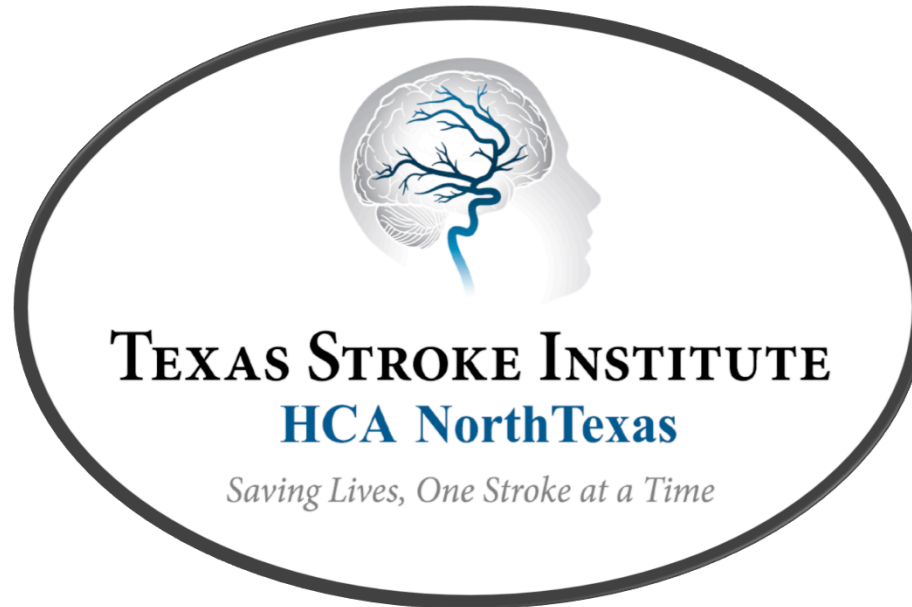


# Standardization of the Neuroendovascular Lab



**Vallabh Janardhan, MD**

**Director, Texas Stroke Institute**

**Stroke & Interventional Neurologist**

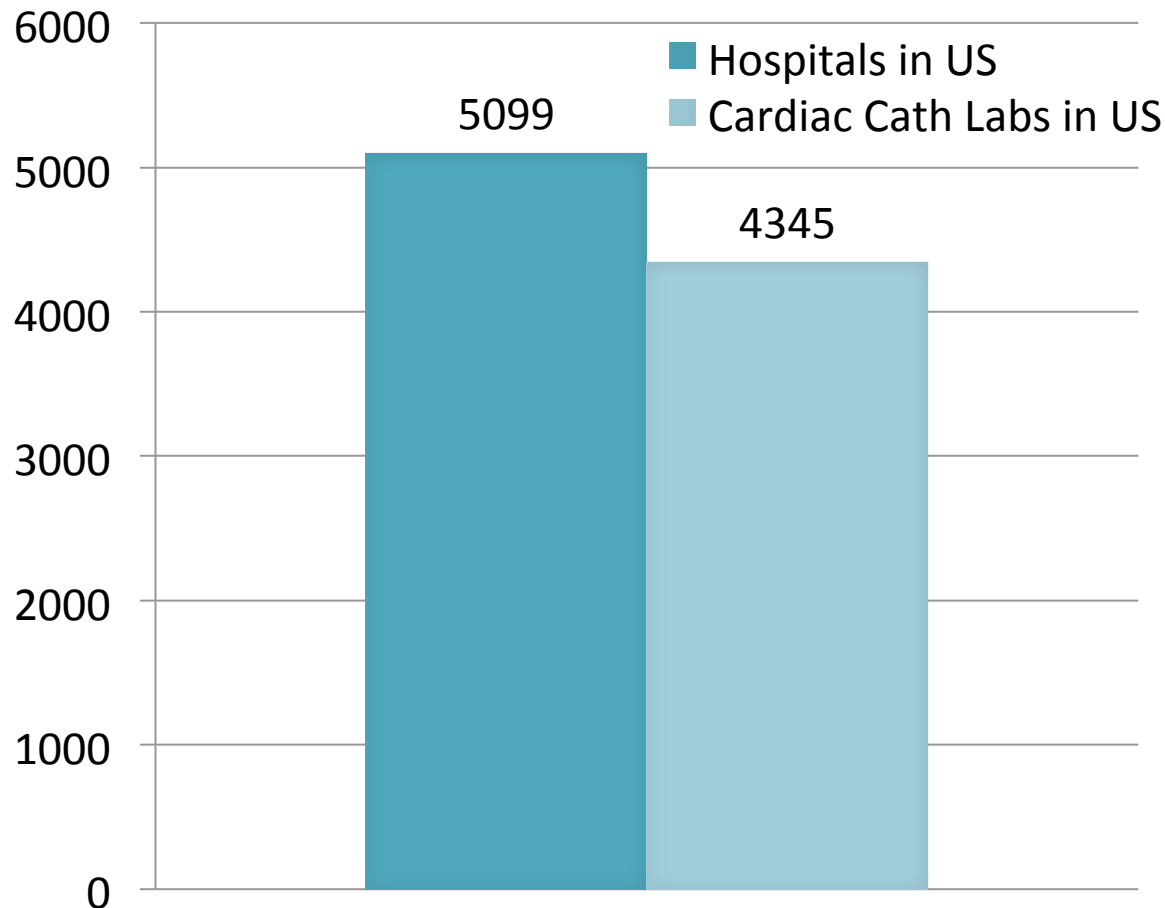
**HCA North Texas Division, Dallas-Fort Worth, TX**

**Founding Board of Director & Treasurer, SVIN**

# Disclosures

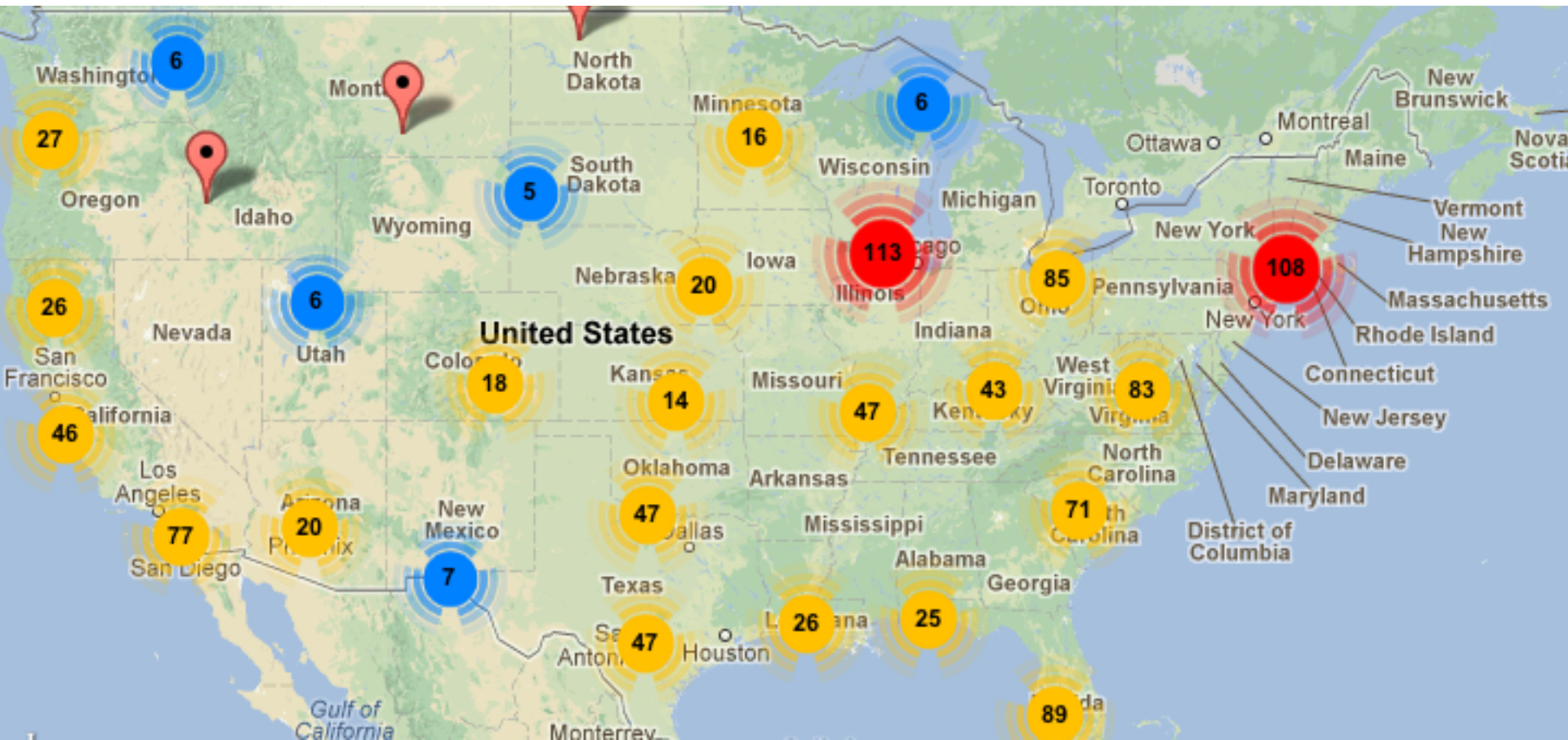
- DSMB, Penumbra Pivotal Trial, Penumbra Inc.,
  - Consultant
- Scientific Advisory Board, Insera Therapeutics Inc.,
- National Science Foundation Grant #0946099
  - Principal Investigator
- FIRST Trial, Penumbra Inc.,
  - Principal Investigator

# Standardization of Cardiac Cath Labs exists: 85.2% of all US hospitals have Cardiac Cath labs






Source: 2012 ACCF/SCAI Expert Consensus document on Cardiac Cath Lab Standards  
*J Am Coll Cardiol.* 2012;59(24):2221-2305.

# With 1100+ certified PSC's and 60+ certified CSC's, there is an unmet need for the Standardization of Neuro-Angiography & Stroke Interventional Labs






Source: JCAHO ([www.jointcommission.org](http://www.jointcommission.org)) and DNV ([www.dnvaccreditation.com](http://www.dnvaccreditation.com))

# Are there any standards for how to develop and maintain a high quality Neuro-angiography lab as part of Primary stroke center Certification?

Standards for Primary Stroke Centers	TJC 	DNV 	HFAP 
Need for Availability of Diagnostic Neuro-Angiography	No	No	Optional
PSC Standards for Neuro-angiography labs: e.g., Equipment, Staffing, Quality	No	No	No
PSC Standards for Neuro-angiography or Carotid stenting performed in cardiac cath labs	No	No	No

# Are there any standards for how to develop and maintain a high quality Stroke Interventional lab as part of Comprehensive stroke center Certification?

Standards for Comprehensive Stroke Centers	TJC 	DNV 	HFAP 
Personnel; Lab Facilities & Supplies; Volume of Procedures; Quality Metrics	Some	Some	Some
Procedures & Protocols	No	Some	No
Radiation Safety, On-Call Staffing and compensation	No	No	No

# Standardization of Stroke Angiography & Interventional Labs: SVIN-SILC Program



# Need for Standardization of Stroke Interventional Labs as well as Neuro/Stroke Angiography Labs:

## I. Personnel & Supervision

- Laboratory Medical Director:
  - Qualifications:
    - E.g., can a stroke center medical director be the lab medical director of the Neuro-angiography lab at a PSC or a Stroke Interventional lab at a CSC?
    - How many years of experience in catheter-based skills
    - Should there be a minimum number of prior procedure logs
  - Job description
    - Monitoring physician and staff behavior & competence
    - Advocate for adequate resources including equipment, devices, & staff
    - Ensure safety and compliance to all regulations including radiation safety
    - Quality Improvement
    - Management skills



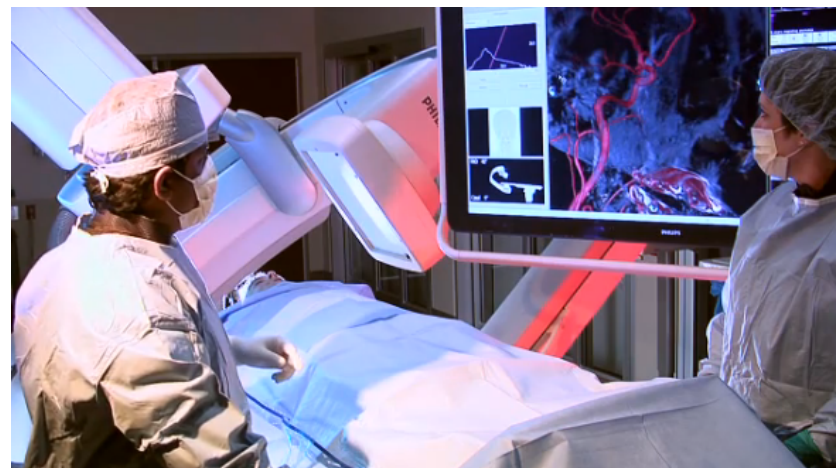
# Need for Standardization of Stroke Interventional Labs as well as Neuro/Stroke Angiography Labs: I. Personnel & Supervision

- Fellowship trainees:
  - Credentials:
    - Function under direct supervision of Attending Physicians
    - Criteria before they can be primary operators
- Physician extenders or Advanced nurse practitioners
  - Credentials:
  - Job description:
    - Pre- and Post-procedural evaluations
    - Follow-up



# Need for Standardization of Stroke Interventional Labs as well as Neuro/Stroke Angiography Labs: I. Personnel & Supervision

- Personnel
  - Techs and Nurses
  - Staffing needs for On-call
    - Back-up team in case of two stroke cases
    - If also trauma center, should there be more back up
  - Stroke Coordinators & Ancillary Staff
  - IRB coordinator
  - Anesthesia support



# Need for Standardization of Stroke Interventional Labs as well as Neuro/Stroke Angiography Labs:

## II. Physical Facilities & Supplies

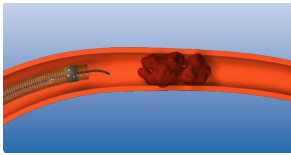
- Physical Facilities & Supplies
  - Physical space of the lab
  - Equipment – Biplane vs. Single Plane
  - Digital Storage and Displays
  - Device Inventory
  - Emergency Medications



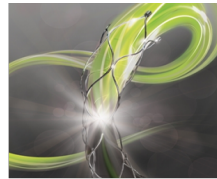
# Need for Standardization of Stroke Interventional Labs as well as Neuro/Stroke Angiography Labs:

## III. Volume of Procedures (Minimal case load / year)

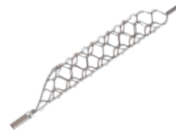
**Ischemic Stroke:** Neuro-angiography, IV t-PA, IA t-PA, angioplasty/stenting, thrombectomy/embolectomy



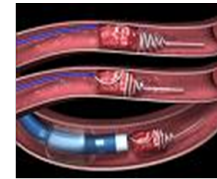
Penumbra



Solitaire



Trevo

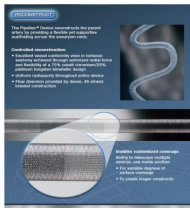


Merci

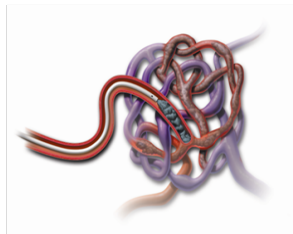


IV / IA tPA

**Hemorrhagic Stroke:** Neuro-angiography, coiling, clipping, flow diversion, embolization, vasospasm treatment



Flow Divertors



Onyx



Coils



Treatments for Vasospasm

Verapamil  
Injection



# Need for Standardization of Stroke Interventional Labs as well as Neuro/Stroke Angiography Labs::

## IV. Process – Procedures and Protocols

- Reporting of study results in medical record
  - Including time metrics and scales
- Procedure indications and informed consent
- Procedure preparation and conduct
- Protocols
  - Contrast induced nephropathy
  - Radiation induced alopecia & dermatitis
- Brain attack activation protocol
  - Nurses, techs, anesthesia, ED neurologist, neuro-interventionalist

# Stroke Interventional Labs:

## IV. Sample Brain attack activation Protocol

### Texas Stroke Institute Stroke Pathway

Sudden onset of any **ONE** of the following:

Central facial droop / paralysis  
Unilateral facial numbness  
Vision loss/ Visual field cut  
Double vision and Vertigo  
Slurred speech / Dysarthria  
Language deficit / Aphasia  
Unilateral arm / leg weakness  
Loss of balance / Incoordination  
Severe Headache (Suspect SAH)  
Decreased Level of consciousness (Suspect Intracranial Hemorrhage)

Patient Arrives in the ED with Stroke Symptoms  
**Activate Brain Attack Team**

**Lab Evaluation:** Two 18-20G IV lines,  
BMP, PT/INR, PTT, CBC, Urine  $\beta$ -HCG (Woman <50 years)

**Emergent CT Imaging**  
**STROKE 1-** Non-contrast CT Brain/Head  
(on all patients including transfers from referring facility)

**No Bleed**

**Clinical Evaluation:**  
Time from Last Known Normal, NIHSS, See BP Management Protocol

< 4.5 hrs

See  
<4.5 hrs Pathway  
Green Packet

4.5-12hrs

See  
4.5-12 hrs Pathway  
Yellow Packet

> 12 hrs

See  
>12 hrs Pathway  
(includes all TIA's  
and unknown last  
known normal)  
Blue Packet

**Bleed**

See  
Non-traumatic  
Sub-arachnoid  
Hemorrhage  
Pathway  
Red Packet

See  
Non-traumatic  
Intracerebral  
Hemorrhage  
Pathway  
Purple  
Packet

See  
Extradural,  
Subdural or  
Epidural and all  
Traumatic  
bleeds  
Grey  
Packet

Example of Possible  
Brain Attack Team Members

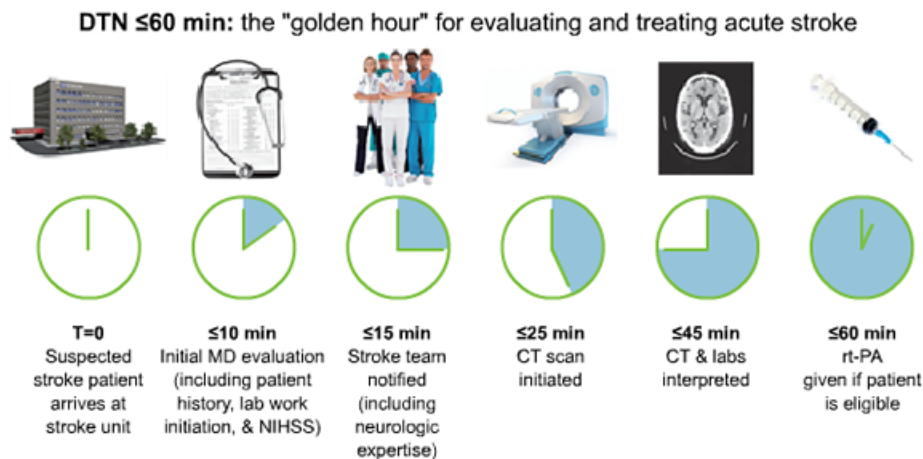
ERMD, ER Nurse, Lab, CT Tech, ER Tech,  
Hospital Supervisor, Bed Boards, ICU Charge Nurse





# V. Quality Improvement

- Quality Improvement (Process and Outcomes)
  - Pre-hospital metrics: e.g., 911-needle, Door-in Door-out at initial hospital, Inter-facility Transfer Efficiencies
  - ER metrics: e.g., Door to needle, Door to imaging, Door to groin
  - Diagnostic Neuro/stroke angiography lab metrics
  - Stroke Interventional lab metrics: e.g., 911-revascularization, door to revascularization, & groin puncture to revascularization
  - Quality improvement and peer review process
  - Access site complications and Cerebrovascular complications



# Stroke Interventional Labs:

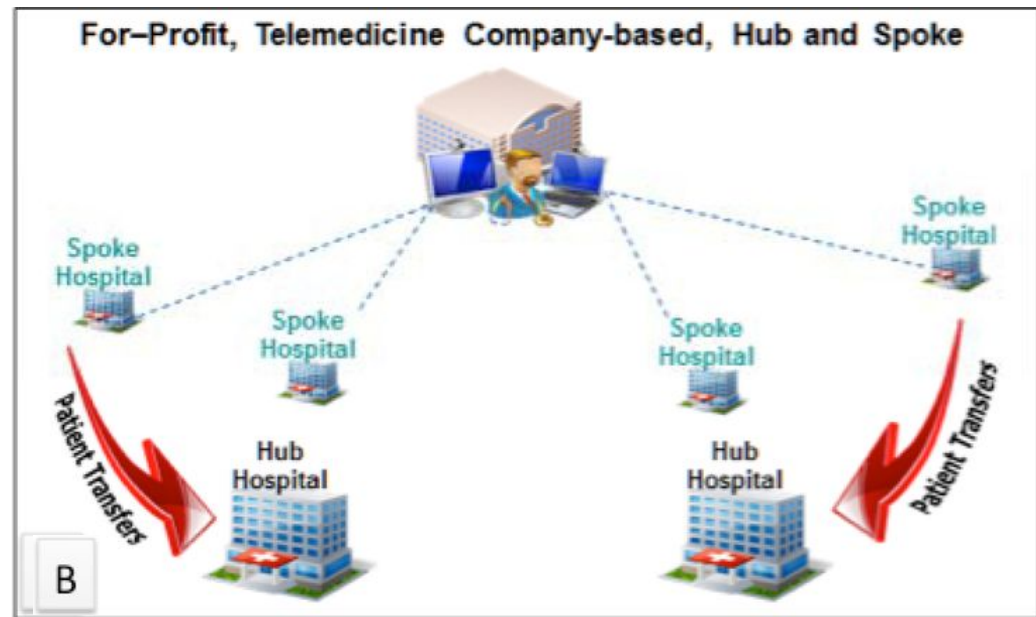
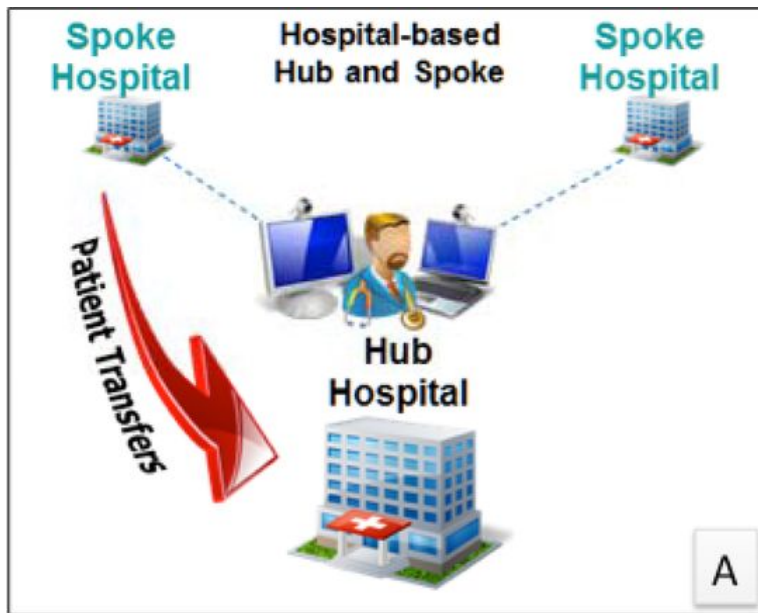
## VI. Radiation & Procedure Safety

- Radiation Safety
  - Flat panel detectors vs. Standard image intensifiers
  - Single monitoring device (thyroid) vs. 2-monitor technique
  - Real time Exposure information: Air Kerma
  - Pregnancy in patient or staff
- Acceptable Fluoroscopic time
- Ionic contrast agents safety





# Stroke Interventional Labs: VII. On-Call Compensation



- Physician and Staff compensation
  - Emergency Interventional Stroke Call
  - Tele-Stroke Call
  - Tele-neurology Call

# Operational Roll-out: SVIN-SILC Program

