The PROSPR Initiative:
Competitive Revision for the Collection of Cervical Cancer Screening Process Data by Two Existing PROSPR Research Centers

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Etiology and Prevention of Cervical Cancer

• Infection with high-risk types of human papilloma virus (HPV) causes virtually all cervical cancers
  – ~70% due to HPV16 and HPV18

• Diagnosis and treatment of precursor lesions (CIN2 and CIN3) can prevent incident cervical cancer

• Since introduction of cervical cytology (Pap) in the U. S., cervical cancer has decreased by 80%
  – Issues of overuse and underuse

• New technologies (HPV testing and vaccination) are changing the landscape of cervical cancer prevention
The Landscape of Cervical Cancer Prevention is Changing Rapidly

• 2012 release of new guidelines/recommendations
  – Longer screening intervals, HPV co-testing, age considerations
  – Are patients and providers accepting of new guidelines?

• Girls vaccinated as adolescents will soon be reaching screening-appropriate ages
  – Will screening strategies need to change further?

• Possibility of specimen self-collection
Rationale for PROSPR: Breakdowns Can Occur at Multiple Points in the Cancer Screening Process

Risk Assessment → Detection → Diagnosis → Cancer or Precursor Treatment → Survivorship → End-of-Life Care

Outcomes:
- Risk Status
- Clinical Status
- Functional Status
- Quality of Life
- Satisfaction
- Mortality
- Quality of Death

Failure to Screen → Failure to Follow up → Failure to Treat → Failure to Detect
PROSPR’s Objective

• Promote coordinated, multidisciplinary, and multi-level research to evaluate and improve the cervical, breast, and colorectal cancer screening processes in clinical practice through:
  
  – Collection of multi-level data
    • Patient, provider, facility, and health care system factors
  
  – Identification of screening process failures and potential remedies
  
  – Evolution of screening strategies beyond age-based to more encompassing risk-based strategies
Research Center Activities

• Submit core screening process data to the central data repository housed at the statistical coordinating center

• Conduct multicenter, collaborative projects

• Conduct three individual research projects
  – Project 1: Comparative effectiveness research (CER) project
    • Measure the benefits and harms of screening processes across risk profiles
    • Examine comparative effectiveness of the screening process for different tests
  – Projects 2 and 3: At the discretion of the applicant
  – Projects linked by an applicant-proposed research theme
Funded PROSPR Research Centers

- Fred Hutchinson Cancer Research Center
- Group Health Research Institute
- Kaiser Permanente Northern and Southern California
- University of New Mexico
- Parkland-University of Texas Southwestern
- University of Vermont
- Geisel School of Medicine at Dartmouth and Brigham and Women’s Hospital
- University of Pennsylvania
- PROSPR Breast Site
- PROSPR Cervical Site
- PROSPR Colorectal Site
- Statistical Coordinating Center
Need for Multiple Research Centers Within Each Organ Site

• Challenges to the successful completion of the screening process may differ in different
  – High-risk populations
  – Healthcare systems

• A thorough understanding of the process requires comparisons across multiple settings

• Ultimately, the goal is to
  – Develop general approaches for improving the process, AND
  – Tailor them for application in different environments
## Composition of Existing PROSPR Research Centers

<table>
<thead>
<tr>
<th>PROSPR Research Center</th>
<th>High-Risk Groups Included</th>
<th>System</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of New Mexico (Cervical)*</td>
<td>Hispanic, Native American, Low-income rural</td>
<td>State-wide registry</td>
</tr>
<tr>
<td>Group Health Cooperative (Colorectal)</td>
<td>Asian American, Medicaid</td>
<td>Integrated health care delivery system</td>
</tr>
<tr>
<td>Parkland-UT Southwestern (Colorectal)</td>
<td>African American, Hispanic, Low-income urban, Under- or uninsured</td>
<td>Safety-net clinical provider network</td>
</tr>
<tr>
<td>Kaiser Permanente Northern and Southern California (Colorectal)</td>
<td>African American, Hispanic, Asian American</td>
<td>Integrated health care delivery system</td>
</tr>
<tr>
<td>University of Pennsylvania (Breast)</td>
<td>African American, Low-income urban</td>
<td>Integrated health care delivery system</td>
</tr>
<tr>
<td>Dartmouth Institute and Brigham and Women’s Hospital (Breast)</td>
<td>African American, Hispanic, Medicaid, Low-income urban</td>
<td>Primary care clinical networks</td>
</tr>
<tr>
<td>University of Vermont (Breast)</td>
<td>Rural</td>
<td>State-wide registry</td>
</tr>
</tbody>
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*Only 1 cervical research center application scored in the fundable range*
PROSPR Can Be Leveraged to Address Important Cervical Cancer Screening Questions

• **Short-Term**
  
  – Does co-testing with HPV and Pap occur more frequently in integrated health care systems than in small private practices? Does use of co-testing differ by provider specialty?
  
  – Despite their lower risk of HPV infection, are vaccinated women more likely to be screened for cervical cancer due to increased likelihood of contact with their health care providers?
PROSPR Can Be Leveraged to Address Important Cervical Cancer Screening Questions

• Long-Term

  – At what intervals are women being screened by Pap only? By co-testing? Are patient-, provider-, or system-level factors the strongest predictors of adherence to recommended screening intervals?

  – Given that racial and ethnic minority women, and particularly recent immigrant populations, are at the highest risk of cervical cancer, what are the most effective and culturally sensitive strategies for improving attendance at screening and follow-up of abnormal screening exams?
Competitive Revisions to Two Existing PROSPR Research Centers

• Capture cervical cancer screening data during a time of rapid change in screening practice

• Effort will focus on
  – Submission of core screening process data to the central data repository housed at the statistical coordinating center
  – Conduct of multicenter, collaborative projects

• Increase PROSPR’s research contributions with relatively modest additional resources compared to the cost required to set up these systems de novo
Advantages of and Justification for Competitive Revisions

• Takes advantage of existing infrastructure, to allow for rapid onset of data collection

• Unique capacity of existing centers
  – Several PROSPR Research Centers are ready to collect (or in the past have collected) cervical cancer screening data
  – No other NIH grants are collecting multilevel data to evaluate the entire screening process
  – CDC surveillance efforts do not capture these types of data

• Would align with final 2 years of parent grants

• Would allow for comparison of the screening process for 2 cancers within the same population
Budget for PROSPR Cervical Enhancement

• Competitive revision to PROSPR Research Centers
  – Total cost based on median annual budget for data collection core within funded PROSPR Research Centers
    • $650K per center per year
  – Total cost for the addition of the 2 cervical centers
    • First year: $1.3M
    • All years (2): $2.6M

• Administrative supplement to the Statistical Coordinating Center
  – Total cost
    • $35K per additional cervical center per year
    • $140K for 2 centers over 2 years
Conclusion

• Goal is to capture cervical cancer screening process data during this time of rapid change
• Address key research questions in high-risk populations and different healthcare systems
• Competitive revisions to the existing PROSPR Research Centers represent the most efficient way to accomplish this goal

Working together to improve cancer screening in communities