Cancer Care and Cancer Research in the Context of the COVID-19 Pandemic

Session 6
Panel Discussion: Collaboration and Coordination to Improve Cancer Care and Cancer Research in the Post-Pandemic Era

SESSION MODERATOR
Richard L. Schilsky, University of Chicago

PANELISTS:
Session 1 Moderators: Nancy Davidson and Lawrence Shulman
Session 2 Moderators: Antoni Ribas and James Doroshow
Session 3 Moderators: Larissa Nekhlyudov and Karen E. Knudsen
Session 4 Moderators: Randall A. Oyer and Robert A. Winn
Session 5 Moderators: Samir Khleif and Donna Rivera

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NATIONAL CANCER POLICY FORUM

SESSION 1: Cancer Care Delivery During the COVID-19 Pandemic and the Impact on Patients with Cancer

Moderators:
Nancy Davidson, Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance
Lawrence Shulman, University of Pennsylvania Abramson Cancer Center

Key Takeaways:

1. A time of uncertainty and fear (even for oncologists) that highlighted preexisting deep disparities in the US
2. A realization that the "show must go on" for oncology patients tempered by the need to work within the larger health ecosystem
3. Capitalizing on our traditional strengths in infection control in oncology
4. Magnified the need for communication, organization, and clear lines of command
5. Confirmed value of preexisting response structures that can pivot for the moment (like adding ID specialists to Incident Command)
6. Facilitated collaboration between traditional competitors (e.g. practices in a single town or different professional societies)
7. Driven by the needs of cancer patients in the context of the larger society

Recommendations from Session 1 Speakers

1. Structure matters in so many ways from societal to institutional.

2. We can work together and we should not lose that collaborative spirit —maintain the connections that have emerged – we can accomplish more, more quickly.

3. Continuous and accurate communication has never been more important to engender trust in all stakeholders.

4. Ability of the health care work force to rapidly innovate and adapt is an asset.

5. Partnership from government, regulatory agencies and payers is crucial to move beyond this pandemic and prepare us for the next crisis.

6. As the pandemic becomes "less pressing" we should use the same sense of urgency and spirit of collaboration and energy going forward – more than half a million people die of cancer every year in the US.

SESSION 2: Clinical Cancer Research During the COVID-19 Pandemic

Moderators:
Antoni Ribas, University of California Los Angeles
James Doroshow, National Cancer Institute

Key Takeaways:

1. COVID-19 forced the most unprecedented change to clinical trial conduct in modern oncology:
   - 0% data verification rates of data entry between March-April 2020
   - Sharp decrease in clinical trial participation, with recovery, but still accruals are 20% below pre-pandemic in NCCN trials
2. Many adaptations to clinical trial conduct forced at the beginning of the pandemic are positive changes that should be carried on post-pandemic:
   - Patient-centered clinical trials, with remote consenting, decentralized interventions, telemedicine
3. Decentralized clinical trials would facilitate participation for more diverse populations
4. Late-stage clinical trials should focus on the primary endpoints and minimize collection of data that is not directly relevant

Key Takeaways:

5. Adaptations of clinical trial conduct were based on the application of existing technologies or new regulations, which the clinical trials enterprise had been reluctant to incorporate

6. There are multiple limitations to continued conduct of clinical trials during the pandemic:
   - Issues with medical record access for monitoring/auditing
   - A decreasing clinical trials workforce, with problems maintaining trained staff or hiring new staff

7. "Don't go back", should not miss the opportunity to implement long term the benefits on clinical trial conduct accelerated by the pandemic

Recommendations from Session 2 Speakers

1. Institutionalize changes to the cancer clinical trials system necessitated by the COVID-19 pandemic while developing the data needed to convince sponsors and regulators that these changes should be long-lived

2. Build upon initial decentralization efforts to expand clinical trial accrual in underserved communities through enhanced collaboration
   - Study how to broaden eligibility criteria further
   - Develop specific trials emphasizing clinical research questions for these communities

ABOVE ALL: Focus on improving the flexibility, speed, and effectiveness of the cancer clinical trials system while ensuring patient safety and scientific integrity

SESSION 3: Telehealth in Cancer Care and Clinical Cancer Research: Opportunities, Constraints, and Unintended Consequences

Moderators:
Larissa Nekhlyudov, Brigham & Women's Hospital/Dana-Farber Cancer Institute
Karen E. Knudsen, American Cancer Society

Key Takeaways:

1. Telehealth has some clear benefits for patients, health care providers, (systems?), and is likely to further expand usage in the cancer care continuum and clinical trials

2. Barriers include disparities related to e-technology & overall health literacy, geography, insurance, SES, regulatory requirements, etc.

3. There are mechanisms to reduce disparities including (use of kiosks, training, availability of voice-only option, expansion of broadband, etc.)

4. Multidisciplinary telehealth approaches (including nurses, NP/PA, other health care professionals) can improve care, communication/coordination with PCPs/specialists

Recommendations from Session 3 Panelists

1. Reduce barriers by removing state licensure requirements or expanding compacts among adjacent states

2. Expand insurance coverage for services provided across state lines, with parity for voice only and video-based visits

3. Promote patient-centered research on which type of clinical visits and clinical trial follow up may be achieved by telehealth (also including provider experience and overall quality of care)

4. Engage with advocates, organizations to refine telehealth usage implementation, to the benefit of patients, caregivers, and providers

SESSION 4: Learning Rapidly to Improve Cancer Care Delivery and Advance Health Equity Beyond the COVID-19 Pandemic

Moderators:
Randall A. Oyer, Penn Medicine Lancaster General
Robert A. Winn, Virginia Commonwealth University Massey Cancer Center

Key Takeaways:

1. Unaddressed social determinants of health (SDOH) undermine medical advances for individuals and populations, yet SDOH are incompletely and unreliably collected, measured, considered, and acted upon.
2. Health care is a community enterprise, yet cancer centers often have inadequate connection with, and sustained presence in, many communities and geographies.
3. Access, quality of services, and outcomes vary unacceptably across communities, distance from cancer centers, and regional geography.
4. Structural inequities, structural barriers, racism, and bias all cause injustice in cancer care delivery and health outcomes.
5. Cancer care delivery is more adaptable than previously realized. To do better than pre-pandemic, we must learn from this experience.

Recommendations from Session 4 Speakers

1. SDOH must be reliably collected, incorporated into care, and acted upon. Collection and utilization of SDOH must be tied to receiving research dollars. Research must identify/vet which SDOH are useful. Teams must learn how to ask and listen for SDOH.

2. NCI should use the cancer center model to require specific features and metrics of community partnership that result in meaningful, sustained, and effective engagement that build trust and improves outcomes in catchment areas.

3. Close gaps in access to care with payment models, digital processes, removing social needs barriers, and building networks that provide cancer center level care outside the cancer center.

4. Acceptance of Medicaid must be an absolute requirement for receipt of federal funding.

5. We must retain professional and lay navigation, high functioning team based care, care coordination, and distributed care closer to home.

SESSION 5: Cancer Care Delivery During the COVID-19 Pandemic and the Impact on Patients with Cancer

Moderators:
Samir Khleif, Georgetown University Medical Center
Donna Rivera, Food and Drug Administration

Key Takeaways

Amid all the challenges, there are silver linings:

Efficiency	• Rapid trial initiation, consenting, and implementation • Approval process of protocols and contracts • Use of remote assessments and rapid enrollment at sites in the community was required and possible
Equity/ Access	• Amplified the need to increase representation and generate more inclusive evidence for broader population • Access to decentralized trials and expanded enrollment
Data and Evidence	• Expanding beyond the traditional RCT to rapidly generate data for public health purposes, including examples of pragmatic designs and use of RWD • Methods required to ensure data management, integrity and quality with new strategies • Fit for purpose evidence development along the RCT→ RWD continuum, including use of novel trial designs
Regulatory Innovation	• Processes that modernize drug development review, authorization, and approval that are patient centric
Collaboration	• Extensive collaboration and stakeholder engagement between academics, industry, and regulators for vaccine and therapeutic trials

Recommendations from Session 5 Speakers

WHAT	HOW
Enhance operational Efficiency	Faster initiation/approval and contracting process Remote execution (consent, auditing etc.) Identify high risk issues and develop mitigation strategies
Enhance equity & Increase Access	Trial at the patient site and engagement of local health team (Need for GCP), Digital/tele health and drug delivery Determine the requirement and incentives
Prioritize Trial Innovation	Fit for purpose: What is the right design (RCT, RWD, pragmatic, hybrid) and data to answer the question? Ensuring data quality - data governance, interoperability and others ..
Modernize Regulatory req	Simplify study endpoints and reporting requirement and end point Retrospective and prospective evaluation of effects of remote assessment and deviations; Risk assessment of such simplification
Maintain collaboration	Maintain sense of urgency Define incentives for wide collaboration (even between competitors)
New Financial Models	Re-evaluation of the role of the middle organizations Restructure trials pricing models & develop healthcare system incentives De-risking of trials through purchase agreements Collaboration of funding agencies

CONCLUDING REMARKS:

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