

## Research Opportunities for All

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## Developing a Research Agenda for the Prevention & Control of Healthcare-associated Infections in Dentistry

Kathy Eklund RDH, MHP  
The Forsyth Institute

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## Background

- 2000: OSAP awarded five-year cooperative agreement by the CDC to promote infection control and safety in dentistry.
- 2005: OSAP received supplemental funds to develop a research agenda for dental infection control.

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## Intent of the Research Agenda

- Identify and prioritize research topics that are feasible and measurable.
- Identify the type of research needed.
- Identify research that has practical applications.

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## Intent of the Research Agenda

- Establish a framework to apply evidenced-based information.
- Develop a document to stimulate research development and funding.

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## Process

- Steering Committee
- Literature Review
- Workshop
- Disseminate Report

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## Workshop

- Alexandria, Virginia on July 31- August 1, 2006.
- Participants were referred to:
  - ADA's research agenda,
  - NIDCR's strategic plan,
  - National Institute of Nursing Research's research agenda,
  - National Occupational Research Agenda (NORA),
  - 2003 CDC guidelines.

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## Workshop Participants

- individuals, associations, businesses, and governmental agency stakeholders in dental infection control.
- experts in microbiology, human behavior, regulatory affairs, public health, manufacturing, education, healthcare, clinical dentistry, infection control and research.

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## Charge

- identify gaps in the science
- prioritize research questions
- establish a framework for translational research and technology transfer
- identify entities to conduct and support research.

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## Presentations

- a dental infection control research update from 2002 to present
- a description of dental practice-based research networks (PBRNs) and supported research by the NICDR
  - Bruce L. Pihlstrom, DDS, MS
    - National Institutes for Dental and Craniofacial Research
- a progress review regarding CDC's 7 Healthcare Safety Challenges
  - Denise M. Cardo, MD
    - Centers for Disease Control and Prevention

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## Limited Evidence

- limited number and quality of existing research
- current practice standards based on limited evidence
- difficulty in proposing research without knowing the scope and magnitude of the needs

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## Scope

- Prevention & Control of Healthcare-Associated Infections (HAIs) among Dental Patients
- Prevention and Control of Occupationally Associated Injuries and Infections among Dental Healthcare Personnel

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## Model

Figure 1



DISCUSSION AND OBSERVATIONS

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## Principles and Assumptions

- Fill gaps in the existing science
- Identify efficient methods for surveillance and data collection
- Enhance translational and interdisciplinary research

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## Principles and Assumptions

- Identify and adopt research findings from other fields
- Integrate cost analyses
- Integrate infection prevention and control assessment throughout product and technology life cycle

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## Opportunities and Barriers

- Dentistry shares many commonalities with other areas of healthcare delivery
  - Learn from and collaborate with other healthcare fields
- The predominance of small group or solo practices complicates efforts to develop a cohesive body of epidemiological data upon which to base clinical interventions.

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## Summary

This research agenda is proposed to stimulate investigations that will develop an evidence-based standard of HAI control and prevention in dentistry.

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## The Challenge

Think outside the existing paradigm

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APCA  
New Orleans '07  
Creating Opportunities

84<sup>th</sup> Annual Session and Exhibition  
Creating Opportunities

## Dental Infection Control Research: Past, Present and Future

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SAFER • HEALTHIER • PEOPLE™ CDC

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## Objectives

- Review scientific support for 2003 recommendations
- Present topics and trends in current research (2002-2007)
- Identify barriers for research
- Discuss opportunities for future research

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## Background

### CDC Recommendations:

- Improve effectiveness and impact of public health interventions
- Inform clinicians, public health practitioners, and the public
- Based on a range of rationale, from systematic reviews to expert opinions
- Set the minimum standard of practice

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## 2003 CDC Guidelines Support for Recommendations

Category	Support	No. of Recs
IA	Strongly recommended Well-designed experimental, clinical, or epi studies	26 (16%)
IB	Strongly recommended Experimental, clinical, or epi studies	81 (48%)
IC	Required as mandated by federal or state regulation or standard	15 (9%)
II	Suggested Suggestive clinical or epi studies or a theoretical rationale	40 (24%)
Unresolved issue	No recommendation Insufficient evidence	4 (3%)
Total		166 (100)

>1/3

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## Categories of Research (2003)

- Educational / Policy / Guidelines
- Laboratory
- Clinical
- Epidemiological or Population-based
- Cost-Benefit / Effectiveness

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## Methods for Research Update 2002-2007

- NOT a systematic review of the literature
- Divided topics by reviewer expertise
- Reviewed articles randomly collected since 2002
- Used Medline search strategy from 2003
- Reviewed Ovid weekly updates and relevant guidelines published since 2002

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## Methods (cont'd)

- For each topic
  - determined the number of new articles
  - organized by research categories
- Summarized trends and quality of research

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## Topics Researched

■ BBPs, Exposure control, Post-exposure	■ Laser plumes
■ Hand Hygiene	■ Dental Water Quality
■ Latex Allergy	■ Frequency of DUWL monitoring
■ PPE	■ Sterile water
■ Saliva Ejectors	■ M. tuberculosis risks
■ Ster/Disinf	■ CJD risks
■ Medical waste	■ Evaluation of dental safety devices
■ Antimicrobial mouth rinses	■ Dental Laboratory
■ Dental radiology	■ Cost effectiveness
■ Handpieces	■ Program evaluation
■ Single use devices	

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## Total Number of Articles by Research Category

■ Educational/Policy/Guidelines	48 (32%)
■ Clinical	47 (31%)
■ Laboratory	31 (21%)
■ Epidemiological or Pop-based	20 (13%)
■ Cost-benefit/ effectiveness	
(Prevention Effectiveness)	6 (4%)
<b>TOTAL 152 (100%)</b>	

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## Example Dental Water Quality (DWQ)

■ Educational/Policy/Guidelines*	10
■ Laboratory	6
■ Clinical	20
■ Epidemiological or Population-based	2
■ Cost-Benefit/Effectiveness	0
<b>TOTAL</b>	<b>38</b>

\* Includes 2003 CDC Guideline, literature reviews and panel reports

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## DWQ -- Research Trends

- Laboratory Studies (Microbiology)
  - Presence of oral streptococci suggests retraction of oral fluids despite anti-retraction mechanisms<sup>1</sup>
  - Increased prevalence of beta hemolytic bacteria in DUW compared to tap water samples<sup>2</sup>
  - Characterization of non-tuberculous mycobacteria<sup>3</sup> and fungi in DUWL<sup>4,5</sup>

1. Petti et al. Infect Control Hosp Epidemiol. 27:504; 2006  
 2. Mayo et al. J Dent Hyg. 76:151; 2002  
 3. Porteous et al. OOO 98:40; 2004  
 4. Szymanska. Ann Agric Environ Med. 12:153; 2005  
 5. Porteous. JADA. 134:853; 2003

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## DWQ -- Research Trends

- Clinical Studies—Product evaluations and comparisons (12)
  - Majority of studies involved commercial product comparisons (11) or development (1)
  - Active ingredients or compounds evaluated included:
    - Chlorhexidine gluconate and alcohol
    - Hydrogen peroxide
    - Chlorine dioxide
    - Sodium hypochlorite
    - Silver compounds (+hydrogen peroxide or percarbonate)
    - Chelating agents and peracetic acid

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## DWQ -- Research Trends

- Clinical Studies -- Monitoring (3)
  - In-office monitoring kits underestimated colony counts compared to standard lab method (R2A agar)<sup>1</sup>
  - Delayed microbial analysis resulted in much higher colony counts than samples processed immediately<sup>2</sup>
  - ATP and endotoxin levels did not correlate with total viable counts<sup>3</sup>

1. Bartoloni et al. JADA 137:363; 2006
2. Palenik et al. Am J Dent, 18:87; 2005
3. Fulford et al. Br Dent J, 196:157; 2004

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## DWQ -- Research Trends

- Clinical Studies -- Other (5)
  - Line drying did not reduce colony counts compared to control<sup>1</sup>
  - Distillation and line cleaning system kept colony counts  $\leq 500$  cfu/ml (CDC recommendation)<sup>2</sup>
  - Flushing DUWL reduced colony counts but failed to meet CDC recommendations<sup>3,4,5</sup>
  - Iodine did not affect orthodontic bonding<sup>6</sup>

1. Fiehn et al. Int Dent J, 52:251; 2002
2. Palenik et al. Am J Dent, 16:385; 2003
3. Cobb et al. J Dent Educ, 66:549; 2002
4. Montebugnolo et al. Am J Dent, 18:270; 2005
5. Rice et al. Public Health Rep, 121:270; 2006
6. Bishara et al. Angle Orthod, 75:1032; 2005

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## DWQ -- Research Trends

- Epidemiological Studies
  - Low prevalence of *Legionella* bacteria in DUW and anti-*Legionella* antibody in UK dentists<sup>1</sup>
  - Temporal onset of asthma may be associated with occupational exposure to contaminated DUWL among dentists in London and Northern Ireland.<sup>2</sup>

1. Pankhurst et al. Br Dent J, 195:591; 2003
2. Pankhurst et al. Prim Dent Care, 12:53; 2005

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## DWQ -- Research Trends

- International effort—19 of 38 articles from outside US
  - UK – 7: 1 review, 3 microbiology, 4 applied clinical
  - Poland – 5: 3 reviews, 1 applied clinical, 1 microbiology
  - Italy – 3: Applied clinical
  - Denmark – 2: Applied clinical
  - Germany – 1: Lab study (product development)
  - Turkey – 1: Applied clinical (product comparison)

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## DWQ -- Research Quality, Consensus and Concerns

- Quality: Better comparability between studies due to standardization of microbial methods (viable plate counts)
  - Efforts underway to develop improved bench-top models
  - Move toward international standards for dental unit water quality and test methods
- Consensus on ineffectiveness of flushing regimes
- Concerns about reliability of anti-retraction mechanisms
- Ethical concerns about use of negative controls in clinical studies

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## CJD – Research Trends (unresolved issue)

- Laboratory (2002-2006) all outside US
  - Found residual protein on endodontic files regardless of cleaning method
  - Two studies investigated the presence of prions in neurological and dental tissues of patients with variant CJD

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## Summary of Prion Detection in Patients with vCJD

-	Alveolar nerve	Gingiva	Dental Pulp	Salivary glands	Tongue
+	Trigeminal Ganglion	Brain	Tonsils		

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## Methicillin Resistant S. aureus (MRSA) Research Trends

- Infection control recommendations – use standard precautions
- Recent studies
  - MRSA contamination of dental surfaces
  - MRSA colonization of oral cavity of burn victims
  - Aerosolization of MRSA from dental drills unlikely

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## Hospital-Acquired Pneumonias Research Trends

- Numerous studies have identified an association between bacterial colonization of oral tissues and pneumonia
- Recent studies
  - Genetic match between dental plaque pathogens and pathogens in lungs of pts with pneumonia
  - Respiratory pathogens in dental plaque increased over time
  - Equivocal data on whether improving dental hygiene will lower HAPs

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## Disasters Research Trends

- CDC guidelines assessing exposure, clean-up and prevention, personal protective equipment, health effects, and public health strategies and recommendations.
- FDA advice about medical equipment exposed to unusual levels of heat and humidity

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## Dentistry and Bioterrorism Research Trends

- No research articles published
- ADA Consensus Workshop report:
  - Dental personnel and facilities can be of great value in responding to a major bioterrorism attack
  - Dentistry's role in responding to a bioterrorism attack remains poorly defined

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## HIV Testing in Dental Offices Research Trends

- CDC guideline recommends screening of entire US population 13-64 years of age
- Rapid oral HIV test available
- Survey of dental schools found faculty and students willing to test but not counsel
- Cost-benefit study of NHANES data that testing in dental clinics could reduce the number of undiagnosed infections

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## Summary of Current Research

- Many (most?) topics lack adequate research (e.g., number of studies, sample size, study duration, quality of research)
- Trends
  - Most research on Applied/Clinical
  - Focus on few topics
  - Few economic analyses
- Manufacturer sponsored research
- Much research conducted outside US

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## Summary (cont'd)

- Few cost benefit/effectiveness studies or program evaluation
- Few or no surveillance activities
- Several emerging topics of concern

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## Barriers to Dental Research

- Ethical reasons
- Small sample sizes
- Lack of interest and funding
- Few qualified dental researchers
- Absence of case definitions
- No centralized sources of data (little capacity for surveillance)
- Previously conducted in other healthcare settings (not specific to dentistry)

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## Opportunities for Future Research

- Define the scope and magnitude of the problem
  - Difficult given the lack of surveillance or adequate reporting systems
- Identify and prioritize research needs
- Find interested and funded investigators
- Identify the most efficient methods for conducting research and responding to emergent needs
- Develop best practices for implementation and evaluation

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 **84<sup>th</sup> Annual Session and Exhibition**

**QUESTIONS?**

**JLCleveland@CDC.GOV**

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 **84<sup>th</sup> Annual Session and Exhibition**

**Research Methods**

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Medicine

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## Research Methods Objectives

- To identify and discuss potential research methodologies (models?) appropriate for each research category
- To provide examples of the use of these methodologies in infection control research

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## Categories of Research\*

- Educational / Policy / Guidelines
- Laboratory
- Clinical
- Epidemiological or Population-based
- Cost-Benefit / Effectiveness

\*Adapted from 2003 CDC Guidelines

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## Laboratory Research

- Product evaluation/comparisons
  - Product development and effectiveness (sterilization methods, safety devices)
  - Simulations (leak tests for gloves, disinfectants)
  - Compatibility of materials (disinfectants and impression materials)

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## Laboratory Research

- Exposure risks
  - Animal models (CJD prions in dental tissues)
  - Assay development (aerosolization of microbes and other potentially harmful substances)
- Biomarkers for infectious and chronic diseases
  - Salivary diagnostics (oral-based rapid HIV test)

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## Clinical Research

11-02

- Product effectiveness
  - User evaluations of clinical products (safety devices)
  - Microbiological assessment (dental waterlines)
  - Meta-analysis
- Exposure risks
  - Assay methods (Measure microbial contamination of environmental surfaces)
  - Accuracy of screening tests (exposure to Mtb)

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## Epidemiology/Population-Based

- Product effectiveness
  - Surveillance data (↓injuries with safety devices)
  - Microbiological assessment (dental waterlines)
- Surveillance (to determine magnitude and scope of problem)
  - Surveys, Medicaid data, HMO medical/dental records, hospital discharge data

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## Slide 53

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**jlc02** WE need to distinguish between the conventional terminology for applied and clinical research. Clinical usually refers to clinical trials and applied means Research designed for the purpose of producing results that may be applied to real world situations.

I guess that could include lab-based science as well. I think what we're talking about is lab research "applied to a clinical setting" yes?

JLCleveland, 3/14/2007

## Epidemiology/Population-Based

- Determinants of risk
  - Case-control
  - Observational
  - Longitudinal/cohort
  - Cross-sectional
  - Meta-analysis
- Behavioral research
  - Survey DHCPs KAPs, compliance with recommended practices, etc.
  - Observe individual behaviors

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## Prevention Effectiveness Research

- Cost benefit
- Cost effectiveness

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## Product Evaluation

- Vertical axis – Infection control products
  - Instrument washers and sterilizers
  - Disinfectants
  - Personal Protective Equipment
  - Needles and syringes
  - Dental waterline treatment products

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## Product Evaluation

- Horizontal axis – Infection control characteristics of dental equipment, instruments and materials
  - Dental units
  - Handpieces
  - Anesthetic systems
  - Dental restorative materials (unit dose)

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## Research Methods

- Product evaluations/comparisons
  - Laboratory
  - Clinical
    - User evaluations of clinical products
- Community survey
  - Knowledge-Attitude-Practice surveys (KAP)

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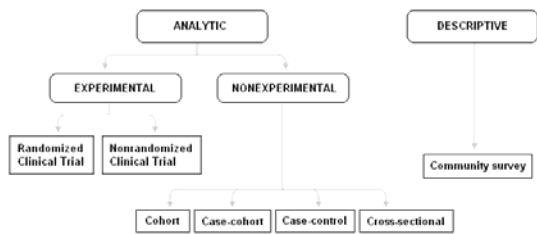
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## Epidemiologic Study Design



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## Descriptive and Analytic Epidemiology

- *Descriptive epidemiology* focuses on identifying and reporting the pattern and frequency of health events (outcomes) in a population
- *Analytic epidemiology* focuses on the search for the determinants of health outcomes
- Most current dental infection control studies are descriptive

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## Epidemiologic Methods

- Randomized Controlled Trials (RCT)
  - Most reliable epidemiologic method
    - Eliminates spurious causality
    - May be open or blinded (more rigorous)
    - Can be used to measure effects on equipment or materials as well as patients

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## Epidemiologic Methods

- Randomized Controlled Trials (RCT)
  - Unfeasible for many infection control products
    - Most products not used directly to treat patients
    - Difficult to blind investigators (placebo needles?)
    - Bioethical concerns with control groups in clinical settings (e.g. waterlines)

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## Epidemiologic Methods

- Cohort Studies
  - Rare events (e.g., HAIs) difficult to study-- need large populations over long time period
  - Predominance of outpatient private practice model complicates data collection and follow-up
  - Example: Percutaneous injury studies in institutional settings

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## Epidemiologic Methods

- Cross-Sectional Study
  - disease and exposure status measured simultaneously in a population.
  - Provide a "snapshot" of frequency and characteristics of disease in a population at a point in time.

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## Epidemiologic Methods

- Cross-Sectional Study
  - disease and exposure status measured simultaneously in a population.
  - Provide a "snapshot" of frequency and characteristics of disease in a population at a point in time.
  - Assesses prevalence of acute or chronic conditions
- Example: Evaluation of occupational asthma risk in dentists. Pankhurst, Prim Dental Care, 2005

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## Epidemiologic Methods

- Population attributable risk assessment
  - Disease prevalence among a population with history of exposure to risk factors compared to similar group without risk factor
  - Examples: Fotos et al, JDR, 1986.
    - Compared *Legionella* antibody titer among dental and medical school personnel
    - Suspected risk factor was contaminated dental unit water
    - Working in dental clinic was a 2x risk factor for exposure to *Legionella*

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## Research Methods

- Meta Analysis
  - Synthesis of previous studies that provides a summary estimate\*
    - Identify studies
    - Define eligibility criteria
    - Abstract data
    - Perform statistical analysis
- Opportunities in dental infection control:
  - Percutaneous injury
  - Dental waterlines (limited by lack of standardized test methods)

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## Considerations

- Ethics
  - Human subjects
- Research Design
- Limitations

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## Considerations

- Sample size
- Validation of surveys
- Collection of data
- Use of software
- Interpretation of results

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## Funding and Resources

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## Funding Sources

- NIH
  - NIDCR
  - Grants.gov
- AHRQ
- Patient Safety Alliance
- Not for profit organizations
  - ADEA sections
- Industry

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## SBIR/STTR Funding

- 8 government agencies
- Solicitations 2-3 times per year
- SBIR
  - Small business
- STTR
  - Collaborative between industry and academia

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## Industry-Sponsored Research

- Product evaluation
- Existing studies
  - Scientific literature
  - FDA guidance documents
- Surveys
- Observational

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## Industry-Sponsored Research

- Study design
- Method of data collection
- Method of data analysis
- Variables
- Intellectual property rights
- Practical aspects
  - Resources required
  - Timing
  - Budget
  - Target (e.g., publication, poster, report, etc.)

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## Clinical Evaluations



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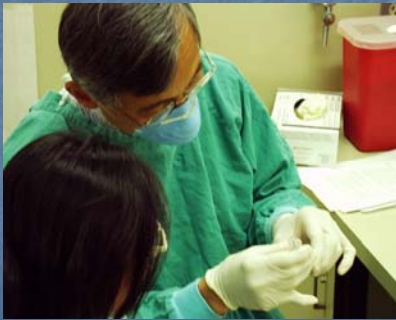
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## Clinical Evaluation



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## Clinical Evaluation



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## Resources and Requirements

- FDA guidance documents
  - Medical devices and products
- ANSI and ISO Standards
  - Dental materials and devices
- IRB review
  - Research that includes human subjects

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## Information Sources

- ADA Survey Center
  - Access to demographic information
  - Assists with development of power analysis and sampling

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## Special Thanks

- OSAP
  - for supporting the Agenda project
- Research Agenda Steering Committee and Workshop Participants
  - for the development of this Draft Agenda.
- ADEA
  - for this opportunity to share the Draft Agenda

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