A checklist for developing and implementing a high-impact monitoring and evaluation system in clinical and translational science programs

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OBJECTIVES/SPECIFIC AIMS: This presentation will highlight the framework and domains of the monitoring and evaluation (M&E) System Checklist created in response to the need for practical guidelines and intended to improve the quality, efficiency, and consistency of monitoring and evaluation of the clinical and translational work. The recently published NCATS Strategic Plan (2016; p. 18) presents the following objectives and guidelines that implicitly suggest the need for sound M&E: “Objective 4-1: Continually assess and optimize internal business processes” and “Objective 4-2: Ensure all scientific programs and operational activities are conducted in a rigorous, robust and data-driven manner.” Given the complexity of clinical and translational work and associated monitoring/evaluation processes and the dearth of practical tools in the CTR evaluation area, the need for a checklist is clear. A “checklist” (a detailed list of items/steps required, things to be done, or points to be considered) is a type of informational job aid used to improve performance, reduce failure, deal with complexity, and ensure consistency and completeness in carrying out work. Checklists are popular in many fields—due to their brevity, concreteness, order, implicit (and sometimes explicit) mandate to do things right, and expectation for a checklist being grounded in good practices and/or strong theory. A notable example is the famed WHO Surgical Safety Checklist (2008). The proposed M&E Checklist has been developed based on the author’s extensive experience in internal evaluation, checklist development and use, and working with the Clinical and Translational Sciences Awards (CTSA)—as the UMN CTSA M&E Director, ACTS Evaluation SIG Chair, and a Co-Lead of the Evaluators Working Group within the NCATS CTSA Common Metrics Initiative. Although there is no “golden” algorithm that will totally suit every organization, the M&E checklist provides useful guidelines for building M&E. The Checklist presents the key concepts and important issues in M&E development and implementation. It also incorporates a synthesis of 8 grounded frameworks: King and Volkov’s Framework for Building Evaluation Capacity (2005), Simister’s Framework for Developing M&E Systems for Complex Organizations (2009), and the award-winning CDC Framework for Program Evaluation in Public Health (1999). For the purposes of the proposed Checklist, an M&E system (or framework/approach) is understood as “a series of policies, practices, procedures, and processes that enable the systematic and effective collection, analysis and use of monitoring and evaluation information” (Simister, 2009. p. 1). A well-designed M&E system ensures a consistent approach to the collection, analysis, and use of information, while allowing considerable scope for different parts of an organization to develop and apply their own solutions in response to their particular situations. The M&E Checklist structured around 3 key domains (adapted from the Volkov and King EBC Checklist, 2007): (1) M&E/Organizational context: taking advantage of the internal and external organizational context, administrative culture, and decision-making processes. (2) M&E structures: creating structures—mechanisms within the organization—that enable the M&E development and use. (3) M&E resources: making M&E resources available and used. For each domain, the Checklist has a number of associated categories and activities. Specifically, the checklist adopts and adapts the following useful steps from Simister’s approach: “Define the scope and purpose,” “Perform a situational analysis,” “Consult with relevant stakeholders,” “Identify the key levels and focus areas,” and “Integrate the M&E system horizontally and vertically,” as well as the CDC Framework’s steps “Engage stakeholders,” “Focus the M&E Design,” and “Establish M&E and share the plan.” With slight modifications, the organizations can also utilize the Checklist as a rubric/assessment tool to gauge the status of their M&E capacity. METHODS/STUDY POPULATION: A case study of methodological/implementation tool development. There are no human subjects in this study, thus, Study Population is not applicable to this study. This study is not subject to IRB review. RESULTS/ANTICIPATED RESULTS: The proposed checklist approach should help organizations to not only implement individual M&E systems and their M&E systems but to also enhance internal evaluation capacity, critical thinking, learning, strategic management, and improvement within clinical and translational science organizations. DISCUSSION/SIGNIFICANCE OF IMPACT: The ultimate goal and impact of the proposed checklist is to help ensure that organizations and their M&E teams consistently follow a few critical steps and thereby maximize the quality, efficiency, and consistency of monitoring and evaluation of the clinical and translational work. The checklist’s impact is significant in that it fills the current gap in the practice, literature, and methodology and provides practical guidance for CTR (and other) organizations and programs striving to improve the quantity and quality of evaluation.

References

National Center for Advancing Translational Sciences. NCATS Strategic Plan [Internet]. 2016. NIH. (https://ncats.nih.gov/strategicplan)
Coping strategies used by caregivers of newly diagnosed pediatric brain tumor patients
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OBJECTIVES/SPECIFIC AIMS: The goal of the study is to use patient-centered qualitative techniques to determine what strategies caregivers use to cope with the stress of a child having recently (i.e., within the past month) undergone surgical removal of a brain tumor. Results will eventually be evaluated and compared with results of quantitative measures of psychosocial risk and distress as well as demographic and medical characteristics.

METHODS/STUDY POPULATION: All caregivers of patients with a newly diagnosed brain tumor requiring neurosurgery admitted to Children’s of Alabama (with English or Spanish-speaking parents) are eligible for enrollment. Participants are enrolled during their child’s initial hospitalization for surgical removal of a brain tumor. Approximately 1 month after hospital discharge, during a routine follow-up visit, caregivers participate in a semistructured interview with a research assistant. Interview questions are used to obtain information about parent and family coping by asking first broadly about stress management over the previous month and then specifically about individual coping strategies. Semistructured interviews are audio recorded, transcribed, and coded for common themes. Interviews are coded by using specific words or phrases to describe various domains of the experience from the caregiver’s perspective. Each participant is given a study ID and study IDs are logged with each code word or phrase endorsed during the interview. RESULTS/ANTICIPATED RESULTS: To date, 22 caregivers have been enrolled and 15 have completed interviews. The most common coping mechanisms fall into the domains of active, avoidance, emotion-focused, and spiritual coping. Active coping consists of information seeking (eg, taking notes, internet research, asking questions), openly communicating emotions, celebrating small victories (eg, focusing on a good scan or test result, thinking that the diagnosis or treatment could have been worse), planning (eg, focusing on 1 d at a time), and maintaining normalcy (eg, maintaining extracurricular activities, returning to school if possible, continuing to see family and friends). Avoidance coping consists of avoiding discussions about emotions, withdrawal from family members, denial (eg, keeping a cancer diagnosis from the child), and avoiding seeing people or participating in activities. Emotion-focused coping consists of crying, laughing, and staying strong in front of the patient. In general, those who self-identify as coping poorly tend to be those who utilized more avoidance-focused coping strategies.

Further, caregivers tended to identify active coping strategies (eg, taking notes, focusing on 1 appointment or treatment at a time) as the most helpful. DISCUSSION/SIGNIFICANCE OF IMPACT: It will be helpful for providers to more deeply understand the experience of caregivers whose children have undergone brain tumor resection and the strategies used to cope with the stress of the first month post-surgery. This information can be used to create standardized interventions for use during posthospitalization clinic visits. For example, if families continue to endorse that active coping mechanisms are the most helpful, providers can assist caregivers in developing these strategies (eg, in the form of pamphlets and encouraging caregivers to keep track of questions and appointment information, pair caregivers who are struggling with others who use more active coping strategies). Those utilizing more avoidance coping strategies may need more coaching and recommendations.

A brief assessment could potentially be developed for caregivers dealing with this diagnosis, in order to quickly assess coping strategies and provide appropriate recommendations. Future analyses will determine whether initial coping strategies and adjustment are predicted by child age or medical information.

Reperfusion strategies when non-stemi is misclassified as stemi myocardial infarction
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OBJECTIVES/SPECIFIC AIMS: A retrospective analysis was done at the Cardiovascular Center to evaluate reperfusion strategies, including stemi infarcts and non-stemi classified as stemi in a period of 2 years. METHODS/STUDY POPULATION: Review the records of stemi infarcts in a period of 2 years. RESULTS/ANTICIPATED RESULTS: In total, 101 cases were classified as stemi, but after strict analysis (time-wise) 24 were stemi: 47% had inferior myocardial infarction and 38% an anterior myocardial infarction with a mean age of 65 years. All cases were immediately catheterized. Although the non-stemi, classified originally as stemi did not meet the time limit (<2 h) for cath. The steni group (77 P.), 58 P. had angioplasty with stent implantation. 19 P. had an EF of 45% and remained that way during follow up. The rest of the P. the EF went up to 50% or more. The non-stemi group (24 P.) had angioplasty with stent implantation. The EF remained around 40% during follow up, which was the EF on admission. Fibrolysis was given erratically. No changes were seen in the EF on follow up in the fibrolytic group. DISCUSSION/SIGNIFICANCE OF IMPACT: This shows the importance of classifying the P. between stemi and non-stemi. The time frame to catheterization should be kept as strict as possible, due to transmural infarcts and to avoid death in patients presenting with a foreign function and its consequences. This strict classification will save money to the institution when emergency catheterization is avoided in the non-stemi group.

Patient and household member colonization and environmental contamination with Staphylococcus aureus in a comparative effectiveness study of home-based interventions to reduce CA-MRSA recurrence and household transmission
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OBJECTIVES/SPECIFIC AIMS: Community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA) skin and soft tissue infections (SSTIs) are commonly seen in primary care, with recurrence rates that range from 16% to 43%, and present significant challenges to clinicians, patients, and families. This comparative effectiveness research study aims to develop and evaluate a home-based intervention implemented by Community Health Workers (CHWs) or “promotors” to prevent recurrence of CA-MRSA SSTIs in patients presenting to primary care with SSTIs and transmission within their households. This presentation will examine associations between wound microbiology, clinical presentation, and housing characteristics, including housing density and household surfaces contamination. METHODS/STUDY POPULATION: In partnership with 3 Community Health Centers and 3 community hospitals in NYC, this study will recruit patients (n=278) with confirmed MRSA SSTIs and their household members. Participants will be randomized to receive either a CHW/Promotora-delivered decolonization-decontamination intervention (based on the REDUCE MRSA trial) or usual care. The highly engaged stakeholder team finalized the intervention protocol, developed and implemented CHW and clinician training, and developed an online health portal application for data management and exchange. RESULTS/ANTICIPATED RESULTS: We have collected 923 isolates from 237 individuals, including 240 wound culture isolates and 683 surveillance culture isolates (nares, axilla, groin). MRSA and MSSA were found in 19% and 21.1% of wound cultures, respectively; 59.5% with MRSA + wound culture had 1 or more MRSA + surveillance culture; 67.8% with MSSA + wound culture had 1 or more MSSA + surveillance culture. Of those with MRSA or MSSA infections, 70% of subjects were male, with an average age of 37.9 (SD = 15.9). The most frequent sites of infection were the leg (20%), axilla (18%), buttck (17%), and abdomen/torso (12%). There was no association between the location and type of infection (MRSA/MSSA) (p-value = 0.09). The kitchen floor (14.05%) and bedroom floor (14%) were the most common surfaces contaminated with MRSA. These were also the most common surfaces contaminated with MSSA, which was recovered from 10.2% and 9.1% of kitchen floors and bedroom floors, respectively. For MRSA, the most common body site for wound infection, there was an average number of 3.2 (SD = 1.6) co-residents per household, and 36.5% of household members were colonized with either MRSA or MSSA. There is no association between household density (number of co-residents)