Design and evaluation considerations for mobile applications and other tools to support death certification

National Center for Health Statistics, Division of Vital Statistics

New and emerging technologies including mobile apps, standards-based interoperability (e.g., Fast Healthcare Interoperability Resources or FHIR), and the proliferation of handheld devices such as smart phones and tablets can make it easier for physicians, Medical Examiner/Coroner (ME/C) and other death certifiers to fill out death certificates. This can potentially improve the timeliness and quality of death reporting. If the solutions are not carefully designed, introducing these innovations may impact data quality, such as the completeness and accuracy of the cause(s) of death. Thus, any impacts of innovations should be measured and evaluated before implementing/integrating change into an existing workflow. To this end, technologists, public health implementers, and mortality data subject matter experts should collaborate in the design and development of all modernization efforts, closely examining the impact of technology introduction on workflow ('as is' and 'to be'), system-user interaction, and data quality, among other considerations. These design considerations should be applicable to mobile death certification apps, death certification tools within an electronic medical record, a ME/C medicolegal death investigation system, and electronic death registration systems. In any development efforts, it is important to utilize death reporting standards, such as the HL7 Vital Records Death Reporting FHIR Implementation Guide,

The following are some key considerations:

User interface
• Utilize User-centered/Human-centered design concepts, which the International Organization for Standardization (ISO) defines as an "*approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors/ergonomics and usability knowledge and techniques.*" This ensures consistency with design elements and guiding principles used in consumer applications, including help screens that provide definitions of terms used during the data entry process.
• Refer to Usability.gov, a one-stop source for user experience best practices, templates and strategies, maintained by the U.S. General Services Administration.
• Accessibility is an important part of designing the application and should be considered throughout the development process. Section 508 is the governing principle for ensuring that the tool is designed in a way that it is accessible to individuals of all abilities.
• Include links to reference materials for death certification in the app in a way that is easily accessible. More specifically, detailed definitions and examples to aid in the design help screens for death certification can be found at the Physicians' Handbook on Medical Certification of Death, Blue Form and Red Form.
• In general, drop-down menus should be avoided, except for fields where all response options are known and can be put in a meaningful order, such as state, county.
• Use **radio buttons** (vs. drop down menus) for fields that have finite choice options in the death certificate (e.g., tobacco use, pregnancy status, manner of death). This eliminates errors introduced by stopping on drop-down menus in the wrong place.
• The cause and manner of death information should NOT be prepopulated in the Electronic Death Registration System (EDRS) based on what is in the Electronic Health Record (EHR) or otherwise. The user interface design should allow the certifier to enter **open-ended free-text data**. The certifier should be using all available information as per current practice coupled with their best medical judgment, to provide a cause-of-death statement for each individual decedent. Supplementary information from the EHR such as the discharge summary, death note and other records informing the underlying cause of death may be helpful to the physician completing the

death certificate. This EHR information can be provided on a review screen or as a stand-alone document in the EDRS at the point of death certification.
• Consider including Electronic Validation System (VIEWS II) or equivalent validation service with the technical solution for data quality checks.
• Allow the certifier to review the cause and manner of death information they entered before final submission (e.g., review screen). Allow certifiers to view a final copy of the death certificate easily from the app, ideally in a format that mimics the print format.
• If designing multiple electronic tools to facilitate death certification, to the extent possible, ensure consistency in the user interface design across the different platforms to ensure a similar 'look and feel' for the end-user. The design should be consistent with the U.S. Standard Certificate of Death.
Underlying workflow
• Review the underlying process flows and data sources that are currently used by the certifier when completing the death certificate ('as is' for example using paper or an EDRS desktop). Design a solution that addresses challenges related to information access or availability for death certification in the existing flow. Ensure that the introduction of the technology does not impact the process flow in a way that compromises the certifier's ability to refer to medical records and other sources when determining the cause(s) and manner of death.
Evaluate the cause-of-death data quality
• Ensure that there is a systematic evaluation plan to measure and assess the quality of data collected using the technical solution compared to the system in place. Consider the completeness, accuracy, and sequencing[1] of the cause-of-death statements. Additionally, consider comparing data quality across different platforms that will be available (e.g., EDRS desktop, mobile app, paper, etc.).
• Ensure there is an evaluation plan to measure the usability of the mobile application or tool using one or more industry standard approaches such as heuristic evaluations and expert review, contextual interview, focus groups, etc.

• Considerations for evaluation include:
 	
   o **Review:** Conduct an 'as is' process analysis to identify any gaps and ensure that the mobile solution that is developed in the 'to be' process is addressing those gaps that gaps and would result in an improvement. Avoid developing mobile solutions that do not serve an underlying program need and/or result in secondary unintended consequences (e.g., you may fix one thing, but it may cause problems somewhere else). Look at the impact of introducing the technology more holistically on the overall System.
 	
   o **Scenarios**: Test for all possible use case scenarios/dataflows that might be encountered in a production environment to ensure it is comprehensive. This includes ideal and unusual paths for the data flow to make sure they are accounted for in the systems design.
 	
   o **Test Cases**: Carry out testing with typical and unusual cause(s) and circumstances of death, temporal, geographic, and demographic information to ensure representation of the types of deaths encountered. For example, test varying levels of data completeness as well as obvious data errors to see if they are identified by the software
 	
   o **Testers**: Make sure to conduct field testing by involving certifiers from a variety of backgrounds and level of experience. Do not rely exclusively on testers from the technical development team.
 	
   o **Measures:** Use a combination of quantitative and qualitative measures in carrying out the evaluation to ensure a well-rounded understanding of the impact of introducing the death certification tool. Compare the cause(s) of death specified in the 'As is' and 'To be' and review for any differences both in terms of what conditions were certified in each scenario and overall user experience.

1. Falci L, Lee Argov EJ, Van Wye G, Plitt M, Soto A, Huynh M. Examination of cause-of-death data quality among New York City deaths due to cancer, pneumonia, or diabetes from 2010 to 2014. Am J Epidemiol 187(1):144-52. 2018.

For questions contact: The NVSS Modernization Initiative at NVSSmodernization@cdc.gov