Peripheral Neuropathy Project Portfolio Analysis

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Peripheral Neuropathy (PN) Portfolio Overview

- As a grouped condition, PN included:
  - Painful diabetic peripheral neuropathy (DPN)
  - HIV/AIDS painful neuropathy
  - Charcot-Marie-Tooth (CMT) pain
  - Chemotherapy-induced painful neuropathy (CIPN)
  - Post-herpetic neuralgia (PHN)
  - Chronic inflammatory demyelinating polyneuropathy (CIDP) pain/painful autoimmune neuropathies
  - Carpal tunnel and other nerve entrapments

- Not included—although have painful PN involvement:
  - Celiac, Lyme, Idiopathic Neuropathy, Small Fiber Neuropathies
Prevalence of Peripheral Neuropathies

The millions in U.S. with peripheral neuropathy include:

- 15-18 million with diabetic peripheral neuropathy \textit{(Neuropathy Association)};
- 79 million with pre-diabetes who are at risk for developing DPN \textit{(CDC)};
- 230,000-575,000 with HIV-neuropathy, or 20-50\% of HIV patients \textit{(CDC)};
- 420,000 with chemotherapy-induced neuropathy, or 30\% of cancer survivors \textit{(American Cancer Society)};
- 125,000 with Charcot-Marie Tooth hereditary neuropathy \textit{(CDC)}. 
Peripheral Neuropathy Project Portfolio Overview

- 69 projects identified across the pain portfolio.
- Projects found across NIH institutes and at the VA--but at no other agencies.
- Basic science constituted core of the portfolio.
- Less than a third of the projects had a translational research component.
- Less than 50% had a clinical research component.
- Of the 39 projects with a basic science component, 28 projects were 100% basic science (40% of PN portfolio).
- Of the 24 projects with a clinical research component, 16 projects were 100% clinical research (23% of PN portfolio)—majority of these projects address diabetes or PHN, with only one project each for CIPN and HIV neuropathy.
Top Tier 2 Categories in the Peripheral Neuropathy Project Portfolio

- Neurobiological/glial mechanisms of nociception and pain: 26%
- Mechanisms of and treatments for transitions in pain phase: 10%
- Development and validation of animal and human pain models: 8%
- Genetics and genomics of nociception and pain: 7%
- Pharmacological mechanisms and treatment: 7%
- Training in pain research: 7%
- Analgesic development: 6%
- Non-pharmacological mechanisms and treatment: 5%
- Unique populations (only pediatric-CMT and elderly considered): 5%
- Biobehavioral and psychosocial mechanisms and treatment of pain: 3%
- Development of device and therapy delivery systems: 3%
- Pain prevention: 3%
- Pain outcomes assessments/measures; novel health IT as tools for decision making support of pain management: 2%
Lowest Tier 2 Categories in the Peripheral Neuropathy Project Portfolio

- Other “omics” of pain: 1%
- Diagnosis/case definitions 1%
- Medical management of pain 1%
- Health disparities in pain, pain management, and access to care 1%
- Pain and women’s and minority’s health research 1%
- Pain and trauma 1%
- Chronic overlapping pain conditions in an individual 1%
- Pain and other non-pain co-morbidities 1%
- Development of informatics, data bases, and IT as tools for pain research 0%
- Pain education 0%
- Epidemiology of pain and pain disorders 0%
- Sex and gender differences in pain 0%
- Comparative effectiveness research 0%
- Pain and substance use and abuse/addiction 0%
- Analgesic drug safety 0%
- Health care utilization 0%
Notable in Portfolio Review

- Emphasis on basis science not surprising given need for more knowledge to lead to clinical development of disease-modifying agents for PN
  - Greater focus needed on nerve repair, nerve regeneration, neuroprotective models
  - Work on HIV-PN neuroprotective models, DPN autonomic neuropathy human models to prevent amputations hold great promise
- PHN only getting attention for prevention
- Research training only focused on DPN
- Only unique populations addressed are pediatric and elderly
Notable in Portfolio Review (cont.)

- With emphasis on basic research, patients left in care and treatment black hole:
  - Challenges in accessing existing care, treatment, supportive therapeutic options
  - Comparative effectiveness of available therapies not addressed
  - Biopsychosocial aspects non-existent
  - Epidemiology does not exist
  - Co-morbidities and overlapping conditions not being considered
  - Lack of education presents barriers to care
Relevance to Other Pain Conditions/Collaboration Opportunities

- Broad base of untapped opportunities both to generate basic science research to benefit many as well as leverage existing care models on behalf of neuropathic pain communities
- Neuroprotective mechanisms could be relevant to all toxic neuropathies, provide support against viral/biochemical imbalances
- Nerve repair/regeneration research: direct correlation to all neuropathic pain conditions
- Shared relevance for education and healthcare utilization for other neuropathic pain conditions.
Potential Overlap/Shared Interests Among Agencies or NIH Institutes

● Given its “footprint,” PN should have been found across the entire government research portfolio

● PN/neuropathic pain ripe for platform/roadmap that is cross-agency/cross-institute

● Current research across the portfolio does not neatly connect to effect real change

● Pain component across the spectrum of neuropathies not adequately realized and recognized by researchers and clinicians alike
Research Gaps and Opportunities

- Greater emphasis needed on nerve repair, nerve regeneration, neuroprotective mechanisms

- Greater emphasis on the areas that are impacting patients NOW: education, access to all therapies available, integrative approaches, better understanding of co-morbidities and overlapping conditions so care moves into the realm of “practical”

- Epidemiological studies would help strengthen documentation of prevalence and healthcare trends to protect access to care until better therapies and cures are found.