

# SACGHS CER/CU Workgroup

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# Update

- In June, Committee learned that the Secretary's discretionary funds had been allocated
- Final awards announced Sept. 30, 2010
- Reviewed by MSW to complete inventory of funded projects

# Results-1

- Title search (search terms Genetic, Genomic, Genome, GWAS, Personal)
- 7 NIH-funded projects identified
  - 4 in Oncology
- No projects identified from Secretary's office, or AHRQ/HRSA/CDC/FDA/HIS/CMS

# NIH studies-Oncology

- Programs in Clinical Effectiveness of Cancer Pharmacogenomics (\$3,996,278)
- Comparative Effectiveness in Genomic & Personalized Medicine for Colon Cancer (\$3,991,808)
- Center for Comparative Effectiveness Research in Cancer Genomics – CANCERGEN (\$4,000,000)
- Clinical Validity and Utility of Genomic Targeted Chemoprevention of Pca (\$3,978,770)

# NIH studies-other

- Comparative Effectiveness in Genomic Medicine (\$3,990,198)
- Using GWAS Data for Enhanced Mendelian Randomization Studies (\$1,494,814)
- Building a Genome Enabled Electronic Medical Record (\$3,527,237)

# Results-2

- Manual search on all titles
- 23 NIH-funded studies of possible relevance to genomics (several disease specific infrastructure grants)
  - 5 in oncology
  - 6 in rheumatology/autoimmune disease
  - 5 in Polycystic Kidney Disease
  - 1 in autism
  - 1 Warfarin dosing in pediatric population
  - 4 general infrastructure grants

# Results-2 cont'd

- AHRQ/HRSA/CDC/FDA/HIS/CMS projects
  - Enhancing Cancer Registry Data for Comparative Effectiveness-CDC
  - Registry of Registries-AHRQ
  - Maternal and Child Health (MCH) Pediatric Research Network Program-HRSA

# Results-2 cont'd

## – AHRQ

- Establish an Entity for Identification of New and Emerging Issues for Comparative Effectiveness Review (CER)
- Evidence Gap Identification
  - 8 task orders, competed among existing U.S. EPCs
  - None specifically reflect genetics/genomics
- Dissemination and translation
  - Comprehensive Informatics Framework for CER Dissemination
  - Innovative Adaptation & Dissemination of CER Products: Autism (iADAPT-ASD)

# Results-2 cont'd

## – AHRQ

- Evidence Generation
  - Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE)
    - » 10 grants of up to \$10 million each
    - » None addresses genetics/genomics
- Enhancing Clinical Effectiveness Research with Natural Language Processing of EMR
  - Focus on Asthma and Smoking cessation
  - No specific information about Family History information
- Request for Registries
- Unfunded Meritorious Applications
  - Funding Method: Multiple grants
  - Project Duration: 2 to 3 years
  - Funding Amount: \$1 million

# Results-2 cont'd

- Secretary's Office
  - Inventory of Comparative Effectiveness Research
    - \$1,649,912
  - Research Evaluation and Impact Assessment of ARRA Comparative Effectiveness Research Portfolio
    - \$4,205,422
- May be others not identified given short time for review

# GAO Patient-Centered Outcomes Research Institute (PCORI)

- Board of Governors announced
  - Apart from the NIH Director, no member has dedicated career in genetics/genomics/personalized medicine
    - Chair has research interest in prenatal genetic testing
    - One governor is a board member of NCI Board of Scientific Advisors, American Association of Cancer Research Foundation and Duke University Cancer Center
- Methodology Committee
  - Members currently being solicited
  - Nominations due October 29, 2010

# Assessment

- Additional funding given for topics of interest to SACGHS
  - Emphasis on oncology, rheumatology
  - A number of the 14 priority diseases are affected by family history, Genetics, Genomics yet projects do not reflect this
- Some important projects involving genomics and informatics (a priority SACGHS issue)
- Potential exists to enhance genetics and genomics in projects
  - Infrastructure
  - Registries
  - Dissemination and Translation
  - Evaluation

# Next (Last) Step

- Letter to Secretary from SACGHS
- Background of workgroup activity recognized following needs:
  - The need for evidence-based recommendations and guidelines
  - Definition of thresholds of evidence that reflected the context of the specific test/intervention such as:
    - Rarity of disorder
    - Clinical situation (e.g., severity of condition, alternative management strategies)
    - Economic impact
    - Population likely to be affected
    - Type of test (screening, diagnostic, prognostic)
  - Need to determine ‘value’ of a given test/intervention (impact on patient outcomes and economic impact on the health system)
  - Ability of current infrastructure (particularly information systems/electronic health records) to support implementation
    - Ability to capture post-market data
  - Aspects of translation unique to genomics/personalized medicine

# Next (Last) Step

- Recommendations
  1. Support adoption of recommendations from the American Health Information Community's Personalized Medicine Workgroup as well as incorporation of knowledge from the ARRA funded study, 'Building a Genome Enabled Electronic Medical Record' (RC2 OD006704-01) by the Office of the National Coordinator of Health Information Technology (ONCHIT).
  2. Encourage incorporation of FH, genetic and genomic information into CER studies for all 14 priority health conditions as appropriate.

# Next (Last) Step cont'd

- Recommendations
  3. Provide ongoing funding to support and expand development of systematic evidence-based recommendations by DHHS-funded centers.
  4. Increasing visibility of FH, Genetics and Genomics for ongoing inventory and evaluation of CER studies
    - a. Direct the entity charged with Identification of New and Emerging Issues for CER (AHRQ-10-10003) to include FH, genetic and genomic issues for consideration
    - b. Designate at least one of the 8 Centers charged with Identification of Evidence Gaps to focus on issues relating to CER/CU of FH, Genetic and Genomics in health care
    - c. Direct the entity charged with developing an inventory of CER (Solicitation Number: 10OS32990) explicitly collect and report information related to the use of FH, Genetics and Genomics in all inventoried projects.
    - d. Direct the entity charged with the Evaluation and Impact Assessment of ARRA CER (Solicitation Number: 10-233-SOL-00191) to specifically account for the contribution of inclusion or exclusion of FH, Genetic, Genomic information for the projects.
    - e. Direct the entity charged with developing the Comprehensive Informatics Framework for CER Dissemination to insure that this framework supports information related to the use of FH, Genetics and Genomics.

# Next (Last) Step cont'd

- Recommendations
  5. If funds are available in the AHRQ Unfunded Meritorious Applications program, direct that some of these funds be prioritized to address the gaps in #3 above.
    - Encourage some of this funding to be directed to projects that study the translation of personalized medicine into clinical practice
  6. As openings become available on the Governing Board of the Patient-Centered Outcomes Research Institute (PCORI) encourage the GAO to solicit a member with specific expertise in genomics/personalized medicine and assure appointment of individuals with expertise in evidence-based genomics to the methodology committee.