Houston Pediatric Quality Project
Guy Clifton et al, UT Houston

To develop a program that would

- improve the care and outcome of high-risk Medicaid children
- be sustainable by reducing Medicaid costs for ED visits, hospitalizations, and PICU admissions sufficiently to cover program cost and share sizable savings with caregivers

Where is the hard evidence that this would be feasible?

Comprehensive Follow-up Care and Life-Threatening Illnesses Among High-Risk Infants

A Randomized Controlled Trial

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Context Inner-city high-risk infants often receive limited and fragmented care, a problem that may increase their risk of illness.

Objective To assess whether access to comprehensive care in a follow-up clinic is cost-effective in reducing life-threatening illnesses among high-risk, inner-city infants.

Design Randomized controlled trial.

Setting and Participants A total of 181 very-low-birth-weight infants born in a Texas County hospital between January 1998 and March 1999 and followed up in a children's hospital clinic. One hundred four infants who became ineligible or died after randomization but before routine discharge were excluded from the analysis.

Interventions Infants were randomly assigned to receive routine follow-up care (well-baby care and care for chronic illnesses; n=88) or comprehensive care (which included the components of routine care plus care for acute illnesses, with 24-hour access to a primary caregiver; n=89).

Main Outcome Measures Life-threatening illnesses (ie, cause death or hospitalization for pediatric intensive care) occurring between routine discharge and age 1 year, assessed by blinded evaluators from inpatient charts and mailed medical and vital statistics records; and hospital costs estimated from department-specific cost-to-charge ratios.

Results Comprehensive care resulted in a mean of 2.1 more clinic visits and 6.7 more telephone conversations with clinic staff ($P<.001$ for both). One-year outcomes were unknown for fewer comprehensive-care infants than routine-care infants (9 vs 28; $P=.01$). Identified deaths were similar (n=1 in comprehensive care vs n=3 in routine care; $P=.68$). The comprehensive-care group had 48% fewer life-threatening illnesses (33 vs 63; $P<.001$), 47% fewer intensive care admissions (23 vs 43; $P=.002$), and 42% fewer intensive care days (256 vs 445; $P=.002$). Comprehensive care did not increase the mean estimated cost per infant for illness ($4,236 with comprehensive care and $5,913 with routine care).

Conclusion Comprehensive follow-up care by experienced caregivers can be highly effective in reducing life-threatening illness without increasing costs among high-risk inner-city infants.

JAMA. 2000;284:2071-2076 www.jama.com

Neonatal follow-up programs were originally developed to improve the outcome of high-risk infants, assess the effects of perinatal events and care, and identify infants needing referral for care of ongoing problems. Unfortunately, this approach has often been associated with a substantial loss to follow-up among families of lower socioeconomic status.[1-4] Moreover, this approach does not address the needs of very-low-birth-weight infants of any socioeconomic situation who lack access to a physician skilled in managing the pulmonary, gastrointestinal, nutritional, neurological, developmental, and other problems common among these infants.[5-8] Some follow-up programs now provide well-baby care and care for chronic illnesses. However, care for acute illnesses typically is not provided. Without prompt, effective treatment, minor illnesses or complications may quickly become life-threatening in these vulnerable infants. This problem is likely to contribute to their increased mortality, morbidity, and cost of care throughout infancy.[9-11]

See also Patient Page.

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Conventional vs. Comprehensive Care

	Conventional FU Care in Dallas	Comprehensive FU Care
Well-Child Care	Yes	Yes
Care for Chronic Illness	Yes	Yes
Care for Acute Illness (5 days/wk, 8hrs/day)	No (by faculty-supervised residents)	Yes
24/7 Access to Primary Caregiver via Pager (PNPs given supplemental pay by phone call)	No	Yes

Comprehensive care resulted in:

- 47% fewer infants with life-threatening illness (death or PICU admit; primary outcome) (33 vs. 62; p=0.001) NNT only 13.
- 57% fewer PICU admits (23 vs. 53, p=0.003) & 42% fewer PCU days (254 vs. 440, p<0.01)
- 25% fewer ER visits (597 vs. 730; p <0.03)

Effort and Costs of Comprehensive Care vs. Conventional Care

- Comp. care resulted in only 3.1 extra clinic visits & 6.7 extra calls /infant to 1 yr
- Total costs to 1 yr (*assessed at SPH societal perspective*): $6265 vs. $9913 without include savings to parents
- Excess of costs over reimbursements: (*hospital perspective*): $1070 vs. $2997, a reason that comprehensive care was continued after trial

Opportunities to Augment Pediatric Care & Reduce Costs at UT Houston

Very high-risk children in 2 Clinics

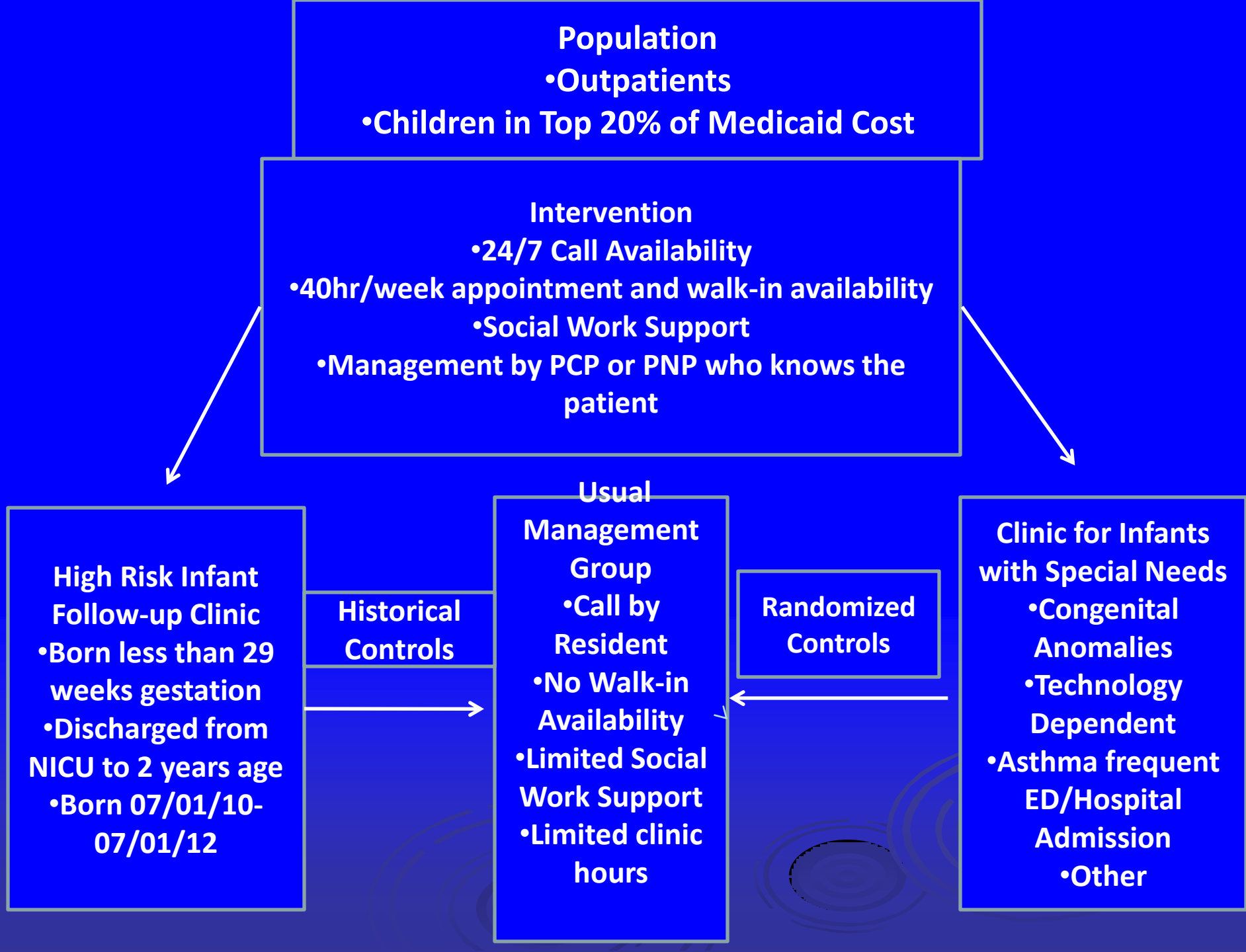
- High Risk FU Clinic : Infants <27 weeks & others discharged from NICU. Limited patients; Partial implementation of comprehensive care (half day clinics; half day clinics)
- Chosen Clinic – Congenital Anomalies, Technology Dependent; others frequently hospitalized; One busy MD; Consultations only; Limited patients; Long waiting list

To meet goals:

What services to provide?

How to assess effects?

What staff to hire?


Population
•Outpatients
•Children in Top 20% of Medicaid Cost
Intervention
•24/7 Call Availability
•40hr/week appointment and walk-in availability
•Social Work Support
•Management by PCP or PNP who knows the patient
High Risk Infant Follow-up Clinic
•Born less than 29 weeks gestation
•Discharged from NICU to 2 years age
•Born 07/01/10-07/01/12
Historical Controls
Usual Management Group
•Call by Resident
•No Walk-in Availability
•Limited Social Work Support
•Limited clinic hours
Randomized Controls
Clinic for Infants with Special Needs
•Congenital Anomalies
•Technology Dependent
•Asthma frequent ED/Hospital Admission
•Other

Expansion of Team Members

- Add & train 2 Pediatric Nurse Practitioners
- Add one MD to work daily in Chosen Clinic and assist Dr. Suny Liaw. No additional MD currently planned for High Risk Infant FU Clinic staffed by Drs. Patricia Evans, Maggie Jimenez, & Saba Siddiqui)
- Add Social worker (to assist Antionette Bowens, MSW). Add one clerical employee.

Comprehensive Follow-Up Care: A T3 Translational Trial in the NRN

Patricia Evans, MD, Jon Tyson, MD, MPH, Roy Heyne, MD, and PIs & Follow Up PIs in all Participating Centers

Why Haven't Comprehensive Care Programs Been Widely Implemented?

A Need for T3 Translational Research

Patricia, you will want to read articles about this published about translational research in JAMA and NEJM in past 3 years

Translational Research

- T1 research: To develop efficacious interventions.
- T2 research: To assess the clinical effectiveness of health care interventions
- T3 research: To assess how to deliver high quality care reliably and in different settings; “dissemination research”

- T3 studies often performed to identify and address barriers to care and better apply effective interventions in clinical practice.
- Appropriate T3 study types include well done qualitative research, surveys, cohort studies, & clinical trials.
- An area receiving increasing emphasis where NRN should be a leader.

Likely Barriers to Use of Comp. Care in Routine FU care:

- Need for funding from 3rd party payers
- Need to inform & broaden perspective of hospital administrators and some division heads or department chairmen
- Need to tailor to local circumstances and develop and support faculty with the commitment and skills needed.

Goals:

Using the strongest feasible design, to conduct a T3 study that

- verifies major benefits across multiple centers that warrant 3rd party funding
- Is supported by hospital administrators, division chiefs, & department chairs
- Facilitates comp. care within local setting & helps develop career of skilled care-givers committed to improving outcomes.

Study Design: Cohort Study of High Risk Infants in Intervention & Control Centers

- Conventional RCT not feasible.
- Well done cohort study likely to be adequate:
  - Major benefits in large single center RCT
  - Plausibility of transitional care between NICU and pediatrician not prepared for such infants
  - Wide acceptance of medical home concept
  - General assumption that outcomes improved by caregivers with special commitment, experience, and availability to patients.

Hypotheses

- Serious illness--death, PICU admission, or prolonged hospital stay--among high risk infants will be progressively reduced after initiation of comp. care relative to that in same center before comp care.
- The decrease in serious illness in intervention centers during the study will exceed that in control centers that do not implement such care.

- Conventional care: current care in center
- Comp. care – minimum requirements in study:
  - Small team of caregivers (MDs +/- PNPs) highly committed to advancing outcomes of high-risk infants over current outcomes
  - Team member(s) in clinic 5 d/wk, 8 h/day
  - Moms have “24/7” page access to team member, preferably primary care provider.
  - Clinic services: social work, develop. assessment, immunizations, anticipatory guidance, management of chronic illnesses, prompt care for acute illnesses

What might help to convince your hosp. administrator to support comp care?

A yes to any of following questions:

- Are your PICU beds often full and patients have to be diverted ?
- Is your reimbursement for a PICU patient worse from Medicaid than other payers?
- Do the reimbursements fail to meet the true cost of care for Medicaid patients?
- Does your Department or ED want / need to reduce the number of ED visits?

- Are there other hospitals that provide pediatric subspecialty services in your area?
- Would earlier discharge of infants from the NICU improve hospital's bottom line or reduce diversion of transfers to competing hospitals?
- With changing health care system, does the hospital administration expect reduced reimbursements for PICU care?

What might help to convince your Chairman to support comp care?

A yes answer to any of the following questions:

- Does your Department need to hire more PICU attendings?
- Aren't PICU attendings much more difficult/expensive to recruit and maintain than neonatologists, general pediatricians / nurse practitioners staffing FU clinic?
- Do PICU attendings need more academic time for research / teaching? If comp care allows earlier discharge from NICU, do NICU attendings need more academic time?

What might help to convince your Division Chief & other members to support comp care?

Patricia you need to spiff this slide up

A yes answer to any of the following questions:

Wouldn't malpractice risk be reduced by providing comp care?

Could junior and senior faculty advance their careers by being involved in:

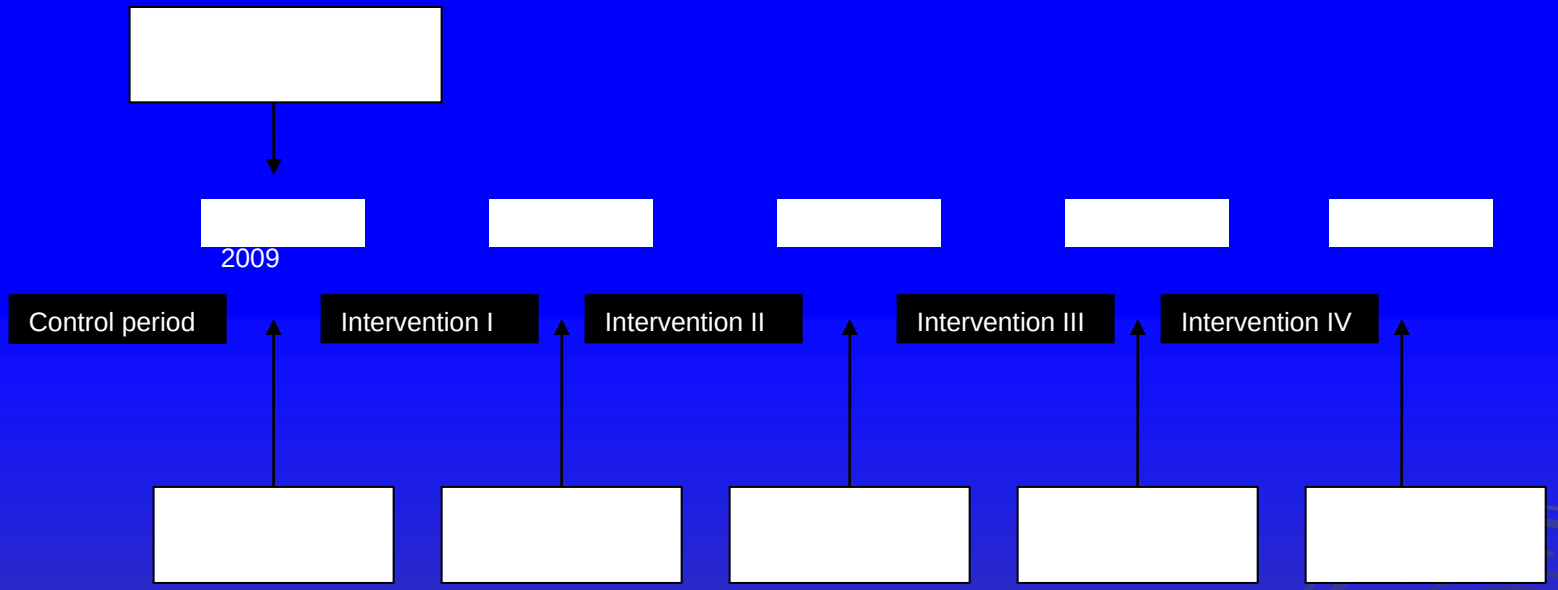
- Multiple journal articles
- Development of evidence-based practice guidelines (book?)
- Opportunity to identify new studies that need to be done

- Patricia, this is as far as I got but I don’t think many more slides are needed or would be wise.

Questions

- Among high-risk infants, would comprehensive follow-up care compared to conventional follow-up care result in decreased severe illness (prolonged hospitalization, PICU admission, death)?
- Among comprehensive care programs, would patient and process outcomes improve as experience providing comprehensive care is gained?

Timeline


2009
Control period
Intervention I
Intervention II
Intervention III
Intervention IV

Potential Intervention Sites

- Alabama
- Case Western
- Dallas
- Duke
- Emory
- Houston
- Iowa
- New Mexico
- Wayne State
- Yale

Potential "Control" Sites

- Brown
- Cincinnati
- Indiana
- Stanford
- Tufts
- Utah

Patients

- Each site will define their own high-risk infant population
- Research team will actively recruit and enroll patients prior to discharge
- Outcomes will be assessed for all eligible infants regardless of whether they opt to receive comprehensive care

Measurements

All Sites

- Death
- PICU Admissions
- Hospitalizations

Intervention Sites

- Death
- PICU Admissions
- Hospitalizations

Sample Size

- Infants expected to die after discharge = 3%
- Infants expected to have prolonged hospital stay = 12%*
- Infants expected to have an ICU admission = 20%**
- Death + ICU admission + Prolonged hospital stay = ~30%

*0.20 with >80th percentile x 0.60 expected proportion of infants hospitalized = 0.12

**0.60 proportion hospitalized x 0.33 with ICU admission on at least one hospitalization

- ~650 infants seen in follow-up per year by current follow-up criteria
- ~20 infants/yr will die between discharge & FU
- If at least 47% of these infants are enrolled in the trial, enrollment will be completed in **2 years**

NEED TO CHANGE THIS SLIDE SINCE ALL SITES NOT PARTICIPATING

Assessment

Patient

- Death
- ICU admission
- Prolonged hospital stay

- Process

Support

- Applying for NIH administrative supplement grant *(deadline 6/30/09; funding to begin 10/01/09)*
- As for all follow-up studies, participating centers will be expected to share the costs.
- Based on the analyses of the Dallas trial, the cost of comprehensive care can be expected to be largely, if not fully, offset by reductions in other costs to society, hospital, and department

Additional Data Slides

Q & A

In the Dallas trial, a very small number of important interactions had a large impact on the primary outcome:

- If ER visit needed, provider facilitated transport (if needed) and communicated with the ER physician
- ER logs reviewed daily and families called for follow-up
- Every attempt made to identify illness early in its course

At UT-H, we define **high-risk infant** as:

- Lives within a 25 mi radius of the clinic
- BWt ≤ 1000 g or GA ≤ 26 weeks
- BPD
- Surgical NEC
- Hypothermia
- Grade 3 or 4 IVH, PVL, or HIE
- Siblings of multiples
- Any baby enrolled in a Network or division study requiring long-term follow-up (ie. VMRI, DTI)

Background and Significance

- Primary care physicians have limited availability and training to treat ongoing and complex medical problems.
- After discharge home, 44% of our patients are rehospitalized one or more times;
- ~ 30% will meet our criteria for **severe illness** (prolonged hospital stay (>80th percentile), PICU admission, or death)

Annual Follow-Up Data Book – 2005 Cohort

To age 12 months, comprehensive care resulted in only:

- 3.1 extra clinic visits / infant
- 6.7 extra phone calls / infant

This surprisingly small extra effort for the major benefits likely due to unusual commitment and experience of the PNPs and MDs (mean 11 yrs providing care to high risk infants in FU clinic)

Why a Network Trial?

- Is trial generalizable to all high-risk infants?
  - Comprehensive care might be less effective than in Dallas trial
    - Higher S.E.S. patients
    - Acute care in Network centers (ER, pediatrician office, resident clinic) possibly better than that in the trial (faculty-supervised resident clinics or ER)

- Comprehensive care might be more effective than in Dallas trial
  - Higher medical risk patients (lower BW and GA)
  - Acute care possibly worse than in trial because of limited availability or interest of private practitioners
  - Well-child care and care for chronic illnesses part of conventional care in Dallas but not in most other Network centers

Other reasons for Network trial

- Such a trial is very unlikely to be performed outside the Network
- A Network trial is crucial to prompt the support & organizational changes needed to develop comprehensive follow-up programs at major centers across the US
- This is what the Network is funded to do. This is our opportunity as Follow-Up PIs to perform a major trial studying a novel intervention.