FINAL PROGRESS REPORT

Clinical decision support optimizing NEC prevention implementation in NICU

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ABSTRACT:

Purpose: The objectives of this mentored training research grant were to train the PI in the methods of implementation science and clinical decision support and to enable the development and testing of new tools for the neonatal intensive care unit (NICU) for prevention and timely recognition of necrotizing enterocolitis in fragile infants, especially CDS.

Scope: An intervention called "NEC-Zero" was designed, in a stakeholder-engaged manner, to identify what best practices were evidence-supported and then to create a toolkit, including NEC-Zero CDS tools to enable their broad use.

Methods: Guided by the Translating Research into Practice (TRIP) framework, three steps were undertaken to design and operationalize NEC-Zero. Step 1, the formalization of evidence with the NEC-Zero expert team was completed through online collaboration to complete a scoping review, assign GRADE criteria and propose implementation strategies. Step 2, workflow mapping of clinician interactions with the electronic health record to fit CDS, was completed in two NICUs in Arizona with clinician participants. An adherence score for NEC-Zero was validated separately and then incorporated into the CDS.

Results: The evidence base was presented in the NEC-Zero scoping review in 2017 and the GRADE criteria were updated in 2019. Four core practices for NEC prevention included human milk prioritized feeding, use of standardized feeding protocols, antibiotic stewardship and risk awareness for timely recognition. Clinician workflow was defined and mapped for nurses and ordering providers (NNPs and MDs) separately. Content analysis yielded 2 process maps and technical recommendations, including a CDS dashboard. Development of the CDS was completed in a virtual space by defining the knowledge base, modeling the logic, framing and revising prototype interfaces and using a data parser to test the logic. Next steps include embedding the dashboard into a local implementation using SMART on FIHR and testing its impact on neonatal and CDS outcomes.

PURPOSE

In neonatal intensive care using clinical decision support, the focus of this career development proposal was to improve application of evidence-based practices for prevention and early recognition of necrotizing enterocolitis (NEC) among premature infants.

SCOPE

NEC is a catastrophic complication threatening the life of fragile premature infants, yet adoption of prevention and early recognition practices (e.g. preferential use of human milk; adoption of standardized feeding protocols; transfusion and antibiotics management) differ
widely as do NEC rates. Parents play a key role in NEC prevention (e.g. providing mother's own milk), but heretofore, have been insufficiently engaged as partners. Accounting for 20% of US NICU costs, NEC develops late in the hospital postnatal course and can strike suddenly but until now, no tools to guide early NEC recognition were available.

Although decades have focused on unraveling its etiology, necrotizing enterocolitis (NEC) remains a chief threat to the health of premature infants. Both modifiable and non-modifiable risk factors contribute to varying rates of disease across neonatal intensive care units (NICUs). To this end, systematic focus on what actions can be taken to prevent NEC and support its early recognition were undertaken with the help of scientific, clinical, and parent experts.
To address this need, a NEC risk decision rule, called GutCheckNEC was derived and validated by our team to accurately discriminate NEC.

Integration of prevention practices into clinical workflow using clinical decision support (CDS) has been shown to improve adherence to recommended care across settings. This study's goal was to fill a gap between the evidence and the actual practice, using practical tools- especially CDS to optimize adoption of NEC prevention practices. An intervention called "NEC-Zero" was designed, in a stakeholder-engaged manner, to identify what best practices were evidence-supported and then to create a toolkit, including NEC-Zero CDS tools to enable their broad use.

Step 1, the formalization of evidence with the NEC-Zero expert team was completed through online collaboration. Step 2, workflow mapping of clinician interactions with the electronic health record to fit CDS, was completed in two NICUs in Arizona with clinician participants. Development of the CDS was completed in a virtual space.

A 20-person group of experts, the NEC-Zero team, were assembled to complete the scoping review. The group of expert stakeholders was selected in four steps. First, a national group of clinical and research experts were invited because they had published significant research and EBP improvement work around NEC. Second, a group of parents who had been impacted by NEC were recommended by the president of the Preemie Parent Alliance. They were purposefully invited because of their role in formalized parent organizations which included the NEC Society (E.U.), Graham's Foundation (L.M.), and Hand to Hold (T.C.). Third, a doctorally prepared Clinical Nurse Specialist from the implementation site invited physicians to participate as representatives of the target NICUs.

For step 2, where clinician participants informed the workflow where CDS could be fit, 27 participants across 2 sites and 12 focus groups were engaged (n= 11 RNs, n= 5 NNPs, n= 8 MDs, n= 1 RD, n= 1 Pharmacist, n= 1 Developmental Care Coordinator).

METHODS

Study Design. Several steps were undertaken to design and operationalize NEC-Zero. First, using the Translating Research into Practice (TRIP) framework, we classified scientific evidence and practice guidelines into four areas: 1) Feeding protocols and transfusion, 2) promoting human milk, 3) early recognition, and 4) medication stewardship. Over 6 months, the team was divided into sub-groups to answer 5 key questions addressing the 1) strength of the evidence, 2) barriers and challenges to implementing the evidence, 3) recommendations for practice, 4) ways to involve parents and 5) key implementation components to address. A scoping review methodology was used to answer the key questions and participants identified implementation strategies and means to overcome barriers to implementation. Evidence and recommendations were evaluated using the GRADE criteria. In step 2, workflow mapping was completed using qualitative description methodology to create workflow maps from data collected during focus groups. In step 3, the CDS for NEC-Zero was designed in multiple steps including: defining the knowledge base, modeling the logic, framing and revising prototype interfaces and using a data parser to test the logic.

Data Sources/Collection. In step 1 where the NEC-Zero team completed the scoping review to determine the best evidence to support the eventual toolkit and CDS, the 20-person team was divided into four subgroups. Each subgroup included a multi-disciplinary group and a parent representative. They reviewed evidence from 11 position statements and 71 research publications. Discussion about the evidence yielded 29 actionable recommendations and guidance on implementation strategies. Evidence was very strong for promoting human milk and using a feeding protocol. Moderate quality of evidence supported avoiding antibiotics beyond 4 days if the initial blood culture is negative and avoiding histamine-2 antagonists. Evidence is lacking on early recognition approaches although 3 tools were identified to support consistent communication when NEC was suspected. Parents recommended how to engage others from diverse groups specifically by guiding on what information to share, when, how, and by whom. Clinician perspectives on "not scaring parents" by giving them too much information about NEC were refuted by parent perspectives that "they should know the risk." Clinicians and parents advised on content for two brochures, a website, and messaging strategies.

In step 2, workflow mapping, focus groups were conducted in two NICUs. NICUs included: 1) an 86 bed level IV unit (per American Academy of Pediatrics NICU classifying criteria) in a non-academic medical center, and 2) a 30 bed level III unit in an academic medical center. Both units had facilities to conduct surgery and pediatric subspecialists available; used neonatal nurse practitioners (NNPs) as NICU providers; and were affiliated with the same non-profit health system. Across six focus groups, 27 clinicians participated. Clinicians included NICU nurses (37%), physicians (30%), NNPs (19%) and other NICU staff (16%). The average number of years of NICU experience was 16.4.

Interventions. The NEC-Zero intervention includes four evidence-based facets that were deemed by stakeholders to be supported by the best evidence and the least controversy: 1) preferential human milk feeding (proportion of total feeding > 50%) beginning with colostrum for oral care; 2) adoption of a unit-approved standardized feeding protocol; 3) stewarding medications particularly restricting culture-negative empiric antibiotics to < 5 days and avoiding histamine-2 antagonists, and 4) adopting a unit-based approach to early recognition using one of the available risk scoring tools. Withholding feedings during packed red blood cell transfusion

was considered, but evidence was found to be inconclusive and it was not included in the multi-faceted intervention. The CDS for NEC-Zero is presented below.

Measures. During the scoping review, the GRADE criteria were applied to determine the level of evidence and strength of recommendation. Experts agreed that clinicians intending to use NEC-Zero practices are likely familiar with the methods for classifying evidence and grading recommendations that are used by UpToDate, specifically the GRADE criteria. The GRADE approach was then used to classify the strength of recommendations and balance the risks, benefits, burden of implementation, cost and confidence in the evidence. In step 2, an interview guide was used to conduct the focus groups.

RESULTS

Principal Findings

For step 1, principal findings were that NEC prevention practices were available, and evidence supported. Because in 2016, the preventability of NEC was somewhat controversial, two intermediary studies were conducted with support from Robert Wood Johnson Foundation to quantify an adherence score for NEC prevention that could be embedded in the CDS and then to identify the relationship of adherence to NEC prevention to NEC rates in US NICUs. The adherence score was later incorporated into the CDS dashboard to enable the clinician to view how adherent an individual infant's care was to prevention practices and to view NEC risk in that context.

In step 2, emergent themes in the workflow of early recognition of NEC were identified that addressed clinical processes to: 1. Identify NEC signs, 2. Interpret signs, 3. Communicate signs and notify (or receive notification) of NEC concern, 4. Address social system influences, and 5. Adapt to practice variations. Findings also suggest that social systems and structures within NICUs such as clinician hierarchies and confidence influence timeliness of care and increase the risk of failure to rescue. Content analysis yielded 2 process maps and many technical recommendations to support clinicians' needs for EHR data visualization via a CDS dashboard. Current state requires them to hunt and peck for data and they were asking for: 1) a NEC-relevant data rich dashboard to support nutrition tracking and NEC early recognition, 2) CDS support features, 3) Breastmilk tracking and administration, 4) Tools for surveillance and quality reporting informed by NEC-relevant indicators, and 5) Local IT optimizations.

In step 3, CDS development, the original plans to embed the NEC-Zero recommendations as alerts and reminders were overthrown by clinician concerns about over-alerting and a lack of willingness by the organization to embed CDS for NEC in such a way. So the CDS was reconceptualized as a clinical dashboard that could be embedded as a SMART on FIHR technology or accessed via a CDS hook in the future.
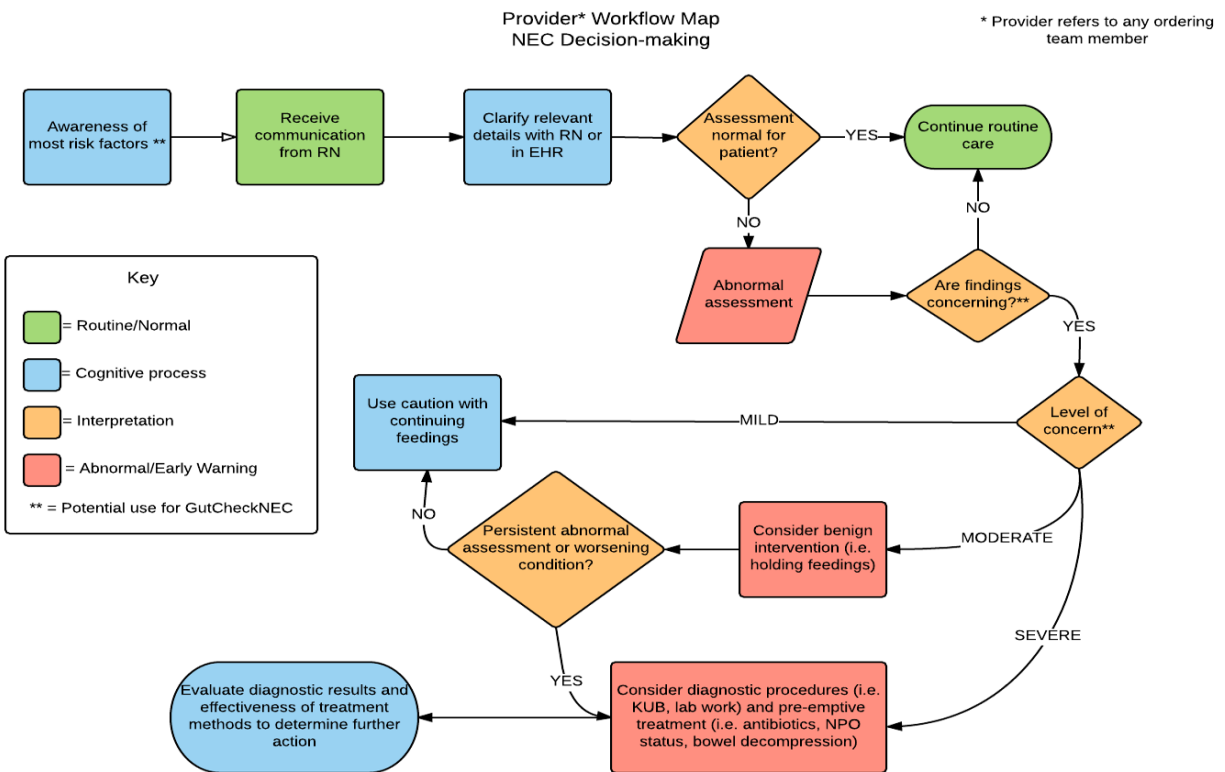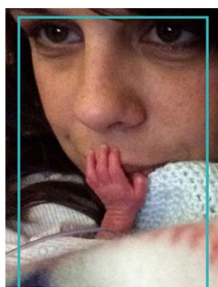
Figure 1. *Workflow map for Provider Decision-Making for NEC Recognition*

Outcomes

The full scoping review and the NEC-Zero toolkit elements are listed in the publications and products section.

The NEC-Zero parent group was adamant that parent education tools were needed and that they needed to be widely accessible. The NEC-Zero website

Parent Education Materials

was designed and launched after several rounds of iterative usability testing (see https://neczero.nursing.arizona.edu/). Pamphlets for parents were designed and evaluated by parents and clinicians, refined, and translated into Spanish, evaluated for adequacy of translation and posted to the website. Tools for clinicians include the GutCheckNEC risk score, a structured communication tool for NEC concern (SBAR), an Avoiding NEC checklist and other tools. Since 2017, the website has been broadly accessed and nearly 8,000 visitors have downloaded the tools.
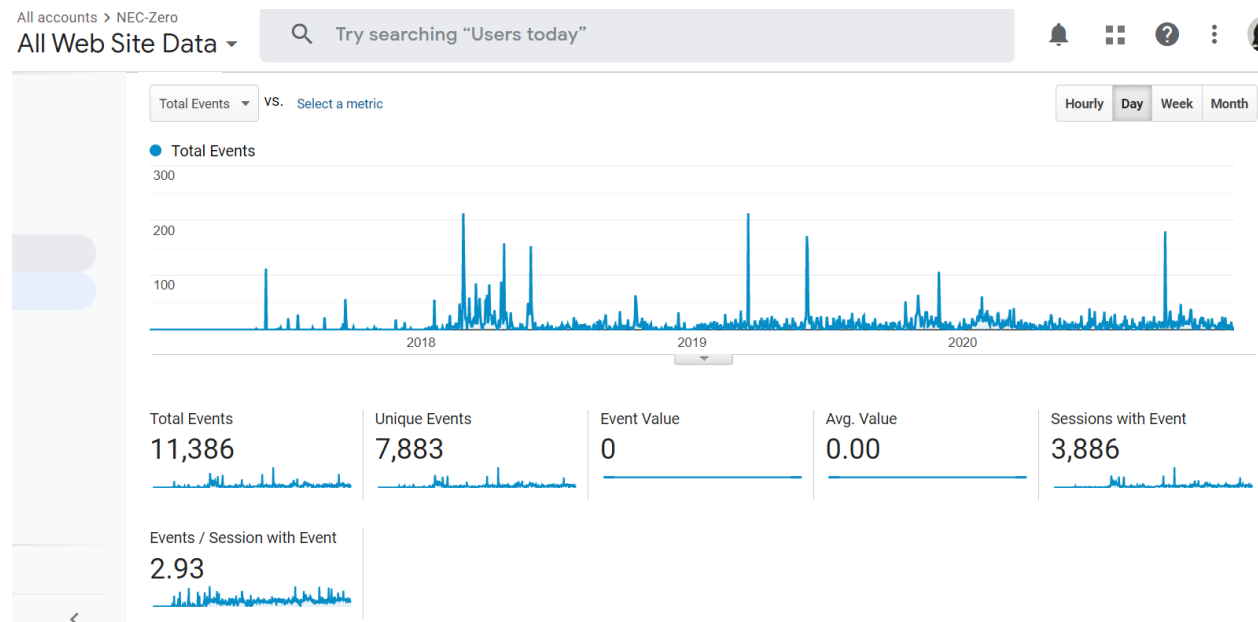

Figure 2. NEC-Zero Website Usage since 2017

One product of engaging with parent stakeholders was coordination with the NEC society, to produce a parent engagement video, "Necrotizing enterocolitis and the importance of collaborative care", which is universally accessible at https://youtu.be/U7vD8v31zb0.

NEC-Zero Clinical Decision Support Development Key Outcomes
- o NEC-Zero Knowledge Bases: The logic for these artifacts is encoded using the open-source Drools expression syntax but utilize/reference HL7 FHIR data models and standardized terminologies such as SNOMED. The analytics behind the demonstration platform are driven by these knowledge bases.
- o NICU Data Generation Tool: This tool is composed of two parts: a) a spreadsheet for defining and auto-generating realistic EMR data for a NICU patient, and b) a parser that reads the data, creates corresponding EMR entries using the correct FHIR resources and terminologies, and stores them in the demonstration system database. This tool creates patient records that generate the analytic results needed to illustrate different use cases.
- o Prototypic EMR: This open-source web portal represents any number of EMR clients in existence today, e.g. Cerner's Power Chart. The portal provides the framework for demonstrating how GutCheckNEC knowledge bases analyze clinical data and generate alerts, how such recommendations can be integrated into bedside workflow, and how for illustrating the value of standardized-based CDS. The

delivered portal includes Cognitive' s CDS "drawer", a dynamic and interactive tool that displays the results of the analytics performed, and our enhanced flowsheet control, that similarly embeds analytic work product within EMR screens used for displaying I&O, vitals, or other clinical data.

- o <u>GutCheck^{NEC} Documentation Tool</u>: This EMR module enables a user to instance a new GutCheckNEC form, complete and store the assessment, score the form, and use the results for calculating process adherence scores.

Logic Modeling

NEC-Zero clinical recommendations were broken into definable logic and workflow decision points were identified through iterative discussion. CDS alerts were designed to target the most relevant decision-maker in the flow of their decision-making workflow. Plans were made to escalate alerts to other healthcare team members when ignored and log for quality review. Eight CDS logic sets address: 1) stopping empiric antibiotics by day 5 of treatment; 2) avoidance of antacids; 3) feeding guidelines by birth weight; 4) holding feeding during transfusion; 5) risk awareness with feeding intolerance algorithm; 6) early initiation of lactation support and colostrum for oral care; 7) human milk tracking; and 8) NEC risk awareness in the presence of NEC clinical signs.

Interface Design for NEC-Zero SMART on FHIR

Using technical requirements identified by the focus groups, a SMART on FHIR App is in development that integrates NEC recognition with workflow support for prevention adherence. Using a CDS hook, it can be linked to from within the EHR and is agnostic to EHR system. Features address tracking of breastmilk administration, nutrition details, NEC risk scores and processes for prevention using a validated adherence score, visible by individual, group or population.
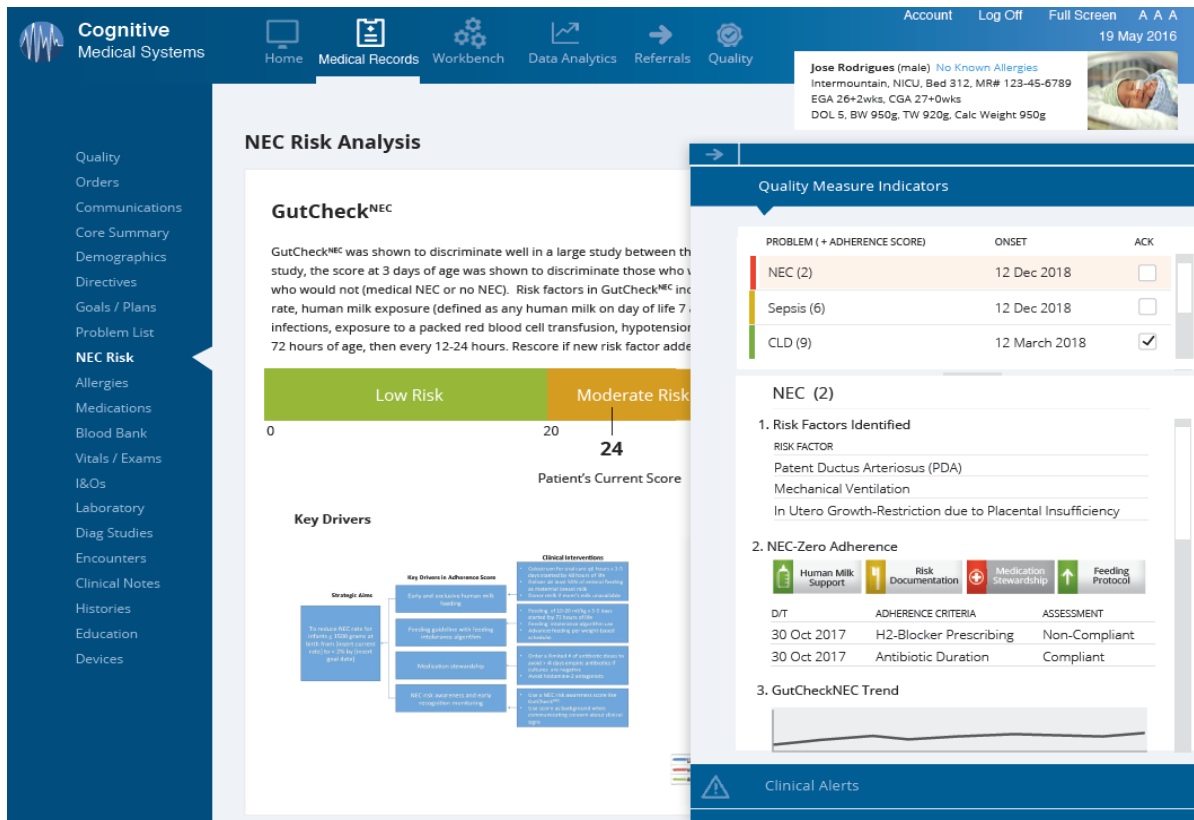
Figure 3. *NEC-Zero Dashboard Incorporating Prevention Adherence and Risk Profiling*

Discussion

Improving early recognition of NEC requires closing the gap between recommended care and existing practice. Sociotechnical influences may act as barriers to recommended practices, leading to gaps in care. Identification of NICU workflows illuminate areas of decision-making and interpretation that were used to inform a NEC-Zero CDS tool, using descriptions of how clinicians currently use information and the EHR to prevent and detect NEC. Other researchers have found that CDS should be dependent on a specified provider workflow and should be situation-specific to affect behavior change. Although different clinicians take different steps and make decisions at different points within care delivery, they all felt that a single dashboard could support their thinking and enhance communication. By accounting for clinicians' workflow and processes, we are able to inform, develop, and refine NEC-Zero CDS. Because of low readiness, the initial intent to embed the CDS in a local EHR using alerts and reminders was not met. Technical barriers also became an issue as the organization who had initially wanted to implement the CDS, had other urgent priorities. To enable broad use of the CDS, we designed it to interoperate across EHRs using the SMART on FIHR approach but then found that the organization was not ready, during the project period, to adopt the app. We are continuing to refine it and look for partners to implement it.

Conclusions

In this study, we defined a knowledge base for NEC-Zero CDS, identified technology requirements for NEC CDS design to support clinician decision-making and developed one-stop visualization of NEC related data in the NEC-Zero dashboard.

Significance

NEC avoidance is a continuing goal of NICUs in the US and internationally, because it can kill babies or leave them with lifelong health consequences. In complex care environments, NICU clinicians continue to need timely and effective decision-support to make their use of evidence efficient and consistent. Tools for bedside providers to evaluate outliers and identify probable causes for suboptimal quality are similarly lacking. At the individual case level, accessing and reviewing disease specific data is often a "hunt and peck" exercise requiring the provider to jump from one EMR section to another to aggregate and memorize relevant data for further analysis. Little to no support is provided by the EMR to automate such tasks and rarely is any assistance available to graph or visual the aggregate in ways that highlight common data patterns indicative of conditions known to be contributory. Similarly, identifying trends in cohorts of patients is typically a task assigned to data analysts and statisticians despite the fact that the techniques employed by such experts are often routine, predictable and amenable to automation. The NEC-Zero tools were designed to support team-based and widespread adoption of NEC prevention in ways that engage families and make best practices repeatable. The NEC-Zero CDS dashboard holds promise to improve adherence and enable more consistent risk awareness for NEC.

Implications

In the years since this project began, the prevailing beliefs among clinicians about NEC preventability have drastically shifted. NEC-Zero has provided synthesized and vetted evidence reviews and tools for clinical use to close the gap between recommended and actual care. Nearly 8,000 downloads from the NEC-Zero site demonstrate that the tools are being accessed and used. Next steps will continue to refine and implement the NEC-Zero CDS. Because it was built in a platform-agnostic manner, once sites are ready to adopt SMART on FIHR or CDS hooks, we are confident that its use will increase. A continuing program of research will investigate its impact on clinical care processes and neonatal outcomes across sites and contexts.

PUBLICATIONS AND PRODUCTS

Publications *(** Denotes product of K08 research, others are outcomes of training support)*

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