patient access through specific biomarker-matched novel therapies. Ideally, biomarker-linked trials would be locally available to patients and thus minimize the need to travel for treatment. There are better study designs and large umbrella protocols that would make it more feasible to help a large number of patients with various mutations.[9–13]

Equitable Access to Testing

Many have commented about the disparity in access to genetic testing as one of the major barriers to wide adoption, aligned with many reports that describe the disparity in testing,[8] for example, describing that among those being tested, there was a double-digit discrepancy in Black versus White patients. When looking at the demographics of patients enrolled in clinical trials in general, but also in PO pharmaceuticals, it is not uncommon to see that most subjects are White as compared to other backgrounds.[1,14–16]

Addressing the Financial Challenges

Financial and economic barriers are one of the most difficult challenges that impede the implementation of PO.[5] There are many concerns related to the associated costs of testing and treatment, including billing and reimbursement of the tests. Lack of coverage for the tests is a major barrier to order testing, but many laboratories have generous financial support for testing. Ordering clinicians may have implicit bias in ordering due to concerns of financial toxicity for patients. Additionally, the existence of various laboratories with different approval procedures for billing and reimbursement is confusing and may be a deterrent for clinicians. Economic studies that show cost-effectiveness and highlight the positive survival and clinical outcomes associated with genetic and pharmacogenetic testing are needed to justify insurance coverage for genomic testing. Having the support of a financial counselor in helping and educating patients, starting the preauthorization process early, and using various patient assistance programs would help in addressing some of these issues. In addition to exploring innovative and collaborative payer agreements, meeting technical assessment standards and developing test-specific appeals can all bolster the revenue for PO testing.

Relevant Activities

Molecular tumor board

A molecular tumor board (MTB) is an essential component of the PO program to help in applying advanced knowledge in patient care. An MTB should include an array of specialists and support clinicians in determining which test to order, how to interpret the data, and how to select the best biomarker-driven treatment. Establishing independent MTBs is important in the initial phase of adoption of PO in the practice, but eventually it will be difficult for the MTB to address all issues related to patients with different diseases; therefore, each site-specific tumor board should enhance its molecular expertise to accommodate the peculiarities of each site for individual patients, as the workload will become overwhelming for one MTB to cover all sites and all scenarios. If the practice lacks the expertise in interpreting the data, potential collaboration with testing laboratories to provide experts in the field may help address this issue. Documenting the MTB discussions is an important step in keeping track of recommendations provided.

Pharmacogenomic pharmacist support

Adoption of pharmacogenomic risk stratification, as well as discussion of testing and implementation of pharmacogenomic-guided prescribing within and beyond oncology, is a key component of enhancing PO Pharmacogenomic pharmacists play a critical role in this implementation process and should be an important consideration.

Educational Activities

Educational programs and activities in different formats that address various stakeholders are important to help advance the implementation of PO in practice. Educating the institution leaders about PO and what is the added value of its implementation would help garner leadership support for the program.

Educating oncology providers about the available tests, ordering process, and accessing and interpreting the data would help to increase the test orders. A centralized scientific review process can help streamline institutional adoption of new tests and technology. As the boundaries between somatic and germline DNA results continue to blur—with germline results being applicable for therapy, and with more patients with cancer identified with germline mutations even when they do not meet National Cancer Comprehensive Network (NCCN)

guidelines for germline testing[17] it is important for clinicians to have some mastery of both genomic sources. There is an ongoing need to develop more formal education in genetics, genomics, and PO beyond what most practicing clinicians received in training. Providers with formal training, board certification, and licensure as genetic counselors or medical geneticists can support education for other clinicians as genomic testing applications expand.

Health Equity Diversity and Inclusion in Precision Oncology

Studies looking at precision medicine have shown a lower uptake and implementation among racial and ethnic minorities, with the need to address disparities.[18] With the automation of protocols free of implicit bias, there is a promise to reduce disparity. EHR integration of genomic testing allows the merging of genomic data, measurable outcomes, and demographic data for improved capabilities to assess health equity in genomic testing and the opportunity for improvement.

Patient Advisory Group

Finally, as the patient remains the center of all healthcare activities, it is very critical to ensure the involvement of patient advisory groups in the process to bring the patient perspective into focus. Moreover, awareness and education can be key in managing patient expectations through the regulatory and scientific processes.

CONCLUSION

The rapid evolution of PO and its effect on patient treatment and outcome dictates the need for a systematic organization approach to overcome implementation barriers of PO and empower individual healthcare members to do their part well in this mission. A group of panelists with multiple expertise from diverse institutions identified these barriers and proposed solutions to accelerate PO in practice. This report is unique as it includes insights from different specialists. The panelists concur on the identified barriers and proposed solutions. They identified barriers such as logistics and infrastructure, lack of consensus among laboratories, need for education efforts, equitability, access, and financial barriers.

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