

Reengineering Clinical Research in Critical Care

RCRCC

HHSN268200425210C; NO1-HC-45210

Alan H. Morris, MD

This is a group effort involving about 25 clinical sites and multiple investigators
IHC Health Services, Inc DBA LDS Hospital
Salt Lake City, Utah

BRIEFING BOOK SUMMARY

May 9 -10, 2007

A. PROGRAM SUMMARY

Please provide a summary of the programs recent accomplishments. DO NOT send your annual report or milestone chart. This section should include original material highlighting your program accomplishments.

1. INTRODUCTION

Our approximately 25 collaborating institutions continue to work enthusiastically in this Roadmap study. We have begun a vigorous program of manuscript preparation and submission while we address some regulatory challenges. We have submitted and application for a one-year extension with funding during which we plan to analyze and report a number of scientific issues linked to our Roadmap project.

B. BUILDING COLLABORATION FOR CLINICAL RESEARCH NETWORKS

Include in this section activities that focus on issues related to the extent of collaboration in your Roadmap program (national and international), identifying current challenges, tools, and best practices.

The ARDS Network is actively engaged in developing a scientific collaboration with the PALISI network. This will join a pediatric research group to the adult clinical trials of adults being conducted by the ARDS Network.

Challenges include barriers to bridging two medical disciplines (Internal Medicine and Pediatrics). These include physiologic differences between children and adults, size and dose differences, cultural differences between pediatricians and adult intensivists, and process and structural disciplines between the two disciplines. The three major conclusions drawn from our investigations have helped us address these challenges.

Our three major conclusions:

1. We have developed an adequately explicit method that enables replicable clinical performance in adult ICUs in different cultures.
2. We have used this method to replicate clinical performance in both adult and pediatric ICUs
3. We have used this method to translate research results into usual clinical practice with performance in practice that is almost indistinguishable from that in the research environment.

C. ROADMAP PRESENTATIONS AND PUBLICATIONS

ABSTRACTS:

K.A. Sward, MS,RN, A.H. Morris, MD, D. Sorenson, PhD, L. Weaver, MD, C. Grissom, MD, H.R. Warner, MD,PhD and for Reengineering Clinical Research in Critical Care Network. A Software Tool to Develop Computerized Bedside Clinical Protocols. [Abstract]. AJRCCM. 2007; 175: A793

A. Morris, MD, A. Randolph, MD, MS, G. Bernard, MD and for Reengineering Clinical Research in Critical Care. Linking Disparate Networks by Reengineering Clinical Research in Critical Care [Abstract]. AJRCCM. 2007; 175: A792

J.Orme, J. Holmen, B. Rocha, A. Morris, T. Clemmer, and for Reengineering Clinical Research in Critical Care. Translation of Research Tools to Clinical Practice [Abstract]. AJRCCM. 2007; 175: A793

Morris AH, Orme JF, Lee KH, Truwit JD, Jefferson L, Willson DF, Zaritsky A, Bogue C, Brower R, Sorenson D, Sward K, Warner HR, Li G, Leong T. (5/22/2006). Unusual Insight from Clinician Compliance with a Bedside Computerized Glucose/IV Insulin Infusion Protocol. [Abstract] AJRCCM. 2006: 174: A380

Thompson BT, Orme JF, Willson DF, Morris AH. (5/31/06). eProtocol-Insulin Development and Refinement in Two Research Networks. Poster session presented at Inventory and Evaluation of Clinical Research Networks (IECRN) National Leadership Forum, Rockville, MD.

Morris AH, Thompson BT, Bernard GR, Brower R. (5/31/06). Re-engineering Clinical Research in Critical Care. Poster session presented at Inventory and Evaluation of Clinical Research Networks (IECRN) National Leadership Forum, Rockville, MD.

Truwit JD, Orme JF, Hirshberg E, Morris AH. (5/31/06). Bedside Electronic Glucose Protocol (eProtocol-insulin) Performance. Poster session presented at Inventory and Evaluation of Clinical Research Networks (IECRN) National Leadership Forum, Rockville, MD.

Morris AH, Sorenson D, Sward K, Warner HR. (05/31/2006). A Software Tool To Develop Computerized Bedside Clinical Protocols. Poster session presented at Inventory and Evaluation of Clinical Research Networks (IECRN) National Leadership Forum, Rockville, MD.

Jan2007: 35e Congrès annuel de la Société de Réanimation de Langue Française, Paris Une enquête nord-américaine sur le contrôle de la glycémie. Réanimation 2007;16: in press

19Feb2007: 36th Annual Critical Care Congress, Orlando FL. Poster: Blood Glucose Control Practices: A survey of Adult and Pediatric ICUs.

PUBLICATIONS;

AH. Morris, MD¹, J Orme, Jr. MD,¹ BH Rocha, MD, PhD², J Holmen, PhD², T Clemmer, MD¹, N Nelson, RN, MS³, J Allen, RN, MS², Al Jephson, BA¹, D Sorenson, PhD⁴, K Sward, RN, MS⁵, H Warner, MD, PhD⁴, for the Reengineering Critical Care Clinical Research Investigators. An Electronic Protocol for Translation of Research Results to Clinical Practice. Manuscript Submitted 05/2007

D Sorenson², C Grissom¹, L Carpenter¹, AH Morris^{1,2}, A Austin¹, K Sward², L Napoli¹, HR Warner², For the Reengineering Clinical Research in Critical Care investigators. A Frame-based Representation for a Bedside Ventilator Weaning Protocol. Manuscript Submitted 05/2007

K. Sward, PhD, RN¹, J. Orme, Jr., MD², D. Sorenson, PhD³, L. Baumann, RN², and A.H. Morris, MD² for the Reengineering Critical Care Clinical Research Investigators. Reasons for Declining Computerized Insulin Protocol Recommendations. Manuscript Submitted 05/2007

Phansalkar S, Sward K, Weir CR, Morris AH. Mapping clinicians' perceptions about computerized protocol use to an IT implementation framework. MedInfo, In Press

PRESENTATIONS:**October 2005**

24Oct2005: Collaborative Pediatric Critical Care Research Network, Bethesda MD. Presentation: Computerized Decision Support Tools in the PICU

November 2005

01-03Nov2005: CHEST 2005, Montreal, Quebec, Canada. Presentation: Developing and Monitoring Adequately Explicit Protocols; NIH/NHLBI ARDS Network and "Re-Engineering Clinical Research in Critical Care"

29-30Nov2005: ARDS Network Mtg, Chicago IL. Presentation: Electronic Tools and Adequately Explicit Protocols in Human Clinical Trial Experiments

January 2006

01-05Jan2006: Collaborative Pediatric Critical Care Research Network, Bethesda MD. Presentation: BAA RM-04-03: Reengineering the Clinical Research Enterprise - Roadmap contract-"Reengineering Clinical Research in Critical Care;" NHLBI contract # HHSN268200425210C

17-20Jan2006: ARDS Network Mtg, New Orleans LA. Presentation: Blood Glucose RCT.

27Jan2006: IHC Advanced Training Program Course, Salt Lake City UT.
Presentations: Human Decision Making Limitations: The Role of Algorithms, Decision Support and Cointervention Control in Medical Care; Adequately Explicit Computerized Protocol Development and Iterative Refinement; Reducing Clinical Variation and Errors with Explicit Methods.

31Jan2006: Behavioral Science and Health Program Capstone Course, University of Utah, Salt Lake City UT. Presentation: Science and Human Decision Making Limitations: The Role of Decision Support in Clinical Trials

February 2006

09Feb2006: St Michael's Hospital Grand Rounds, Toronto, Ontario, Canada.
Presentation: Decision Support Tools Can Enable Clinical Quality Improvement

22Feb2006: Pediatric Critical Care Colloquium, Snowbird UT. Presentation: Computerized Decision Support Tools in the PICU.

March 2006

07-08Mar2006: BAA Semi-Annual Committee Meeting, Salt Lake City UT.
Presentation: BAA Update "Reengineering Clinical Research in Critical Care".

10Mar2006: PALISI Semi-Annual Meeting, Snowbird UT. Presentation: BAA Update "Reengineering Clinical Research in Critical Care".

16Mar2006: University of VT Grand Rounds, Burlington VT. Presentation: Clinical Decision Makers: Why We All Need Help. Research Seminar Title: Scale of Inquiry and Clinical Trial Experimental Design

30Mar2006: 16th Conference on High Frequency Ventilation of Infants, Children and Adults, Snowbird UT. Presentation: Explicit Clinical Protocols: A Response to Human Decision Making Limitations.

April 2006

14Apr2006: University of Utah Medical Informatics Department Presentation, Salt Lake City UT. Presentation: Human Clinical Trial Experimental Design and the Role of Adequately Explicit Protocols

18Apr2006: University of Utah Dept of Medicine Housestaff Conference, Salt Lake City UT. Presentation: Why Human Decision-Makers Need Help.

20Apr2006: 2006 Legacy of Life Scientific Recognition Award Conference, LDS Hospital, Salt Lake City UT. Presentation: Why Human Decision Makers Need Help.

21Apr2006: MD Anderson Cancer Center, Houston TX. Presentations: Human Decision Making Limitations: The Role of Algorithms, Decision Support and Cointervention Control in Medical Care; Adequately Explicit Computerized Protocol

Development and Iterative Refinement; Reducing Clinical Variation and Errors with Explicit Methods.

May 2006

22May2006: ATS International Conference 2006, San Diego CA. Presentation: Implementation of Computer Protocols to Tightly Control Glucose in the Pediatric and Adult ICU.

30May2006: IECRN National Leadership Forum, Rockville MD. Presentation: BAA Update.

June 2006

26Jun2006: Collaborative Pediatric Critical Care Research Network Meeting, Washington DC. Presentation: Reengineering Clinical Research in Critical Care

July 2006

14Jul2006: IHC Advanced Training Program Course, Salt Lake City UT. Presentations: Human Decision Making Limitations: The Role of Algorithms, Decision Support and Cointervention Control in Medical Care; Adequately Explicit Computerized Protocol Development and Iterative Refinement; Reducing Clinical Variation and Errors with Explicit Methods.

September 2006

14-15Sep2006: Northern New England Critical Care Conference, Stowe VT. Presentation: Electronic Decision Support Tools: A Response to Human Decision-making Limitations

18-20Sep2006: PALISI Semi-Annual Meeting, Newport RI. Presentation: BAA Contract Update

October 2006

25Oct2006: CHEST 2006, Salt Lake City, UT. Presentation: Bedside Electronic Glucose Protocol (eProtocol-insulin) Performance

25Oct2006: CHEST 2006, Salt Lake City, UT. Presentation: eProtocol-insulin Development, Refinement and Validation of a Protocol Common to Adults and Children.

November 2006

07Nov2006: University of Utah Department of Medical Informatics Decision Support Systems Course, Salt Lake City, UT. Presentation: Human Clinical Trial Experimental Design and the Role of Adequately Explicit Protocols.

09Nov2006: MD Anderson Cancer Center, Houston TX. Presentations: Human Decision Making Limitations: The Role of Algorithms, Decision Support and Cointervention Control in Medical Care; Adequately Explicit Computerized Protocol

Development and Iterative Refinement; Reducing Clinical Variation and Errors with Explicit Methods.

15Nov2006: AHRQ Electronic Guidelines Meeting, Washington DC. Presentation: Standardized Clinician Decisions in Clinical Research and Clinical Practice with Adequately Explicit Bedside Decision-support Protocols.

22Nov2006: Grand Rounds, Department of Pediatrics, Sainte-Justine Hospital, Université de Montréal Impact scientifique et clinique d_un système-expert.

March 2007

23Mar2007: PALISI Semi-Annual Meeting, Snowbird UT. Presentation: BAA Update "Reengineering Clinical Research in Critical Care"

April 2007

12Apr2007: MD Anderson Cancer Center, Houston TX. Presentations: Human Decision Making Limitations: The Role of Algorithms, Decision Support and Cointervention Control in Medical Care; Adequately Explicit Computerized Protocol Development and Iterative Refinement; Reducing Clinical Variation and Errors with Explicit Methods.