MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISSION MEETING

Tuesday September 17, 2013

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order @ 9:33 a.m.

A. Members Present:

Gail J. Clarkson, RN
Kathleen Cowling, DO
James B. Falahee, Jr., JD, Chairperson
Marc Keshishian, MD, Vice-Chairperson
Denise Brooks-Williams
Charles Gayney
Robert Hughes
Gay L. Landstrom, RN
Suresh Mukherji, MD
Luis Tomatis, MD
Gay L. Landstrom, RN

B. Members Absent

Brian Klott

C. Department of Attorney General Staff:

Raymond Howd

D. Michigan Department of Community Health Staff Present:

Scott Blakeney
Tulika Bhattacharya
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Mukherji, seconded by Commissioner Keshishian, to approve the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of June 13, 2013

Motion by Commissioner Tomatis, seconded by Commissioner Clarkston, to approve the minutes of June 13, 2013 as presented. Motion Carried.

V. Open Heart Surgery (OHS) Services – Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the public hearing summary (see Attachment A).

A. Public comment

Robert Meeker, Spectrum Health
Karen Kippen, Henry Ford Health System
Dennis McCafferty, Economic Alliance of Michigan (EAM) (see Attachment B)

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Gayney, seconded by Commissioner Hughes, to amend Section 7 of the language to increase the maintenance volume from 150 to 200. Motion Failed in a vote of 2 - Yes, 8 - No, and 0 - Abstained.

Motion by Commissioner Tomatis, seconded by Commissioner Muhkerji, to accept the language as presented (see Attachment C) and to move it forward to the Joint Legislative Committee (JLC) and the Governor for the 45-day review period. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VI. Neonatal Intensive Care Services/Beds (NICU) – Workgroup Final Report

Commissioner Landstrom gave an overview of the workgroups final report.. (see Attachment D).

Ms. Nagel gave a PowerPoint presentation on “MDCH Proposed Process for Approving CONs for Special Care Nurseries (SCN)”. (see Attachment E)

A. Public Comment

Rosemary Asman, MDCH - Neonatal Intensive Care Special Care Beds
Robert Meeker, Spectrum Health
Dennis McCafferty, Economic Alliance of Michigan (EAM)

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Keshishian, seconded by Commissioner Cowling, to accept the language as presented (see Attachment F) and to move it forward to the JLC and for Public Hearing. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Break from 11:15 AM - 11:30 AM

VII. Urinary Extracorporeal Shock Wave Lithotripsy Services/Units – Workgroup Final Report

Mr. Goldman gave a summary of the workgroup’s final report. (see Attachment G).

A. Public Comment

Kelly Neward, AKSM
Anne Mitchell, Public (Attachment H & I)

B. Commission Discussion

Discussion followed.

C. Motion by Commissioner Gayney, seconded by Commissioner Clarkston, to continue to regulate Lithotripsy and to keep the current standards without changes except for any technical changes submitted by the Department.including ICD-9 to ICD-10 conversion language. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VIII. Air Ambulance Services – Workgroup State Update

Commissioner Cowling gave a verbal update.

IX. Computed Tomography (CT) Scanner Services – Workgroup Status Update

Commissioner Mukherji gave a verbal update.

X. Nursing Home Workgroup Update

Chairperson Falahee gave a verbal update.

XI. Legislative Report

Mr. Blakeney gave a brief update on HB 4787; the fee increase bill.

Chairperson Falahee and Vice Chairperson Keshishian gave an appreciation to those who worked on the House CON workgroups.

XII. Administrative Update

A. Planning & Access to Care Section Update

1. Ms. Nagel gave a verbal reminder to all Commissioners to submit travel vouchers for reimbursement as the end of the fiscal year is approaching. She gave a brief update on the MRI standards that will become effective on September 18th. Also, the Department will be changing over from ICD-9 to ICD-10 October 1, 2014. Ms. Nagel provided a presentation (see Attachment J) on the transition to ICD-10 in the CON Review Standards.

B. CON Evaluation Section

1. Compliance Report (see Attachment K)
2. Quarterly Performance Measures (see Attachment L)

XIII. Legal Activity Report

Mr. Howd provided a brief report (See Attachment M).

XIV. Future Meeting Dates – December 12, 2013, January 28, 2014 (Special Commission Meeting), March 18, 2014, June 12, 2014, September 25, 2014, and December 11, 2014

XV. Public Comment

Robert Meeker, Spectrum Health

XVI. Review of Commission Work Plan

Ms. Rogers gave a brief summary of the Work Plan (see Attachment N).

A. Commission Discussion.

B. Commission Action

Motion by Vice Chairperson Keshishian, seconded by Commissioner Landstrom, to delegate to Chairperson Falahee to develop the specific question to provide to the public on initiation and expansion volume requirements and how we should handle the wide discrepancy in that area and to ask for comment during the public comment period in October for our Work Plan for next year. Motion Carried in a vote of 9 - yes, 0 - No, 1 - Abstained.

Motion by Commissioner Brooks-Williams, seconded by Commissioner Cowling, to accept the Work Plan as presented. Motion Carried in a vote of 10 - yes, 0 - No, 0 - Abstained.

XVII. Adjournment

Motion by Commissioner Hughes, seconded by Commissioner Cowling, to adjourn the meeting @ 1:05 p.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Michigan Department of Community Health (MDCH or Department)
MEMORANDUM
Lansing, MI

Date: July 25, 2013

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Open Heart Surgery (OHS) Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the OHS Standards at its June 13, 2013 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed OHS Standards on July 17, 2013. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from six (6) organizations and is summarized as follows:

Frank Sottile MD, Crittenton Hospital Medical Center

- Supportive of the recommendation to insert robust quality standards into the evaluation of programs and the rejection of volume standards as a surrogate for quality metrics.
- Suggests that continued adherence to volume criteria puts many OHS programs out of compliance with the current regulations and at risk for punitive action.
- Maintains that volume standards should never be a sole determinate of the maintenance of existing programs, but one piece of a broader analysis of the overall performance of the program.
- Maintains that the value of any program and the resource it consumes is directly related to its measurable quality and the outcomes of the patients they serve.

Monica Harrison, Oakwood Healthcare

- Supports the inclusion of quality metrics into the CON standards.
- Specifically recommends the utilization of the Society of Thoracic Surgeons (STS) composite star metrics for quality measures being weighed heavily; with volume being only one of the many considerations.

Michael Bekheet, Henry Ford Health System (HFHS)

- Supports the proposed volume changes to the OHS standards with regard to lowering the attending surgeon's annual volume requirement to 50 adult OHS cases and reducing the annual maintenance volume requirement to 150 adult OHS cases.
- In addition, HFHS supports the use of the STS Composite Star Rating System as a means to measure OHS quality and risk-adjusted outcomes, as well as an additional method for assuring compliance with the OHS standards.

Sean Gehle, Ascension Health

- Supports the modifications to the CON OHS standards as proposed and acted upon by the CON Commission at its last meeting.
- Specifically, supports the inclusion of language in the project delivery requirements requiring applicants to participate in data registry administered by the Department as a means to measure quality and risk adjusted outcomes.
- Supports utilizing the STS Composite Star rating system and the corresponding actions required by programs who achieve sub-par ratings within this rating system.

Robert Meeker, Spectrum Health

- Supports the inclusion of quality standards as part of the project delivery requirements, based on a star-ranking system developed by the STS.
- Does not support the proposed reduction of 150 OHS cases as an annual maintenance volume. Stating that this change was neither debated nor recommended by the OHS SAC.
- Strongly urges the Commission to reconsider the annual maintenance volume stating that an annual requirement of 150 cases is not based evidence.
- Strongly recommends that the next review of the OHS Standards be changed from 2014 to 2016, in order to provide the full three-year cycle to evaluate the effectiveness of the new Standards.

Dennis McCafferty, Economic Alliance for Michigan (EAM)

- Recommends reducing the annual maintenance volume to 200. This avoids a fourth tier of annual minimum maintenance volume requirements.
- Supports maintaining the initiation volume of 300 as a determiner of community need for new OHS programs.
- Recommends that the CON Standards also use the scores for the absence of mortality and the absence of morbidity in addition to the composite score as the basis for taking compliance action.
- Proposes that the actual numerical score for the composite and each of the four quality rating measurements be used rather than using the star rating system.

- Recommends that the Department uses the Composite Score of 96% or below as an indicator of the need for a compliance review.
- Recommends that the Department use the risk adjusted Absence of Mortality score of below 97% as an indicator of the need for a compliance review.
- Recommends that the Department use the risk adjusted Absence of Morbidity scores of less than 81% as an indicator of the need for a compliance review.
- Recommends that once the new standards become effective, the Department when deciding which OHS programs should be selected for compliance review, look at those OHS programs with annual volumes below their maintenance minimums that have chosen not to make their STS scores public.

Recommendations

The Department recommends that the Commission take final action to approve the language as presented at the June 13, 2013 meeting.

STS "Composite Score

- **Two outcome measurement scores,**

  1. Risk adjusted absence of mortality score and

  2. Risk adjusted absence of morbidity score.

STS "Composite Score

- Two outcome measurement scores,

  1. Risk adjusted absence of mortality score and

  2. Risk adjusted absence of morbidity score.

- **Two process compliance scores,**

  3. % of patient where the mammary artery was used,

  4. % of patients who received the required medications.

STS "Composite Score

- Gaming the Quality Score

OHS programs are able to improve their "Composite Score" without improving Patient outcomes!

Recommendation #1

in addition to the Composite Score,
Use the STS Outcome Measurement scores;

- Absence of Mortality
- absence of morbidity

as the basis for the MDCH taking compliance action based upon quality concerns.

Minimum Annual Maintenance Volume

Under CON, we currently have 3 different annual maintenance volumes for OHS Programs;

- 12 Programs who are grandfathered at "0"
- 10 Programs who have 200
- 11 Programs who have 300

Minimum Annual Maintenance Volume

Proposed change to the OHS Standards is to add a new minimum annual maintenance volume of 150

Minimum Annual Maintenance Volume

Goal is to get the low volume OHS program who are not meeting the annual minimum volume under their CON to adopt the new standards with the STS Quality Reporting Requirements

Minimum Annual Maintenance Volume

This will result in adding a 4th annual minimum maintenance volume for Mich. OHS Programs:

- Programs who are grandfathered at "0"
- Programs who have 200
- Programs who have 300
- Programs who have 150

Recommendation #2

Reduce the annual maintenance volume in the new Standards to 200

Recommendation #2

Avoid adding a 4th tier of annual maintenance volumes

Recommendation #2

Over time, as overall OHS volumes continue to decline, more of the lower volume OHS programs would be willing to adopt the newest OHS Standards with the STS Quality Reporting Requirements.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR OPEN HEART SURGERY (OHS) SERVICES

(By the authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. -1. (1) These standards are requirements for approval OF THE INITIATION OR ACQUISITION OF OHS SERVICES, and delivery of THESE services ~~for all projects approved and certificates of need issued~~ under Part 222 of the Code ~~which involve open heart surgery services~~. PURSUANT TO PART 222 OF THE CODE,

~~(2)~~OHS~~pen heart surgery~~ is a covered clinical service ~~for purposes of Part 222 of the Code~~.

~~(3)~~The Department shall use ~~sections 3, 4, 6, 8, and 9, as applicable,~~THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws~~.~~ AND

~~(4)The Department shall use Section 7 in applying~~ Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~(5)The Department shall use Section 5 in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Adult ~~open heart surgery~~ OHS" means ~~open heart surgery~~OHS offered and provided to individuals age 15 and older as defined in subsection (i).

(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of ~~open heart surgery~~OHS.

(c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Department" means the Michigan Department of Community Health (MDCH).

(F) "HOSPITAL" MEANS A HEALTH FACILITY LICENSED UNDER PART 215 OF THE CODE.

(G) "ICD-9-CM code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

(~~g~~H) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396~~r~~ TO 1396G and1396~~r-8~~I to ~~1396v~~1396U.

(~~h~~I) "Michigan inpatient data base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(~~i~~J) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These

procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(~~j~~K) "Open heart surgical case" means a single visit to an operating room during which one or more ~~open heart surgery~~OHS procedures are performed. THE LIST OF OHS PROCEDURES SHALL BE MAINTAINED BY THE DEPARTMENT.

(~~k~~L) "~~Open heart surgery~~OHS service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An ~~open heart surgery~~OHS service performs ~~open heart surgery~~OHS procedures on an emergent, urgent and scheduled basis.

(~~l~~M) "Pediatric ~~open heart surgery~~OHS" means ~~open heart surgery~~OHS offered and provided to infants and children age 14 and younger, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99.

(~~m~~N) "Planning area" means the groups of counties shown in Section 10.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements ~~for all applicants proposing~~ to initiate ~~open heart surgery~~OHS services

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric ~~open heart surgery~~OHS as a new service shall be A HOSPITAL AND operating or approved to operate a diagnostic and therapeutic adult or pediatric cardiac catheterization service, respectively.

(2) A hospital proposing to initiate ~~open heart surgery~~OHS as a new service shall have a written consulting agreement with a hospital which has an existing active ~~open heart surgery~~OHS service performing a minimum of 400 open heart surgical cases per year for 3 consecutive years. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) Work with the medical staff and governing body to design and implement a process that will annually measure, evaluate, and report to the medical staff and governing body the clinical outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant proposing to initiate adult ~~open heart surgery~~OHS as a new service shall demonstrate 300 adult open heart surgical cases based on the methodology set forth in Section 8.

(4) An applicant proposing to initiate pediatric ~~open heart surgery~~OHS as a new service shall demonstrate 100 pediatric open heart surgical cases based on the methodology set forth in Section 9.

Section 4. Requirements ~~for approval for applicants proposing~~ to acquire an existing open heart surgery service

Sec. 4. An applicant proposing to acquire a hospital that has been approved to perform ~~open heart surgery~~OHS services may also acquire the existing ~~open heart surgery~~OHS service if it can demonstrate that the proposed project meets all of the following:

(1) An application for the first acquisition of an existing ~~open heart surgery~~OHS service after ~~the effective date of these standards~~FEBRUARY 25, 2008 shall not be required to be in compliance with the applicable volume requirements on the date of acquisition. The ~~open heart surgery~~OHS service shall be

operating at the applicable volume requirements set forth in Section 7 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(2) Except as provided for in subsection (1), an application for the acquisition of an existing ~~open heart surgery~~OHS service after ~~the effective date of these standards~~ FEBRUARY 25, 2008 shall be required to be in compliance with the applicable volume requirements, as set forth in the project delivery requirements, on the date an application is submitted to the Department.

(3) The applicant agrees to operate the ~~open heart surgery~~OHS service in accordance with all applicable project delivery requirements set forth in Section 7 of these standards.

Section 5. Requirements for ~~all applicants~~MEDICAID PARTICIPATION

Sec 5**.** An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services~~,~~ if a CON is approved.

Section 6. Requirements for MIDB data commitments

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric ~~open heart surgery~~OHS services, an applicant shall demonstrate or agree, as applicable, to all of the following:

(1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult ~~open heart surgery~~OHS services shall not use any of its adult MIDB data in support of any other application for adult ~~open heart surgery~~OHS services prior to 7 years after the initiation of the ~~open heart surgery~~OHS service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its adult MIDB data in support of another application for adult ~~open heart surgery~~OHS services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate ~~open heart surgery~~OHS services.

(2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric ~~open heart surgery~~OHS services shall not use any of its pediatric MIDB data in support of any other application for pediatric ~~open heart surgery~~OHS services prior to 7 years after the initiation of the ~~open heart surgery~~OHS service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its pediatric MIDB data in support of another application for pediatric ~~open heart surgery~~OHS services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate ~~open heart surgery~~OHS services.

(3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric ~~open heart surgery~~OHS service or have a valid CON issued under Part 222 to operate an adult or pediatric ~~open heart surgery~~OHS service.

(4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5) The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231 of the Code, being Section 333.22231 of the Michigan Compiled Laws.

Section 7. Project delivery requirements ~~--~~AND terms of approval for all applicants

Sec. 7. ~~(1)~~ An applicant shall agree that, if approved, the OHS services shall be delivered in compliance with the following terms of CON approval:

(~~a~~1) Compliance with these standards.

~~(b) Compliance with applicable operating standards.~~

(~~c~~2) Compliance with the following quality assurance standards:

(~~i~~A) ~~The open heart surgery service shall be operating at an annual level of 300 adult open heart surgical cases or 100 pediatric open heart surgical cases, as applicable, by the end of the third 12 full months of operation, and annually thereafter.~~

~~(ii~~B) ~~-~~Each physician credentialed by the ~~applicant -~~hospital to perform adult ~~open heart surgery~~OHS cases, as the attending surgeon, shall perform a minimum of ~~75~~ 50 adult ~~open heart surgery~~OHS cases per year. The annual case load for a physician means adult ~~open heart surgery~~OHS cases performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.

~~(iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.~~

(~~iv~~B) The service shall have the ~~capability for rapid mobilization of a~~ cardiac surgical team ~~for~~ AVAILABLE ON CALL FOR emergency cases 24 hours a day, 7 days a week.

(C) THE APPLICANT HOSPITAL SHALL PARTICIPATE WITH THE SOCIETY OF THORACIC SURGEONS (STS) NATIONAL DATABASE AND THE MICHIGAN SOCIETY OF THORACIC AND CARDIOVASCULAR SURGEONS (MSTCVS) QUALITY COLLABORATIVE AND DATABASE OR A DESIGNEE OF THE DEPARTMENT THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES.

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

(~~v~~A) ~~An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.~~ THE SERVICE SHALL ACCEPT REFERRALS FOR OHS FROM ALL APPROPRIATELY LICENSED PRACTITIONERS.

(~~d~~B) THE APPLICANT HOSPITAL shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.~~The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:~~

(~~i~~C) ~~provide open heart surgery~~ THE ~~service~~APPLICANT HOSPITAL~~s~~ ~~to all individuals based on the clinical indications of need for the~~ SHALL NOT DENY OHS serviceS TO ANY INDIVIDUAL ~~and not~~BASED on THE ability to pay or source of payment~~; and~~.

~~(ii) maintain information by source of payment to indicate the volume of care from each source provided annually.~~

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE OHS SERVICES SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

(4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

(~~e~~A) The OHS service shall be operating at an annual level of ~~300~~150 adult open heart surgical cases or 100 pediatric open heart surgical cases, as applicable, AS SUBMITTED TO THE STS DATABASE, by the end of the third 12 full months of operation, and annually thereafter.

(B) The applicant HOSPITAL shall prepare and present to the medical staff and governing body reports describing activities in the ~~open heart surgery~~OHS service including complication rates and other morbidity and mortality data.

(~~f~~C) The applicant HOSPITAL shall participate in a data collection network established and administered by the Department or its designee. The data may include but is not limited to annual budget and cost information, operating schedules, ~~and~~ PATIENT demographicS, diagnostic, morbidity and mortality information, ~~as well as~~AND the volume of care provided to patients from all payor sources. The applicant~~.~~ HOSPITAL shall provide the required data in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~g~~D) The applicant HOSPITAL shall participate in a data registry administered by the Department or its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN OHS PROGRAMS. THE DEPARTMENT SHALL USE THE STS COMPOSITE STAR RATING SYSTEM WHICH CURRENTLY INCLUDES CORONARY ARTERY BYPASS GRAFT COMPOSITE (CABG), AORTIC VALVE REPLACEMENT COMPOSITE, AND PLANS TO ADD ADDITIONAL CARDIAC SURGICAL COMPOSITES EACH YEAR.~~monitors quality and risk adjusted outcomes.~~ The Department or its designee shall require that the applicant HOSPITAL submit a summary report as specified by the Department. The applicant HOSPITAL shall provide the required data in a format established by the Department or its designee. The applicant HOSPITAL shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant HOSPITAL shall become a member of the data registry specified by the Department upon initiation of the service~~.~~ AND CONTINUE TO ~~Participation~~ PARTICIPATE ~~shall continue~~ annually thereafter FOR THE LIFE OF THAT SERVICE. The outcomes database must undergo statewide auditing.

(~~h~~E) ~~An~~ THE applicant HOSPITAL ~~that fails to comply with the quality assurance standards under subsection (c2) shall be required to provide its quality and risk adjusted outcomes data from the data registry to the Department, or its designee, as part of the Department's enforcement and compliance activities.~~ SHALL UTILIZE AND REPORT THE STS COMPOSITE STAR RATING SYSTEM FOR ALL PROCEDURES AS FOLLOWS:

(I) IF THE PROGRAM RECEIVES A ONE-STAR RATING IN ANY COMPOSITE METRIC, THEY SHALL SUBMIT A REPORT TO THE DEPARTMENT EXPLAINING THE REASON(S) FOR THE UNSATISFACTORY RATING.

(II) IF THE PROGRAM RECEIVES TWO ONE-STAR RATINGS IN A ROW IN THE SAME COMPOSITE METRIC, THEY SHALL SUBMIT AN ACTION PLAN TO THE DEPARTMENT DETAILING SPECIFIC ACTIONS TO RECTIFY THE PROGRAM DEFICIENCIES.

(A) IF THE PROGRAM RECEIVES TWO ONE-STAR RATINGS WITHIN THE SAME COMPOSITE METRIC, THE PROGRAM MAY HAVE TWO YEARS TO OBTAIN A MINIMUM TWO-STAR RATING WITHIN THAT COMPOSITE METRIC. UPON RECEIPT OF A TWO-STAR OR HIGHER RATING, THE PROGRAM MAY BE CONSIDERED IN COMPLIANCE.

(F~~i~~) The applicant HOSPITAL shall provide the Department with ~~a notice stating the date on which the first approved service is performed and such~~TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION ~~notice shall be submitted to the Department~~ consistent with applicable statute and promulgated rules.

(5) NOTHING IN THIS SECTION PROHIBITS THE DEPARTMENT FROM TAKING COMPLIANCE ACTION UNDER MCL 333.22247.

(~~25~~6) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 8. Methodology for computing the number of adult open heart surgical cases

Sec. 8. (1) The weights for the adult principal and non-principal diagnoses tables found in Appendix A are calculated using the following methodology. For these two tables, only the MIDB data from licensed hospitals that have operational ~~open heart surgery~~OHS programs in Michigan will be used.

Using ~~a~~ THE hospital~~'~~s' actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, ~~an applicant shall identify~~ the discharges that were from patients aged 15 years and older SHALL BE IDENTIFIED. These discharges shall be known as the "adult discharges."

(a) To calculate the weights for the principal diagnosis, the following steps shall be taken:

(i) For each diagnostic group in the principal weight table, the ~~number of~~ discharges ~~is counted~~ HAVING A PRIMARY DIAGNOSIS MATCHING ANY DIAGNOSIS IN THE DIAGNOSTIC GROUP ARE IDENTIFIED. THE NUMBER OF DISCHARGES ARE COUNTED.

(ii) For the discharges identified in subsection 8(1)(a)(i), any occurrence of an open heart procedure code will be ~~counted~~ CONSIDERED as a single ~~open heart surgery~~OHS case. FOR EACH DIAGNOSTIC GROUP, THE NUMBER OF OHS CASES ARE COUNTED.

(iii) The number of ~~open heart surgery~~OHS cases for each diagnosis category IDENTIFIED IN SUBSECTION 8(1)(A)(II) will be divided by the number of discharges identified in subsection 8(1)(a)(i). This will be the weight for that diagnostic group. This number should show six decimal positions.

(iv) All discharges utilized for the computation of the principal weight table are to be removed from subsequent analyses.

(b) To calculate the weights for the non-principal diagnosis table, the following steps shall be taken, separately, in the sequence ~~shown,~~ OF THE GROUP ORDER FOUND IN THE NON-PRINCIPAL DIAGNOSIS TABLE:

(I) ~~and e~~Each remaining discharge will be examined for any mention of the diagnostic codes from that group. If a match is found, that discharge is assigned to that diagnostic group and removed from subsequent analyses~~:~~. THE NUMBER OF DISCHARGES IN EACH DIAGNOSTIC GROUP IS COUNTED.

(i~~l~~) For each diagnostic group taken separately, in the sequence shown, any occurrence of an open heart procedure code for each discharge will be counted as a single ~~open heart surgery~~OHS case. If a match is found, the discharge will be ~~counted~~ CONSIDERED as an open heart surgical case for that diagnostic group and removed from subsequent analyses. THE NUMBER OF OPEN HEART SURGICAL CASES IN EACH DIAGNOSTIC GROUP ARE COUNTED.

(ii) The number of ~~open heart surgery~~OHS cases for each non-principal diagnosis category identified in subsection 8(1)(b)(i~~l~~) will be divided by the number of discharges identified in subsection 8(1)(b)(I). This will result in the non-principal weight for that diagnostic group. This number should show six decimal positions.

(2) An applicant shall apply the methodology set forth in this section for computing the projected number of adult open heart surgical cases using both the principal and non-principal diagnosis tables. The following steps shall be taken in sequence:

(a) For each diagnostic group in the principal weight table in Appendix A, identify the corresponding number of discharges.

(b) Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of ~~open heart surgery~~OHS cases for that group. All discharges identified in subsection 8(2)(a) are removed from subsequent analysis.

(c) The non-principal weight table identifies the sequence that must be followed to count the discharges for the appropriate group. An applicant shall start with the first diagnostic group and shall count the number of discharges with any mention of a non-principal diagnosis corresponding to that specific diagnostic group. When a discharge that belongs in the specific non-principal diagnostic group is identified, it is assigned to that group. This discharge is then removed from the data before counting discharges for the next diagnostic group. The discharges counted for each group will be used only with the non-principal diagnosis weight table in Appendix A and will be entered into its respective diagnostic group. Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of ~~open heart surgery~~OHS cases for that group.

(d) The total number of projected open heart cases is then calculated by summing the projected number of open heart cases from both principal and non-principal weight tables.

(3) The major ICD-9-CM groupings and Open Heart utilization weights in Appendix A are based on the work of the Bureau of ~~Health~~ Policy~~,~~ AND Planning ~~and Access~~, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a) The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b) Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c) The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d) The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix A and shall be included as an amended appendix to these standards.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

Section 9. Methodology for computing the number of pediatric open heart surgical cases

Sec. 9. (1) The weights for the pediatric diagnosis table found in Appendix B are calculated using the following methodology. Only the MIDB data from licensed hospitals THAT HAVE OPERATIONAL OHS PROGRAMS in Michigan will be used.

(a) Using ~~a~~ THE hospital~~'~~s' actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, ~~an applicant shall count~~ the discharges that were from patients of any age that have a diagnosis (any mention) of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Appendix B SHALL BE COUNTED. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from subsequent analyses.

(b) For those discharges identified in subsection 9(1)(a), any occurrence of an open heart procedure code will be ~~counted~~ CONSIDERED as a single ~~open heart surgery~~OHS case. THE NUMBER OF OPEN HEART SURGICAL CASES ARE COUNTED.

(c) The number of ~~open heart surgery~~OHS cases for the "Congenital Anomalies" category IDENTIFIED IN SUBSECTION 9(1)(B) will be divided by the number of discharges identified in subsection 9(1)(a). This will be the weight for the "Congenital Anomalies" diagnostic group. This number should show six decimal positions.

(d) Using ~~a~~ THE hospital~~'~~s' remaining inpatient discharges, ~~an applicant shall identify~~ the discharges that were from patients aged 14 years and younger SHALL BE IDENTIFIED. These discharges shall be known as the "pediatric discharges."

(e) Using the "pediatric discharges" identified in ~~subdivision~~ subSECTION 9(1)(d), ~~an applicant shall count~~ the number of discharges that have a diagnosis (any mention) of the ICD-9-CM codes listed in the "All Other Heart Conditions" category in Appendix B SHALL BE COUNTED. Discharge records which do not have one or more of the “All Other Heart Conditions” codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(f) For those discharges identified in subsection 9(1)(e), any occurrence of an open heart procedure code will be ~~counted~~ CONSIDERED as a single ~~open heart surgery~~OHS case. THE NUMBER OF OPEN HEART SURGICAL CASES ARE COUNTED.

(g) The number of ~~open heart surgery~~OHS cases for the "All Other Heart Conditions" category IDENTIFIED IN SUBSECTION 9(1)(F) will be divided by the number of discharges identified in subsection 9(1)(e). This will be the weight for the "All Other Heart Conditions" diagnostic group. This number should show six decimal positions.

(2) An applicant shall apply the methodology set forth in this section for computing the projected number of pediatric open heart surgical cases. In applying discharge data in the methodology, each

applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in Appendix B. In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, an applicant shall count the discharges that were from patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Appendix B. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "All Other Heart Conditions" category in Appendix B. Discharge records which do not have one or more of the “All Other Heart Conditions” codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d) An applicant shall multiply the count for the "Congenital" and "All Other Heart Conditions" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical cases for the applicant.

(3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights in Appendix B are based on the work of the Bureau of ~~Health~~ Policy~~,~~ AND Planning ~~and Access~~, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a) The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b) Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c) The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d) The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix B and shall be included as an amended appendix to these standards.

(4) Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

PLANNING AREA		COUNTIES	
1	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
2	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE
3	BARRY	CALHOUN	ST. JOSEPH

	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	
4	ALLEGAN	MASON	NEWAYGO
	IONIA	MECOSTA	OCEANA
	KENT	MONTCALM	OSCEOLA
	LAKE	MUSKEGON	OTTAWA
5	GENESEE	LAPEER	SHIAWASSEE
6	ARENAC	HURON	ROSCOMMON
	BAY	IOSCO	SAGINAW
	CLARE	ISABELLA	SANILAC
	GLADWIN	MIDLAND	TUSCOLA
	GRATIOT	OGEMAW	
7	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GD TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
8	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

Section 11. Effect on prior planning policies; comparative reviews

Sec. 11. (1) These CON Review Standards supersede and replace the CON Review Standards for ~~Open Heart Surgery~~OHS Services approved by the CON Commission on ~~March 9, 2004~~DECEMBER 11, 2007 and effective on ~~June 4, 2004~~FEBRUARY 25, 2008.

(2) Projects reviewed under these standards shall not be subject to comparative review.

Appendix A

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL CASES
PRINCIPAL DIAGNOSIS

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.~~755521~~730737
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.~~474638~~641457
C	745 – 747.99	Congenital Anomalies	.~~304878~~362101
D	414 – 414.99	Other Chronic Ischemic	.~~175495~~224163
E	410 – 410.99	Acute Myocardial Infarct	.~~119218~~101479
F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	All Other Heart Conditions	.~~013789~~013366

NON-PRINCIPAL DIAGNOSES

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	745 – 747.99	Congenital Anomalies	.~~021698~~016876
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.~~020900~~030120
C	410 – 410.99	Acute Myocardial Infarct	.~~014470~~012099
D	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.~~008064~~007648
E	414 – 414.99	Other Chronic Ischemic	.~~001879~~001466

F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	All Other Heart Conditions	.~~001190~~001206

Source: Calculated based on the 20~~05~~10 Michigan Inpatient Data Base

Appendix B

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES

MAJOR ICD-9-CM CODE GROUP	CATEGORY	PEDIATRIC OPEN HEART UTILIZATION WEIGHTS
745.0 – 747.99	Congenital Anomalies	.~~174027~~234512
164.1, 212.7 390 – 429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51 786.5-786.59 901.0 – 901.9 996.02	All Other Heart Conditions	.~~018182~~018991

Source: Calculated based on the 20~~05~~10 Michigan Inpatient Data Base

Final Report of the Michigan Certificate of Need Commission

Workgroup on NICU Issues

Chair – Commissioner Landstrom

September 17, 2013

Purpose:

In 2012, the American Academy of Pediatrics (AAP) and the American College of Obstetrics and Gynecology (ACOG) revised national perinatal level of care guidelines and issued an expanded classification system. The expanded classification system includes: Level I basic care and well newborn nursery, Level II specialty care and special care nursery, Level III subspecialty care and neonatal intensive care unit (NICU), and Level IV regional subspecialty perinatal health care center with a regional NICU. The workgroup was charged with examining the issues around definitions of Nursery services and recommending any changes in standards language. Of note was a concern that Level II services were not defined or included in the current standards.

Workgroup:

The workgroup held four meetings in Lansing, with each meeting noting an attendance in excess of 30 members. After the first meeting, additional attendance was requested to ensure that current hospitals advertising a Special Care Nursery or Level II Nursery, and hospitals in rural areas of Michigan were represented. Meetings #2-4 included individuals representing Levels 1-4 services, as described by AAP.

Process:

The workgroup received information they identified as critical to forming recommendations, including:

- American Academy of Pediatrics Policy Statement on Standards for Levels of Neonatal Care, revised 8/27/12
- Report of the Perinatal Regionalization Workgroup on Birth Hospitals Level of Care (2009)
- Input from BCBS regarding the insurance industry's view of different levels of NICU care
- Summary of all hospitals describing themselves (via websites) as having a Special Care Nursery or Level II Nursery (n=13 that did not also have a CON for NICU)
- Review of the 20 Michigan hospitals with CON for NICU
- Review of the recommended MDCH process for approving Special Newborn Care Services (Level II), including legal recommendations
- Letter of support from Matthew M. Davis, Chief Medical Executive for the recommendations of the workgroup (in draft form) and the AAP/ACOG Perinatal Level of Care Guidelines, 7th Edition
- Review of anticipated outcomes and capacity issues if special care nurseries are regulated

Recommendations:

Because of the recent changes and additional clarity introduced by the AAP/ACOG standards, a number of language changes are recommended (attached). These recommendations work with the assumptions that:

- Special Care Nurseries are considered a Level II neonatal service and/or a “Special Newborn Nursing Service”.
- No one in Michigan currently holds a CON for a Special Care Nursery.
- Special Care Nurseries are a new *service* within CON; bassinets will not count against the number of licensed beds within a facility.
- All providers of Special Care Nurseries (with the exclusion of those currently holding a CON for Level III NICU) will need to obtain a CON.

No changes in language related to Level IV NICU were recommended.

Acknowledgements:

Special thanks should go to Mr. Bob Meeker for his assistance in early drafts of revised standards language and Arlene Elliot for taking minutes. Additionally, I extend my thanks to all the staff members of MDCH for their support and assistance with this workgroup.

Respectfully submitted,

Gay Landstrom, PhD(c), RN, NEA-BC

September, 9, 2013

MDCH Proposed Process for Approving CONs for Special Care Nurseries (SCN)

Assumptions

- The MI Public Health Codes gives CON the ability to regulate “Special Newborn Nursing Services”
- SCN services are a considered a Special Newborn Nursing Service
- SCNs are not currently regulated by CON
- No one in Michigan holds a CON for an SCN
- SCN services are a new service within CON
- All providers of SCN services will need to obtain a CON

Proposed Process

- All SCNs will have to apply for a CON to continue operations within ## months of the effective date of the standards
  - SCNs will be allowed to continue service within the ## month window of time until the application is processed
- All SCNs will need to meet the initiation criteria and the project delivery requirements that are specific to SCNs within the NICU standards (as opposed to the entire NICU standard as noted in the standard)
- After the ## month window, all SCNs will be subject to CON standards, compliance

Proposed Process

Points of Clarification

- All programs believed to be an SCN will need to apply for a CON
  - **EXCEPTION:** CON approved NICU programs will not need to apply for a CON for any SNC programs within the same physical location as the NICU program.
- MDCH will provide a window of time for all proposed SCNs to meet the standards
- Proposed SCNs will **not** be required to discontinue service while applications are being processed
- SCNs will be considered a service and beds will **not** count against the number of licensed beds within a facility

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/BEDS AND SPECIAL NEWBORN NURSING SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, relocation, expansion, ~~relocation,~~ or acquisition ~~replacement~~ of neonatal intensive care services/beds and the delivery of neonatal intensive care services/beds under Part 222 of the Code. FURTHER, THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL OF THE INITIATION OR ACQUISITION OF SPECIAL CARE NURSERY (SCN) SERVICES. Pursuant to Part 222 of the Code, neonatal intensive care services/beds AND SPECIAL NEWBORN NURSING SERVICES ~~is~~ ARE ~~a~~ covered clinical serviceS. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

~~(a) "Acquisition of a NICU" means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.~~

~~(b)~~a) ~~"Bassinet" means an unlicensed bassinet in the obstetrical or newborn service that provides care for the uncomplicated newborn.~~

~~(c~~ba) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(~~d~~b) "Code" means Act No. 368 of the Public Acts of 1978 as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(~~e~~c) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

(~~f~~d) "Department" means the Michigan Department of Community Health (MDCH).

(~~g~~e) "Department inventory of beds" means the current list for each planning area maintained on a continuous basis by the Department of licensed hospital beds designated for NICU services and NICU beds with valid CON approval but not yet licensed or designated.

(~~h~~f) "Existing NICU beds" means the total number of all of the following:

(i) licensed hospital beds designated for NICU services;

(ii) NICU beds with valid CON approval but not yet licensed or designated;

(ii) NICU beds under appeal from a final decision of the Department; and

(iii) proposed NICU beds that are part of an application for which a proposed decision has been issued, but is pending final Department decision. ~~The term includes those beds designated by the Department as special newborn nursery unit (SNNU) beds.~~

~~(h) "Expansion of NICU services" means increasing the number of hospital beds designated for NICU services at a licensed site.~~

(~~i~~g) "Hospital" means a health facility licensed under Part 215 of the Code.

~~(j) "Initiation of NICU services" means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a~~

~~NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.~~

(~~l~~h) "Infant" means an individual up to 1 year of age.

(~~m~~i) "Licensed site" means in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(~~n~~j) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

(~~o~~k) "Maternal referral service" means having a consultative and patient referral service staffed by a physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in maternal/fetal medicine.

(~~p~~l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396~~r-6 and1396r-8~~ to ~~1396v~~1396w-5.

~~(q) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

~~(r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(~~s~~m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth, AND/OR LESS THAN 32 WEEKS GESTATION;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) TOTAL parenteral nutrition.

(~~t~~n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which is both capable of providing neonatal intensive care services and is composed of licensed hospital beds designated as NICU. This term does not include UNLICENSED SCN BEDS ~~bassinets or special newborn care bassinets~~.

(~~u~~o) "Neonatal transport system" means a specialized transfer program for neonates by means of an ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

(~~v~~p) "Neonate" means an individual up to 28 days of age.

(~~w~~q) "Perinatal care network," means the providers and facilities within a planning area that provide basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.

(~~x~~r) "Planning area" means the groups of counties shown in ~~Section 12~~APPENDIX B.

(~~y~~s) "Planning year" means the most recent continuous 12 month period for which birth data is available from the Vital Records and Health Data Development Section.

(~~z~~t) "Qualifying project" means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.

(~~aa~~u) "Relocation of the designation of beds for NICU services" means a change within the same planning area in the licensed site at which existing licensed hospital beds are designated for NICU services.

~~(bb) "Replacement of NICU beds" means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.~~

~~(cc) "Replacement zone" means a proposed licensed site which is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.~~

(~~dd~~v) "Special ~~newborn~~ care NURSERY ~~bassinet~~SERVICES" OR "SCN SERVICES" means ~~an unlicensed bassinet identified within the hospital obstetrical or newborn service which provides~~ PROVISIONS OF the services identified in subsections (i) through (v~~i~~) for infants WITH PROBLEMS THAT ARE EXPECTED TO RESOLVE RAPIDLY AND who WOULD NOT BE ANTICIPATED TO NEED SUBSPECIALTY SERVICES ON AN URGENT BASIS ~~require minimal care that goes beyond that of the uncomplicated newborn, or transitional care or developmental maturation in preparation for discharge home~~. REFERRAL TO A HIGHER LEVEL OF CARE SHOULD OCCUR FOR ALL INFANTS WHO NEED PEDIATRIC SURGICAL OR MEDICAL SUBSPECIALTY INTERVENTION. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital. FOR PURPOSES OF THESE STANDARDS, SCN SERVICES ARE SPECIAL NEWBORN NURSING SERVICES.

(i) Care for low birth weight infants ~~between~~ weighing 1,500 ~~and 2,499~~ grams or more~~;~~ AND/OR GREATER THAN OR EQUAL TO 32 WEEKS GESTATION;

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

~~(iv) antibiotic therapy in an infant not needing ventilatory support or pressor support;~~

(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(v~~i~~) ~~the administration of oxygen by hood or nasal canula~~PROVIDE MECHANICAL VENTILATION ~~FOR BRIEF DURATION (LESS THAN 24 HOURS)~~ OR CONTINUOUS POSITIVE AIRWAY PRESSURE OR BOTH FOR A BRIEF DURATION (NOT TO EXCEED 24 HOURS COMBINED).

~~(ee) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Bed need methodology

Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following formula:

(a) Determine, using data obtained from the Vital Records and Health Data Development Section, the total number of live births which occurred in the planning year at all hospitals geographically located within the planning area.

(b) Determine, using data obtained from the Vital Records and Health Data Development Section, the percent of live births in each planning area and the state that were less than 1,500 grams. The result is the very low birth weight rate for each planning area and the state, respectively.

(c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight rate. The result is the very low birth weight rate adjustment factor for each planning area.

(d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The result is the bed need formula for each planning area adjusted for the very low birth weight rate.

(e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for the applicable planning area adjusted for the very low birth weight adjustment factor as determined in subsection (1)(d).

(2) The result of subsection (1) is the number of NICU beds needed in the planning area for the planning year.

Section 4. Requirements ~~for applicants proposing~~ to initiate NICU services

Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.

(1) An applicant proposing to initiate NICU services by designating hospital beds as NICU beds shall demonstrate each of the following:

(~~1~~a) There is an unmet bed need of at least 15 NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year as a result of application of the methodology set forth in Section 3.

(~~2~~b) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(~~3~~c) A unit of at least 15 beds will be developed and operated.

(~~4~~d) For each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Section 5. Requirements ~~for applicants proposing~~ to ~~expand~~ REPLACE NICU services

Sec. 5. Replacement of NICU beds means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.

(1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:

(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and

(b) the proposed licensed site is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.~~replacement zone~~.

Section 6. Requirements for approval to relocate NICU beds

Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:

(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.

(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.

(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.

(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.

(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:
(a) the proposed project involves the establishment of a NICU of at least 15 beds; and
(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.

(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:
(a) the proposed project involves the establishment of a NICU of at least 15 beds; and
(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.

(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.

(10) Beds approved pursuant to Section ~~5~~7(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.

~~Sec. 5. (1) An applicant proposing to expand NICU services by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.~~

~~(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:~~

~~(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.~~

~~(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.~~

~~(c) Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 √ADC. The result is the maximum number of beds that may be approved pursuant to this subsection up to 5 beds at each licensed site.~~

~~Section 6. Requirements for approval to relocate NICU beds~~

~~Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:~~

~~(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.~~

~~(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.~~

~~(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.~~

~~(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.~~

~~(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.~~

~~(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.~~

~~(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:~~

~~(a) the proposed project involves the establishment of a NICU of at least 15 beds; and~~

~~(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.~~

~~(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:~~

~~(a) the proposed project involves the establishment of a NICU of at least 15 beds; and~~

~~(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.~~

~~(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.~~

~~(10) Beds approved pursuant to Section 5(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.~~

Section 7. ~~Requirements for approval for replacement of NICU beds~~ REQUIREMENTS FOR APPROVAL TO EXPAND NICU SERVICES

Sec. 7. (1) An applicant proposing to expand NICU services AT A LICENSED SITE by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:

(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.

(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.

(c) Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 √ADC. The result is the maximum number of beds that may be approved pursuant to this subsection up to 5 beds at each licensed site.

~~Sec. 7. (1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:~~

~~(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and~~

~~(b) the proposed licensed site is in the replacement zone.~~

Section 8. Requirements for approval to acquire a NICU service

Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

(1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds designated for NICU services, at the licensed site to be acquired;

(b) the licensed site does not change as a result of the acquisition, unless the applicant meets Section 6; and,

(c) the project does not involve the initiation, expansion or replacement of a covered clinical service, a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the applicant facility, unless the applicant meets other applicable sections.

SECTION 9. REQUIREMENTS TO INITIATE, ACQUIRE, OR REPLACE, SCN SERVICES

SEC. 9. AN APPLICANT PROPOSING SCN SERVICES SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE, BY VERIFIABLE DOCUMENTATION:

(1) ALL APPLICANTS SHALL DEMONSTRATE THE FOLLOWING:

(a) A BOARD CERTIFIED NEONATOLOGIST SERVING AS THE PROGRAM DIRECTOR

(b) THE HOSPITAL HAS THE FOLLOWING CAPABILITIES AND PERSONNEL CONTINUOSLY AVAILABLE AND ON-SITE:

(i) THE ABILITY TO PROVIDE MECHANICAL VENTILATION AND/OR CONTINUOUS POSITIVE AIRWAY PRESSURE FOR UP TO 24 HOURS;

(ii) PORTABLE X-RAY EQUIPMENT AND BLOOD GAS ANALYZER;

(iii) PEDIATRIC PHYSICIANS AND/OR NEONATAL NURSE PRACTITIONERS; AND

(iv) RESPIRATORY THERAPISTS, RADIOLOGY TECHNICIANS, LABORATORY TECHNICIANS AND SPECIALIZED NURSES WITH EXPERIENCE CARING FOR PREMATURE INFANTS.

(2) INITIATION OF SCN SERVICES MEANS THE ESTABLISHMENT OF AN SCN AT A LICENSED SITE THAT HAS NOT HAD IN THE PREVIOUS 12 MONTHS A DESIGNATED SCN OR DOES NOT HAVE A VALID CON TO INITIATE AN SCN.

(a) IN ADDITION TO THE REQUIREMENTS OF SECTION 9(1), AN APPLICANT PROPOSING TO INITIATE AN SCN SERVICE SHALL HAVE A WRITTEN CONSULTING AGREEMENT WITH A HOSPITAL WHICH HAS AN EXISTING, OPERATIONAL NICU. THE AGREEMENT MUST SPECIFY THAT THE EXISTING SERVICE SHALL, FOR THE FIRST TWO YEARS OF OPERATION OF THE NEW SERVICE, PROVIDE THE FOLLOWING SERVICES TO THE APPLICANT HOSPITAL:

(i) RECEIVE AND MAKE RECOMMENDATIONS ON THE PROPOSED DESIGN OF SCN AND SUPPORT AREAS THAT MAY BE REQUIRED;

(ii) PROVIDE STAFF TRAINING RECOMMENDATIONS FOR ALL PERSONNEL ASSOCIATED WITH THE NEW PROPOSED SERVICE;

(iii) ASSIST IN DEVELOPING APPROPRIATE PROTOCOLS FOR THE CARE AND TRANSFER, IF NECESSARY, OF PREMATURE INFANTS;

(iv) PROVIDE RECOMMENDATIONS ON STAFFING NEEDS FOR THE PROPOSED SERVICE; AND

(v) WORK WITH THE MEDICAL STAFF AND GOVERNING BODY TO DESIGN AND IMPLEMENT A PROCESS THAT WILL ANNUALLY MEASURE, EVALUATE, AND REPORT TO THE MEDICAL STAFF AND GOVERNING BODY THE CLINICAL OUTCOMES OF THE NEW SERVICE, INCLUDING:

(A) MORTALITY RATES;

(B) MORBIDITY RATES INCLUDING INTRAVENTRICULAR HEMORRHAGE (GRADE 3 AND 4), RETINOPATHY OF PREMATURITY (STAGE 3 AND 4), CHRONIC LUNG DISEASE (OXYGEN DEPENDENCY AT 36 WEEKS GESTATION), NECROTIZING ENTEROCOLITIS, PNEUMOTHORAX, NEONATAL DEPRESSION (APGAR SCORE OF LESS THAN 5 AT FIVE MINUTES); AND

(C) INFECTION RATES.

(b) SCN SERVICES SHALL BE PROVIDED IN UNLICENSED SCN BEDS LOCATEDWITHIN THE HOSPITAL OBSTETRICAL DEPARTMENT OR NICU SERVICE. UNLICENSED SCN BEDS ARE NOT INCLUDED IN THE NICU BED NEED.

(3) REPLACEMENT OF SCN SERVICES MEANS NEW PHYSICAL PLANT SPACE BEING DEVELOPED THROUGH NEW CONSTRUCTION OR NEWLY ACQUIRED SPACE (PURCHASE, LEASE OR DONATION), TO HOUSE AN EXISTING SCN SERVICE.

(a) IN ADDITION TO THE REQUIREMENTS OF SECTION 9(1), AN APPLICANT PROPOSING A REPLACEMENT SCN SERVICE SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(i) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO REPLACE THE ENTIRE HOSPITAL.

(ii) THE APPLICANT CURRENTLY OPERATES THE SCN SERVICE AT THE CURRENT LICENSED SITE.

(iii) THE PROPOSED LICENSED SITE IS IN THE SAME PLANNING AREA AS THE EXISTING LICENSED SITE.

(4) ACQUISITION OF AN SCN SERVICE MEANS OBTAINING POSSESSION AND CONTROL OF AN EXISTING SCN SERVICE BY CONTRACT, OWNERSHIP, LEASE OR OTHER COMPARABLE ARRANGEMENT.

(~~i~~a) IN ADDITION TO THE REQUIREMENTS OF SECTION 9(1), AN APPLICANT PROPOSING TO ACQUIRE AN SCN SERVICE SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(~~ii~~i) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO ACQUIRE THE ENTIRE HOSPITAL.

(~~iii~~i) THE LICENSED SITE DOES NOT CHANGE AS A RESULT OF THE ACQUISITION, UNLESS THE APPLICANT MEETS SUBSECTION 3.

Section ~~9~~10. Additional requirements for applications included in comparative reviews.

Sec. 109. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), and which have the highest number of points when the results of subsection (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an application is submitted to the Department. If 2 or more qualifying projects are determined to have an identical number of points and each operates a NICU at the time an application is submitted to the Department, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the submission date and time, as determined by the Department when submitted.

(a) A qualifying project will have points awarded based on the geographic proximity to NICU services, both operating and CON approved but not yet operational, in accordance with the following schedule:

Proximity	Points Awarded
Less than 50 Miles to NICU service	0
Between 50-99 miles to NICU service	1
100+ Miles to NICU service	2

(b) A qualifying project will have points awarded based on the number of very low birth weight infants delivered at the applicant hospital or the number of very low birth weight infants admitted or refused admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the number of qualifying projects. The number of points to be awarded to each qualifying project shall be calculated as follows:

(i) Each qualifying project shall document, for the 2 most recent years for which verifiable data are available, the number of very low birth weight infants delivered at an applicant hospital, or admitted to an applicant's NICU, if an applicant operates a NICU, the number of very low birth weight infants delivered to expectant mothers transferred from an applicant's hospital to a hospital with a NICU, and the number of very low birth weight infants referred to an applicant's NICU who were refused admission due to the lack of an available NICU bed and were subsequently admitted to another NICU.

(ii) Total the number of very low birth weight births and admissions documented in subdivision (i) for all qualifying projects.

(iii) Calculate the fraction (rounded to 3 decimal points) of very low birth weight births and admissions that each qualifying project's volume represents of the total calculated in subdivision (ii).

(iv) For each qualifying project, multiply the applicable fraction determined in subdivision (iii) by the total possible number of points.

(v) Each qualifying project shall be awarded the applicable number of points calculated in subdivision (iv).

(c) An applicant shall have 1 point awarded if it can be demonstrated that on the date an application is submitted to the Department, the licensed site at which NICU services/beds are proposed has on its active medical staff a physician(s) board certified, or eligible to be certified, in maternal/fetal medicine.

(d) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

Hospital Indigent Volume	Points Awarded
0 - <6%	0.2
6 - <11%	0.4
11 - <16%	0.6
16 - <21%	0.8
21 - <26%	1.0
26 - <31%	1.2
31 - <36%	1.4
36 - <41%	1.6
41 - <46%	1.8
46% +	2.0

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Hospital and Health Plan Reimbursement Division pursuant to Section 7 of the Medical Provider manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(3) Submission of conflicting information in this section may result in a lower point reward. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Section ~~10~~11. Requirements for ~~approval for all applicants~~MEDICAID PARTICIPATION

Sec. ~~10~~11. An applicant for NICU SERVICES AND SCN SERVICES shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section ~~11~~12. Project delivery requirements ~~--~~ AND terms of approval ~~for all applicants~~

Sec. ~~11~~12. ~~(1)~~ An applicant shall agree that, if approved, the ~~project~~ NICU AND SCN SERVICES shall be delivered in compliance with the following terms of ~~CON~~ approval:

(~~a~~1) Compliance with these standards.

~~(b) Compliance with applicable operating standards.~~

(~~c~~2) Compliance with the following applicable quality assurance standards FOR NICU SERVICES:

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.
(b) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.
(c) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.
(d) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.
(e) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.
(f) An applicant shall develop and implement a system for discharge planning.
(g) A board certified neonatologist shall serve as the director of neonatal services.
(h) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.
(i) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.
(j) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.

(3) COMPLIANCE WITH THE FOLLOWING APPLICABLE QUALITY ASSURANCE FOR SCN SERVICES:
(a) AN APPLICANT SHALL COORDINATE ITS SERVICES WITH OTHER PROVIDERS OF OBSTETRICAL, PERINATAL, NEONATAL AND PEDIATRIC CARE IN ITS PLANNING AREA, AND OTHER PLANNING AREAS IN THE CASE OF HIGHLY SPECIALIZED SERVICES.
(b) AN APPLICANT SHALL DEVELOP AND IMPLEMENT A SYSTEM FOR DISCHARGE PLANNING.
(c) A BOARD CERTIFIED NEONATOLOGIST SHALL SERVE AS THE SCN PROGRAM DIRECTOR.
(d) THE HOSPITAL CONTINUES TO HAVE THE FOLLOWING CAPABILITIES AND PERSONNEL CONTINUOSLY AVAILABLE AND ON-SITE:
(i) THE ABILITY TO PROVIDE MECHANICAL VENTILATION AND/OR CONTINUOUS POSITIVE AIRWAY PRESSURE FOR UP TO 24 HOURS.
(ii) PORTABLE X-RAY EQUIPMENT AND BLOOD GAS ANALYZER;
(iii) PEDIATRIC PHYSICIANS AND/OR NEONATAL NURSE PRACTITIONERS; AND
(iv) RESPIRATORY THERAPISTS, RADIOLOGY TECHNICIANS, LABORATORY TECHNICIANS AND SPECIALIZED NURSES WITH EXPERIENCE CARING FOR PREMATURE INFANTS.

(~~i~~4) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:
~~An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:~~
(~~A~~a) THE NICU AND SCN SERVICES shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.
(~~B~~b) THE NICU AND SCN SERVICES SHALL not deny NICU and SCN services to any individual based on ability to pay or source of payment.~~;~~
(~~B~~c) THE NICU AND SCN SERVICES SHALL provide NICU and SCN services to any individual based on clinical indications of need for the services.~~;~~
(~~C~~d) THE NICU AND SCN SERVICES SHALL maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.
(~~E~~e) Compliance with selective contracting requirements shall not be construed as a violation of this term.

~~(ii) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.~~

~~(iii) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.~~

~~(iv) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.~~

~~(v) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.~~

~~(vi) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.~~

~~(vii) An applicant shall develop and implement a system for discharge planning.~~

~~(viii) A board certified neonatologist shall serve as the director of neonatal services.~~

~~(ix) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.~~

~~(x) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.~~

~~(xi) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.~~

(5) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

(~~xii~~a) The ~~applicant~~ NICU AND SCN SERVICES shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, THROUGH-PUT SCHEDULES, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(i) THE SCN SERVICES SHALL PROVIDE DATA FOR THE PERCENTAGE OF TRANSFERS TO A HIGHER LEVEL OF CARE, HOURS OF LIFE AT THE TIME OF TRANSFER TO A HIGHER LEVEL OF CARE, ADMISSIONS TO THE SCN AT LESS THAN 32 WEEKS GESTATION, NUMBER OF ADMISSIONS REQUIRING RESPIRATORY SUPPORT GREATER THAN 24 HOURS IN DURATION, NUMBER OF ADMISSIONS TO SCN, AND RATES OF MORBIDITY INCLUDING: INTRAVENTRICULAR HEMORRHAGE (GRADE 3 AND 4), RETINOPATHY OF PREMATURITY (STAGE 3 AND 4), CHRONIC LUNG DISEASE (OXYGEN DEPENDENCY AT 36 WEEKS GESTATION), NECROTIZING ENTEROCOLITIS, AND PNEUMOTHORAX.

(~~xiii~~b) The ~~applicant~~ NICU AND SCN SERVICES shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the initiation, expansion, replacement or relocation of the NICU service is placed in operation and such notice shall be submitted to the Department~~ OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

~~(xivC) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.~~

(6) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

~~**Section 12. Planning areas**~~

~~Sec. 12. The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group of counties as follows:~~

~~**Planning Areas Counties**~~

~~1 Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne~~

~~2 Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee~~

~~3 Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren~~

~~4 Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa~~

~~5 Genesee, Lapeer, Shiawassee~~

~~6 Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola~~

~~7 Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford~~

~~8 Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft~~

Section 13. Department inventory of beds

Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning area.

Section 14. Effect on prior CON review standards; comparative reviews

Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care ~~and Special Newborn Nursery~~ Services/Beds approved by the Commission on ~~September 18, 2007~~ JUNE 10, 2010 and effective on ~~November 13, 2007~~AUGUST 12, 2010.

(2) Projects reviewed under these standards shall be subject to comparative review except for:

(a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;

(b) The designation of beds for NICU services being relocated pursuant to Section 6 of these standards; or

(c) Beds requested under Section ~~5~~7(2).

(d) SCN SERVICES REQUESTED UNDER SECTION 9.

APPENDIX A

CON REVIEW STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/BEDS

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX B

The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group of counties as follows:

Planning Areas	Counties
1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
5	Genesee, Lapeer, Shiawassee
6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford
8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft

Comments from Ed made July 31:
Urinary Extracorporeal Shock Wave Lithotripsy (UESWL)
Certificate of Need (CON) Workgroup
Summary Report from June 27 and July 31, 2013 Meetings

Workgroup Charge: The UESWL workgroup will determine if the service (UESWL) should be deregulated, or if continuing to regulate, review the volume criteria for expansion.

First meeting: June 27, 2013
Second meeting: July 31, 2013

Present: See attached lists of attendees for both meetings.

Summary: At the June 27 meeting, Ed Goldman outlined the history of UEWSL in Michigan under CON and the charge for the workgroup. The charge is to determine if the service (UESWL) should be deregulated, or if continuing to regulate, review the volume criteria for expansion.

The group agreed that the plan is to finish workgroup meetings and submit a report to the Commission at their September meeting.

Following introductions and background, each participant gave their opinion. Discussion followed.

Participants acknowledged the CON Commission should always be on the lookout for areas no longer in need of regulation, but in this case, participants believe the Commission needs to be concerned about possible over use and increased costs through purchase of un-needed machines.

The discussion continued at the July 31 meeting. Topics included emergency regulation, expansion requirements, temporary CON for machine repair and need for continued regulation.

Workgroup consensus was that UESWL ought to continue to be regulated for the following reasons:

1. Access is appropriate, and there is existing capacity in the system to allow for both scheduled and unscheduled treatments.

2. Costs are lower in Michigan than States where there is no regulation.

3. Limiting the number of machines in the State contributes to quality since this keeps the number of treatments high so radiologic technologists are able to keep their skills at a high level.

4. De-regulation could result in additional machines which would not add necessary access but could diminish quality and may even result in un-necessary treatment for small stones in order to recover the cost of the machines.

Thus, while participants understood and acknowledged the need for on-going review and the need to only regulate high cost issues, they believed that UESWL was not yet ready for de-regulation.

Discussion then turned to any possible changes to the existing regulations. There was a question about the number of procedures necessary for expansion with additional discussion regarding a lower expansion threshold for rural/micropolitan statistical area counties. There was no consensus or data/documentation to support any suggested changes at this time, but if data is presented to the Commission in the future, expansion for access purposes may be a possibility. All participants agreed there was existing capacity in the existing system, and new machines are not currently a high priority.

There was discussion about the need for machines to fill in while maintenance was being performed, and the possibility that the standards may need an emergency or maintenance standard. It was clarified that emergency CONs were covered in statute and administrative rules and are not a topic for this workgroup.

The work group raised the question of a need for requirements for temporary replacement when a machine is being serviced. The workgroup agreed that this is an issue for all equipment and concluded that this could be a topic for future discussion by the Commission since this would involve a possible broader change to all applicable CON review standards.

Participants submitted data supporting their claims concerning cost, access and quality. Participants supplied information prior to the July 31st meeting. Participant information is attached to and made a part of this report.

Following receipt of materials, a draft report along with the participants submissions were posted on line for review, and the July 31st meeting was scheduled.

At the July 31st meeting, the participants reviewed this report, made changes and agreed that it reflected the opinions and conclusions of the workgroup. Thus, the workgroup submits this report to the Commission for its review.

Respectfully Submitted,
Edward Goldman,
Head of the UESWL workgroup.

SIGN IN LOG

Meeting Date: Thursday, June 27, 2013
Meeting Purpose: UESWL Workgroup Meeting

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Voluntary Sign In.
MCL 15.263 "Sec. 3(4) A person shall not be required as a condition of attendance at a meeting of a public body to register or otherwise provide his or her name or other information or otherwise to fulfill a condition precedent to attendance."

SIGN IN LOG

Meeting Date: Thursday, June 27, 2013
Meeting Purpose: UESWL Workgroup Meeting

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Voluntary Sign In.
MCL 15.263 "Sec. 3(4) A person shall not be required as a condition of attendance at a meeting of a public body to register or otherwise provide his or her name or other information or otherwise to fulfill a condition precedent to attendance."

SIGN IN LOG

Meeting Date: Wednesday, July 31, 2013
Meeting Purpose: UESWL Workgroup Meeting

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Voluntary Sign In.
MCL 15.263 "Sec. 3(4) A person shall not be required as a condition of attendance at a meeting of a public body to register or otherwise provide his or her name or other information or otherwise to fulfill a condition precedent to attendance."

SIGN IN LOG

Meeting Date: Wednesday, July 31, 2013
Meeting Purpose: UESWL Workgroup Meeting

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Voluntary Sign In.
MCL 15.263 "Sec. 3(4) A person shall not be required as a condition of attendance at a meeting of a public body to register or otherwise provide his or her name or other information or otherwise to fulfill a condition precedent to attendance."

URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

WORKGROUP CHARGE

Approved by the Certificate of Need (CON) Commission on January 29, 2013

The UESWL workgroup will determine if the service (UESWL) should be deregulated, or if continuing to regulate, review the volume criteria for expansion.

To: The Michigan Department of Community Health ("**Department**")
From: American Kidney Stone Management, Ltd. ("**AKSM"**)
Re: Materials Regarding the Department's recommendation to deregulate Urinary Extracorporeal Shock Wave Lithotripsy ("**UESWL**") Services
Date: July 24, 2013

AKSM respectfully provides the following Workgroup materials with respect to the Department's recommendation to deregulate UESWL.

AKSM agrees with the Workgroup's recommendation to continue regulation based on data derived from its experience as a national provider and manager of UESWL services and its management of Greater Michigan Lithotripsy, LLC ("**GML**"), which oversees three mobile UESWL Routes in Michigan.

AKSM also recommends: (i) modification of the UESWL services expansion requirements to provide greater elasticity to accommodate the needs of patients, physicians and facilities; and (ii) refinement of the emergency CON requirements to avoid cancellation and rescheduling of patient treatments in the event a UESWL unit requires non-routine maintenance or repairs.

I. AKSM AGREES WITH THE WORKGROUP RECOMMENDATION TO MAINTAIN UESWL REGULATION AND CERTIFICATE OF NEED ("CON") REQUIREMENTS.

A. QUALITY AND SAFETY

1. Radiation Technologists

a. UESWL is a surgical procedure performed by physicians with specialized technical assistance from Radiation Technologists ("**Technologists**"). For safe, efficient and effective UESWL treatment, Technologists must be able to:

- properly and quickly visualize and position the urinary calculus ("**Stone**").
  - "… accurate stone localization and targeting, especially using a lithotripter with a narrow focal zone of 6.5mm, are necessary for success". Variation in Clinical Outcome Following Shock Wave Lithotripsy *The Journal of Urology 163,* 721-725 (2000) – ***See Exhibit 1.***

- apply gel to effectively couple the patient to the water filled bellows in the UESWL equipment to enable the shock waves to be transmitted into the body. The coupling zone is not generally visible to the Technologist. Air pockets in the coupling area

block the shock wave delivery which reduces the effectiveness of Stone disintegration.

- "Air bubbles in coupling media used during SWL procedures create acoustic interfaces that impeded the efficiency of shock wave transmission, and it has been demonstrated that manually displacing macroscopic air bubbles can improve shock wave efficacy." Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy *Radiologic Technology* 80, 20-24 (2008) – ***See Exhibit 2***.
- See also Monitoring the Coupling of the Lithotripter Therapy Head with Skin during Routine Shock Wave Lithotripsy with a Surveillance Camera and Coupling graphic. *The Journal of Urology 187,* 157-163 (2012) – ***See Exhibits 3 and 4***.

- properly pause the UESWL equipment between priming shocks and treatment to reduce tissue damage.
  - "Our findings also suggest that the interval between the initial shocks and the clinical dose of SWs [shock waves], in our one-step ramping protocol, is important for protecting the kidney against injury." Effect of Initial Shock Wave Voltage on Shock Wave Lithotripsy-Induced Lesion Size During Step-Wise Voltage Ramping *BJU International* 103, 104-107 (2008) - ***See Exhibit 5***.
  - See Pause for the Cause graphic BJU *Int.* 103(1), 104-7 (2009) – ***See Exhibit 6***.

b. The learning curve for UESWL Technologists is steep and to become proficient in the necessary skills and techniques, a Technologist must practice frequently.

- Studies show that the more experience the Technologist has, the more effective the UESWL treatment.
  - "Efficacy with SWL, as measured by stone-free rates, improved with increasing experience of the radiographer. Ongoing supervision and mentorship might be helpful in the first year of service". ". . . efficacy progressively increases from the first year of CRLT experience with SWL procedures to the third year of experience." Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy *Radiologic Technology* 80, 20-24 (2008) – ***See Exhibit 2***.
  - ". . . efficacy progressively increases from the first year of CRLT experience with SWL procedures to the third year of experience." Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy – ***See Exhibit 2***.
  - See also Litho Tech Learning curve graphic (2008)*Radiologic Technology* 80, 20-24 – ***See Exhibit 7.***

2. <u>Regulation Enhances Patient Care and Safety.</u>

a. Due to CON regulation of UESWL in Michigan, lithotripsy providers in this state have both the opportunity and the legal obligation to perform a greater number of

treatments than in non-regulated states. As a result, our Technologists are able to focus exclusively on UESWL and to provide assistance on a great number of treatments. This practice allows our Technologists to develop and retain the critical skills described in Item 1.

For example, GML Technologists:

- are dedicated exclusively to UESWL;
- have an average of 4+ years UESWL experience;
- provide, on average, treatment assistance on 680 UESWL patients per year; and
- receive annual and periodic training by AKSM, a national leader in UESWL services.

3. <u>Deregulation Will Jeopardize Patient Care and Safety.</u>

a. Without CON regulation, higher volume facilities can reasonably be expected to purchase their own UESWL machines.

b. Because even the highest volume facilities will not have sufficient Stone volume to ensure full time Technologist utilization, facilities will assign Technologists who are part-time or tasked with other duties to perform UESWL.

c. Technologists who are not dedicated to UESWL and/or not performing high volumes of UESWL treatments cannot develop and maintain the critical skills described above. The lack of skilled Technologists will reduce the effectiveness of UESWL treatment and jeopardize patient safety without a reduction in cost (See B. below) or an increase in access (See C. below).

d. Facilities that remain on existing mobile routes will be served by less proficient technologists, because treatment volumes will necessarily decrease due to proliferation.

B. <u>COST</u>

1. <u>Proliferation will not reduce costs.</u>

a. GML's average UESWL contract charge in Michigan is on par with AKSM's national average UESWL contract charge. ***See Exhibit 8***.

b. GML's average UESWL contract charge in Michigan is already lower than the average UESWL contract charge of AKSM owned or managed UESWL providers in deregulated neighboring states. ***See Exhibit 8***.

2. Proliferation may increase costs.

a. The proliferation of UESWL services can be expected to cause costs to increase as facilities and vendors entering the market will not have the efficiency and expertise that the current CON providers have.

b. Facilities purchasing UESWL equipment will:

- incur costly upfront UESWL equipment costs between $500,000 and $1 million, as well as incurring costly, but necessary, annual service and maintenance costs to treat Stones that are already being treated with the existing UESWL equipment. This will result in an unnecessary capital expenditure and diversion of funds from other needed healthcare services; and

- not effectively utilize the UESWL equipment or UESWL personnel resulting in increased cost.

C. ACCESS

1. Deregulation will not improve access.

a. Currently all patients requiring UESWL are able to receive treatment.

b. The three GML mobile machines managed by AKSM have, on average, slots available daily to provide UESWL services.

2. Deregulation may reduce access.

a. Proliferation can be expected to result in a loss of utilization (treatment volumes) of current UESWL providers and, therefore, a reduction in the number of UESWL Technologists and machines.

b. It is likely machines will be purchased by facilities in urban areas.

c. The potential reduction of availability of the current UESWL providers coupled with the likelihood that Facilities that purchase UESWL machines will be in urban areas may result in a loss of access to UESWL in smaller and rural locations.

II. AKSM RECOMMENDS MODIFICATION OF THE EXPANSION REQUIREMENTS TO PROVIDE ELASTICITY TO ACCOMMODATE PATIENT NEEDS.

A reduction in the number of procedures per UESWL unit required for a services provider to add an additional unit, would provide elasticity to ensure urgent cases can be accommodated in a timely fashion without jeopardizing the benefits regulation has brought to the State.

Therefore, AKSM recommends a minor edit to Section 8 of the CON Review Standards for UESWL Services, entitled "Requirements for approval to expand an existing UESWL service", by making the change marked below to the first sentence of Sub-section 8 (1):

> "All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of a least ~~1,800~~ 1,200 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data."

III. AKSM RECOMMENDS REFINING THE EMERGENCY CON REQUIREMENT FOR REPLACEMENT OF UESWL EQUIPMENT.

A provider whose equipment requires non-routine repairs can face days or weeks without the equipment while the original equipment is being fixed and the replacement equipment awaits an emergency CON. This results in the UESWL services provider being forced to cancel and reschedule patient treatments. To alleviate delays in patient treatment caused by non-routine equipment repairs, AKSM recommends adding a new section to the CON Review Standards for UESWL Services.

The new section would provide that the Department will issue an emergency CON for replacement UESWL equipment within one business day of request if:

- the CON holder stipulates the following:

  1. the emergency CON is for an UESWL unit that is a temporary replacement for a unit being serviced;

  2. the original unit and the replacement unit will not be utilized at the same time; and

  3. the replacement unit will not be used for more than thirty (30) days.

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VARIATION IN CLINICAL OUTCOME FOLLOWING SHOCK WAVE LITHOTRIPSY

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From the Urolithiasis Program, Division of Urology, The University of Toronto, Toronto, Ontario, Canada

ABSTRACT

Purpose: We measure and compare operator specific success rates of extracorporeal shock wave lithotripsy (ESWL*) performed by 12 urologists in 1 unit to determine interoperator variation.

Materials and Methods: From January 1, 1994 to September 1, 1997 a total of 5,769 renal and ureteral stones received 9,607 ESWL treatments by 15 urologists with a Dornier MFL 5000* lithotriptor. The 3-month followup data are available for 4,409 stones. Outcome measures consisted of patient demographics, stone characteristics, technical details of lithotripsy, and stone-free and success rates by treating urologists.

Results: Treatment results were analyzed for 12 urologists (surgeons A to L) who treated more than 100 stones each, totaling 4,244 with followup information available. Mean stone-free and success rates were 50.6% and 72.3%, respectively. Surgeon A had significantly higher stone-free and success rates of 56.2% and 76.7%, respectively ($p < 0.05$), with treatment results from 877 stones, which was a significantly higher number than others ($p < 0.05$). Significant differences existed in mean number of shocks delivered among urologists ($p = 0.0001$), with surgeons A and J delivering the highest mean numbers (2,317 and 2,801, respectively). There was no difference in treatment duration ($p = 0.75$) but variation existed among urologists in terms of mean maximum treatment voltage ($p = 0.0001$). Mean fluoroscopy time at 4.1 minutes was higher for surgeon A than others ($p < 0.05$). Mean complication rate following ESWL was 4.9% with no difference among urologists ($p = 0.175$). Re-treatment was required in 21.7% of cases and surgeon A had the lowest rate (15.9%, $p < 0.05$).

Conclusions: We demonstrated clinically and statistically significant intra-institutional differences in success rates following ESWL. The best results were obtained by the urologist who treated the greatest number of patients, used a high number of shocks and had the longest fluoroscopy time. Accurate targeting is crucial when using a lithotriptor, such as the Dornier MFL 5000, with a narrow focal zone of 6.5 mm. in diameter. Other centers should be encouraged to develop similar programs of outcome analysis in an attempt to improve performance.

KEY WORDS: lithotripsy, treatment outcome, benchmarking, comparative study, kidney calculi

With its low morbidity[1] and acceptable success rate extracorporeal shock wave lithotripsy (ESWL) has become the preferred treatment for stone disease by patients and urologists.[1–3] Benchmarking comparisons of treatment results by center and specific device have been reported[4–7] but to our knowledge those by individual operator at 1 center are lacking. Outcomes research in cardiac surgery reported mortality rates following coronary artery bypass by individual surgeon and respective surgical volume.[8] Local recurrence and disease specific survival for colorectal cancer surgery were improved with colorectal surgical subspecialty training and higher surgical volume.[9] Houghton cited positive and negative studies of the relationship between volume and outcome, and emphasized that it varies for different conditions and operative procedures.[10] Outcome analysis has been a controversial but apparently effective tool of quality assessment and improvement but there are few reports for urological procedures.

Benchmarking is a formalized approach to comparative care process analysis.[11] A fundamental assumption of outcome analysis is that patient outcomes vary according to the quality of care.[12] With fiscal accountability it is important to evaluate the cost and effectiveness, and monitor the quality of medical care.[13] By measuring variation in outcome rates among surgeons and/or institutions with adjustment for possible differences in patient characteristics it is possible to identify areas for quality improvement strategies.[13]

An analysis of interoperator variation in success following ESWL has not been reported to our knowledge. We report our experience with 5,769 renal and ureteral stones treated during a 4-year period, with 3-month followup in 58.5%. We measure and compare the operator specific success rates of ESWL performed by 12 urologists at 1 unit to determine interoperator variation.

MATERIALS AND METHODS

From January 1, 1994 to September 1, 1997, a total of 5,769 renal and ureteral stones were treated and studied prospectively at the E. C. Bovey Lithotripsy Unit at the University of Toronto. Lithotripsy was performed by 15 urologists who were assigned day long sessions. Staffing of the unit was done on a daily rotational basis. All procedures were performed on an outpatient basis. Data on patient age and gender, and size and location of stone(s) were collected for each urologist and stored in a lithotripsy stone tracking database.

All treatments were performed with a Dornier MFL 5000 lithotriptor. The treatment protocol has been previously described.[14, 15] Double pigtail ureteral stents were inserted in patients with high grade obstruction, a solitary kidney and stones larger than 15 mm. in diameter. Stones larger than 25 mm. were considered too large for ESWL. Although more

Accepted for publication October 15, 1999.
* Dornier Medical Systems, Inc., Marietta, Georgia.

than 1 stone may have been treated during 1 session, each was tracked independently and the results were reported separately. Patients received intravenous analgesic sedation administered by an anesthesiologist. Treatment was terminated when complete fragmentation of the stone(s) was identified on fluoroscopy and confirmed by a magnified fluoroscopic spot film, or a maximum number of shocks for the kidney or ureter had been delivered. Our guidelines for treatment specify a maximum of 3,000 and 4,000 shocks per session for renal and ureteral stones, respectively. The number of stones treated, number of re-treatments, number of shocks, maximum energy used (kV.), fluoroscopy time (minutes) and treatment duration (minutes from first to last shock) were recorded.

Patient followup at our clinic was scheduled 2 weeks and 3 months after the last ESWL. Patients living more than a 1-hour drive from the unit were followed by the referring urologists, who were sent a detailed outcomes questionnaire. Treatment results were evaluated with plain abdominal x-ray and/or renal tomogram for renal calculi and abdominal x-ray or excretory urogram for ureteral stones. Films were reviewed by a urologist who may or may not have been the treating urologist, and a nurse clinician and a radiologist for the first half of the study period. Only patients with symptomatic fragments or fragments greater than 5 mm. were re-treated. Residual stone sizes were recorded by actual stone dimension so that treatment results could be determined with various definitions for success. Treatment was considered a success if the patient was stone-free or had asymptomatic fragments less than 4 mm. at 3-month followup. All post-ESWL complications were recorded, including hospitalization, pain requiring a visit to the emergency room, fever (temperature greater than 38C), documented perirenal hematoma and the need for a ureteral stent or percutaneous nephrostomy. Data were collected prospectively and statistical software was used for analysis. Chi-square and logistic regression analyses were used to test significant individual variation in the overall success and stone-free rates, and with respect to stone location, stone size and by year of treatment.

RESULTS

During the study period 5,769 stones were treated and 9,607 ESWL treatments were performed. Male-to-female ratio was 1.9:1. Average age was 50.3 years (range less than 1 to 91) for men and 47.9 (range less than 1 to 94) for women. One ESWL session was performed for 65.3% of stones, 2 for 19.4%, 3 for 7.7%, 4 for 3.7% and greater than 4 for 3.9%. The 3-month followup data were available for 4,244 stones. Of the stones 70.7% were renal and 29.3% were ureteral, and 54.9% were less than 10 mm., 42.6% were 10 to 20 mm. and 2.5% were greater than 20 mm. Of the 15 urologists who treated more than 100 patients each 12 performed 78.5% of the procedures. Treatment results are shown in table 1. Stone distribution by size and location for each urologist is shown in table 2.

Mean number of shocks per treatment was 2,125 overall, and 1,975 for renal and 2,291 for ureteral stones. There was a significant difference in the number of shocks by stone location ($p < 0.0001$). Surgeon A delivered more shocks than surgeons B to F, H and M ($p < 0.05$). Mean fluoroscopy time was 2.9 minutes overall, and the same for renal and ureteral stones. There was a significant difference ($p < 0.05$) in mean fluoroscopy times among surgeons, with surgeon A having a significantly higher time than all others ($p < 0.05$). Mean treatment duration was 51.2 minutes overall, and 50.9 and 49.5 for renal and ureteral stones, respectively (not significantly different, $p > 0.05$). There was no significant difference in mean treatment duration among urologists ($p > 0.05$). Mean maximum voltage was 24.3 kV. overall, and 24.0 and 24.8 for renal and ureteral stones, respectively. There was a significant difference in the mean maximum energy use for the 2 types of stones ($p < 0.05$). For renal stones the highest mean voltage (24.3 kV.) was used by surgeon B and the lowest (23.4) was used by surgeon J. For ureteral stones the highest energy (25.1 kV.) was used by surgeons E and M, and the lowest (24.3) was used by surgeons D and G. There was a significant difference in mean maximum voltage ($p < 0.05$).

The stone-free rate at 3-month followup was 50.6% overall (range 41.1% to 56.2%), with significant differences among urologists ($p = 0.006$). Surgeon A had the highest overall stone-free rate (56.2%), which was significantly higher than that of surgeons B to E and H to L ($p < 0.05$). Stone-free rates were not statistically different for surgeons F and G (53.8% and 50.5%) compared to surgeon A ($p > 0.05$).

Overall success rate was 71.9% and 73.2% for renal and ureteral stones, respectively (table 3). There was a difference among urologists for renal and ureteral stone-free status ($p = 0.0001$). The stone-free rate for renal stones was the highest (51.4%) for surgeon A, and the rates for ureteral stones were highest for surgeons K and A (74.2% and 66.9%, respectively). The stone-free rate by stone location was higher for surgeon A than for surgeons B to E, H, J and L ($p < 0.05$). The success rate, defined as asymptomatic fragments less than 4 mm., was also significantly different by urologist and stone location ($p = 0.0403$). Surgeon A had the highest success

TABLE 1. *Treatment results and technical data following lithotripsy*

	Surgeon												Overall
	A	B	C	D	E	F	G	H	I	J	K	L	
No. pts. treated	1,450	1,059	762	722	646	550	354	590	372	252	194	248	7,547
Mean shocks (renal stones)	2,059	1,754	1,945	927	1,832	1,769	1,989	1,947	2,180	2,484	2,229	1,810	1,975
Mean shocks (ureteral stones)	2,665	2,165	2,390	2,405	1,999	2,084	2,341	1,832	2,214	3,248	1,941	1,538	2,291
Mean shocks (overall)	2,317	1,949	2,074	2,169	1,913	2,005	2,261	1,892	2,285	2,802	2,170	1,722	2,126
Mean mins. fluoroscopy	4.1	2.5	2.8	2.7	2.2	2.9	2.1	3.1	2.7	2.9	2.3	2.9	2.9
Mean mins. duration	55.2	51.3	44.7	52.2	48.2	48.8	44.7	55.8	50.5	49.1	50.3	59.3	51.2
Mean max. voltage (kV)	24.2	24.7	24.1	24.0	24.5	24.3	23.9	24.3	24.6	24.0	24.3	24.3	24.3
% Followup	61.6	53.2	60	62.5	58.4	61.5	51.4	64.7	59.4	48.0	63.9	61.3	58.5
% Complications	4.3	3.4	5.0	5.5	4.5	4.7	7.1	7.1	6.8	2.5	4.9	2.6	4.9
% Re-treatment	15.9	26.2	23	23.7	24.3	20.6	21.9	22.9	23.6	18	21.9	23.5	21.7
% Stone-free:	56.2	50.4	48.6	47.9	48	53.8	50.5	49	49.3	46.3	47.2	41.1	50.6
1994	46.7	43.4	39.7	38.1	41	56.2	—	47.5	51.7	—	45.5	41.2	44.7
1995	56.9	55.5	61.4	46.5	56.7	51.3	59.3	48.8	56.1	—	46.7	41.2	53.2
1996	60.8	50	49.6	51.5	45.2	61.3	48.9	51.9	41.8	54.5	48.4	25.	52.5
1997	61.4	52.3	40.6	61.3	46.9	45.5	49.2	—	45.2	41.6	46.7	62.5	51.7
Less than 10 mm.	67.8	59	54.4	59.1	56.6	58.6	53.9	51.6	56.9	49.1	62.7	45.1	59
10–20 Mm.	43.8	39.1	44.4	34.5	34.5	50	46.7	47.3	38.4	43.3	32.8	39.5	42
Greater than 20 mm.	37	22.2	0	30	54.5	12.5	40	18.2	40	50	33.3	20	29
% Success*	76.7	71.8	70.5	70.1	69.8	72.2	68.1	69.9	75.6	76.9	73.2	67.8	72.3

* Stone-free and/or residual sand particles less than 2 mm. and/or asymptomatic particles less than 4 mm.

TABLE 2. *Stone distribution by size and location for each urologist*

Surgeon	% Renal Stones			% Ureteral Stones		
	Less than 10 Mm.	10–20 Mm.	Greater Than 20 Mm.	Less than 10 Mm.	10–20 Mm.	Greater Than 20 Mm.
A	32.5	33.6	2.9	20.0	10.8	0.2
B	34.6	28.4	1.4	23.8	11.5	0.2
C	35.0	35.9	2.0	17.7	9.0	0.4
D	38.8	35.0	1.6	16.0	8.0	0.7
E	42.2	28.9	2.4	16.4	9.5	0.5
F	38.8	29.6	2.4	16.3	13.0	0
G	37.4	28.6	2.7	18.7	12.6	0
H	39.8	28.0	2.6	18.6	10.7	0.3
I	39.4	28.5	2.3	19.5	10.4	0
J	30.6	36.4	2.5	16.5	13.2	0.8
K	35.8	37.4	1.6	12.2	12.2	0.8
L	32.2	40.1	3.3	14.5	9.9	0

For stones less than 10 versus 10 to 20 versus greater than 20 mm. $p = 0.001$, for renal versus ureteral stones $p = 0.001$ and among urologists $p = 0.068$.

TABLE 3. *Stone-free and success rates by stone location and size*

Size (mm.)	% Stone-Free	% Success
Renal:		
Less than 10	53.7	80
10–20	38.4	64.4
Greater than 20	28.1	43.8
Ureteral:		
Less than 10	67.8	79.6
10–20	51.1	63.6
Greater than 20	38.5	50

For stone-free versus success rates, renal versus ureteral stones and less than 10 versus 10 to 20 versus greater than 20 mm. $p = 0.001$.

rates for renal and ureteral stones (75.7% and 79%, respectively).

Stone-free rates for stones less than 10 mm., 10 to 20 mm. and greater than 20 mm. were 59%, 42% and 29%, respectively, and the success rates were 80%, 64% and 43.6%, respectively. There were significant differences by stone size in stone-free ($p = 0.0001$) and success ($p = 0.001$) rates among urologists. Stones less than 10 mm. were the most common and stone-free rates varied ($p < 0.05$), with surgeon A having the highest (67.8%). For stones 10 to 20 mm. surgeon F had the highest stone-free rate (50%), and for stones greater than 20 mm. surgeon E the highest (54.5%), although the smaller number of larger stones was such that these figures did not reach statistical significance. However, the overall stone-free rate by stone size was significantly higher for surgeon A than for surgeons B to E, H, I and L ($p < 0.05$). Similarly, the success rate by stone size was higher for surgeon A than for surgeons B to H ($p < 0.05$).

As 3-month followup represents the final result regardless of the number of treatments, the re-treatment rate is noteworthy. Of the 4,244 treated stones 78.3% required 1 and 21.7% required 2 or more treatments. The re-treatment rate was 21.7% overall, 21.5% for renal and 22.4% for ureteral stones, and 14.7% for those less than 10 mm., 29.8% for those 10 to 20 mm. and 50% for those greater than 20 mm. There was a significant difference ($p < 0.05$) among urologists for number of stone treatments required. Surgeons A and J had re-treatment rates significantly lower (15.9% and 18%) than others ($p < 0.05$). Surgeon B had the highest re-treatment rate (26.2%).

Mean stone-free rate for each year recorded from January 1 to December 31 was 44.7%, 53.2%, 52.5% and 51.7% for years 1994 to 1997, respectively. There was a significant difference among urologists for the stone-free rate by year ($p = 0.0012$) and a significant difference in mean stone-free rate by year ($p = 0.0108$). Surgeon A had improving stone-free rates of 44.7%, 56.9%, 60.8% and 61.4% during the 4-year period.

The overall complication rate following ESWL was 4.9%. There were no significant differences ($p > 0.05$) in the complication rate among urologists but rates were significantly different for renal and ureteral stones (5.5% and 3.4%, respectively, $p = 0.003$). There was no difference in the complication rate by stone size (4.9% overall, 4.6% for those less than 10 mm., 5.1% for those 10 to 20 mm. and 7.3% for those greater than 20 mm., $p = 0.385$). The overall percentage of stone treatments with followup was 58.5% and was significantly different among urologists ($p < 0.05$). Surgeon H had the highest followup rate (64.7%) and surgeon J had the lowest (48%).

Surgeon A results were analyzed to discover treatment variables that may predict success. Multivariate analysis suggested that the only characteristics predicting success were the number of shocks delivered and fluoroscopy time. The number of shocks for patients who became stone-free was 2,060, whereas those with failure to become stone-free received a significantly higher number (2,238, $p < 0.05$). Fluoroscopy time was not statistically different for surgeon A patients who became stone-free at 4.11 minutes and for those with failure to be stone-free at 4.15 minutes. There was no difference in lithotripsy complications in regard to the number of shocks or fluoroscopy time ($p > 0.05$).

DISCUSSION

We demonstrated a small but consistent variation in success rates following ESWL and an overall stone-free rate of 50.6% for all urologists. Bierkens et al reported similar stone-free rates (45%) in a multicenter comparative study of second generation lithotriptors.[4] Psihramis et al previously reported a stone-free rate of 55.7% overall at 3-month followup for all calculi, and 52% and 76%, respectively, for renal and ureteral stones.[14] One surgeon had a significantly higher stone-free rate of 56.2% compared to others, and rates were significantly different when stone location and size were considered ($p = 0.0001$). There was also a difference in the mean stone-free rate by year ($p = 0.0108$), suggesting that there is a measurable learning curve to ESWL.

The overall success rate 3 months following lithotripsy was 72.3%. Again, there were small but significant differences in the success rate by urologist for stone size and location ($p < 0.05$). As expected, stone location affected complication rates (mean 4.9). There was no difference based on the size of the stone but stents were inserted before ESWL on all larger stones (greater than 1.5 cm. in diameter).

There was a difference among the urologists for the number of shocks delivered ($p < 0.05$). Overall, renal stones received less shocks than ureteral stones ($p < 0.0001$). Mean fluoroscopy time was 2.9 minutes, with no difference for the 2 types of stones but significant differences among urologists ($p < 0.05$). Fluoroscopy time is defined as time spent by the operator visualizing and adjusting the position of the stone. Mean treatment duration was 51.2 minutes, with no difference for renal and ureteral calculi or among urologists ($p > 0.05$). Mean maximum voltage was 24.3 kV., with higher

voltages used for ureteral stones ($p < 0.05$), which may suggest that as fragmentation is less obvious in the ureter there is a tendency to increase the energy. The difference in mean maximum voltage among urologists ($p < 0.05$) did not translate into a difference in success as the difference in peak pressures obtained by increasing above 23 kV. is negligible using the MFL 5000 lithotriptor.

Surgeon L treated the second fewest number of stones (248), delivered the lowest number of shocks per stone (1,722), and had the lowest stone-free (41.1%) and success (67.8%) rates. Surgeon A treated the highest number of stones (1,450) with followup results for 60.6%, delivered more shocks than 7 others surgeons and had a stone-free rate of 56.2%, which was higher than 9 other surgeons ($p < 0.05$). Surgeon A had improving stone-free rates of 44.7%, 56.9%, 60.8% and 61.4% during the 4-year period. It is noteworthy that a clinical fellow performed the majority of the treatments during the first year (1994), which may account for the marked difference in this year. Mean fluoroscopy time was greater (4.1 minutes) for surgeon A than all others ($p < 0.05$), with no increase in treatment duration. This finding suggests that accurate stone localization and targeting, especially using a lithotriptor with a narrow focal zone of 6.5 mm., are necessary for success.

In the surgical literature few studies are devoted to outcomes analysis, particularly intra-institutional variation. In 1996 Clark reported a weak statistical correlation of volume to mortality after coronary artery bypass graft, although the results were not clinically relevant and surgeon specific data were lacking.[8] Surgical practice patterns also vary as evidenced by the geographic variation found in the rate of surgical procedures.[16–20] Furthermore, differences in outcome for surgical procedures exist between hospitals and individual surgeons.[10] Comparisons of ESWL treatment results by center and specific device have been reported, whereas to our knowledge there is only 1 report comparing treatment results by operator within 1 center. In 1995 Ilker et al reported that the results obtained by an experienced technician were just as reliable as those obtained by an experienced urologist using the Dornier MFL 5000.[21] It has been suggested that outcomes analysis at the local level may be useful in improving physician practice patterns.[22]

Analysis of this type requires research by unbiased investigators, and we attempted to reduce reporting bias on stone-free and success rates by having all radiographic films reviewed by a urologist who may or may not have been the treating urologist, a nurse clinician working at the lithotripsy center for the entire study duration and a radiologist. However, for logistical reasons from August 1995 to September 1997 the reported results were based on interpretation by the urologist and nurse clinician. Interobserver and intraobserver variability in x-ray review following ESWL has been reported.[23] Differences occurred 52% of the time among radiologists reporting on plain abdominal films and 24% by the same radiologist rereading the films. This difference among radiologists was decreased to 28% when plain abdominal films and tomograms were read together. Thus, our reporting of stone-free rates may be overestimated.[23]

Because our center is 1 of only 2 lithotripsy sites in the province of Ontario, covering a population of 12 million, patients who live more than 1 hour from the center are instructed to have followup performed by the referring urologist. This protocol would account for the high proportion of unknown treatment results (41.5%), which we attribute to lack of followup data submission by referring urologists. One could also argue that treating urologists, who know that a poor result was achieved with lithotripsy by seeing no fragmentation of the stone on initial treatment, may opt to refer the patient back to the referring urologist for other therapies. However, the percentage of patients followed did not correlate with success. The results of treatment were attributed to the first treating urologist. In some instances further ESWL treatments may not have been performed by the initial treating urologist but all attempts have been made to have patients re-treated by that urologist. In addition, stone composition was not recorded in our database, although Smith et al reported decreasing success rates following ESWL with increasing stone size and noted that treatment outcome was not influenced by stone composition.[1]

Clinical outcomes are strongly influenced by differences among patients as well as the standards of medical care.[13] In 1992 Manheim et al reported highly significant regional differences in Medicare hospital mortality which may have been related to important underlying differences in the quality of medical practice.[24] In an effort to provide quality health care the principles and techniques of modern industrial quality science should be applied.[25] Furthermore, discussion of identified outcomes, variations and best practice characteristics with the physicians involved is a powerful educational tool.[11] By measuring outcomes of individual urologists, variation may be observed that may lead to quality improvement strategies.

CONCLUSIONS

This prospective study demonstrates clinically and statistically significant intra-institutional variation in stone-free and success rates following ESWL. The best results appear to have been obtained by the urologist who treated the greatest number of patients, used a high number of shocks and had the longest fluoroscopy time. Accurate stone localization and targeting are crucial for success when using a lithotriptor with a small focal zone, such as the Dornier MFL 5000. Other centers should be encouraged to develop similar programs of outcome analysis to provide continuous feedback of information to surgeons in an attempt to improve performance.

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PEER REVIEW

Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy

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Introduction *The purpose of this study was to evaluate the impact of a radiographer's learning curve on extracorporeal shock wave lithotripsy (SWL) efficacy.*

Methods *Five registered technologists who were certified to assist in SWL procedures but had no prior lithotripter experience were evaluated during a 4-year period. Stone-free (no residual fragments on plain radiographic imaging), re-treatment and post-SWL procedure rates were evaluated for the first 3 years of radiographer employment.*

Results *The overall stone-free rate increased from 55% (efficiency quotient [EQ] 45) in the first year to 68% (EQ 50) in the third year. The treatment success rate for the lower ca* Exhibit 1 *the first year to 62% (EQ 44) in the third year. There was no difference in re-treatment or post-*

Conclusion *Efficacy with SWL, as measured by stone-free rates, improved with increasing experience of the radiographer. Ongoing supervision and mentorship might be helpful in the first year of service.*

Urinary stone disease is a common problem in America and costs more than $2 billion each year.[1] The most common treatment of stone disease is extracorporeal shock wave lithotripsy (SWL).[2] The administration of SWL relies on a partnership between the treating urologist and a registered technologist (R.T.) who has been certified in renal lithotripsy procedures. For the purposes of this article, this R.T. will be referred to as the certified renal lithotripsy technologist (CRLT).

The learning curve associated with new technologies recently has come under scrutiny.[3-5] When SWL first became widely available in the United States, certified SWL training centers were set up by the American Urological Association (AUA) to ensure that urologists practicing SWL had received appropriate training.[6] In 1990 the AUA began certifying R.T.s for renal lithotripsy procedures to improve the standard of stone treatment care. To qualify as a CRLT, R.T.s must pass written exams and observe at least 50 SWL procedures.[7] Once certified by the AUA, CRLTs may assist with SWL procedures. Experienced CRLTs have proven to be as effective as experienced urologists in treating stones.[8]

This study evaluates the impact of the CRLT's learning curve on stone treatment efficacy. The hypothesis to be tested is that SWL treatment success (ie, a stone-free result) depends on the experience of the CRLT.

Methods

A retrospective chart review was conducted. Five CRLTs with no prior lithotripter experience were trained in SWL and their success tracked over the course of 3 years. Each of these 5 CRLTs had prior experience in diagnostic radiology as radiographers and currently were employed full time as CRLTs. All lithotripter units and treatment sites were staffed on a rotating basis by the same 5 CRLTs. Patient positioning and radiographic targeting of the stone were performed in collaboration with the treating urologist. The urologist decided when to end the treatments based on radiographic evidence of adequate fragmentation.

The choice of anesthesia and treatment rate (gated vs ungated) was at the discretion of the urologist and the anesthesiologist. Biplanar digital imaging was used for stone localization with the Medstone STS lithotripter, a second-generation electrohydraulic lithotripter. The Medstone STS Lithotripter (Medstone International

Inc, Aliso Viejo, California) uses a centered, spark-gap ellipsoid design. It has a voltage range of 18 to 24 volts, a focus range of 1.4 to 3 cm and a throw (F1-F2) of 17 cm.

Outcome reporting was conducted by a standardized mailing to the treating urologists as part of an ongoing quality assurance program. They documented treatment parameters, reported follow-up that included plain abdominal radiography to calculate stone-free rate (no residual fragments), recorded the need for auxiliary procedures or re-treatment and noted any complications. Re-treatment rates are defined as the need for a second SWL session; secondary procedures included ureteral stenting or endoscopic procedures for retained fragments.

Stone-free (no residual fragments on plain radiographic imaging at 1-month follow-up), re-treatment and post-SWL procedure rates were evaluated for the first 3 years of each CRLT's employment. Overall treatment success was stratified by stone size, and special attention was paid to the success rate of lower pole caliceal stones. An efficiency quotient (EQ) was calculated using the following formula:

$$\frac{\text{stone free \% x 1000}}{\text{100 + (re-treatment rate \% + auxiliary procedure \%)}}$$

The EQ, as reported, is not amenable to statistical comparison.[9] Statistical analysis was performed using the Fisher exact test to compare stone-free, re-treatment, auxiliary procedure and complication rates by year of training.

Results

The 5 CRLTs assisted in 779 SWL procedures during their first year of employment. The 5 CRLTs assisted in 1354 and 785 procedures in their second and third years, respectively. All treatments used the Medstone STS lithotripter machine.

For all procedures performed, average patient age was 48.4 years, and 58% were men. The distribution of stone sizes and locations treated are presented in Figures 1 and 2, respectively. There was no significant difference in average number of procedures performed per year per CRLT. There also was no significant difference in treatment parameters such as average number of shocks or patient body-mass index.

The overall stone-free rate increased significantly from 55% (EQ 45) in the first year to 68% (EQ 50, $P = .02$) in the third year (see Figure 3). It is important to note that, as a calculated value, statistical comparison of the EQ is not recommended in the urologic literature.[9] For stones 1 to 10 mm in size, stone-free rates increased from 60% (EQ 50) in the first year to 72% (EQ 55, $P = .008$) in the third year. Stone-free rates also increased for stones 11 to 20 mm in size (55% to 63%, EQ 41 to 45, $P = .04$) and stones greater than 30 mm (25% to 41%, EQ 19 to 24, $P = .02$); there was no significant change in the stone-free rate for stones 21 to 30 mm in size (55% to 52%, EQ 40 to 35, $P = .21$) (see Figures 4 and 5). Stone-free rates also increased between the first and third years for stones treated in the lower calyx (50% to 62%, EQ 41 to 44) (see Figure 6). There was no significant difference in re-treatment ($P = .68$) or secondary procedure rates ($P = .45$).

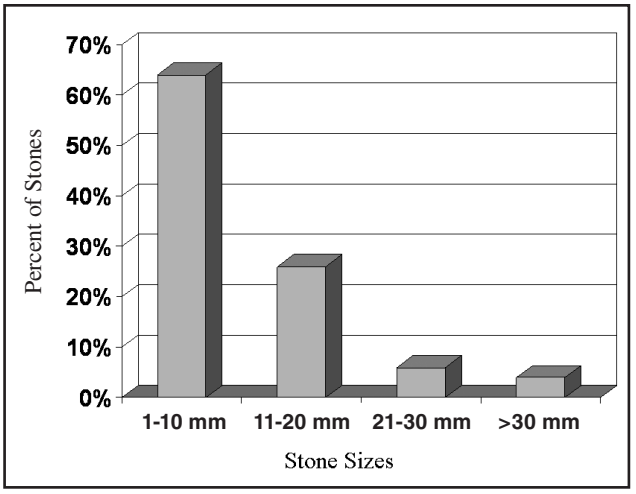

Figure 1. *Distribution of stones by size.*

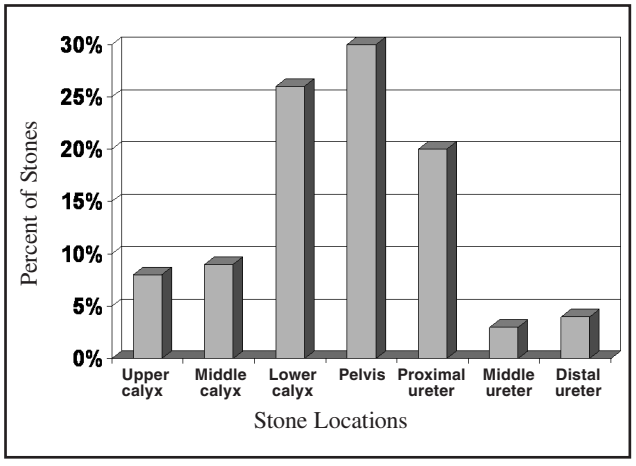

Figure 2. *Distribution of stones by location.*

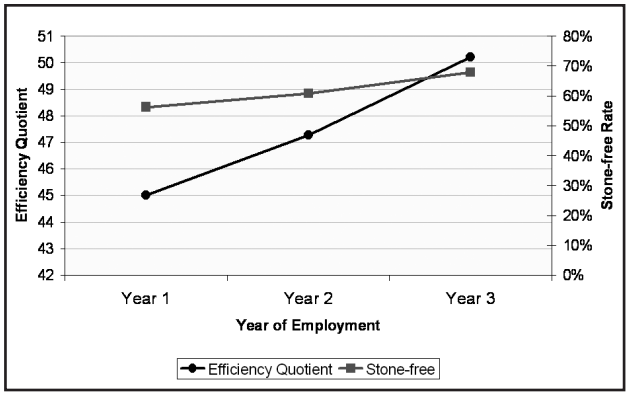

Figure 3. *Overall efficacy by year of employment.*

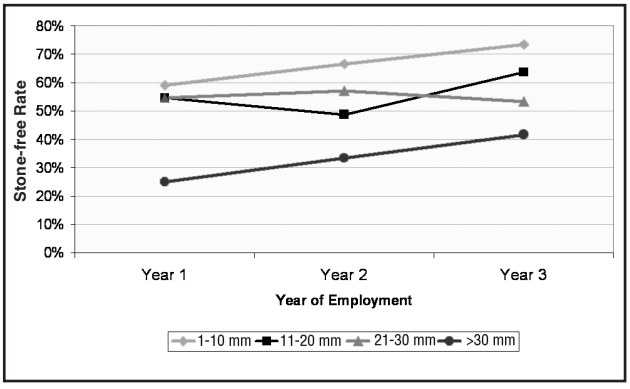

Figure 4. *Stone-free rates by size of stone and year of employment.*

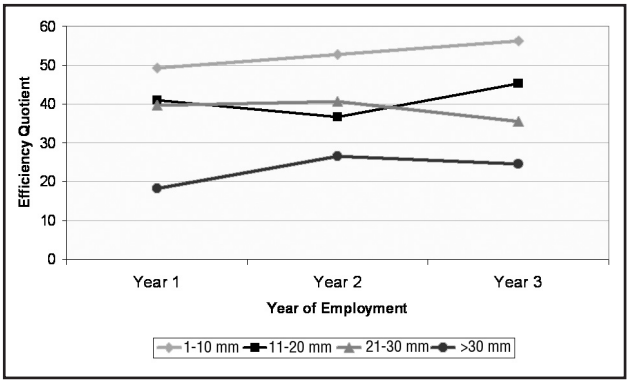

Figure 5. *Efficiency quotient by size of stone and year of employment.*

Discussion

Traditionally, the success of SWL procedures was thought to depend upon patient characteristics and stone location, size and composition. More recently it has been demonstrated that skin-to-stone distance (a surrogate marker of patient obesity) can help predict the likelihood of success with SWL.[10] An average skin-to-stone distance of more than 10 cm predicts failure (see Figure 7). Similarly, it has been reported that stone density as measured by CT Hounsfield units can help predict success of stone fragmentation procedures (see Figure 8).[11] Hounsfield units greater than 1000 HU predict a lower rate of stone fragmentation. Last, researchers have demonstrated that the lower pole renal anatomy can help predict the likelihood of stone clearance (see Figure 9). SWL success is not favorable for patients who have stones with a lower pole angle of less than 70°, an infundibular length of more than 3 cm or an infundibular width of 5 mm or less.[12]

New treatment strategies are helping to improve the success of SWL. Recent studies demonstrated that treating stones at a low energy setting and "ramping up" and treating at a slow gated rate can improve the efficiency of stone fragmentation, decrease renal trauma and improve stone-free results.[13-15] Air bubbles in coupling media used during SWL procedures create acoustic interfaces that impede the efficiency of shock wave transmission, and it has been demonstrated that manually displacing macroscopic air bubbles can improve shock wave efficacy.[16]

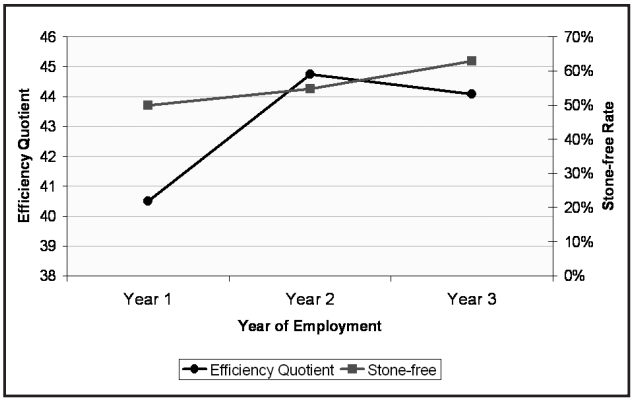

Figure 6. *Lower calyx efficacy by year of employment.*

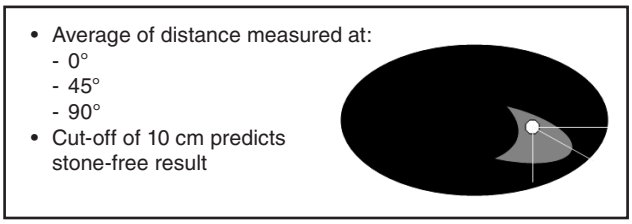

Figure 7. *Calculating the average skin-to-stone distance.*

To date, the only study evaluating the impact of operator experience suggests that the best results were obtained by the urologist who treated the greatest number of patients, used a high number of shocks and had the longest fluoroscopy time.[17] To our knowledge our study is the first to evaluate the impact of CRLT experience on SWL procedure success.

This study suggests that treatment efficacy progressively increases from the first year of CRLT experience with SWL procedures to the third year of experience. There was a marked improvement in stone-free rates for lower pole calculi. Because lower calyceal stone-free rates usually are about 20% lower than stone-free rates for other renal locations, any method to improve success specifically in this area deserves additional attention.

It is important to note that the most significant and linear improvement in stone-free rates occurred for smaller stones (1 to 10 mm). It is possible that success rates for smaller calculi could depend more heavily on patient positioning and stone localization during treatment and, consequently, would be more dependent on the skill and experience of the treating urologist and CRLT. In contrast, the impact of experience appeared to be more variable for lower pole calculi, with fluctuations in EQ noted from year 2 to year 3. This could be because treatment success for lower pole calculi depends on variables, such as lower pole anatomy, that are independent of the skill and experience of the treating urologist and CRLT.

This study was conducted in a retrospective manner; however, the large sample size helps to diminish the potential for study bias. A strength of this study is that 1 lithotripter machine was used for all treatments included in the evaluation.

It seems logical that more experience with SWL procedures would result in a greater success rate; however, the difference in the treatment success rates in this study from year 1 to year 3 is notable. Thus, closer supervision and mentorship by the attending urologist or an experienced CRLT during the new CRLT's first year of work could help ensure the highest level of

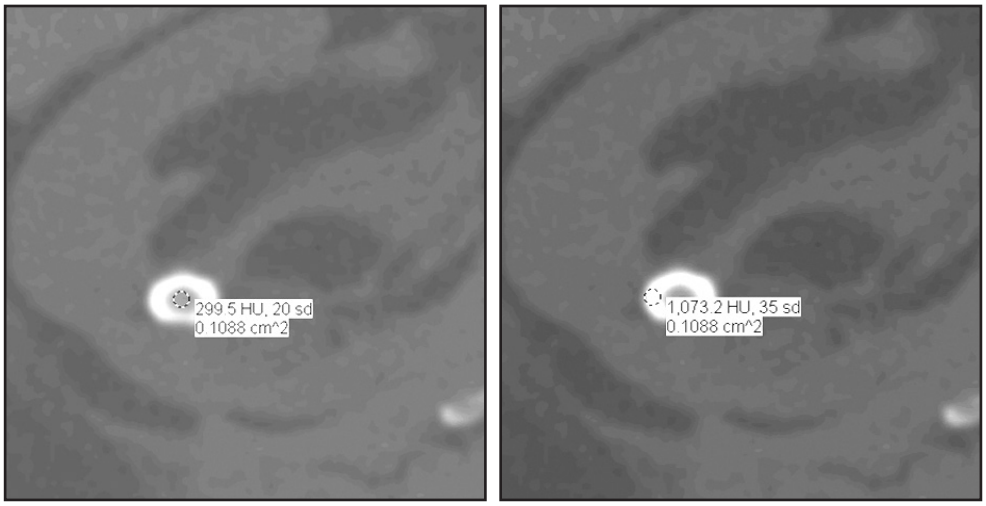

Figure 8. *Hounsfield units in bone windows demonstrate a hard shell (1073 HU) with a soft core (300 HU).*

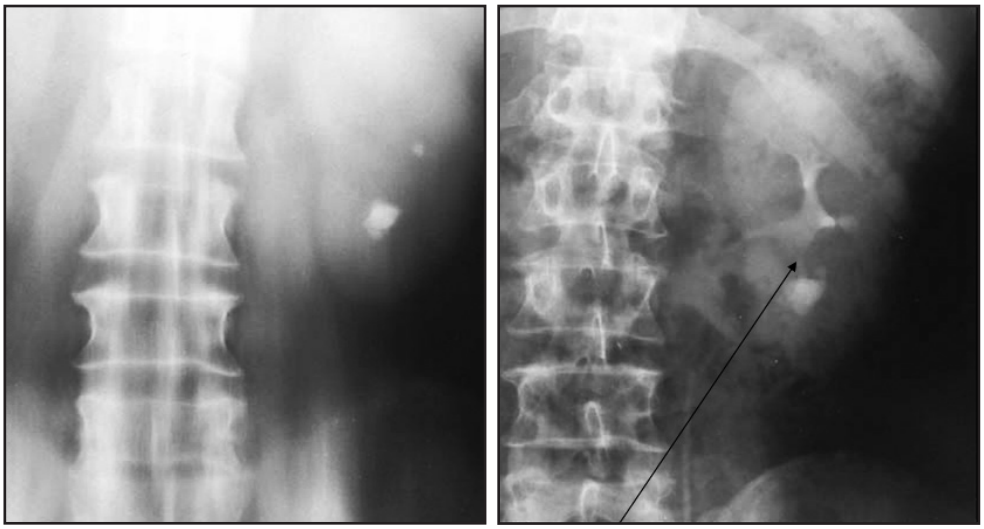

Figure 9. *Unfavorable lower pole anatomy with a long, narrow infundibulum (arrow) at an acute dependent angle.*

stone treatment success possible. Specifically, focusing on the areas of patient positioning, coupling and stone localization would be the most helpful.

Conclusion

Efficacy with SWL improves with increasing experience of the CRLT. Overall, there was an increased stone-free rate as the CRLT gained more experience. This was also true for stones located in the lower calyx. Although CRLTs are a proven benefit in the treatment of stone disease, ongoing supervision and mentorship in the first year of service may be helpful.

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Monitoring the Coupling of the Lithotripter Therapy Head With Skin During Routine Shock Wave Lithotripsy With a Surveillance Camera

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Purpose: With lithotripters today the shock waves are typically transmitted into the body via water filled bellows using coupling gel to make contact with the skin. Usually the coupling zone is not visible to the operator. We investigated coupling quality during routine clinical shock wave lithotripsy and the associated effect on shock wave disintegration efficiency.

Materials and Methods: During 30 routine shock wave lithotripsy treatments the coupling zone was continuously monitored by a video camera integrated into a DoLi SII lithotripter (Dornier MedTech, Wessling, Germany). However, it was not shown to the blinded operator to resemble the standard clinical situation. We used 3 coupling gels, including LithoClear®, Sonogel® and a custom-made gel of low viscosity. The ratio of air in the relevant coupling area was measured. Lithotripter disintegration efficiency was evaluated by in vitro model stone tests at an air ratio of 0%, 5%, 10% and 20%.

Results: Only in 10 of 30 treatments was good coupling achieved with an air ratio of less than 5%. In 8 treatments the ratio was greater than 20%. The best coupling conditions were achieved with low viscosity gel. The mean ± SD number of shock waves needed for complete fragmentation in the model stone tests was 100 ± 4 for bubble-free coupling, and 126 ± 3 for 5%, 151 ± 8 for 10% and 287 ± 5 for 20% air bubbles.

Conclusions: At 20 of 30 shock wave lithotripsy sessions there was imperfect coupling, accompanied by significant loss of disintegration capability. A surveillance camera is useful to monitor and improve coupling.

Key Words: urinary calculi, lithotripsy, high-energy shock waves, equipment and supplies

Abbreviations and Acronyms

A_{air} = coupling area air ratio

A_{SWL} = coupling area

D = skin-to-stone distance

SW = shock wave

SWL = SW lithotripsy

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† Financial interest and/or other relationship with Dornier MedTech Systems.

With the HM3 (Dornier MedTech), the first commercially available lithotripter, the patient was immersed in a tub.[1–3] SWs were generated in the water in which the patient was immersed to provide perfect acoustic coupling.

Later generation lithotripters used coupling bellows. Ultrasound gel, oil or petroleum jelly typically serve as the coupling medium.[4–7] The function of the coupling medium is basically to remove any air gap between the coupling bellows and the skin since air produces strong SW reflections. Various in vitro studies have been done on the effect of air pockets in the coupling surface on disintegration capability.[7–12] Pishchalnikov et al found that only 2% coverage by air pockets decreased stone breakage by 20% to 40%.[8]

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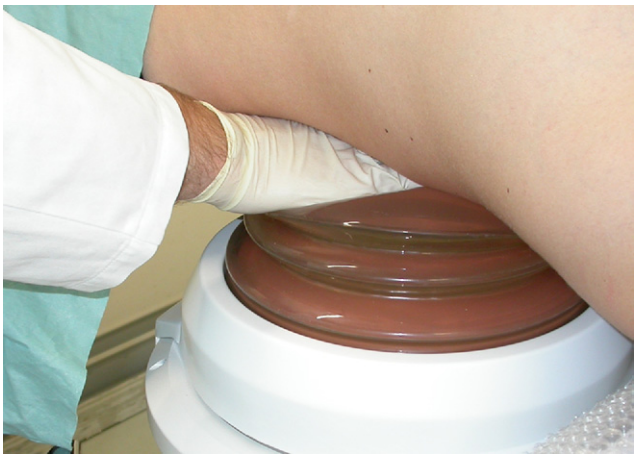

Figure 1. When removing air bubbles by wiping cushion, cushion inflation pressure must be maintained so that bellows remains in contact with patient skin.

Although bubble-free coupling is essential, the coupling surface cannot be visually monitored with most lithotripters. Some devices are equipped with an inline ultrasound system that may be used for this purpose.[12–15]

Guidelines to optimize coupling were deduced from previous studies.[12,14,16] Briefly, 1) the patient skin should be shaved. 2) The ultrasound gel supplied by the manufacturer should be bubble free. 3) A large opening instead of a small diameter nozzle should be used when dispensing gel from a bottle or container. 4) A reasonably large amount of gel should be applied to the center of the coupling bellows as a mound. Spreading the gel uniformly over the bellows and patient skin is not recommended. 5) Contact between the cushion and the patient should be achieved by inflating the bellows or slowly lowering the patient on the bellows. Typically the gel spreads radially without air entrapment. 6) After good coupling is attained the contact between cushion and patient must not be lost during treatment or coupling must be restored. 7) Coupling can be improved by manually wiping the cushion with the hand (fig. 1). Wiping is recommended after decoupling or frequent patient repositioning steps.

We investigated coupling quality during routine clinical SWL. We determined the problems that may occur and factors with the greatest impact. For this purpose a lithotripter was equipped with a camera to allow monitoring of the coupling area throughout treatment. Our second goal was to evaluate the effect of observed air inclusions on disintegration efficiency by model stone tests. We also determined whether such a coupling monitor could improve SWL.

MATERIALS AND METHODS

Enrolled in the study were patients with urinary stones who underwent SWL between February 2010 and January 2011. Four urologists performed therapy. All patients were treated while supine and most received intravenous analgesia with remifentanil. The cushion was attached from the dorsolateral side when the stone was targeted by x-ray, and from the dorsal side when it was targeted by isocentric ultrasound. The way that the operator applied the gel to the cushion was noted by an observer. Three ultrasound gels were used, including Sonogel (250 ml bottle), LithoClear HV (5 l container) and a polyacrylic acid type, custom-made gel from the hospital pharmacy (500 ml bottle). The viscosity of all 3 gels was measured at 20C and 37C at a laboratory specializing in rheology.

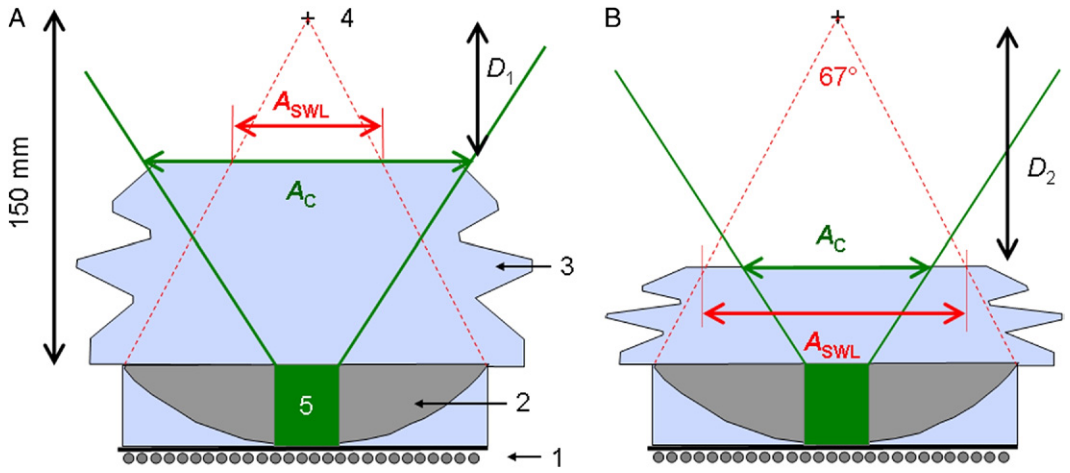

Figure 2. SW source. Electromagnetic SW emitter (*1*) generates plane acoustic waves focused by acoustic lens (*2*) with focus (*4*). Aperture angle is 67 degrees. Water filled cushion (*3*) serves as acoustic path between SW lens and skin. Red double-headed arrow indicates relevant area for SW transmission at skin level. Surveillance camera is in watertight housing at lens center (*5*) to monitor coupling area, of which part is visible (A_C). *A*, cushion inflated short D (D_1). *B*, cushion deflated long D (D_2).

A small video camera was installed in the water cushion of a DoLi SII lithotripter (fig. 2). Since the cushion is transparent, the coupling interface between cushion and patient skin could be imaged. The coupling area was not displayed to the operator during treatment but the observer viewed the monitor and manually corrected coupling as needed (fig. 1). Thus, coupling could be examined under standard clinical conditions while optimized treatment was provided to the patients. Data were obtained under a waiver from the institutional ethical review board.

Coupling Quality Quantitative Evaluation

The coupling area was analyzed off line using a Matlab custom designed program (MathWorks®). We measured D using markers at the cushion top (figs. 2 and 3, *A*). On the image the spacing of the pattern in pixels depends on the distance between camera and cushion and, thus, on D. For calibration, pattern spacing was measured with a disk mounted on the lithotripter at a known distance to the lithotripter focus, ie D.

A_{SWL}, which is the relevant area for SW transmission (fig. 2), was determined by D and the SW aperture angle. For that calculation the SW path was approximated as a cone with the SW lens as the base and the SWL focus as the top.

The boundary lines of bubbles in the gel were drawn manually using the computer mouse (fig. 3). Using circles as markers with known distances on the cushion the depicted bubbles were transformed into an orthogonal, scaled coordinate system allowing the correction of image distortion due to the uneven cushion surface and camera optics. Thus, bubble size could be calculated. Total bubble area was then divided by A_{SWL}, resulting in the ratio A_{air}.

Model Stone Tests

The effect of air bubbles in the gel on disintegration capability was estimated using standard model stone tests.[17] Gypsum stones (Dornier MedTech) were disintegrated in a 2 mm mesh, which allowed the debris to fall out (fig. 4). The test result represented the number of shocks needed until all stone fragments had passed through the mesh.

Air bubbles 10 mm in diameter that had been cut out from packaging foil were pasted to the cushion. They were uniformly distributed in each square, in every second or in every fourth square of the cushion marking pattern. A prepared cushion was coupled to the test tank using otherwise bubble-free LithoClear gel, resulting in a coupling with an A_{air} of 20%, 10% and 5%, respectively. The tests were done at 2 Ds (51 and 90 mm) from the SW focus at a

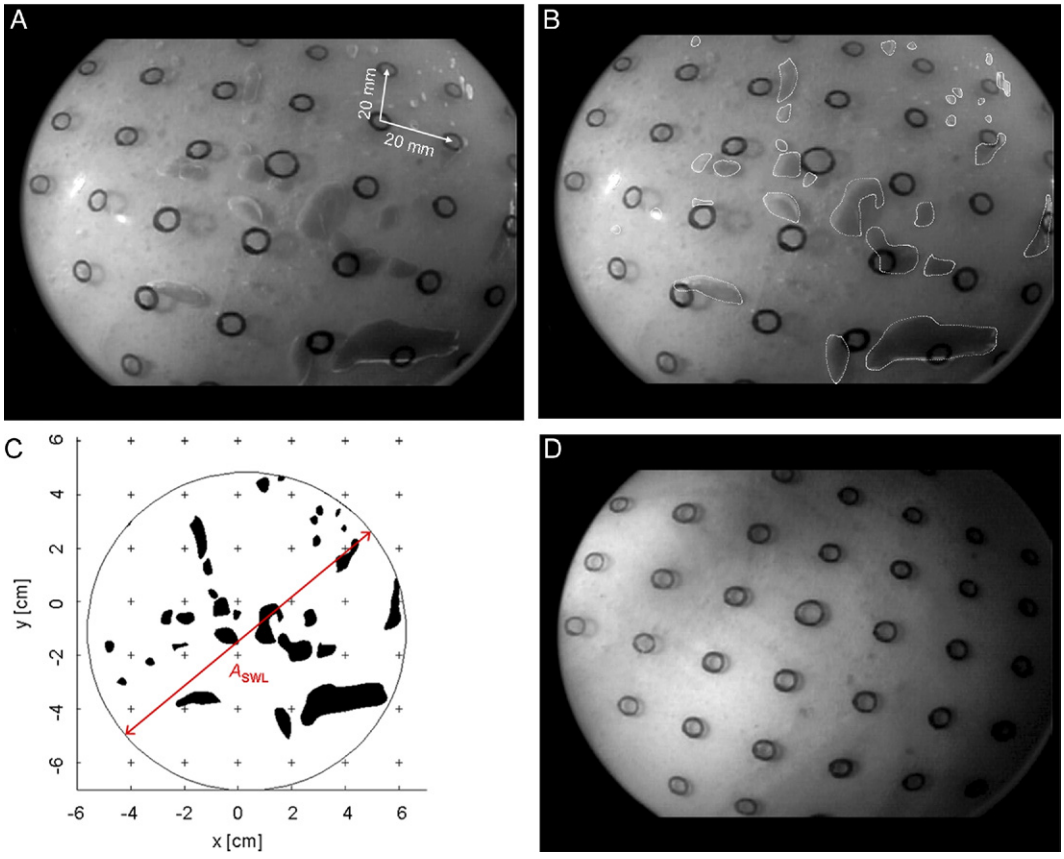

Figure 3. *A*, video image shows coupling area with numerous air bubbles trapped in ultrasound gel. For quantitative evaluation cushion top was provided with squared pattern of circular markings. *B*, bubble boundaries were manually drawn for offline evaluation. *C*, bubbles and circle centers in scaled orthogonal coordinate system after transformation. Bubble area (black areas) was related to area relevant to SW transmission (circle with diameter A_{SWL}). In this example total bubble area was 9.6 cm^2 at 81 mm D and 11% A_{air}. *D*, coupling surface after manual bubble removal.

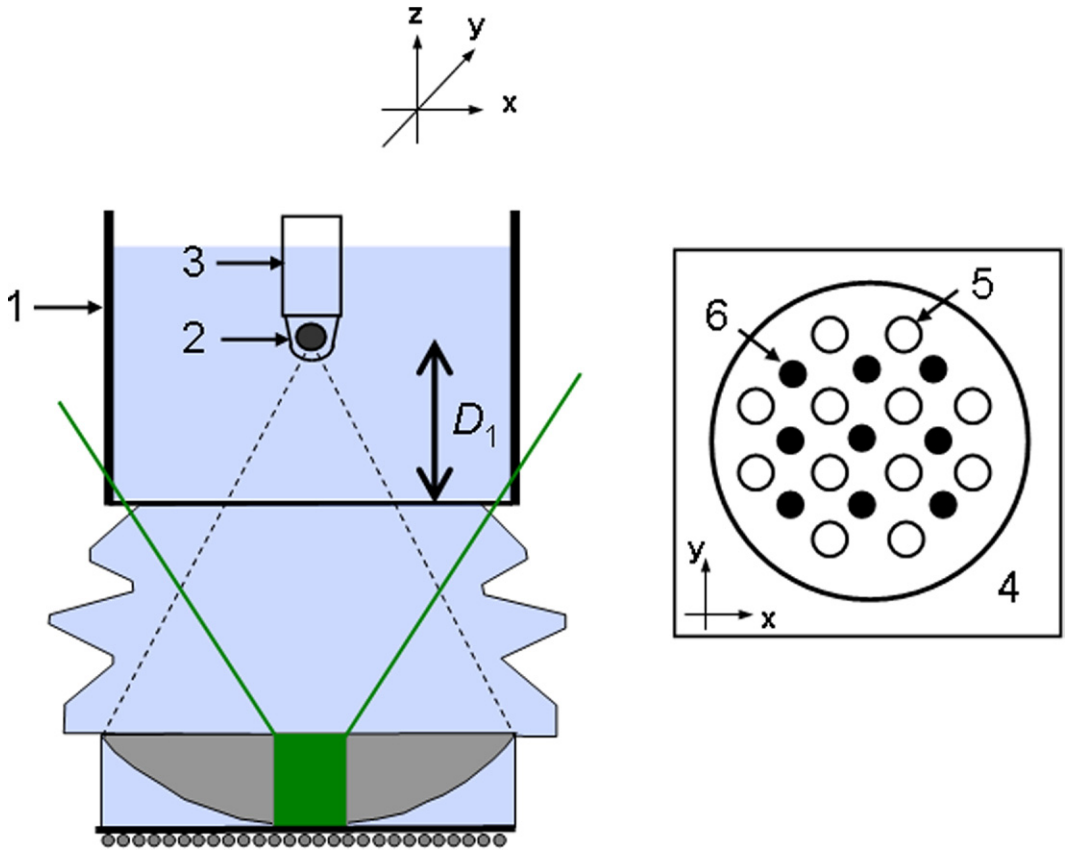

Figure 4. Experimental setup for model stone test. Test basin (*1*) with degassed water was mounted to SW source. Model stone (*2*) was positioned at SW focus by holder (*3*). Test was done under different coupling conditions, ie different number of artificial air bubbles. Coupling area (*4*) is shown with markings (*5*) and artificial air bubbles (*6*).

typical energy setting (level 7). At each test condition 3 model stones were fragmented.

RESULTS

Patients and Gel Application

Included in study were a total of 30 SWL treatments in 21 male and 5 female patients. The stone was located in the kidney at 26 treatments and in the ureter at 4. The stone was imaged by x-ray in 20 cases and by isocentric ultrasound in 10. Mean ± SD patient body mass index was 27.2 ± 4.5 kg/m^2.

At 20C and 37C the viscosity of the custom-made gel (43 and 43 Pa-seconds) was significantly lower than that of Sonogel (145 and 150 Pa-seconds) or LithoClear (124 and 119 Pa-seconds, respectively). The custom-made gel flowed easily catching bubbles when the gel bottle was turned upside down. When applying Sonogel or LithoClear, the corresponding containers had to be squeezed more and the gel remaining in the bottle showed some bubbles, which did not disappear. Stickiness was advantageous since after application Sonogel or LithoClear adhered to the cushion surface even when it was rotated at an angle while the custom-made gel flowed down toward the floor.

The gel was applied to the cushion as a mound or spread by hand in 15 cases each. The amount of gel varied between 75 and 250 ml. If the cushion lost contact after coupling, the operators did not restore the coupling or wipe the cushion.

Coupling Quality Quantitative Evaluation

Figure 3 shows an example of the imaged coupling zone and the calculation of A_{air}. Table 1 lists the results of the 30 treatments by gel type.

Table 1. *Coupling quality of all 30 treatments by 3 coupling gels, respectively*

	No. Treatments		
% A_{air}	LithoClear	Sonogel	Custom
Less than 5	3	—	7
5–10	1	5	1
10–20	3	2	—
Greater than 20	3	3	2
Totals	10	10	10

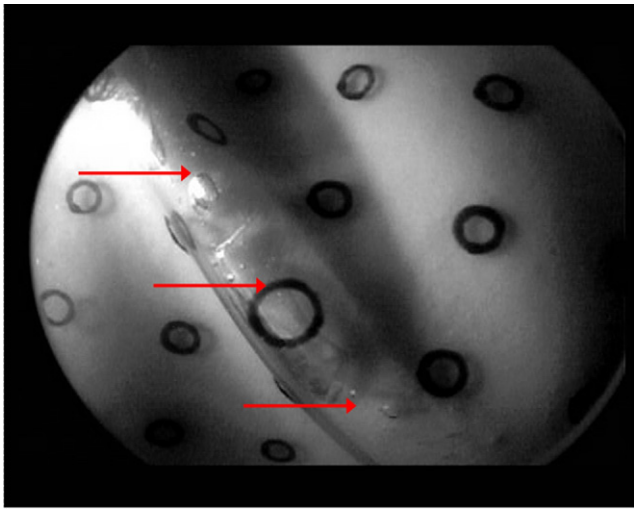

Figure 5. Coupling cushion with air filled fold (arrows). When cushion does not lie flat to skin, coupling is strongly disturbed.

In 8 cases A_{air} was greater than 20%, including 5 in which the cushion only partially contacted the patient. In these cases the gel was applied as a mound and did not spread sufficiently after contact. In another 2 cases the coupling was disturbed by an air-filled fold (fig. 5).

Most air bubbles entered the gel at the moment when the cushion touched the skin, immediately at the first coupling or after an intermediate decoupling. Decoupling events occurred at 11 treatments when the patient had to be repositioned, the cushion was retracted to obtain a better x-ray image under difficult to scan conditions or the patient moved. Otherwise the air bubble distribution remained stable throughout treatment. Only bubbles smaller than 2 mm oscillated at the SW release frequency. These small bubbles often moved toward the SW center and coalesced but without significantly increasing in size. Adjusting patient position by moving the stretcher did not result in new bubbles.

A_{air} was less than 5% in 3 and 0 of 10 treatments using the high viscous LithoClear and Sonogel gels, respectively (table 1). There were fewer bubbles when the gel was applied as a mound instead of spreading it by hand on the cushion. All 3 good results (A_{air} less than 5%) were achieved with gel applied as a mound. However, this method did not automatically lead to satisfactory results due to later decoupling or to the gel not spreading appropriately.

Results were better with the custom-made gel of low viscosity in that A_{air} was less than 5% in 7 of 10 treatments. It made no significant difference whether the gel was applied as a mound or spread by hand. Also, coupling recovered quite well after contact was lost while numerous bubbles appeared in LithoClear or Sonogel after a decoupling event.

Mean D ±SD between cushion surface and SW focus was 85 ± 24 mm (range 28 to 138). In 10 of 30 treatments D was greater than 100 mm, ie the cushion was rather deflated. In this group 5 cases showed strongly disturbed coupling with A_{air} greater than 20%. In the other 20 treatments with D less than 100 mm this poor coupling condition was observed in only 3 cases.

If the monitor showed air inclusions in the coupling zone, the observer removed the bubbles by wiping (fig. 1). Perfect coupling could be achieved in all cases. Improvement was readily visible on the monitor (fig. 3, *D*).

Model Stone Tests

Table 2 shows the results. Compared with the bubble-free coupling situation the number of shocks needed for complete stone fragmentation was already about a factor of 1.2 greater when A_{air} was 5%. Under poorer coupling conditions, ie an A_{air} of 20%, the number of shocks was about 3 times greater.

DISCUSSION

To our knowledge we report the first clinical study of the quality of acoustic coupling during SWL. Previous reports relied on in vitro studies or examinations with probationers.[4–12,16]

Visualizing the coupling area using a camera showed that coupling was disturbed during most treatments (table 1). In all cases with A_{air} greater than 5%, ie in 20 of 30, transmitted SW energy would have been significantly decreased if coupling had not been manually improved. Particularly when A_{air} was greater than 20%, treatment most likely would have failed. The in vitro model stone tests using the same lithotripter as for patient treatment confirmed the results of previous studies showing that the disintegration efficiency of a lithotripter is sensitive to air inclusions in the gel (table 2).[7–12]

The study provides evidence of the previous assumption that acoustic coupling is a relevant problem in clinical SWL.[7,13,18] Insufficient cou-

Table 2. *SWs needed for fragmentation during model stone tests with different coupling conditions and at 2 Ds between SW focus and coupling surface*

	Mean ± SD No. Shocks	
Coupling Condition	51 mm D	90 mm D
Bubble free	103 ± 2	100 ± 4
% A_{air}:		
5	122 ± 5	126 ± 3
10	177 ± 6	151 ± 8
20	387 ± 32	287 ± 5

pling appears to be an important factor of the less satisfactory treatment outcomes of modern lithotripters compared with those of the HM3. Using the latter device perfect coupling is guaranteed using the bathtub.

When the cushion was deflated, ie when there was a substantial skin-to-stone distance, coupling was more often disturbed. Studies using modern lithotripters showed that a great skin-to-stone distance correlates with a poor treatment outcome[19,20] while no such relationship was identified for the HM3.[18] Insufficient coupling could explain these differing results.[13]

We could not correlate perfect or poor coupling conditions with the corresponding treatment results of the study patients. Due to incomplete followup protocols, the lack of an appropriately documented control group and our low patient number the clinical effect was not verified. Thus, this is the objective of a subsequent study.

To avoid SWL failure due to poor acoustic coupling we must address coupling problems. Our series revealed that a camera is ideal for this purpose since it allows the operator to monitor coupling and improve it as needed. Thus, the camera feature that we used should become standard with future lithotripters. Inline ultrasound can be used in a similar way.[12] However, a camera is better suited since it presents the whole coupling area at a glance. With inline ultrasound the transducer must be rotated for a complete scan. Therefore, evaluating the magnitude of air inclusions and removing the disturbance by manual wiping becomes more difficult.

When the coupling area cannot be visualized by a camera or inline ultrasound, it is essential to follow the guidelines for good coupling.[12,14,16] In addition to the previous recommendations, our study showed that the gel may sometimes not fully spread as intended when applied as a mound. Thus, particularly when the cushion is deflated, it is recommended to improve gel spreading by wiping (fig. 1). At the same time any possible folds may be removed. Without camera feedback wiping may not always result in perfect coupling but it should at least avoid poor conditions under which A_{air} is greater than 20%. This is also recommended when coupling is temporarily interrupted. Such decoupling events, which were observed quite frequently, could negate all previous efforts to apply gel properly.

A low viscosity gel appears to be an effective way to improve coupling in clinical practice.[7,11] In an in vitro study Bergsdorf et al observed that fewer air inclusions result from using low viscosity gel than middle and high viscosity gels.[11] Nonetheless, the magnitude of the effect in the clinical situation was surprising (table 1). The low viscosity gel was much less susceptible to bubble uptake. However, it is questionable whether low viscosity gel would be widely accepted since it tends to flow downward toward the floor, requiring additional cleaning after treatment.

CONCLUSIONS

This clinical study shows the practical relevance of coupling for SWL. During most treatments the applied SW energy was decreased due to disturbed coupling. Video monitoring of the coupling area is ideal to achieve perfect coupling.

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Coupling

- Air pockets in the coupling medium
  - 2% surface area = 40% decrease in fragmentation
    - J Urol. 2006 Dec;176(6 Pt 1):2706-10

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Effect of initial shock wave voltage on shock wave lithotripsy-induced lesion size during step-wise voltage ramping

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OBJECTIVE

To determine if the starting voltage in a step-wise ramping protocol for extracorporeal shock wave lithotripsy (SWL) alters the size of the renal lesion caused by the SWs.

MATERIALS AND METHODS

To address this question, one kidney from 19 juvenile pigs (aged 7–8 weeks) was treated in an unmodified Dornier HM-3 lithotripter (Dornier Medical Systems, Kennesaw, GA, USA) with either 2000 SWs at 24 kV (standard clinical treatment, 120 SWs/min), 100 SWs at 18 kV followed by 2000 SWs at 24 kV or 100 SWs at 24 kV followed by 2000 SWs at 24 kV. The latter protocols included a 3–4 min interval, between the 100 SWs and the 2000 SWs, used to check the targeting of the focal zone. The kidneys were removed at the end of the experiment so that lesion size could be determined by sectioning the entire kidney and quantifying the amount of haemorrhage in each slice. The average parenchymal lesion for each pig was then determined and a group mean was calculated.

RESULTS

Kidneys that received the standard clinical treatment had a mean (SEM) lesion size of 3.93 (1.29)% functional renal volume (FRV). The mean lesion size for the 18 kV ramping group was 0.09 (0.01)% FRV, while lesion size for the 24 kV ramping group was 0.51 (0.14)% FRV. The lesion size for both of these groups was significantly smaller than the lesion size in the standard clinical treatment group.

CONCLUSIONS

The data suggest that initial voltage in a voltage-ramping protocol does not correlate with renal damage. While voltage ramping does reduce injury when compared with SWL with no voltage ramping, starting at low or high voltage produces lesions of the same approximate size. Our findings also suggest that the interval between the initial shocks and the clinical dose of SWs, in our one-step ramping protocol, is important for protecting the kidney against injury.

KEYWORDS

tissue injury, animal models, renal protection

INTRODUCTION

While extracorporeal shock wave lithotripsy (SWL) is considered a highly effective treatment for upper urinary tract stones, concerns about the safety and efficacy of SWL have dampened enthusiasm for the treatment [1–3]. These concerns have been heightened by the fact that second generation and more recent lithotripters appear less effective at breaking stones [4–7] and cause more tissue injury [8,9] than the original unmodified Dornier HM-3 lithotripter.

Our research has focused on the development of new treatment strategies to improve the safety and efficacy of SWL. One of these strategies involves 'step-wise voltage ramping' where treatment commences at a low SW voltage and then is subsequently increased with time. Originally, voltage ramping appears to have been introduced in the clinic as a means to reduce patient discomfort during SWL by allowing patients to acclimate to the SWL treatment without anaesthesia. Subsequent *in vitro* [10,11] and *in vivo* [12] studies applying this approach suggested that voltage ramping also improves stone fragmentation. More recently, a clinical comparison of voltage ramping against standard SWL treatment showed improved stone comminution with voltage ramping while using only a modest (11–13 kV) step-wise increase in SW voltage [13].

While voltage ramping appears promising for enhanced stone breakage, it is equally important to understand the consequences of step-wise voltage ramping on SWL-induced kidney injury. Willis *et al.* [14] provided the first data showing an effect of single-step voltage ramping on tissue injury. In that study porcine kidneys were treated with a limited number of low-energy (12 kV) SWs followed by a larger number of high-energy (24 kV) SWs, the latter being consistent with a standard dose of SWs used in the clinic. This strategy substantially reduced the acute haemorrhagic lesion normally observed in porcine kidneys after conventional SWL.

However, questions remain as to why a step-wise change in treatment voltage would 'protect' kidneys from injury. One such question concerns the starting SW voltage. Some groups begin their voltage-ramping protocol at 11 kV [13] while others report

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