Common Standards and Conditions for Practical Interoperability

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Considerations for Common Standards

- ❑ Enables collection and comparison of data through consistently employed formats or processes

- ❑ Requires approach that becomes well-established and endorsed by global community

- ❑ Basic considerations include variables, differences in method output, file formats, data delivery methods, quality standards, and consistent interpretative criteria and language

- ❑ When no accepted standards exist, neccesitates adoption of "best practice" with sufficient flexibility for future advancements including new methods and variables

- ❑ Challenge is existing disparate data sets with different variables and lack of standardization for terms or values included

Conditions for Practical Interoperability

❑ Goal primarily to integrate data (e.g., genotypic, phenotypic, and clinical when available) from multiple datasets into a single database that improves accessibility and analytic capacity for different end users

❑ Requires establishment of common standards and engagement to eliminate or minimize barriers to data sharing

❑ Considerations should include defining needs for all end users (e.g., R&D, clinical trials, surveillance, and clinical care)

❑ Interoperability could include ability to exchange data with surveillance or laboratory information management systems

Common Standards and Conditions for Practical Interoperability

STANDARDIZING LABORATORY REPORTING LANGUAGE

Standardization of Reporting Tuberculosis Molecular Diagnostic Results

- ❑ Consultation to gather expert opinion on optimal terminology, data components, interpretive language, and format for results reporting
  - ▪ Consensus was not sought and all views were recorded

- ❑ Focused on molecular detection of drug resistance and merging of molecular and phenotypic drug susceptiblity test results

- ❑ Consultation hosted by U.S. CDC and Association of Public Health Laboratories in October 2013

- ❑ Discussed laboratory reports for clinical use and outlined considerations for surveillance reporting

- ❑ Participants included healthcare providers, surveillance staff, U.S. TB programs, and laboratorians

Consultation Discussion Points

❏ Most participants indicated that reports would optimally include
  ▪ Sample type
  ▪ Method performed
  ▪ Gene name
  ▪ Performance characteristics
  ▪ Result (mutation as 3 letter amino acid designation when applicable or resistant/susceptible for phenotypic testing)
  ▪ Test limitations
  ▪ Simple language (mutation detected/ not detected)
    ○ Avoid use of technical terminology (e.g., synonymous, nonsynonymous, single nucleotide polymorphism, and frame shift)

❏ Interpretive comments essential and based on specific drug and target
  ▪ Must evolve with changing science and improved understanding
  ▪ Should reflect clinical significance when known
  ▪ Should provide overall conclusion when phenotypic results available

Consultation Discussion Points (2)

❑ Development of a publically available, curated database for aggregating available data

- ▪ Limit contributing laboratories based on strictly defined criteria for genotypic and phenotypic methods (e.g., experience, testing volume, approved/endorsed methods, EQA, consultation expertise, licensing/ accreditation, and quality management systems)

- ▪ Content might include drug, specimen collection date, source, gene, mutation, method/platform, phenotypic method, phenotypic result, interpretive comments, lineage)

- ▪ Link to clinical outcome data when available

- ▪ Include literature citations

Consultation Discussion Points (3)

❑ Recognized need to facilitate standards development for reporting language through engagement with partner organizations (e.g., Clinical and Laboratory Standards Institute)

❑ Engage in global efforts for database development

Considerations for Standardization

❑ What is considered the "gold standard" for interpretation?

❑ What interpretive comments are provided for novel mutations?

❑ How are silent mutations described?

❑ How much information should be provided to aid in understanding discordant results?

❑ What is the threshold when the complexity of information provided challenges data accuracy for surveillance reporting?

Need to Know

Nice to Know

Final Thoughts

- ❑ Common language needed for laboratory reporting and unified database
  - ▪ Saves resources through reducing duplication of effort
  - ▪ Improves accessibility of data and understanding of results
  - ▪ Aids in modification or development of surveillance systems as data are standardized
  - ▪ Must be usable and widely accepted to ensure sustainability

- ❑ A complex network of potential end-users
  - ▪ Database could be used for many purposes including research and development of diagnostics, alternative clinical algorithms, surveillance, and laboratory reporting for clinical use
  - ▪ CPTR effort identified the need for a database to serve all purposes

- ❑ Must keep this complexity in mind with the ultimate goal of improving patient outcomes and public health

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