

Evaluation of Genomic Applications in Practice and Prevention (EGAPP)

Update on EGAPP Activities

SACGHS

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EGAPP

Evaluation of
Genomic
Applications in
Practice and
Prevention

- CDC-funded pilot project
- Non-regulatory
- Independent, non-federal, multidisciplinary Working Group
- Integrate existing processes for evaluation and appraisal
- Minimize conflicts of interest
- Evidence-based, transparent, and publicly accountable

Goal

- To establish and evaluate a systematic, evidence-based process for assessing genetic tests and other applications of genomic technology in transition from research to practice.

Caution



- EGAPP's methods are still under review
- Most products are not final
- Presenting a description of work in progress
- Stakeholder evaluation to come

Infrastructure

- Working Group
 - 13 original members from May, 2005
 - 6 meetings, countless subcommittee teleconferences
 - Next meeting January 29-30, 2007

Infrastructure

- Support
 - Interagency Agreement with AHRQ
 - Staff and consultants
 - CDC National Office of Public Health Genomics
 - Technical consultants & contractors
 - Centers for Genomics and Public Health –
Stakeholder Advisory Group on EGAPP

Infrastructure

- Steering Committee
 - Critical early input
 - Planning
 - Selection of Working Group members
 - Moving into next phase
 - New members
 - Review of process and products
 - Input on evaluation phase (Spring, 2007)
 - Considering a sustainable process

Scope of topics for pilot phase

- Begin with applications recognized as important or more common
 - Tests used in a clinical scenario to guide intervention (diagnostic workup, treatment, prevention)
 - Screening tests
- Tests with potential for broader public health impact
- Portfolio of test applications that challenge the methods

EGAPP approach

- Lessons from ACCE process
 - In addition to clinical validity and utility, formal assessment of analytic validity and relevant ELSI
 - Use of questions to organize collection of information
 - Attempt synthesis of information
 - Identify gaps in knowledge
- Integration from existing processes
 - Reviews by evidence-based practice centers (EPCs)
 - Formal analytic frameworks with key questions
 - Explicit search strategies

EGAPP approach

- Assessment of quality of individual studies and strength of evidence
- Provide recommendations with clear linkage to the evidence
- Identify research agenda
- New
 - Attempt shorter time frame reviews → targeted, practical
 - Focus on “hard” medical outcomes (morbidity/mortality) and consider specific family or societal outcomes if appropriate
 - Assess the usefulness of modeling
 - Address cost effectiveness / cost-utility

Products

- Evidence reports
 - Peer-review of drafts
 - Posted on web and summaries published
- Recommendations
 - Developed by Working Group
 - Peer review of drafts
 - Publication and posting (ideally concurrent with evidence report), links widely distributed
 - *Genetics in Medicine*
- Publication of methods and evaluation
 - Stakeholder surveys

Topics in review

- EPC evidence report released by AHRQ – collaboration with CDC's DCPC
 - *Genetic Testing for Detection and Management of Ovarian Cancer*
 - Draft recommendation on proteomic tests in internal review
- EPC evidence report complete, pending release
 - *Testing for Cytochrome P450 (CYP450) Polymorphisms in Adults with Depression Treated with SSRI Drugs*
 - Draft recommendation in internal review

Topics in review

■ Draft reports

- *Testing for Hereditary Nonpolyposis Colorectal Cancer (HNPCC) in Newly Diagnosed CRC Patients and Family Members*
 - Final EPC report in development
- *UGT1A1 Mutation Analysis in Colorectal Cancer Patients Treated with Irinotecan*
 - Non-EPC draft report moving toward peer review

Topics in review

- Topics recently selected
 - *Impact of Gene Expression Profiling Tests on Breast Cancer Outcomes*
 - Awarded to EPC in late October
 - *Screening for CYP450 Polymorphisms to Predict Response to Pain Management with Codeine*
 - Request for proposals in development
 - *Use of Genomic Profiling to Assess Risk for Cardiovascular Disease and Identify Individualized Prevention Strategies*
 - In planning

EGAPP is not alone.....

- One of a spectrum of non-regulatory initiatives for translation and evaluation of genetic tests
 - U. S. Preventive Services Task Force (USPSTF) – AHRQ
 - Technology assessments
 - ACMG Foundation funded rapid ACCE review
 - Health plan examples: BCBSA TEC, Intermountain Healthcare
 - Collaboration, Education, and Test Translation (CETT) Program - ORD, NIH
 - Evidence-based Evaluation and Decision Process - *Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children*, HRSA
 - *Access to Credible Genetics (ATCG) Resources Network* – Genetic Alliance and partners, CDC funded

Next steps

- Maintaining momentum
- Publication of methods and what has been learned
- Publication and dissemination of products
- Initiating project evaluation
- Translation of knowledge gained into informational messages for different target audiences



Website

- Independent website requested by EGAPP Working Group
- Formal notification of waiver approval yesterday
- Enhance interaction with stakeholders
 - Post topics list, methods and process, evidence reports (or links), recommendations, informational materials
 - Solicit feedback, suggested topics



Building a sustainable process

- Future composition of Working Group?
- Expand the scope of topics?
- Evaluate with broader range of stakeholders?
- Support for a sustainable process?
 - Roles of HHS agencies?
 - Public-private partnerships?
- Process for post-market data collection?

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Thanks to

- EGAPP Working Group
- Partners
 - Interagency Steering Committee
 - AHRQ – Gurvaneet Randhawa
 - Centers for Genomics & Public Health
- NOPHG Staff
 - Katherine Kolor, Michael Douglas, Jeanette St. Pierre, Sheri Jordan
- Technical consultants
 - Toby Citrin, Siobhan Dolan, Karen Edwards, Judith Johnson, Debra Leonard, Glenn Palomaki
- Technical contractors
 - McKing Consulting, Inc., RTI International