MICHIGAN DEPARTMENT OF COMMUNITY HEALTH (MDCH)
CARDIAC CATHETERIZATION
STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Tuesday February 8, 2011

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call to Order

Chairperson Eagle called the meeting to order @ 9:32 a.m.

A. Members Present:

Fouad Ashkar, Garden City Hospital
Bart Berndt, Lakeland Regional Medical Center
Barton Buxton, Ed.D, Lapeer Regional Medical Center
David Dobies, MD, Genesys Regional Medical Center
Kevin Donovan, Muskegon Construction
Basil Dudar, MD, FACC, Beaumont Hospitals
Kim Eagle, MD, Chairperson, University of Michigan Health System
Robert Goodman, MD, MHSA, FACEP, Blue Cross Blue Shield/Blue
John Heiser, MD, West MI Cardiothoracic Surgeons, PLC
Barry Lewis, DO, Botsford General Hospital
Michelle Link, Bronson Methodist Hospital
Elizabeth J. Pielsticker, MD, Michigan Heart PC via conference call
Arthur L. Riba, MD, Oakwood Healthcare, Inc.
Theodore Schreiber, MD, Detroit Medical Center
Frank D. Sotille, MD, Crittenton Hospital Medical Center
Douglas W. Weaver, MD, Henry Ford Health System
Lawerence O. Wells, Michigan League for Human Services arrived @ 9:38 a.m.

B. Members Absent

Roland Palmer, Vice-Chairperson, Alliance for Health

C. Michigan Department of Community Health Staff present:

Jessica Austin

Sallie Flanders
William Hart Jr.
Larry Horvath
Natalie Kellogg
Brenda Rogers
Tania Rodriguez

II. Declaration of Conflicts of Interests

No conflicts of interests declared.

III. Review of Minutes

Michelle Link was not listed as being present for the last two meetings minutes. Motion by Mr. Buxton and seconded by Mr. Ashkar to modify the minutes to reflect Michelle Link being present and to accept the minutes as modified. Motion carried in a vote of 16- Yes, 0- No, and 0- Abstain.

I. Review of Agenda

Motion by Mr. Buxton and seconded by Dr. Weaver to accept the agenda as modified with two additions under Item XIII. Review of Charge: 1) Department Presentation and 2) Dr. Schreiber's Presentation. Motion carried.

II. Presentation and discussion of equivalents

Dr. Lewis gave a verbal and written presentation on "Equivalent Measurements." (See attachment A)

Discussion followed.

Chairperson Eagle suggested Dr(s). Lewis, Dobies, Riba, and Schreiber form a subcommittee to do some additional work to provide further information on the equivalents issue. All agreed and will present at the next meeting.

VI. Information from Blue Cross Blue Shield looking at the linkage between diagnostic coronary angiography and subsequent percutaneous coronary intervention within 2 weeks at another hospital

Dr. Goodman gave a brief presentation on "Separate Angioplasty Event After diagnostic Cardiac Catheterization: BCBSM/BCN Experience." (See attachment B)

Discussion followed.

VII. Potential draft language for elective PCI without on-site surgical backup for discussion

Dr. Weaver gave a brief presentation on "Further Discussion of Requirements for PCI without on-site Cardiac Surgery." (See attachment C)

Discussion followed.

Chairperson Eagle suggested Dr. Dobies assemble a subcommittee to present the SAC with detailed information regarding cost. Dr. Riba volunteered to work with Dr. Dobies on this project and present at the next meeting.

Break @ 11:15 a.m. - 11:31 a.m.

VIII. Dr. Schreiber's Presentation (See attachment D)

Dr. Schreiber gave a verbal summary of his thoughts with regards to Dr. Weaver's presentation and highlighted the New York State CON model recommendations for PCI without on-site Cardiac Surgery.

Discussion followed.

Dr(s). Weaver, Schreiber, and Sottile will prepare a recommendation for draft language and present at the next meeting. They will, if necessary, seek assistance from the Department.

IX. Dr. Weaver presented on "Additional Changes in the Primary PCI and Diagnostic Cath Guidelines to Be Considered" (See attachment E)

Discussion followed.

Dr. Pielsticker will collaborate with Mr. Buxton and Dr(s). Weaver, Schreiber, and Dobies to discuss and report on diagnostic volumes, specifically, the scientific data, in relation to the existing standards, at the next meeting.

X. Streamlined Standards presented by Bill Hart & Larry Horvath

Bill gave a written and verbal presentation on the "CON Preface" (See attachment F)

Larry gave a verbal & written presentation on "CON Review Standards for CC (See attachment G) and "Geographical Access to CC in Michigan: A Preliminary Analysis" (See attachment H).

Discussion followed.

Dr. Sottile asked Larry if he could provide the SAC with maps that were within a 1-hour time frame for the next meeting.

XI. Public Comment

None

XII. Next Steps and Future Agenda Items

A. Dr(s). Lewis, Dobies, Riba, and Schreiber will provide further information on the equivalents issue.

B. Dr(s). Dobies and Riba will present the SAC with detailed information regarding cost information.

C. Dr(s). Weaver, Schreiber, and Sottile will prepare a recommendation for draft language for elective PCI without open heart surgery backup and present at the next meeting.

D. Dr. Pielsticker will collaborate with Buxton and Dr(s). Weaver, Schreiber, and Dobies to discuss and report on diagnostic volumes, specifically, the scientific data, in relation to the existing standards.

XIII. Future Meeting Dates

A. March 10, 2011
B. April 6, 2011
C. May 4, 2011 (if needed)

XIII. Adjournment

Motion by Mr. Buxton and seconded by Dr. Dobies to adjourn the meeting @ 12:57 p.m. Motion carried.

EQUIVALENT MEASUREMENTS

February 8, 2011

"I think what you are describing is some kind of privately derived relative value system."
"It may value some services in different ways and have less units of precision than the RBRVS used for medicare payment. I'm not sure of the origin of these…"

Brian Whitman, Associate Director Regulatory Affairs

Background

Catheterization regulated since early 1980's

- First set of standards: 1986
- Weights applied: 1988
  - Diagnostic
  - Therapeutic

- Volumes initially utilized to get more labs or replacement labs
  - Categories subsequently developed:
    - Diagnostic
    - Therapeutic
    - Diagnostic & Therapeutic
    - Other
- Based on time concept

All therapeutic sessions are not equal, but weighted:

- Credit for session
- Credit for procedures performed within session
- Credit for complexity

Multiple procedures get more weight, but not full weight based on time.

Done primarily for purposes of determining when a hospital qualifies for more labs or to replace existing laboratory equipment.

In 2008, methodology became more complex with more procedure categories and detailed count of procedures per session as well as a reduction methodology for multiple procedures done in same session.

Radiology

Regulated from 1978 until 1986

1986: If no cardiac catheterization performed then radiology rooms were not regulated except for radiation safety.

Possible reasons why:

- Catheterization entailed more risk
- Charges were greater

Attachment A

Procedure Type	Procedure Equivalent	
	Adult	Pediatric
Diagnostic Cardiac Cath	1.0	3.0
Therapeutic Cardiac Cath	1.5	3.0
Therapeutic Other (PFO/ASD/Vplasty/LVAD	2.5	3.5
Diagnostic Peripheral	1.0	2.0
Therapeutic Peripheral (Carotid/Subclavian/Renal/Iliac/Mesenteric)	1.5	2.5
Therapeutic Peripheral: SFA Infrapopliteal Aorta	2.5 3.0 4.0	2.5 3.0 4.0
Diagnostic EP	2.0	3.5
Therapeutic EP: PPM/ICD Ablation (Non-AF) Ablation (AF/VT) Cardioversion	2.5 3.0 4.0 1.0	5.0 5.0 6.0 1.0
•Other (IVC Filter/TTVP/IABP, other rad procedure	1.0	2.0

Attachment A

Procedure	Time
Diagnostic Cath	65 minutes
Scheduled PCI	99 minutes
Diagnostic & PCI	86 minutes
Diagnostic EP	156 minutes
Device: PPM	104 minutes
Device ICD	111 minutes
Ablation (all)	171 minutes
Carotid	91 minutes
Renal	78 minutes
Iliac	78 minutes
SFA/Popliteal/Tibial	134 minutes
PFO	71 minutes
ASD	123 minutes
Valvuloplasty – Aortic	76 minutes
Valvuloplasty – Mitral	121 minutes
Evalve MitraClip	4 hours
TAVI	2.5 hours

Pediatrics

Entirely different:

- Infants to teenagers
- Anesthesia
- Congenital vs Acquired

Times "all over the place"

Fluoroscopy

Questions

- Continue to utilize equivalents?
- Count procedures or sessions only?
- Count cardiac and peripheral together?

Separate Angioplasty Event After Diagnostic Cardiac Catheterization: BCBSM/BCN Experience

MDCH Certificate of Need Cardiac Catheterization Standard Advisory Committee
February 8, 2011

Robert Goodman, DO
Blue Care Network

Cardiac Catheterization SAC Issue: Should CON Standards be Changed to Decouple Elective Angioplasty from Open Heart Surgery?

- The Coalition of Health Systems asserts that many patients (1,000/year) with a positive finding on diagnostic cardiac catheterization do not require an emergent angioplasty, but do require ambulance transfer (at a cost of $386) to another facility for elective angioplasty, with a total cost of $7,350 per case
- Another presentation stated the total cost for such an occurrence is about $4,000 per case, along with 3 member copays valued at $700 and transport costs of $900
- No actual claims data on the number or costs of split events
- No chart review as to the actual reasons for split events that do occur

Can we get a sense of the actual number, proportion and circumstances of split procedures?

Study of the Historical BCBSM and BCN Experience: Data Sources Available

- BCBSM/BCN commercial and Medicare Advantage members only
- No Medicaid or Medicare Supplemental
- All ages
- Paid claims administrative data (utilization information only) from 1/1/2008 to 7/31/2009
- MDCH tables of CON regulated Michigan facilities and their CON status (as of 2009) in regard to diagnostic catheterization, emergency angioplasty, elective angioplasty and pediatrics

Does BCBSM/BCN Membership Represent a Sufficiently Sized Slice of the Michigan Population?

- BCBSM commercial and Medicare Advantage membership in 2008 was about 3.85 million*
- BCN commercial and Medicare Advantage membership in 2008 was about 625,000*
- State of Michigan population about 10 million**
- Thus, these data represent a snapshot of a substantial portion of the Michigan population (~45%)

*BCBSM/BCN 2009 Fact Book

**http://www.michigan.gov/cgi/0,1607,7-158-54534-228598--,00.html

Study of the Historical BCBSM and BCN Experience: Analysis Specifications

- Identified all cases using paid claims when a member had a diagnostic cardiac catheterization (DCC) date of service during the 18 months from 1/1/2008 to 6/30/2009
  - Cannot determine from these data whether patient presented through the emergency department or was scheduled for outpatient elective diagnostic catheterization
- Identified cases of a DCC when member then also had a separate angioplasty (PCI) procedure claim billed and paid within 14 days of the DCC claim discharge date
- Restricted analysis to only those events that included a DCC at MDCH CON regulated facilities
- Adjusted the denominator of all DCC cases for estimated non-MDCH regulated facilities in these data
  - The DCC denominator for the 18 month time frame was adjusted down to 45,235

Study of the Historical BCBSM and BCN Experience: Split Procedures

- For the 18 month measurement period there were a total of 361 split procedures
  - None of these cases involved Children's Hospital of Michigan
  - Spectrum-Butterworth and University of Michigan are also CON designated as pediatric sites, along with adults
  - Assumption is therefore that none of any split events that may be in these data involving Spectrum-Butterworth or University of Michigan were likely to involve pediatrics
  - Pediatric cases could be included in the total count of all DCC events (45,235)
- Additional detail available in claims data can further refine this number

Study of the Historical BCBSM and BCN Experience: Split Procedures, Same Site

- Of the 361 cases, 144 cases were cases when the DCC and the later PCI were done at the same facility
  - 143 of the 144 split cases were done at facilities categorized by MDCH as allowed to perform elective PCI
  - 1 case involved a facility that is designated for DCC and emergency PCI only
    - Medicare patient had a DCC during a 2 day length of stay and then returned the day following the DCC discharge date and had an emergency PCI (as facility would be in violation of CON regulations if did an elective procedure)
    - Actual details unknown without medical record review

Study of the Historical BCBSM and BCN Experience: Split Procedures, Same Site

- There were an additional 3 cases (beyond the 144) that involved a site that is not allowed to do either emergent or elective PCI, but that site's sister hospital is designated for elective PCI
  - These two sister facilities are identified in BCBSM commercial data under a single identifier
  - Cannot tell from claims data alone whether these 3 BCBSM commercial member cases had all care at the site with open heart surgery, or were any cases transferred between these two sites
  - In the absence of chart review, will take a conservative approach and count these cases later in the analysis

Study of the Historical BCBSM and BCN Experience: Split Procedures, Same Site Summary

- Of the 361 split cases, 143 times there was no CON regulatory barrier to performing PCI at the time of the DCC
- Cannot tell from these data the exact rationale for the split procedures, but would be due to physician and/or patient choice alone (clinical or other reasons)
- These known split procedures of choice (as opposed to regulatory necessity) represent 40% of all split procedures in the BCSBSM/BCN data

This demonstrates that among split procedures, it is common for the rationale behind not performing PCI at the time of the DCC is for reasons that have nothing to do with CON cardiac catheterization regulations

Study of the Historical BCBSM and BCN Experience: Split Procedures, Different Sites

- In these data there were also cases when the patient had the DCC at one site, and then PCI at a different site
- The total of such events was 217 (214 plus the 3 cases that could not be categorized as same site with certainty)
- Of the 214 known different site cases, 17 were instances of the site where the DCC took place was allowed to perform elective PCI under their CON
  - **<u>These 17 cases are also clearly due to physician and/or patient choice</u>**

Study of the Historical BCBSM and BCN Experience: Split Procedures, Different Sites

- Of the remaining 200 cases to consider there would also be some number of occurrences of split procedures involving two sites *not* due to CON regulations, but rather due to physician and/or patient choice

- The 17 different site split procedures noted along with data on same-site split procedures establishes that delays in elective PCI after DCC due to physician and/or patient choice alone are a reality

Study of the Historical BCBSM and BCN Experience: Split Procedures, Different Sites *with Ambulance Transport*

- How many cases required ambulance transfer from the DCC site to the PCI site?
- Ambulance claims not part of these data
- However, do know date of DCC discharge and date of PCI admission
- If transferred by ambulance from one site to another for an elective PCI, then these two dates should be the same
- Of the 200 different site cases when the DCC site was not allowed to do elective PCI as per CON, **116** had the same DCC discharge date and PCI admit date

Study of the Historical BCBSM and BCN Experience: Split Procedures, Different Sites *with Ambulance Transport* Summary

- Of note, for 80 of these cases (69% of the 116) the DCC occurred at a site that, under CON, could have done an emergency PCI if needed
- These 116 cases of split procedure cases at different sites in these BCBSM/BCN data represents 18 months of activity
- All 116 cases were BCBSM commercial members
- These 116 cases represent 0.26% of all BCBSM/BCN DCC events (45,235) during these 18 months

The scenario of interest, as defined by The Coalition of Health Systems and others, is a *rare* event

Costs: Split Procedures, Different Sites

- BCBSM/BCN data did not contain cost information
- The two total direct added cost estimates of split procedure events presented at prior SAC meetings vary considerably ($7,350 vs. $4,000)
- One estimate ($4,000 total) includes a valuation of added member cost sharing
  - Member cost sharing is complex and exact certificate of coverage dependent
  - There generally exist annual copay/coinsurance maximums
  - Deductibles are capped by definition
  - Not clear how such nuance was incorporated into the supposition of $700 in added member cost sharing

Costs: Split Procedures, Different Sites

- For easier understanding, annualized the 18 month BCBSM/BCN count of split-site DCC and PCI cases that most likely were also transferred by ambulance
- Annualized count is **77**
- Considering that during 2009 the Michigan Blues (all lines of business) paid a total of $19.8 billion in claims*, any impact on the annual overall cost of health care in Michigan due to direct cost savings by eliminating these rare events would appear to be nearly imperceptible

*http://bcbsm.com/home/bcbsm/fastfacts.shtml

Summary of Cardiac Catheterization SAC Issue

- According to The Coalition of Health Systems presentation slide #19: “only 0.2% of patients suffer PCI complication requiring bypass surgery within 2 h (16)”*

- Thus, both different site split procedures with ambulance transfer, and PCI complication requiring surgery within 2 hours, are both nearly equal in rarity (0.26% vs. 0.2%) within their respective contexts

* Reference 16: Lotfi M, Mackie K, Dzavik V, Seidelin P. Impact of delays to cardiac surgery after failed angioplasty and stenting. J Am Coll Cardiol 2004;43:337– 42.

Summary of Cardiac Catheterization SAC Issue

- While much data has been presented at SAC meetings thus far, including experiences in other countries, it would seem that the issue can be distilled down to a simple question that needs to be answered on behalf of the citizens of Michigan

Should a State of Michigan regulation designed to provide a safety hedge against a rare but ***catastrophic*** event (PCI complication requiring surgery within 2 hours), with a negligible impact on the overall cost of health care in Michigan, be eliminated to avoid an equally rare but ***non-catastrophic*** event (split-site DCC/PCI with ambulance transfer)?

Cardiac Catheterization SAC February 8, 2011

Further Discussion of Requirements for PCI without on-site cardiac Surgery

W. D. Weaver, M.D

Draft Items/Language Proposal

Definitions

Back-up Requirement

Program Monitoring

Delivery Requirements

Documentation of Projections

Definitions
"Therapeutic Cath Lab without On-site cardiac surgery":

- Percutaneous coronary intervention would be permitted-both for STEMI as well as for non-emergent indications
- Like "diagnostic labs", pacemakers, implantable defibrillators, and right sided heart catheter arrhythmia therapeutic procedures permitted
- **Transcatheter valve, other structural heart disease procedures and left sided arrhythmia therapeutic procedures are not permitted**

Definitions
“PCI”:

Percutaneous coronary intervention includes percutaneous transluminal coronary angioplasty (PTCA), stent implantation, and any other catheter related procedure used in conjunction to aid in the performance of PTCA or stent implantation

Operator Qualifications

- Board Certified in Interventional Cardiology
  - At least 2 operators
- Individual outcomes meet ACC/NCDR outcomes
- Minimum 300 PCI's since fellowship
- Minimum 75 PCI's in each year of the preceding 24 months
- A minimum of 30 hours of CME directed toward interventional cardiology every 24 months

Additional qualifications and requirements

- Hospital Credentialing Criteria for PCI physicians which include each of the specified individual operator requirements
- The operators must participate in two-thirds or more of the case reviews and the quality improvement activities
- Documented training and proficiency of all other cath lab professional and technical staff

Case Selection/Review

- Regular Joint cardiology/cardiac surgery conferences to review the PCI cases and outcomes
- Written policy and procedures for training, staffing , and program review
- Development and ongoing review of PCI patient selection

Dehmer et al, Catheterization and Cardiovascular Interventions 2007

Case Selection/Review

- Development and ongoing review of PCI patient selection—*or*……
  - Decompensated heart failure without acute ischemia, recent stroke, advanced malignancy, known clotting disorders, EF less than 25%, Left main disease unprotected by prior surgery, lesions that jeopardize >50 % of myocardium, diffuse disease and excessive tortuosity, degenerated vein grafts, substantial thrombus, aggressive measures to open chronic total occlusions, inability to protect major side branches

Backup Requirements and Collaboration Agreements

- Patients
  - Immediate transfer available 24/7, 365 days/yr
  - Consent obtained by transferring physician
  - Consent acknowledgement no SOS and transfer may be necessary
- Images
  - Electronic images to back-up facility for case review if needed

Dehmer et al, Catheterization and Cardiovascular Interventions 2007

Program Monitoring

Program Monitoring and Compliance

- Minimum Case Loads Required
  - Dependant on Geographic location
    - < 1 hr from an OHS
      - 200 PCI's (300 procedure equivalents) in second 12 months
    - > 1 hr from PCI and/or OHS
      - 150 PCI's (225 procedure equivalents) in second 12 months

Program Monitoring and Compliance

- Compliance Action:
  - Geographic location
    - < 1 hr from an OHS

      IF <150 PCI's (225 procedure equivalents) in second 12 months

      OR <200 PCI's (300 procedure equivalents) in third 12 months

      Action: Department shall revoke CON
    - > 1 hr from an OHS

      IF <150 PCI's (225 procedure equivalents) in third 12 months

      Action: Department shall revoke CON

      Action: For all labs performing less than 200 PCIs per year- All cases must be reviewed by external review body for appropriateness and outcome

Program Monitoring and Compliance

- Must participate in a benchmarked PCI data registry
  - Participation includes:
    - Patient and clinical descriptions
    - Measures of outcomes
    - Measure of the ACC appropriate use of the procedure including SYNTAX or STS score in each patient
    - submission of all PCI cases
    - all costs are applicant's responsibility
    - submission of an annual summary report
    - The site should have a data management person to insure timely and accurate reports are made available to the registry and reviewing bodies

Program Monitoring and Compliance

- Mandatory Internal and External Review Bodies
  - Internal
    - Minimum Personnel Required
      - CMO- Chief Medical Officer of applicant hospital
      - Directors of Cardiology of both applicant and OHS facility
      - A surgeon from the back-up OHS program
    - Committee Charge
      - Quarterly review of complication rates, # of procedures performed per operator, success rates, appropriate use, patient transfers
      - Produce an annual report

Program Monitoring and Compliance

- Mandatory Internal and External Review Bodies
  - External
    - An oversight body composed of either all participating institutions plus a minimum of 3 totally impartial persons—or—possibly an workgroup of the state ACC Chapter—or a contracted impartial group
    - Review Body Charge
      - Produce an annual report of all the programs containing the complication rates, # of procedures performed per operator, success rates, appropriate use, patient transfer
      - Review the findings with each of the participating hospitals as a groups
        - » The findings are made public
      - Review all cases in programs with less than 200 PCIs per year

Applying for a Therapeutic Cath Lab without on-site Surgery

Requirements and Projection Documentation

Applying for a Program

- Only facilities with a current diagnostic lab may apply
- Facilities will project a minimum of 200 patients requiring PCI in a year

Projection Documentation

Volume Projection Source:

- Physician commitments of PCI cases performed at an existing cardiac catheterization service within 20 Miles of applicant facility.
- Existing patient transfers from the applicant facility
- PCI cases being performed at the facility; e.g STEMI cases

Projection Documentation

- Projection Volume Documentation:
  - Name of physician
  - Total # of PCI cases for physician and PCI site
  - Location of PCI cases to be transferred
  - Signed commitment of physician to perform transferred PCI volume for 3 yr
- Existing Patient Transfers:
  - Documentation of patients seen in the facility and transferred/ scheduled at another for emergent or elective PCI
  - Other evidence of PCI patients being transferred in previous 12 months
- Existing PCI cases
  - Documentation of PCI cases in the prior 12 months

DMC CARDIOVASCULAR INSTITUTE
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Detroit Medical Center, 3990 John R., Detroit, MI 48201 | 1-888-DMC-2500 | DMC.org

February 9, 2011

Dear Kim:

Certainly all the physicians on the SAC, if not all the members, want to see the following goals achieved by any regulations that may be recommended for adoption:

1. No increase, and if possible, a DECREASE, in the morbidity/mortality of PCI in our state;
2. No augmentation, and if possible, a decrement in the number of "borderline" cases done;
3. No intra-procedural or post-procedural calamities;
4. An increase in the efficiency of resource consumption during PCIs.

I think we all agree that to achieve these goals, PCIs at potential standalone facilities need to be done by:

1. VERY experienced operators;
2. Very experienced support teams;
3. With the availability of the most up-to-date rescue equipment currently, percutaneous LVADS such as Impella, with experienced operators on site, should immediately be available to institute such bailouts.

I believe that even appropriate case selection for standalone PCI, as per such criteria as are proposed by the SCAI document, will NOT eliminate coronary perforations, left main dissections, or electromechanical dissociation. In fact, the broader catheterization of ill patients with ACS that is likely to result from the broader access that standalone PCI facilities are likely to provide, even if only cath and not PCI is performed, will paradoxically increase the number of such calamities.

Therefore, I propose the following modifications to the attached document from "the alliance", or I am willing to use the New York State regulations that I presented at the last meeting as a template for consideration, with the following items EMPHASIZED:

- A rigid adherence to a minimum annual standalone facility volume of 400 separate PCI cases by the end of the second year of operation, with loss of permit mandatory if less than 300 annually, and probation for 300-400 with PUBLIC admonition of impending termination if another year at <400;
- Any operator at a standalone PCI facility should have:
  a) Board certification in Interventional Cardiology- with NO grandfathering;
  b) One-Thousand lifetime PCI cases as primary operator, including approved interventional fellowship primary operator cases, with tight scrutiny of case logs for verification;

c) At least TWO HUNDRED PCI cases annually for each of the two years prior to service at a standalone facility, and subsequent ANNUAL documentation of ongoing 200/year overall (including all facilities that the operator practices at) primary operator experience to work at a standalone facility.

The Medical Director of the standalone cath/interventional lab should perform at least 50% of all his/her PCIs at the standalone facility.

- A contractually defined "hub and spoke" operational model for the standalone facility with requirement for ongoing on-the-ground participation by interventionalist(s) from the hub, either as primary operator or first assistant, documented at least once weekly at the spoke facility; conversely, the standalone program Director should also do at least one case weekly at the HUB; in this way, there is mandatory, real life operational translation of issues, QA initiatives, and maintaining up-to-date status at the spokes, and vice versa.
- SCAI guideline-excluded "high risk" PCI cases generated at the spoke would be steered by contractual agreement to the hub, thus providing for continuity of care and avoidance of "leakage" of cases out of the hub-and-spoke model.
- Clear, annual demonstration, for ongoing CON approval, that the most up-to-date bailout equipment is available at the standalone facility, together with the presence of experienced interventionalists for same, as well as trained, experienced support staff. In my view, in 2011 this means intra aortic balloon pumps, Impella LVADs, Jomed covered coronary stents, etc.

Subsequent to Dr. Weaver's presentation, my suggestions should be viewed as an amendment to the overall framework he suggested.

Thank you.

Sincerely,

Theodore L. Schreiber, MD, FACC
Specialist in Chief, Cardiovascular Medicine
President, DMC Cardiovascular Institute
Division Chief, Clinical Cardiology
Program Director, Interventional Cardiology Fellowship

Cardiac Catheterization SAC February 8, 2011

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  - Internal
    - Minimum Personnel Required
      - CMO- Chief Medical Officer of applicant hospital
      - Directors of Cardiology of both applicant and OHS facility
      - A surgeon from the back-up OHS program
    - Committee Charge
      - Quarterly review of complication rates, # of procedures performed per operator, success rates, appropriate use, patient transfers
      - Produce an annual report

Program Monitoring and Compliance

- Mandatory Internal and External Review Bodies
  - External
    - An oversight body composed of either all participating institutions plus a minimum of 3 totally impartial persons—or—possibly an workgroup of the state ACC Chapter—or a contracted impartial group
    - Review Body Charge
      - Produce an annual report of all the programs containing the complication rates, # of procedures performed per operator, success rates, appropriate use, patient transfer
      - Review the findings with each of the participating hospitals as a groups
        - » The findings are made public
      - Review all cases in programs with less than 200 PCIs per year

Applying for a Therapeutic Cath Lab without on-site Surgery

Requirements and Projection Documentation

Applying for a Program

- Only facilities with a current diagnostic lab may apply
- Facilities will project a minimum of 200 patients requiring PCI in a year

Projection Documentation

Volume Projection Source:

- Physician commitments of PCI cases performed at an existing cardiac catheterization service within 20 Miles of applicant facility.
- Existing patient transfers from the applicant facility
- PCI cases being performed at the facility; e.g STEMI cases

Projection Documentation

- Projection Volume Documentation:
  - Name of physician
  - Total # of PCI cases for physician and PCI site
  - Location of PCI cases to be transferred
  - Signed commitment of physician to perform transferred PCI volume for 3 yr
- Existing Patient Transfers:
  - Documentation of patients seen in the facility and transferred/ scheduled at another for emergent or elective PCI
  - Other evidence of PCI patients being transferred in previous 12 months
- Existing PCI cases
  - Documentation of PCI cases in the prior 12 months

CON Special Commission Meeting, January 26, 2011

There are new voices in Michigan interested in reshaping regulations to promote a more business friendly climate. They are interested in quality requirements even if such requirements may add costs to providers.

We propose a new, focused approach across all the standards over the next three year review cycle. The Department proposes to review all standards for uniformity, streamlined methodologies, and simplified project delivery requirements.

1) Review standards for uniformity. For example, imaging standards (PET, MRI, CT) should be compared to assure uniformity among the imaging modalities. Things like replace and upgrade concepts should be similar among these standards unless there is truly an identified distinction why one service will be treated different than the others. MRI has different replace and upgrade requirements than CT and PET. These differences should be looked at as they bring confusion to the provider community. Certain things can be done in CT that are not allowed in MRI, but there is no real basis for the difference other than a different SAC recommended the language. This also holds true for beds (hospital, nursing home, psych). While there will always be some difference, we need to be sure that there are justifiable reasons for the differences. Otherwise the provider community becomes confused on why a provider can do one thing in one imaging modality but not in another.

2) Simplify methodologies. Many of our methodologies are very labor intensive and only have value to CON. Methodologies should not be complex or labor intensive for the provider or the department. Methodologies should be based on data already collected by and available to providers, thus reducing costs. Many of our current methodologies require providers to collect very finite data that is of value solely to the CON methodology that requires it. For example, the PET methodology requires existing providers to collect detailed information on every scan provided by individual patient because they must identify patient specific bed positions, number of tracers, etc. This means a PET provider needs to collect thousands of lines of code to calculate the proper weights called for within the methodology. The data we collect should have a dual purpose: to determine compliance with the standards for pending applications as well as approved CONs, and to tell us something about the health care system.

3) Streamline project delivery requirements. Project delivery requirements are the terms and condition of approval. These requirements should be reduced, not overly burdensome to the provider community, but specific enough to help improve quality and access. Delivery requirements should not duplicate already existing and widely accepted medical practices or other licensing requirements.

These requirements should be unique to CON. For example, many standards have numerous delivery requirements that are either ambiguous, impossible to measure, or have little value. These should be removed. Remaining measures should be unique and widely agreed upon to improve the quality and outcomes of the covered service as well as improving access to the covered service. If fewer in number, the department can do a better job in monitoring compliance and enforcing these requirements.

The three concepts above would move the CON program closer to a more streamlined regulatory process that is not overly burdensome to the provider community but has actual cost savings as well as measurable deliverables in health care data, quality and access.

1/26/2011

CON Review Standards for Cardiac Catheterization Services

February 8, 2011

Cardiac Catheterization Charge

- Continue regulating service?
- Allow elective therapeutic services at hospitals without on-site open heart surgery?
  - If yes, what criteria?
- Update methodologies?
- Revise primary PCI requirements?
- Create percutaneous cardiac valves requirements?
- Revise replace/upgrade requirements?
- Review other needed changes?

Cardiac Catheterization Charge

- Continue regulating service?
- Allow elective therapeutic services at hospitals without on-site open heart surgery?
  - If yes, what criteria?
- Update methodologies?
- Revise primary PCI requirements?
- Create percutaneous cardiac valves requirements?
- Revise replace/upgrade requirements?
- Review other needed changes?

Department Request

- **Update expansion methodology:**
  - Create simple methodology to expand number of laboratories (not initiating new services)
  - Metric should used data already collected
  - Metric should be easy to calculate
  - Practitioners should be able to easily identify if qualify to expand or compliant
  - Proposed volume metric will be based on 2008 and 2009 data already collected, but open to modification

Department Request

- **Revise replacement requirements:**
  - Create non-volume related requirements to replace laboratory equipment
    - Is the equipment depreciated
    - Does the replacement equipment offer technological advantages
    - Add quality requirement(s) check?
  - Allowing for routine replacement that should benefit patient care

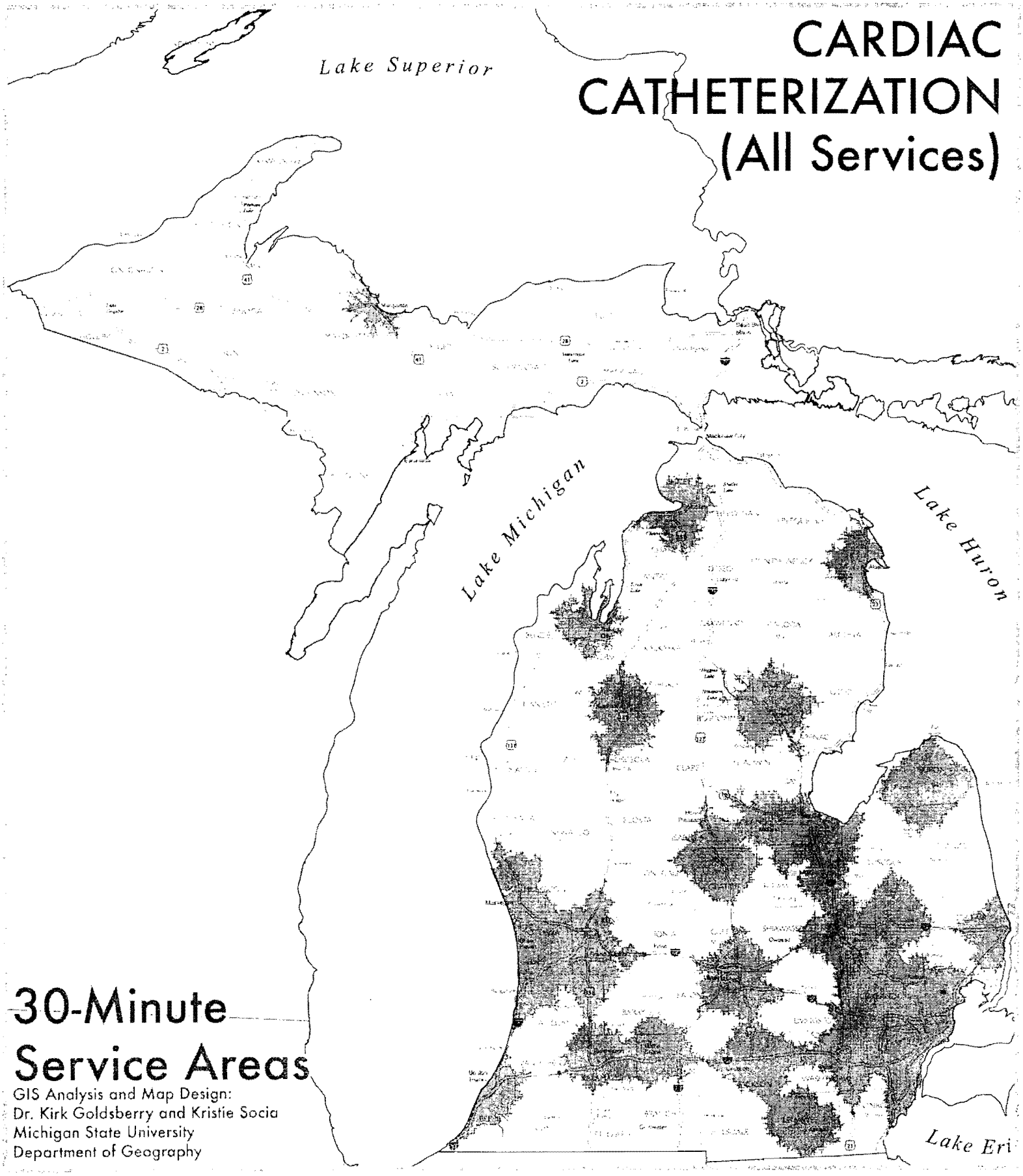
Department Request

- **Revise other requirements:**
  - Revise project delivery requirements
    - Reduce number of requirements
    - Assure requirements are objective and measurable
    - Several measures each focusing on cost, quality and access
  - Eliminate mobile laboratory networks
  - Eliminate upgrade requirements
  - Clarify diagnostic counts for primary PCI

Questions

GEOGRAPHICAL ACCESS TO CARDIAC CATHETERIZATION IN MICHIGAN: A PRELIMINARY ANALYSIS

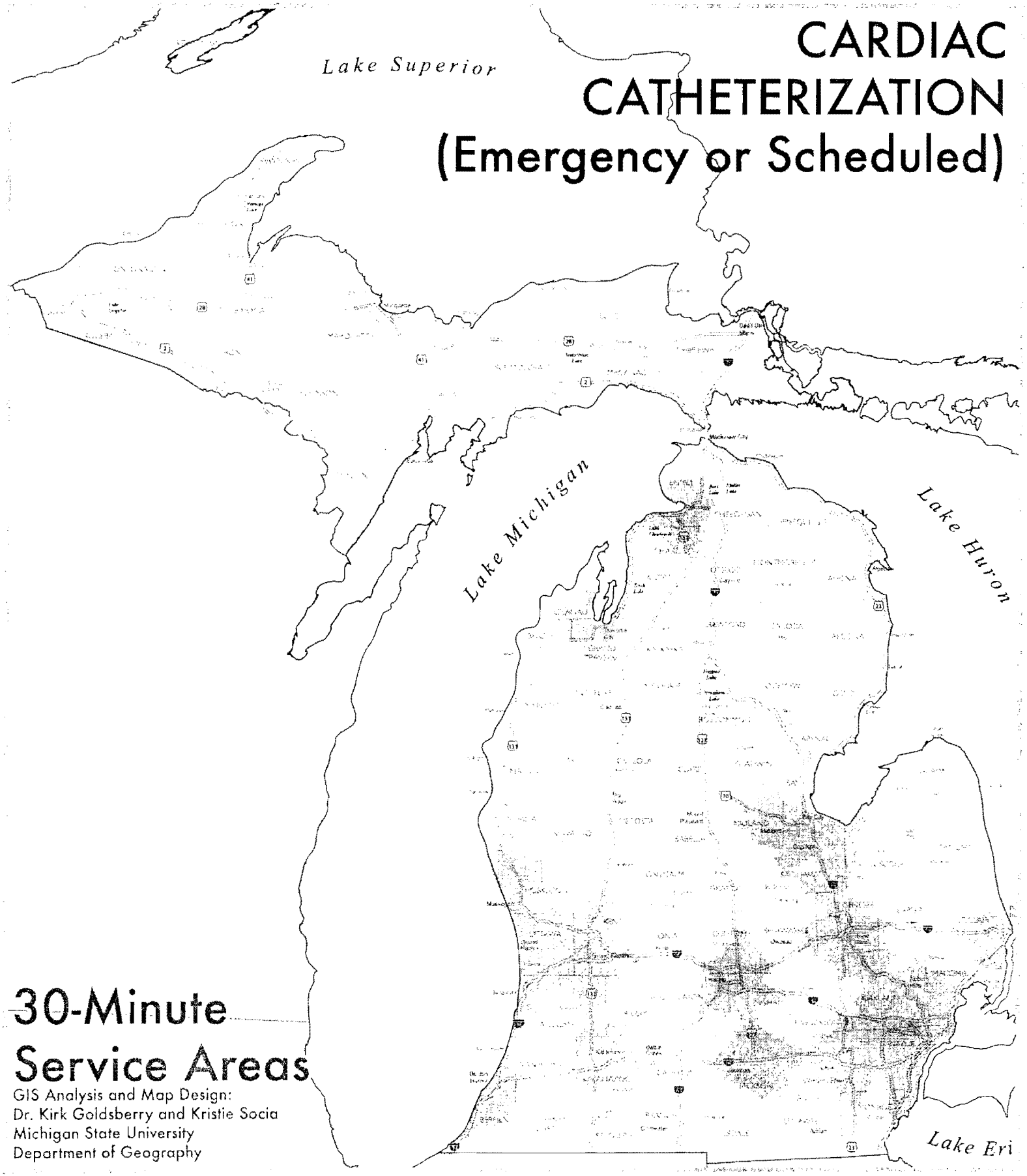
DR. KIRK GOLDSBERRY
MICHIGAN STATE UNIVERSITY
DEPARTMENT OF GEOGRAPHY



CARDIAC CATHETERIZATION (All Services)

30-Minute Service Areas

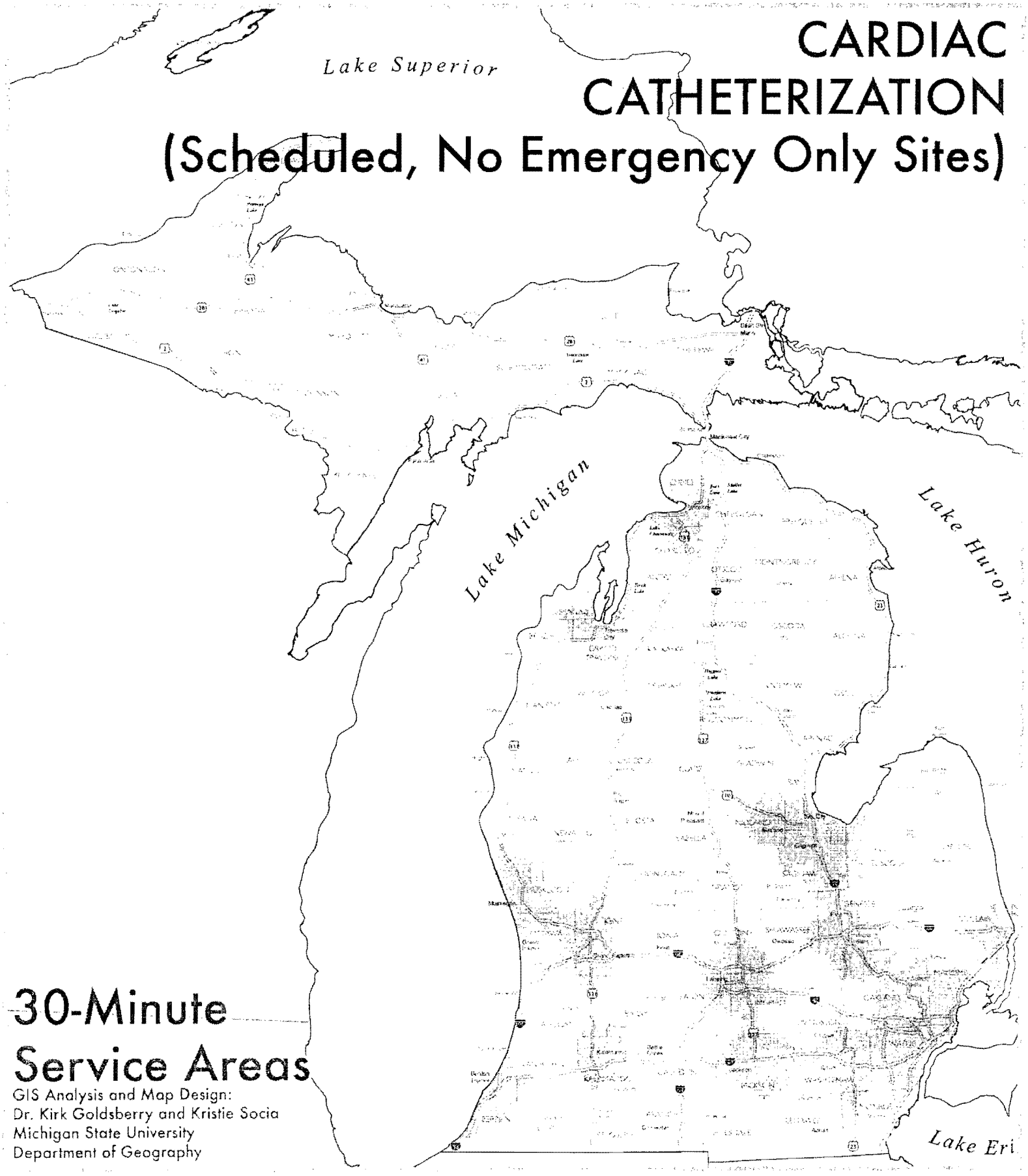
GIS Analysis and Map Design:
Dr. Kirk Goldsberry and Kristie Socia
Michigan State University
Department of Geography



CARDIAC CATHETERIZATION (Emergency or Scheduled)

30-Minute Service Areas

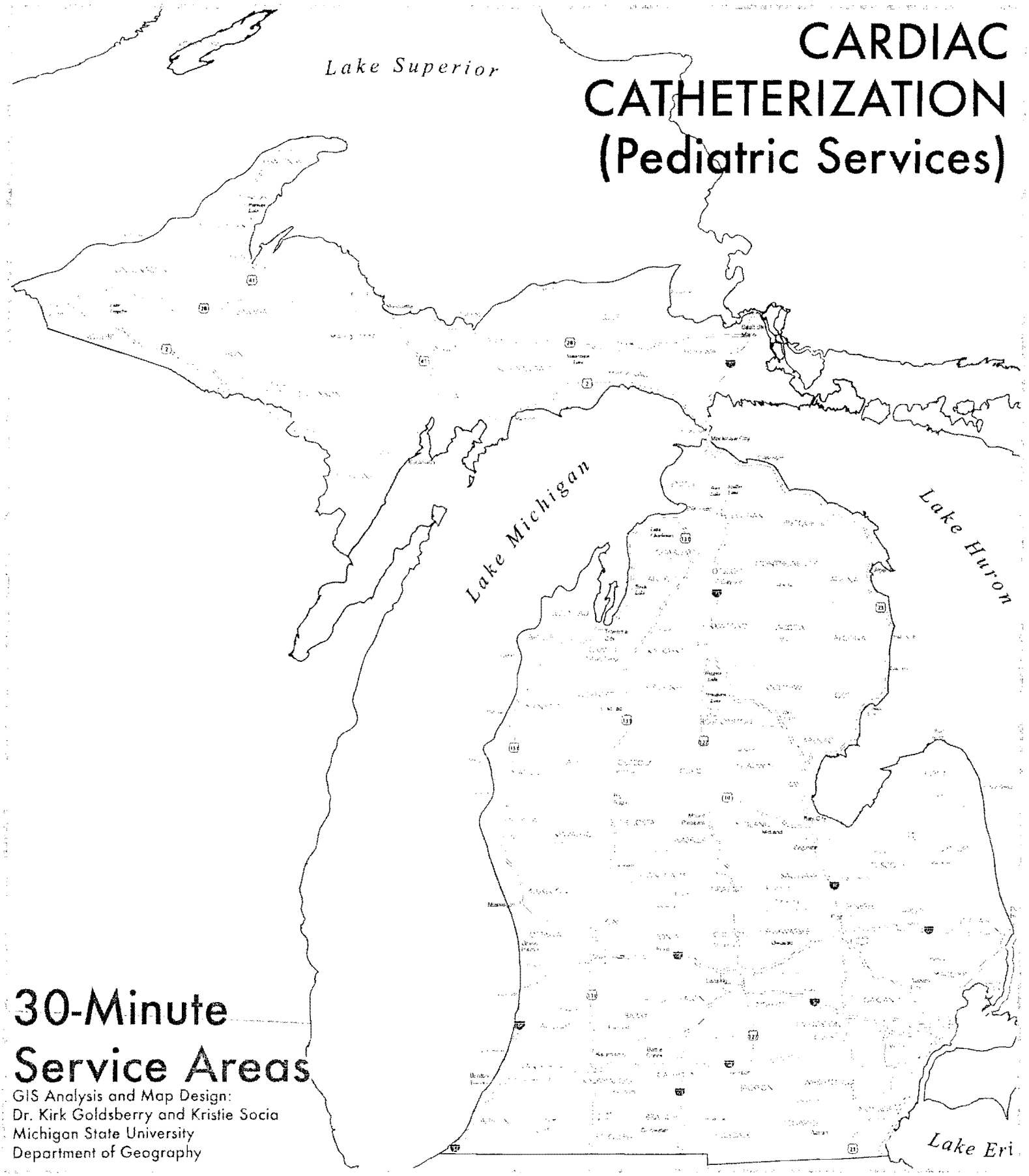
GIS Analysis and Map Design:
Dr. Kirk Goldsberry and Kristie Socia
Michigan State University
Department of Geography



CARDIAC CATHETERIZATION
(Scheduled, No Emergency Only Sites)

30-Minute Service Areas

GIS Analysis and Map Design:
Dr. Kirk Goldsberry and Kristie Socia
Michigan State University
Department of Geography



CARDIAC CATHETERIZATION (Pediatric Services)

30-Minute Service Areas

GIS Analysis and Map Design:
Dr. Kirk Goldsberry and Kristie Socia
Michigan State University
Department of Geography

Analysis of geographic accessibility to Cardiac Catheterization Services. Distribution of state population within 30-minute drive of service:

Cardiac Catheterization: Form of Service	People within 30-minutes	Not within 30-minutes
Cardiac Catheterzation Any Form	7,787,105	2,148,624
Emergency or Scheduled	7,218,920	2,716,809
Scheduled Only (No Emergency)	6,864,701	3,071,028
Pediatric Serivces	3,372,777	6,562,952