The University of New Mexico Comprehensive Cancer Center

A National Cancer Institute Designated Comprehensive Cancer Center The Official Cancer Center of the State of New Mexico

Legislative Health and Human Services Committee

UNM COMPREHENSIVE CANCER CENTER JULY 24, 2019



Mission

- To provide access to state of the art, integrated multispecialty cancer diagnosis and treatment for <u>all</u> New Mexicans.
- To provide statewide access for <u>all</u> New Mexicans to new cancer treatments and cancer clinical trials (discovery, screening, prevention, therapeutic) through community collaboration.
 - Cancer Genomic Sequencing for Targeted Therapeutics; Immunotherapy
 - Bone Marrow and Stem Cell Transplantation; Therapeutic Radioisotopes (Theranostics)
- To conduct outstanding research in our laboratories, clinics, and communities to discover the causes and cures for cancer, particularly those cancers disproportionately affecting New Mexico's minority, underserved, and rural populations, and to translate discoveries into more effective means to prevent, diagnose, and treat cancer.
- To reduce New Mexico's cancer burden by discovering the genetic, environmental, social, and behavioral factors that contribute to the unique patterns of cancer incidence, mortality, and disparity in our catchment area, and, to conduct research and interventions to overcome these factors.
- To educate, train, and mentor cancer health professionals and scientists, with an emphasis on training under-represented minorities.
- To promote economic and workforce development through our discoveries and missions.



History

- 1971: Founded by the State Legislature and UNM School of Medicine Funded as one of the State's first Research and Public Service Projects (RPSP)
- **1999:** Willman appointed as Director & CEO
- 2000: Began process to achieve federal funding and National Cancer Institute (NCI) Designation Awarded NCI P20 Cancer Center Planning Grant
- 2003: Received new state appropriations and funding in support of NCI Designation process and for recruitment of cancer physicians, scientists, and staff
 Designated by State Legislature as The Official Cancer Center of the State of New Mexico Formed one of the nation's first statewide networks for access to cancer clinical trials
- 2005: Achieved designation and federal funding as a NCI Cancer Center
- 2010: Renewed federal designation as a NCI Cancer Center
- 2015: Attained highest federal designation as a NCI Comprehensive Cancer Center One of only 49 elite NCI Comprehensive Cancer Centers in the U.S. Ranked among the top 3% of the nation's 1800 Cancer Centers



Ambulatory Clinical Care and Clinical Research Facility



UNMCCC Cancer Treatment & Clinical Research Facility

- Ambulatory Cancer Treatment Facility: Fully integrated multispecialty clinical practice; Infusion; Imaging; ORs; Tricore Lab; Cyclotrons; Clinical Trials Office
- Completed in 2009; Finish Out 2016; 206,432 sq. ft.; \$152 million
- New Mexico's most highly accredited and ranked cancer program (NCI, US News & World Report, TJC, ASCO, ACOS)

Clinical Accomplishments / Impact

NM Largest Team of Cancer Specialists

- 142 Oncology Physicians
- 124 Cancer Research Scientists
- 548 Staff
- **158** Students, MD, PhD Trainees

Clinical Volumes:

FY19: 12,238 Patients; 148,500 Visits **Las Cruces:** 570 Pts; 5300 Visits **Silver City:** Clinic Opened: 10/20/17

Patients Served:

65% of NM Adults Affected by Cancer60% of NM Children Affected by Cancer52%: Racial/Ethnic Minorities

Net Ambulatory Clinical Revenues: FY19: \$107,754,209

Federal Grant Funding: FY19: \$38 Million

Uncompensated Ambulatory Care: FY19: \$15,343,911 (est.); 14% of Patients Bernalillo County Support: \$1.9 Million FY19 State Support: \$5,741,062

N E W M E X I C O



	1	T	
Patients Treated in 2018 (fiscal year)	In State: 11,994	Out of State: 244	Total: 12,238

Why is Being Diagnosed and Treated at an NCI Comprehensive Cancer Center so Essential?

The Benefit of Science!, Access to Clinical Trials, Integrated Multispecialty Practice

Precision Medicine

- Genomic
 Sequencing of
 Human Cancers
- New Treatments Targeted to Specific Cancer Mutations



Immunotherapy

- Enhancing the Body's Immune System to Fight Cancer
- Cancer cells evade the immune system by expressing PD-L1 and blocking anticancer T cells
- New anti PD-L1 treatments





Cancer Research Facility



UNMCC Cancer Research Facility (CRF)

- 5 floor, 125,000 sq. ft. research facility completed in 1999; (36 wet labs; 2 dry floors)
- Ground Floor: Epidemiology, Population Health, Biostatistics, Bioinformatics, New Mexico Tumor Registry
- 1st Floor: Cancer Genomics; Basic Molecular Sciences; Genomics / Sequencing Cores
- 2nd Floor: Cancer Cell Biology and Signaling; Cellular Imaging Cores
- 3rd Floor: Clinical and Translational Laboratory Research; Cancer Immunology
- Master Strategic Plan (2020): Plan New Wet Laboratory Facilities (CRF Expansion or New Site)



Research Accomplishments / Impact

- Discovered unique cancer patterns, outcomes, and disparities in NM populations
- Created nation's first prospective HPV/PAP cancer screening registry; now building registries for colorectal cancer screening and HCV/liver cancer screening
- Built one of the nation's first statewide collaborative networks to assure all New Mexican's have access to new cancer treatments in cancer clinical trials (New Mexico Cancer Care Alliance)
- Discovered new cancer diagnostics and treatments for leukemias, ovarian cancer, breast cancer, melanoma, colorectal cancers, liver and hepatobiliary cancers, prostate cancer, kidney cancer, neuroendocrine tumors, brain tumors
- Discovering the role and mechanism of environmental exposures on cancer causation
- Developed resolutions with New Mexico Indigenous Pueblo Nations for collaborative studies of cancer etiology related to environmental exposures and the American Indian Cancer Genome Project
- Trained over 1500 students and fellows in cancer medicine, surgery, research, nursing, pharmacy, enhancing New Mexico's workforce
- Developed >200 patents and discoveries and 13 New Mexico biotechnology companies



New Mexico / NCI SEER Tumor Registry



Charles Wiggins, MD NMTR Director PI, NCI SEER Grant

٠

٠





- 1966: Established by SOM; NM Legislature mandated reporting of all cancer cases statewide
 1973: Founding member of the NCI SEER Program
- **Coverage:** Conducts population-based cancer surveillance throughout New Mexico and American Indian Communities in Arizona (>300,000 registry patients)
- Leadership:Guided development of indigenous cancer registries nationwide (Arizona Tribal Nations,
Navajo Nation, Cherokee Nation, Hawaii & Pacific Islanders, Alaskan Native Registry)Linkages:Virtual linkages to diagnostic pathology, clinical laboratory records (ePATH), GPSControl of the sector of the sect
 - coding, and archived tissue samples enabling hypothesis-driven research
- New Initiative: NIH / NCI Moonshot: Integrated National AI Cancer Registry (SEER, CDC, IHS)

Cancers of the Colon and Rectum Average Annual Age-Adjusted Incidence Rate Male New Mexico Residents, 1982-2014

Non-Hispanic White

Hispanic American Indian





Hepatocellular Carcinoma Average Annual Age-Adjusted Incidence Rate New Mexico Residents, 1982-2014



NM HPV Pap Screening Registry



Cervical Cancer

Cosette Wheeler, PhD

- Expert in molecular epidemiology of HPV and cervical cancer in NM and globally
- Co-led first landmark clinical trials standardizing HPV screening and testing HPV vaccines (*NEJM*, 2002; Lancet, 2004)

Addressing Critical Questions:

- Determine the effectiveness of HPV vaccines in cervical cancer prevention
- Determine the benefits and harms of changing national guidelines for HPV/PAP screening
- Study and improve how guideline recommendations are implemented in real-world clinical practice

The Nation's only Statewide Prospective HPV/Pap Screening Registry)

- UNM HSC, UNMCCC, NM DOH and Legislature implemented changes to New Mexico law mandating reporting of screening data and biospecimen collection (*New Mexico Administrative Code: 7.4.3.12.Notifiable Diseases and Conditions Mandated Reporting: US Population-Based Cervical Screening Registry*)
- Integrated informatics: Screening registry linked to NM Tumor Registry to correlate screening data with incidence, outcome, and registry data for cervical and other HPV-associated cancers
- >4,00,000 data elements on 783,672 women and girls (98% NM population)
- Working with NM DOH to Develop Prospective Colorectal Screening Registry and HCV / Hepatocellular Cancer Screening Registries

Relative Reduction of HPV Prevalence in New Mexico by Birth Cohort A Real-world Assessment of HPV Vaccine Impact in the United States



Difference in HPV Prevalence for Different HPV Types New Mexico Statewide Population: A Real-World HPV Vaccine Study



Role of Catchment Area Environmental Metal Exposure From A Legacy Of Hard Rock and Uranium Mining and Cancer Etiology and Disparity Collaboration with College of Pharmacy



- >50% of Tribal Nations located in 13 States near 161,000 abandoned hard rock mines
- 600,000 American Indians live within 10km of an abandoned min
- 40% of western watershed headwaters contaminated from these mines (USEPA)
- Metals: Uranium, Arsenic, Lead, Copper, Cadmium Molybdenum, Mercury



Density of hard rock metallic mines in the western US. American Indian Reservation land is indicated by hatched polygon areas and mine densities are associated with intensity of red hues. Symbols indicate location of >10,000 abandoned uranium mine waste sites in 15 States, on or in close proximity to tribal lands including Navajo, Hopi, Pueblo, Laguna, Crow, and Sioux. Noted in red are project sites of UNMCCC environmental assessment, community engagement, and intervention. Biomedical Consortium Resolution with Indigenous Pueblo Nations (Eight Northern Indian Pueblo Council; Southern Pueblo Council Resolutions): From Cancer Screening, to Discovery and Precision Medicine July 29-30, 2019: Meeting of NM, AZ, OK Tribal Nations



Development of New Immunotherapy for Advanced, Recurrent Ovarian Cancer

- Immune therapy has revolutionized cancer treatment:
 - Restores the ability of immune cells to recognize and kill cancer cells.
 - Dramatically improved survival in several poor prognosis cancers
- Hypothesized that inhibiting the DNA repair machinery in ovarian cancer (PARPi) would sensitize the cancer to immunotherapy (CTLA4 antibody).
- Phase I Trial completed at UNM; dramatic responses
- National Phase II Trial, led by UNMCCC; Moffitt Cancer Center, U Virginia, Ohio State Cancer Center
- Selected as a NCI NRG National Trial



Baseline Cycle 6





Sarah Adams, MD GYN Oncology



Development of New Immunotherapy for Melanoma, Pancreatic, Colorectal Cancer

- Identified a novel receptor for estrogen in human cells (GPER)
 - Synthesized agonists (G-1) that activate and antagonists (G36) that inhibit GPER
 - GPER also plays a critical role in aging and cardiovascular disease
- Collaboration with UPENN found that G-1 combined with immunotherapy inhibits growth of several poor prognosis cancers in animal models
- New UNM-UPENN partnership with start up company *Linnaeus Therapeutics* (IND, FDA)
- First in human clinical trials will be be conducted in New Mexico at UNMCCC





Challenges and Opportunities

CMS Reimbursement Cut to Public Safety Net Hospitals

- Effective 1/1/18, through Executive Order, the Centers for Medicare & Medicaid (CMS) implemented a new federal rule that reduced reimbursement by \$1.6 billion annually to public safety net hospitals and cancer centers participating in the Congressionally-mandated 340b drug purchasing program
- The 340b program requires drug manufacturers to sell drugs at discounted prices (30-40%) to hospitals and cancer centers that provide a disproportionate share of care to low income, rural, poor, and underserved patients.
- The net effect of the CMS reduction was to wipe out the 340b benefit and eliminate any net margin for program investment or recruitment.

• Impact:

- \$9.75 million annual reduction in federal reimbursement to UNMCCC.
- While already providing \$15 million in unreimbursed ambulatory cancer care, this additional federal cut leads to a \$25 million hit to the Cancer Center's bottom line.
- Reduced staff (35) and postponed critical physician and scientist recruitment; challenge with retention of physicians and scientists
- Ceased development of new clinical, research programs, and education programs
- Seriously jeopardized competitive renewal of NCI Designation and Federal Funding



Challenges and Opportunities: FY20 RPSP Expansion Request

Postponement of NCI Federal Renewal Application (Due 9/25/2019) to 2020

- A major evaluation metric for NCI Designation is state and institutional funding support:
 - FY19 State Funding: **\$5,741,062**
 - FY20: Requested **\$5 million increase**; Received **\$750,000 recurring; \$1.25 M non-recurring**
 - Insufficient recurring funding to proceed with critical recruitments led to recommendation by the UNMCCC External Scientific Advisory Board and leadership to delay NCI renewal submission
 - While NM state support was considered exceptional, it has now fallen behind other NCI Centers (Oklahoma: \$11M; Hawaii: \$13M; Virginia: \$15M; U Miami Sylvester: \$36M)

• FY20 RPSP Expansion Request: \$4.25 Million Recurring

- Recruitment of 4 cancer physicians and 8 scientists and associated research staff
- Hiring critical staff to develop new therapeutics programs not available in NM (bone marrow/stem cell transplantation, immunotherapy, theranostics, cancer surgery clinics)
- Increased support for statewide clinical trials network and community outreach
- Stabilize and increase investments in education and training programs for workforce development
- Improve informatics and electronic data systems for clinical care and research (new NCI Metric)



Challenges and Opportunities

- Significant Increases in Patient Volumes: 525 vs. 800 New Patients Per Month Causes:
 - UNMCCC provides cancer specialty care and unique medical and surgical cancer treatments not available elsewhere in New Mexico, which only UNM can deliver
 - Aging of New Mexico's population is leading to a significant increase in cancer incidence
 - New cancer therapies are dramatically improving patient survival and cancer is becoming in many patients a manageable chronic disease
 - Must maintain patient access and continue to build staff and programs to meet patient need
 - Now provide care for a large number of New Mexico veteran's in collaboration with the VA Hospital



Challenges and Opportunities: Facility Expansion Request





Matthew Fero, MD, PhD

Leslie Andritsos. MD



Heloisa Soares, MD, PhD



Reed Selwyn, PhD





Building Cancer Service Lines Not Currently Available for New Mexico's Cancer Patients

- **Bone Marrow and Stem Cell Transplantation & Cell-Based** • Immunotherapies (Only FACT Accredited Program in NM)
 - **Need:** GMP Cell Processing Laboratory for Clinical • Program and Access to New Therapies from Industry
- **Targeted Radioisotopes / Theranostics**
 - **Need:** GMP Radiochemistry/ Radiopharmacy Laboratory, Theranostics Shielded Infusion Suite, Interventional Radiology Room
- Stereotactic Radiosurgery (Brain & Spinal Cord Tumors; • **Organ Metastases; Vascular Malformations)**
 - **Need:** New Vault and Linear Accelerator



UNMCCC Radiation Oncology and GMP Laboratory Facility Expansion

Expansion and Renovation of Current Clinical Facility

ADDRESSING CHALLENGES AND NEEDS

- Significant Increase in patient volumes: 525 vs.
 800 new cancer patients per month
- Insufficient RO capacity (4 Vaults): Capacity: 75 pts/day; Demand: 95 pts/day
- Recently informed that Tomotherapy Accelerator (IMRT: 25 pts/day) at end of life in 2021
- NM need for state of the art stereotactic radiosurgery accelerator (for brain and spinal cord tumors and organ metastases)
- Need for infrastructure laboratories to assure access to marrow/stem cell transplantation and new immunotherapies and radiotherapies

PROJECT BENEFITS

- Addresses tremendous growth in cancer patient volumes and meets patient need
- Assures access to state of the art radiation oncology technologies and procedures
- Provides and assures access for New Mexicans to newer cancer treatment modalities not currently available in NM that only UNM can deliver:
 - Bone Marrow/Stem Cell Transplantation (UNM: New Mexico's only FACT Accredited Program)
 - New Therapeutic Radioisotopes
- Provides new health profession and workforce training programs and clinical research opportunities



UNMCCC Radiation Oncology and GMP Laboratory Expansion

Expansion and Renovation of Current Facility: Project Plan

- 1. Radiation Oncology Expansion / Theranostics (New 11,060 GSF; Ground Floor)
 - New Radiation Oncology Vault: State of the Art Linear Accelerator for Stereotactic Radiosurgery
 - Replacement Linear Accelerator for End-of-life Tomotherapy (Renovating Existing Vault).
 - New Theranostics Therapy Suite: Shielded for Intravenous Delivery of Targeted Radioisotopes
 - Interventional Radiology Room for Intra-Body/Organ Delivery of Targeted Radioisotopes
- 2. GMP Radiopharmacy / Radiochemistry Laboratory for Theranostics (Shelled 1410 GSF)
 - Renovation of Shelled 1410 GSF for GMP Laboratory to Produce Innovative New Therapies
- 3. GMP Cell Based Processing Laboratory for Transplantation & Immunotherapy
 - New 2700 GSF, FDA 351/361 certified cGMP Laboratory: Support FACT Accredited Marrow and Stem Cell Transplant Program; New Cell Based Immunotherapies (CAR-T Cells; Cancer Vaccines)
- 4. Administrative / Office Space (11,060 GSF): Clinical Research Office; Administration, IT



UNMCCC Radiation Oncology and GMP Laboratory Expansion





Summary FY 20 Legislative Requests UNM Comprehensive Cancer Center

- 1. RPSP Expansion Request: \$4.25 Million, Annual Recurring
- 2. Facility Expansion Request: \$22 Million

