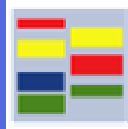
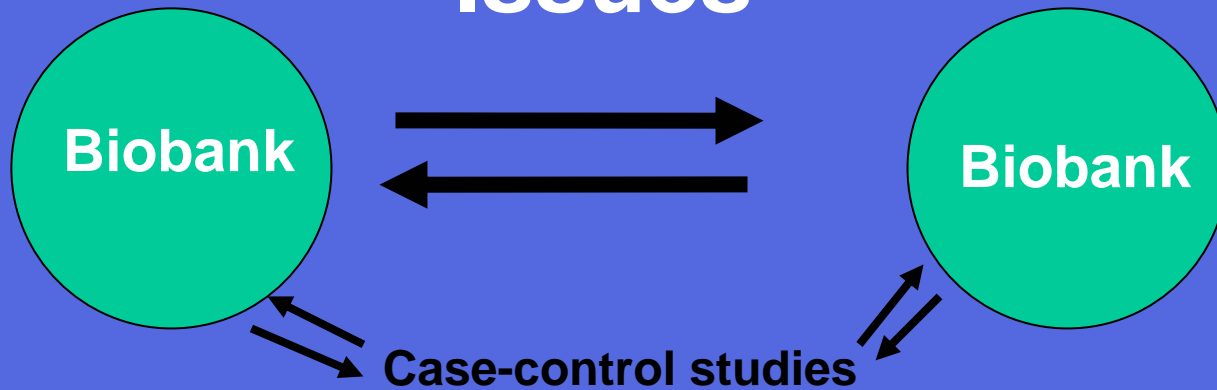


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Genomic Medical Research

Issues



- Observations and findings from one Biobank study need to be replicated and confirmed in others
- Small effects observed in one study may require a meta-analysis of multiple datasets for confirmation and precise estimation of size
- Hypotheses generated in large prospective population studies may need to be tested in the context of case-control studies and vice-versa
- Observations need to be tested and interpreted in a range of ethnic backgrounds
- Gene-environment interactions are likely to require meta-analysis

Consequences

These issues will require:

- **Major national and international collaboration between large population projects in genetics with agreed terms of reference**
- **Agreement on what are minimum critical datasets and quality standards**
- **Introduction of harmonisation/standardisation and for phenotype/genotype definition and data collection and management**

- **Minimum standards for biological sample storage**
- **Comparability of environmental exposure data**
- **Compatibility of environmental exposure data**
- **Compatibility of statistical and analytical approaches**
- **Minimum descriptors for study design, analysis and reporting of results**

Results

- **Web-based detailed description of study design and protocol**
(Perhaps a centralised inventory?)
- **Context in which dataset (subset) has been selected and defined e.g. disease phenotype definition and minimum critical data fields e.g. gender, age at disease onset, ethnicity**
- **On-line access to original datasets on which analysis has been performed, intermediate summary tables and results reported**
- **Predicted effect sizes**
- **Extent of multiple testing**

Concerns

- **Standardisation of procedures and reporting should not inhibit or stifle innovation of analytical approach, biological interpretation or hypothesis generation**
- **Confidentiality or ethical framework of original studies should not be compromised**
- **Secondary or meta-analysis of datasets may reveal new observations and interactions for which original investigators will not be acknowledged or IP credited**