NIDCR - Sponsored Practice-Based Research Networks (PBRN)

Designed to gather "real-world" evidence for the prevention and treatment of oral diseases

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Dental Practice-Based Research Networks - Purpose

- Answer questions facing general dental practitioners in the routine care of their patients
- Strengthen knowledge base for making clinical decisions
 - Observational studies
 - Clinical trials
 - Establish/use a flexible, adaptable electronic network/platform for connectivity, data sharing, & communication within and between dental and medical networks

- Ideas to be generated by practicing dentists and dental hygienists (i.e., practitioner-investigators)
- Primary objectives:
 - Conduct 16-22 short-term clinical studies over 7 years
 - Emphasis on effectiveness of oral health treatment & disease prevention
 - Clear & clinically meaningful outcomes
- Secondary objective: Provide data on disease and treatment trends and obtain estimates of the prevalence of less common conditions

- Establishes partnership between practitioners and experienced researchers
- PBRN's conduct research in the real world of dental practice
 - Draw on experience & insight of practitioners to help identify and frame questions
 - Findings likely to be immediately relevant to dental practice
 - Results are likely to be accepted and implemented in dental practice
 - Certain types of studies can be conducted more costeffectively than if supported as stand-alone studies

- Many questions faced by dentistry are most appropriately addressed in practice-based dental settings
- Dental PBRNS may implement protocols developed by one another
- To prevent duplicity of studies in NIDCR portfolio, Dental PBRNs provide NIDCR a summary of prospective protocol prior to development

 At least 100 dental practices per Dental PBRN will be recruited to participate during the first year of operations.

 Each PBRN will involve large numbers of practitioner-investigators in at least <u>two</u> <u>population centers.</u>



Participating PBRN Dentists (n \approx 400) by U.S. State (24) & Countries (3) after First Year









Delaware



Florida



Georgia



Idaho



Northwest PRECEDENT

Massachusetts (PEARL





Pennsylvania



Michigan



Rhode Island



Mississippi



Utah



Montana



Virginia



New Hampshire (PEARL)



Vermont



New Jersey



Washington



New York (PEARL



Washington DC PEARL



Ohio



Oregon



Scandinavia



Sweden Denmark Norway

Dental Practice-Based Research Networks – Organization

- Network Chair
- Coordinating Center
- Executive Committee
- NIDCR Staff

- Protocol ReviewCommittee
- IRB
- DSMB (Phase III Trials)

Dental Practice-Based Research Networks – Executive Committee

Composition

- Network Chair
- PI of Coordinating Center
- 5-6 elected practitioner-investigators
- NIDCR staff

Dental Practice-Based Research Networks – Executive Committee

Responsibilities

- Executive and administrative arm of PBRN
- Main governing body of PBRN
- Prioritizes research topics for submission to Protocol Review Committee
- Reviews and approves protocols prior to submission to Protocol Review Committee

Dental Practice-Based Research Networks – Practitioner Investigators

- PBRN trained and certified dentists and dental hygienists engaged in daily practice
- From more than one state and population center
- Representative of gender / racial / ethnic distribution of PBRN region
- Limited number may be from outside U.S. if standard of dental care is comparable to that in U.S

Dental Practice-Based Research Networks – Practitioner Investigators

Roles and Responsibilities

- Participate in Annual Meeting
- Elect representatives to Executive Committee
- Suggest studies to Executive Committee
- Contribute to protocol development
- Conduct studies in their practices
- Conform to IRB, DSMB, HIPAA regulations
- Contribute to manuscript preparation

Dental Practice-Based Research Networks - Review

Ideas for individual studies proposed to the PBRN Executive Committee

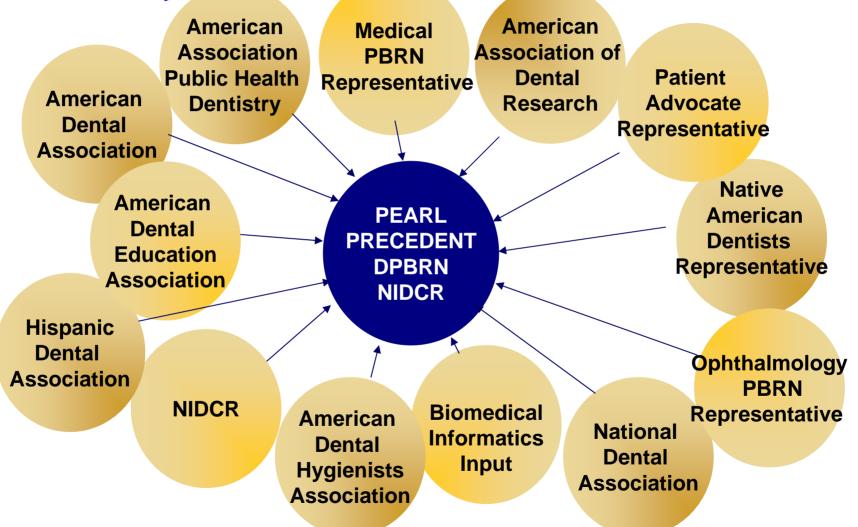
- After review by the PBRN Executive Committee, all protocols must be approved by:
 - Protocol Review Committee
 - IRB
 - DSMB for Phase III Trials

Monitoring Committee (MC) for Dental Practice-Based Research Networks

Provides NIDCR and PBRNs with feedback regarding research being proposed and conducted

Includes membership from various stakeholder groups

Dental PBRNs' MC



MC Provides Feedback to PBRNs & NIDCR

- General Organization and Operation of the PBRNS
- Informatics, Data sharing capabilities, and networks' interoperability
- Clinical Relevance
- Demographic and Ethnic Diversity
- Network Outcomes and Progress
- Knowledge Transfer to Practitioners and Public

PBRN Research Activities – First Year

 PEARL: First studies are focusing on treatment strategies for advanced dental caries

 DPBRN: First studies are focusing on treatment strategies for treating early carious lesions

PRECEDENT: First study is a survey of oral disease in PBRN practices

PBRN Collaborative Research Activities First year

Networks are collaborating on a proposal to study risk factors for osteonecrosis of the jaw in relation a variety of factors including use of bisphosphonate drugs

NIDCR is including a patient advocate on the Protocol Review Committee for this study

Networks are collaborating with the NIH National Cancer Institute's Center for Bioinformatics in defining common data elements and establishing a common data vocabulary repository