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Governance issues in whole genome diagnostics

The "easy" issues

- Quality assurance
  - Ensuring analytic validity
  - Ensuring proper sample handling so that the patient retrieves his or her own results
  - **"23andMe's Accidental Sample Swap"**
- Truth in advertising
  - Consumer protection laws

The challenge – what information to disclose to patients

- Whole genome approaches will inevitably provide much more information than is necessary to answer any particular clinical question
  - Problem of incidental findings and the downstream costs and adverse events that often follow
- These approaches will almost always provide insufficient information to make accurate predictions about the future

What criteria for disclosing?

- Clinical utility
  - Informs diagnosis
  - Alters clinical management
- Reproductive planning
- Personal meaning
  - This is typically not a criterion for testing in the clinical setting
- Everything

- Can there be different levels of disclosure based on patient preference?

Who can/should decide what is disclosed?

- Government agencies
- Expert/evidence based panels
- Test providers
  - Direct to consumer v. tests ordered by clinicians
  - Former may create its own responsibilities
- Clinicians
  - Shaped by existing ethical and legal obligations

- Growing importance of consumer demand

Some essential elements

- Transparency about the criteria used
- Provisions for clinicians and patients to be informed about what the information means