

# The new landscape for stroke research

**Enrique Leira M.D., M.S.**

Associate Professor of Neurology

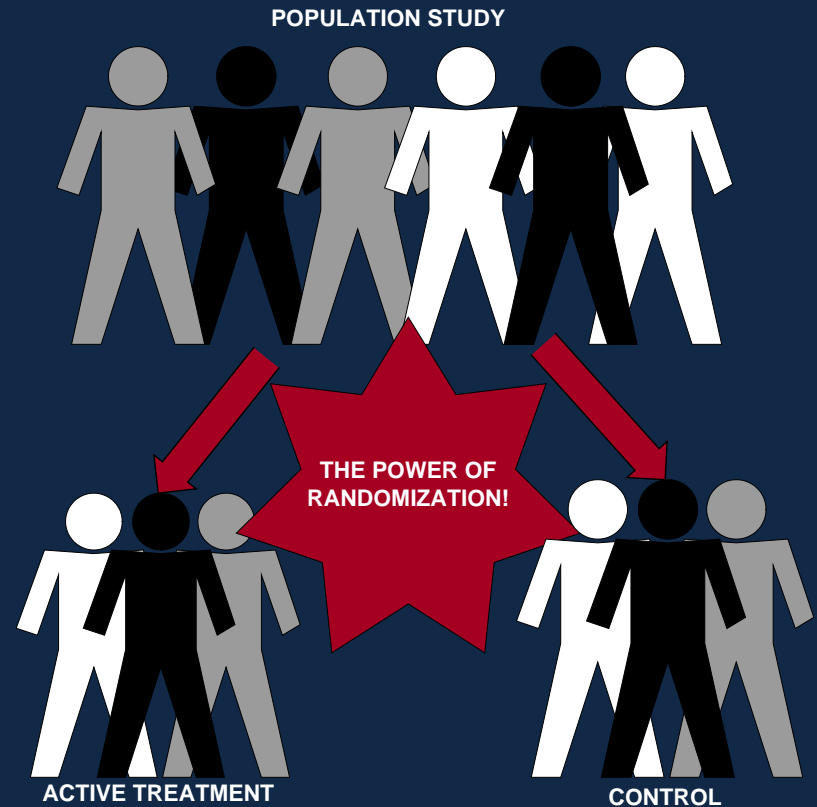
University of Iowa

PI: UIRCC StrokeNet



# NIH Randomized Clinical Trials (RCT)

- Provide best evidence causality
- Quantifies risk-benefit
- Best protection against biases
- Advanced Stroke Care



# Challenges for NIH-sponsored Stroke RCTs

- RCTs are very costly
- Limited resources (\$30-\$70 million /yr)
- Delays peer-review process
- Too few grants awarded (20-50 phase II-III)
- Delay building trial Infrastructure
- Regulatory delays (contracts, IRBs)
- Delays enrollment



# Delayed Enrollment in RCT

**Loss of Sponsorship & Early Termination**

**Underpowered  
False Negative**

**Exposing Patients  
Unnecessary Risk**

**Excessively Long  
Trials**

**Increased Cost**

**Delay in Obtaining  
Societal Answers**

**Evolution  
Intervention &  
Ancillary Care**

# Evolution Intervention & care



PLANNED RECRUITMENT

ACTUAL RECRUITMENT

# Causes Delayed Enrollment RCT

- Clinical Research is Sporadic work
- Competing priorities
- Competing RCT protocols
- Funding goes to few trial leaders
- Fixed number of patients around urban tertiary centers

# Low participation RCT in Rural Areas

- 25% of the US population
- Dispersion population
- Fewer research centers
- Distances to research centers
- Barriers to acute trials with short time window
- Barriers to prevention/recovery trials



# Potential Solutions RCTs

- Increased capture patients from real world, particularly rural areas
- Expand pool researchers
- Motivate clinical investigators
- Coordinate basic and clinical scientists
- Established dedicated research teams and infrastructure
- Harmonized research capable of Metadata analysis



# NIH Stroke Trial Network

- 25 Regional Centers supported by a central coordinating center
- Established permanent structure of researchers
- Foster interdisciplinary collaboration for translational research
- Train translational scientists in stroke
- Efficiency in performing trials
- Accept central IRB and master agreements

# The University of Iowa Statewide Stroke Research Network (1U10NS086521-01)

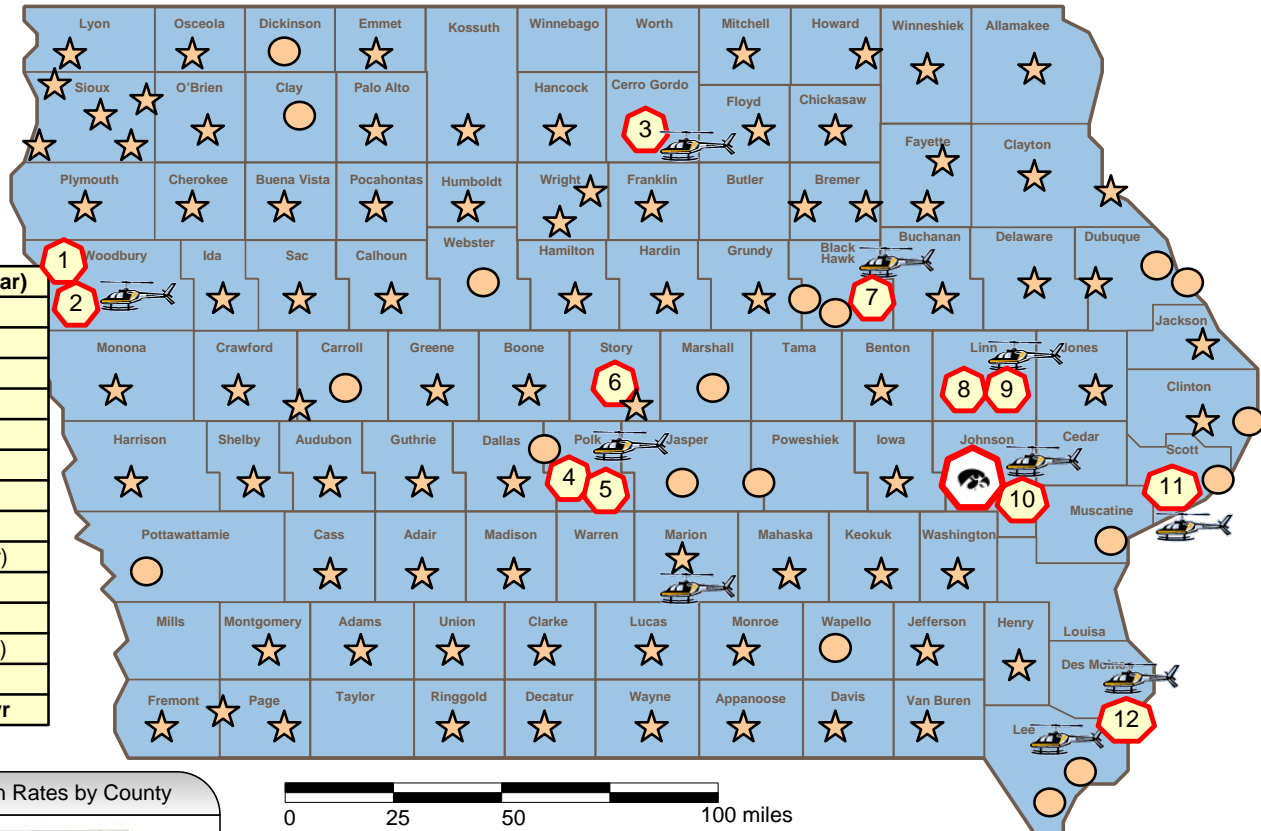
- **Aim 1**: *Establish the University of Iowa Regional Coordinating Center (UIRCC) as a statewide research network for improving subject recruitment for NINDS-funded and other stroke trials.*
- **Aim 2**: *Develop innovative translational research proposals that will lead to multicenter clinical trials through the NINDS stroke network.*

# Stroke Network Centers



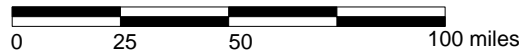
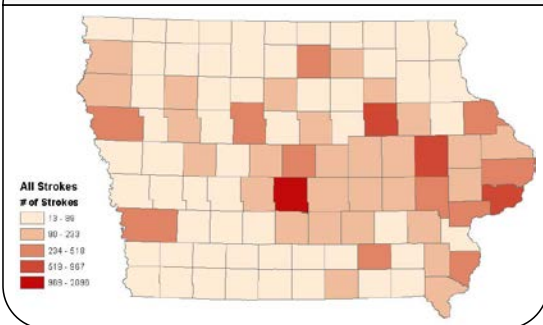
Census Region: West      Midwest      South      Northeast

Fig 1. UIRCC Statewide Stroke Trials Infrastructure



Trial-Ready Hospital ( # patients/year)	
1.	Mercy, Sioux City (381/year)
2.	St. Luke's, Sioux City (70/year)
3.	Mercy, Mason City ( 300 /year)
4.	Methodist, Des Moines (288/year)
5.	Methodist, Des Moines (740/year)
6.	Mary Greeley, Ames (140/year)
7.	Allen Hospital, Waterloo (200/year)
8.	Mercy, Cedar Rapids (220/year)
9.	St. Luke's, Cedar Rapids (125/year)
10.	Mercy, Iowa City (165/year)
11.	Genesis, Davenport (204/year)
12.	Great River, Burlington (109 /year)
	UICSC (900/year)
<b>TOTAL: 3842 acute stroke patient/yr</b>	

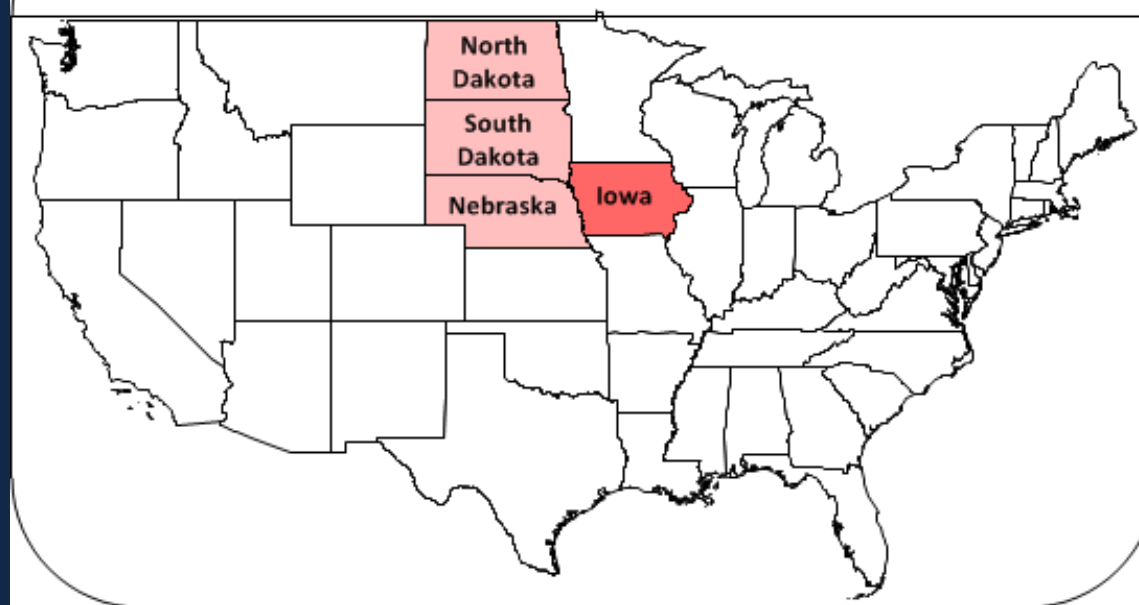
Fig 1A. Stroke Hospitalization Rates by County



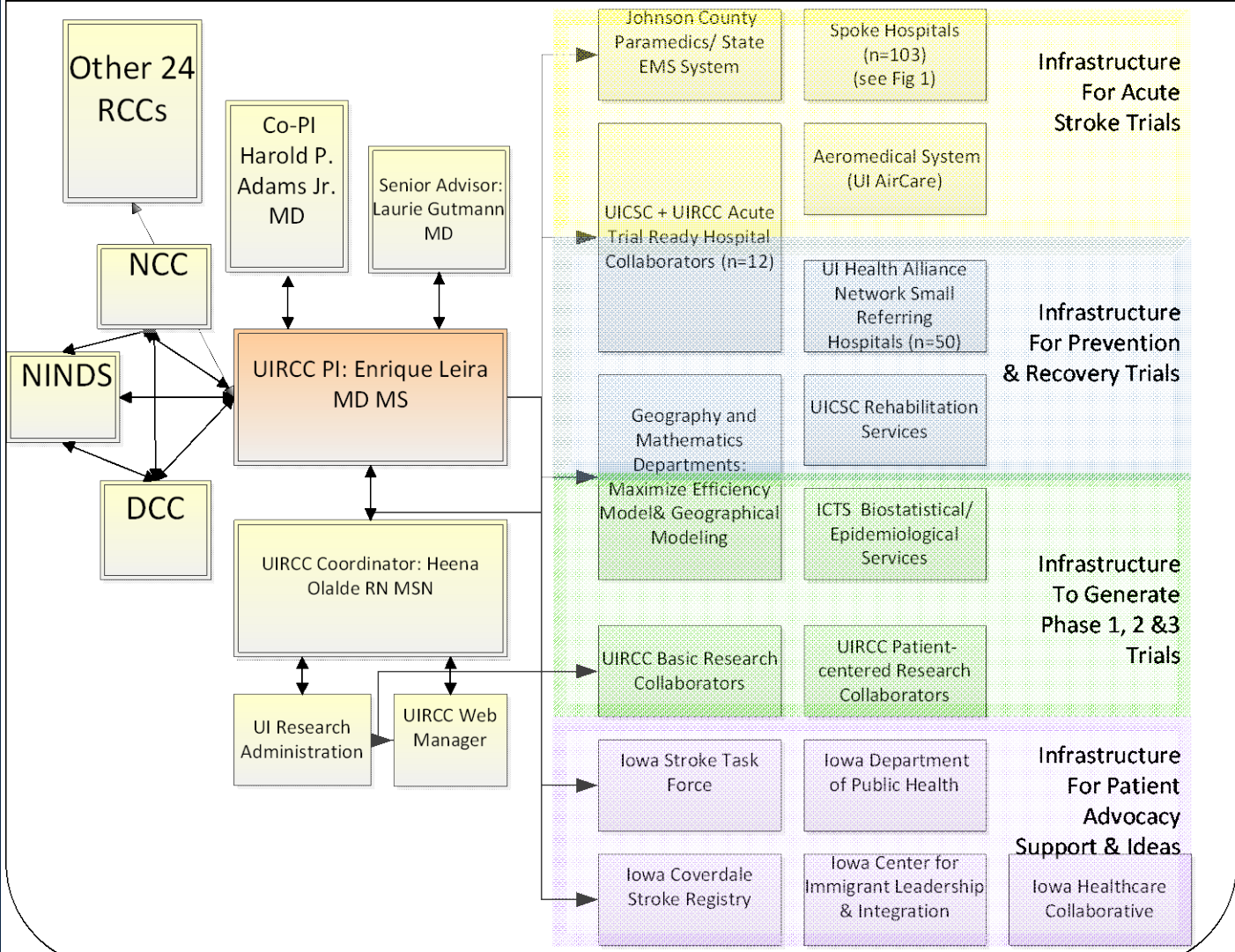
**Map Legend**

- = UI Comprehensive Stroke Center (UICSC)
- = Stroke Trial-capable Hubs rehabilitation units (n=12)
- = Critical Access Spoke Hospitals (N=82)
- = Other Spoke Hospitals (N=21)
- = Aeromedical Transport Base

Fig 2. Future Expansion of the UIRCC: Heartland RCC



**Fig 3. Organization & Infrastructure UIRCC**



# Opportunity for the State of Iowa

- Contribute to advance stroke research (acute trials, prevention, and recovery)
- Facilitate promising translational research and clinical trials with community input
- Advocates for rural stroke care
- Potential for helping recruitment by expanding pool subjects
- Generalize stroke trials to “real life” rural patients