

Beaumont Hospitals*

October 23, 2008

Certificate of Need Commission
201 Townsend
7th Floor, Capitol View Building
Lansing, MI 48913

Kenneth J. Matzick
President and
Chief Executive Officer

Dear Commissioner:

Since June 2005, Beaumont Hospitals has been advocating that the 20-year-old bone marrow transplant (BMT) standards be reviewed and updated to improve access to these services by going to institution-specific criteria. Beaumont provided information as to why the arbitrary limit of three BMT programs in the state was an impediment to some patients receiving timely, life-saving cancer treatment (see attached letter to CON Commission dated June 15, 2006). We also provided our rationale as to why Beaumont should be allowed to provide this service. In summary:

- Beaumont diagnoses more new cancer cases than any other hospital in the state.
- Beaumont has two BMT-trained physicians, so would not be incurring additional costs or “robbing” another program to provide this service.
- Beaumont provided peer-reviewed articles (*New England Journal of Medicine*) that said bone marrow transplant was an underutilized treatment that would be increasing with older patients and for more medical conditions.

A workgroup was established to review the BMT standards. The CON Commission listened to those facilities that had BMT programs and their rationale for not revising the standards:

- The number of bone marrow transplants in Michigan had not increased for a number of years.
- The number of BMTs would likely decrease due to new, less toxic, non-transplant targeted therapies and new chemotherapy agents that could replace transplants. Existing BMT programs had capacity to treat other patients (despite the fact capacity measures are not a consideration in any other CON standard).
- BMT programs are enormously expensive to initiate and maintain.

In the two years since the workgroup met and the CON Commission decided not to modify the BMT standards, the following has taken place:

- As Beaumont predicted, the number of bone marrow transplants performed in the U.S. has grown significantly due to the combination of the National Marrow Registry Donor and cord blood stem cell banks increasingly being used for non-sibling donor matches; the use of stem cell transplants for treatments for more types of cancers and other diseases; and, older patients being successfully treated with stem cell transplants. [See the attached graphs from the Center for International Blood and Marrow Transplant Research (CIBMTR)] Both Karmanos and University of Michigan, which argued BMT services were in a decline, have increased the number of BMTs performed since 2004: Karmanos from 125 to 233 procedures, and University of Michigan from 218 to 248 procedures.

Comments were made at the public hearing on the 2009 Commission work plan dealing with pancreas transplants and the need for more programs in the state of Michigan. We believe the compelling arguments made for pancreas transplants hold true for bone marrow transplants:

1. There is a federal certifying organization that guarantees a level of quality for transplant programs. In the case of bone marrow transplant, it is the Foundation for Accreditation of Cellular Therapy (FACT), and all information on patient outcomes must be submitted to the CIBMTR.
2. Costs of adding a pancreas transplant program are not significant for hospitals that have kidney transplant programs. The same would be true for Beaumont establishing bone marrow transplant, in light of our other transplant programs.
3. There is no evidence to link higher volume of procedures to better outcomes, despite allegations that there needs to be a higher number of bone marrow transplants at only the existing centers in order to maintain quality.
4. Most importantly, patients who have established relationships with physicians and hospitals should not be made to go to another facility to receive life-saving treatment.

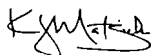
The CON Commission may be persuaded by these arguments to modify the CON criteria for pancreas transplants, and Beaumont does not see any reason that the same arguments should not apply for modifying bone marrow transplant services.

The Certificate of Need Commission may want to consider updating standards for all transplant services in view of the development of data from national organizations that does not link volume with quality; that costs of implementing transplant programs may not be significant; and, that medicine has changed in the last ten years. The most compelling argument we believe, however, is that patients are being negatively impacted if they are forced to leave their existing physician and hospital when that physician and hospital have the capability of providing the transplant service. The CON Commission has not studied increased health care costs, nor impacts on the patients, of these transfers.

Again, Beaumont Hospitals would like to request the Certificate of Need Commission appoint a Standard Advisory Committee (SAC) to revise the 23-year-old standards that no longer reflect the standard of care for bone marrow transplant services. We encourage the Commission to instruct the SAC to either recommend that BMT standards be rescinded or develop institution-specific criteria for BMT services with minimum volume thresholds.

Given the fact that BMTs can now be performed on an outpatient basis and often cost significantly less than chemotherapy or other cancer treatments, there are now reasons for changing this standard.

Sincerely,



Kenneth J. Matzick

Enclosures referenced above were hand delivered to Andrea Moore and are considered inclusive with these comments.

Beaumont Hospitals*

June 15, 2006

Certificate of Need Commission
c/o Brenda Rogers, Health Policy Section
Michigan Department of Community Health
201 Townsend Street, 7th Floor
Lansing, MI 48913

Re: Bone Marrow Transplantation Services (BMT)

Dear Certificate of Need Commissioners:

Beaumont has long been a strong supporter of certificate of need because we believe it is in the best interest of the citizens of the State in terms of helping to balance costs, quality and access to health care services. Michigan's C.O.N. program has a well-designed process for updating C.O.N. review standards, by virtue of PA 619's requirement that C.O.N. standards be reviewed by the Commission every three years. Since the June 2005 C.O.N. Commission meeting, Beaumont has been advocating that BMT standards be reviewed and updated to improve quality and access to BMT services at reasonable cost. Beaumont and others provided testimony at the January 31, 2006 public hearing on BMT services, and at the March 2006 C.O.N. Commission meeting the Commission established a Workgroup on BMT services. Commissioner Michael Young, D.O., has been appointed as the C.O.N. Commission Liaison for the BMT Workgroup, and the first workgroup meeting was held May 25, 2006. Commissioner Young will be providing a status report on this workgroup at the June 21 C.O.N. Commission meeting. As Dr. Young will likely report, the workgroup was divided along competitive lines regarding whether the BMT standards should be revised using a needs-based methodology.

The trend for many years in C.O.N. in Michigan has been to move away from identifying a fixed number of programs for C.O.N. covered services and toward an "institution specific" approach, whereby if an applicant can demonstrate need based on the patients it currently serves (or in combination with others), the applicant can qualify for the service. In fact, other than beds (hospital, NICU, nursing home, psychiatric), the ONLY C.O.N. standards besides BMT (out of 12) that identify a fixed number of programs is heart/lung/liver transplants. For example, pancreas transplantation services used to have a fixed limit of three programs for the State; 13 years ago in 1993, these standards were changed to an institution-specific, needs-based methodology based on the number of kidney transplants performed. **Accordingly, Beaumont**

asks that the Commission endorse an approach to revising the BMT standards that is needs based, institution-specific and not subject to comparative review. In previous written communication to the Commission and the Department, Beaumont has suggested one such approach using tumor registry data. If such an endorsement is not provided, it is unlikely that the workgroup or even a SAC would adopt any methodology that would allow large programs like Beaumont (the largest cancer program in the State in terms of newly diagnosed patients) to qualify for BMT services.

Quite simply, the reason that the standards should be changed to allow Beaumont to offer BMT is to better serve the patients that already look to Beaumont for their care. Consider the following:

- In terms of volume, Beaumont diagnoses the most new cancer cases in the State. New cancer case data from tumor registries in Michigan are shown below for 2003 (most recent public data):

Tumor Registry	<u># New Cancer Cases</u>
Beaumont	4,065
University of Michigan	3,927
Henry Ford	2,732
Spectrum	2,650
Harper/Karmanos	1,943
Oakwood	1,443
St. John	1,323

Source: American Cancer Society

- Oncologists at large cancer centers like Beaumont without a BMT program must refer patients to outside centers and outside physicians for this treatment. This interrupts their continuity of care and negatively impacts the strong doctor-patients relationships that are established. Even when a patient is referred to an outside BMT program, the patient sometimes does not go to the outside program because of the hardships involved or because he or she does not wish to leave the cancer program with which they are familiar and comfortable. And even when the patient does go to an outside center for BMT, patients can have severe negative experiences when needed BMT follow-up care is not readily available (see attached letter detailing the patient experience of Representative John Garfield). Note also that there are no BMT programs in the State to the north or east of Beaumont. Allowing Beaumont to offer BMT would allow us to better treat the patients who are already coming to us.

- Based on our Tumor Registry figures, we estimate that Beaumont would perform 50-75 bone marrow transplants per year. Many of these patients are currently being referred to Karmanos and to a lesser extent U-M and out-of-state programs; however some of these patients are not currently accessing BMT services at all for the reasons discussed above. Regardless, the volume impact on existing programs in the State would be quite limited.
- According to the National Marrow Donor Program (NMDP), the number of bone marrow transplants performed in the U.S. is projected to grow. This growth will be fueled by the capability to now treat older patients, the use of a Donor Marrow Registry that increasingly allows non-sibling donor matches, and use of BMT for diseases that have not traditionally been treated with transplants (including lupis, rheumatoid arthritis, multiple sclerosis, renal cell carcinoma and other solid tumors, and sickle cell disease). BMT may also become a viable strategy for heart disease. Two physicians from existing BMT programs in the State have argued that BMT is not growing and may lose favor as a cancer treatment option and that the future for BMT volume is stable at best with potential for decline. In contrast, Beaumont transplant physicians believe this is an exciting time for transplant as a treatment option not only for an expanded number of cancer patients, but also for patients with other previously mentioned medical conditions.
- Studies on BMT outcomes have revealed that transplant success can be highly dependent on transplant timing. Establishing an initial treatment plan that includes a possible BMT reduces the chance that complications could prevent a patient from receiving a transplant when needed (Source: National Marrow Donor Program). Therefore, presence of a BMT program at large cancer centers will increase the likelihood that the most appropriate treatment planning will occur to include the potential for BMT. Proper treatment planning enables a patient to move quickly to transplant, if needed, before disease progresses or complications develop. The immediate availability of a complete range of oncology services, including BMT, ensures that a large number of patients will receive the right level of care at precisely the right time.
- The costs to develop and operate a new BMT program are dependent on the physical and programmatic resources that are already available at the institution. Beaumont already has in place most of the elements required for a successful BMT program, including two experienced bone marrow transplant physicians trained at Johns Hopkins. The two major capital investments required to initiate the program at Beaumont are a stem cell laboratory and HEPPA filters on an inpatient unit – at a total capital cost of less than \$2 million.

- Some have argued that because existing programs are not at capacity, that no new programs should be added, especially in Southeast Michigan. As discussed above, this limitation causes significant hardships for patients and is not consistent with how other C.O.N. standards have been rewritten. For example, if an applicant can demonstrate need (using hospital discharge data), new lithotripsy services can be initiated, even if the existing lithotripsy services are not all operating at capacity. In addition, referrals to outside centers also require significant re-testing and re-staging. These tests add substantial costs to the health care system and impose unnecessary hardships for these patients.
- If the BMT standards are revised to include a needs-based, institution-specific methodology, there will not be a large proliferation of new BMT programs. In addition to the high “hurdle rate” that any such methodology would likely include, a major limiting factor is availability of transplant physicians. Also, a limited increase in BMT programs across the State would not have a significant impact on the quality of BMT services provided at existing centers, because the volumes at these centers will still far exceed the minimum volume levels specified in the existing BMT C.O.N. standards. In addition, in the unlikely event that Beaumont is unable to meet minimum volume requirements, we would not continue offering the service; note that when Beaumont’s heart-transplant program failed to meet minimum volumes, we voluntarily ended the program.

Note also that per the American Health Planning Association, only 17 states cover Bone Marrow Transplants under C.O.N. at all. And, there is no correlation between the number of BMT programs by state, and whether or not that state covers BMT under C.O.N. (Source: American Health Planning Association, NMDP Transplant Directory).

- A BMT program would also have a major positive impact on the academic/educational activities at the Hospital which are essential to the Hospital’s education and research mission. Beaumont-Royal Oak is the largest hospital in Michigan and is a tertiary academic medical center and research facility. Beaumont maintains an accredited Medical Oncology Fellowship Program. ACGME Oncology Fellowship requirements mandate training in bone marrow transplants. Currently, fellows must leave the institution to obtain this required training. A bone marrow transplant program would also offer new rotations for other Beaumont residents/fellows in the fields of internal medicine, family practice, infectious disease and radiation oncology – many of these physicians go on to practice medicine at Beaumont, with a service area of 2 million people.

- Establishing a BMT program would have a major positive impact on medical research at Beaumont:
 - The National Cancer Institute has designated Beaumont as a Community Clinical Oncology Program (CCOP), and we currently have 245 open clinical trials in cancer research areas. Beaumont is an attractive research site because of the access we provide to a large number of patients.
 - Led by William O'Neill, M.D., Corporate Chief of Cardiology, Beaumont has an international reputation in the field of cardiology. Dr. O'Neill believes that stem cell transplantation is going to play a major role in the treatment of patients with coronary artery disease, and presence of a BMT program at Beaumont will help to advance the investigation of BMT as a treatment for heart disease. See attached letter of support from Dr. O'Neill. Without a BMT program, Beaumont would not have a stem cell lab, which would be needed to support stem cell research in the field of cardiology.
 - Beyond Beaumont, arbitrarily limiting the number of centers in Michigan which can perform transplants is a major hurdle in the research and development of potentially curable treatment options for otherwise disabling and life-threatening conditions.
- Finally, given the condition of Michigan's economy the State has embarked on a major initiative to diversify its economy and attract high paying jobs in growing knowledge-based fields such as biotechnology and medical devices and instrumentation. Beaumont is participating in these efforts (through partnerships with technology-based companies and participation in Automation Alley), and establishment of a BMT program will help to advance the State's capabilities in these emerging sectors.


In addition to Beaumont's above request for the Commission to endorse development of an institution-specific, needs-based methodology for BMT services, Beaumont also asks that the Commission immediately approve and move to public comment language that would allow for acquisition of an existing BMT program. While Beaumont still strongly supports moving forward with development of a needs-based methodology, acquisition would allow for redistribution of existing programs without increasing the number of C.O.N. approved programs- an option that is not currently permitted. Beaumont has provided language to the Department that would accommodate this.

Certificate of Need Commission
c/o Brenda Rogers, Health Policy Section
Re: Bone Marrow Transplantation Services (BMT)

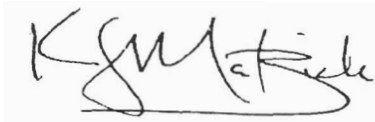
June 15, 2006
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In closing, Beaumont is seeking to serve its patients better and can do so with a capital investment of less than \$2 million. The cost impact to payors in the State will be minimal. Thank you for your consideration of this important patient care issue.

Sincerely,



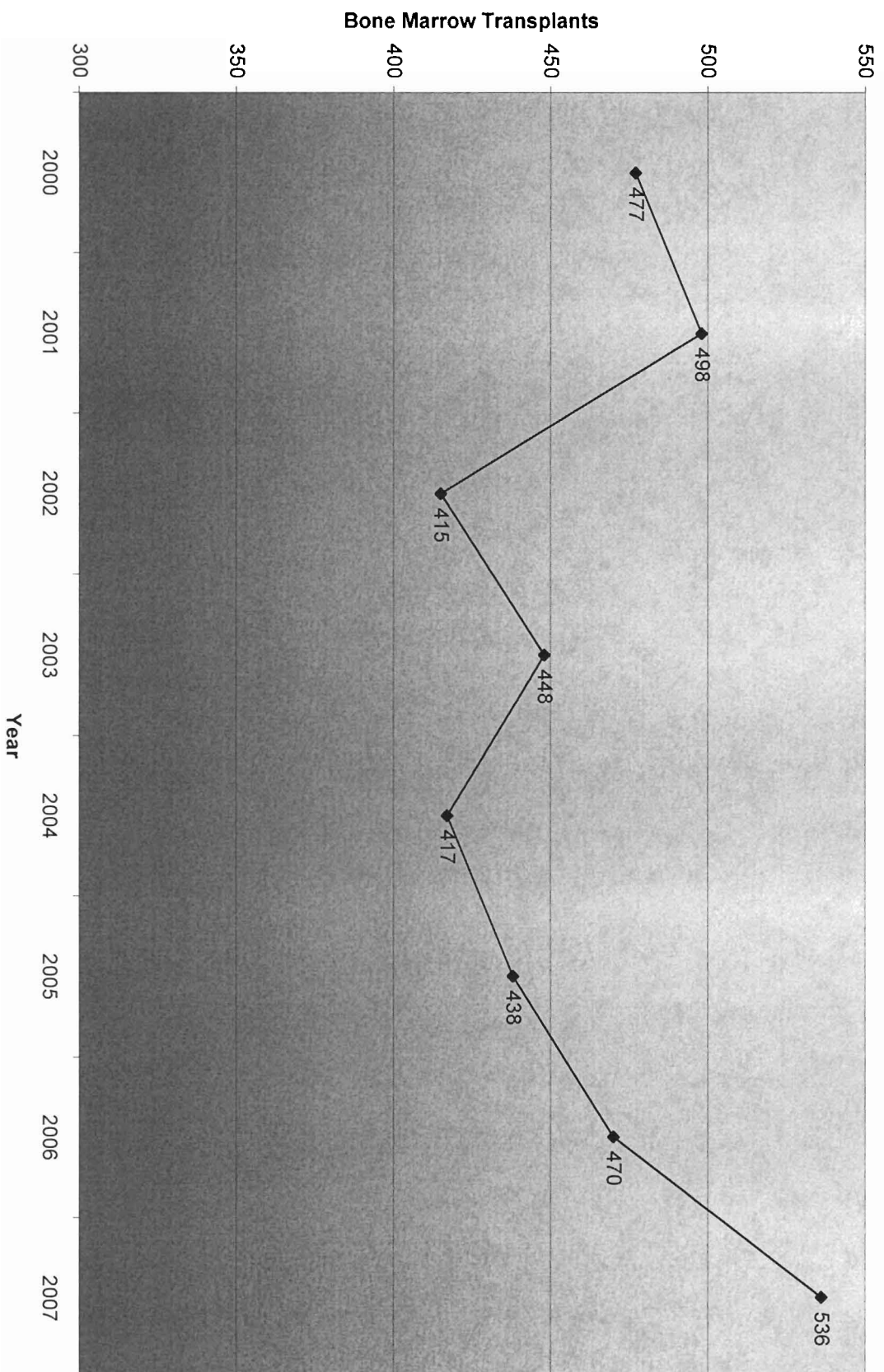
Ronald B. Irwin, M.D.
Executive Vice President and Chief Medical Officer
(and practicing bone cancer surgeon)



Kenneth J. Matzick
President and Chief Executive Officer

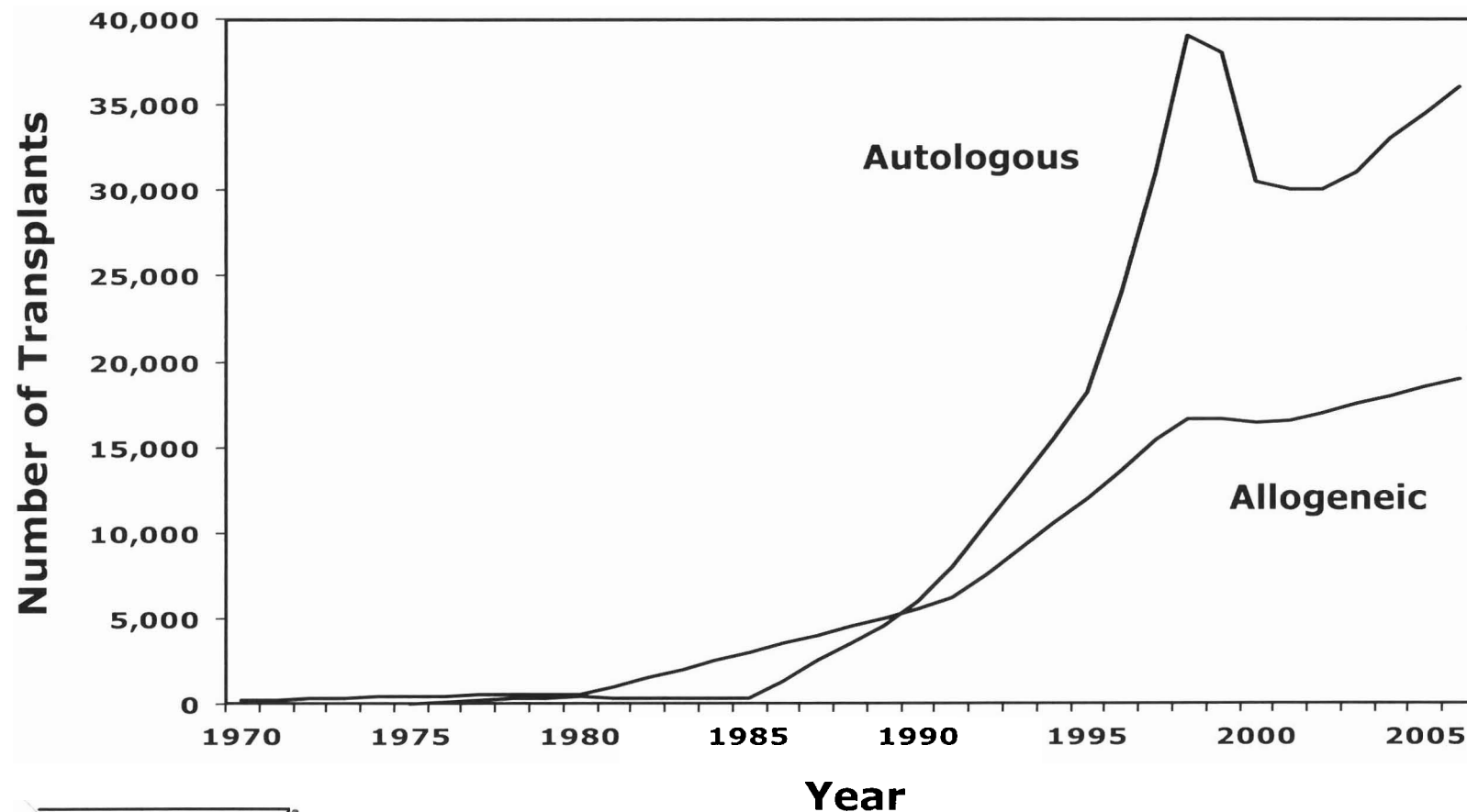
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Attachments

Bone Marrow Transplants 2000-2007 - State of Michigan

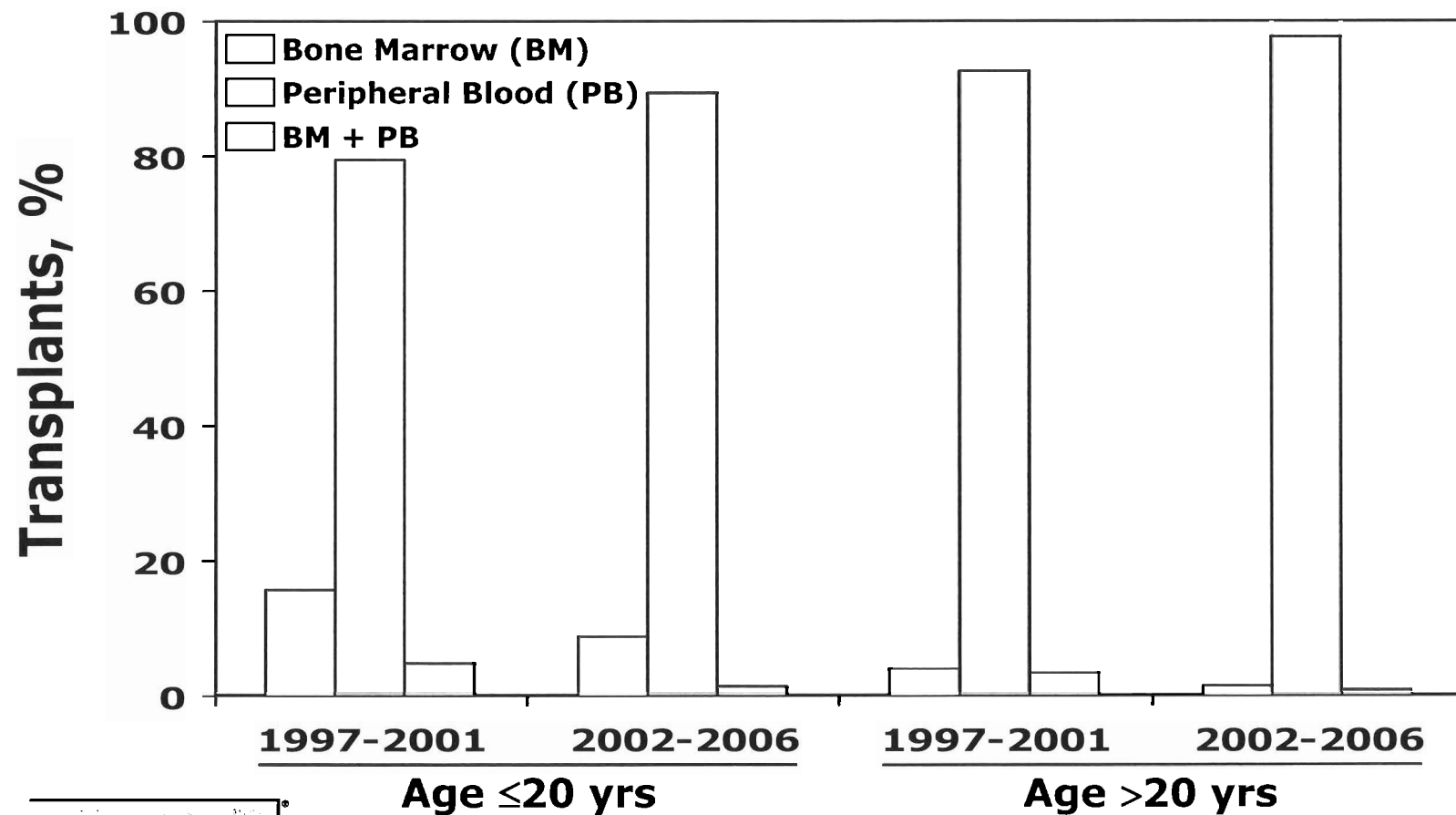


Annual Numbers of Blood and Marrow Transplantations, 1970-2006

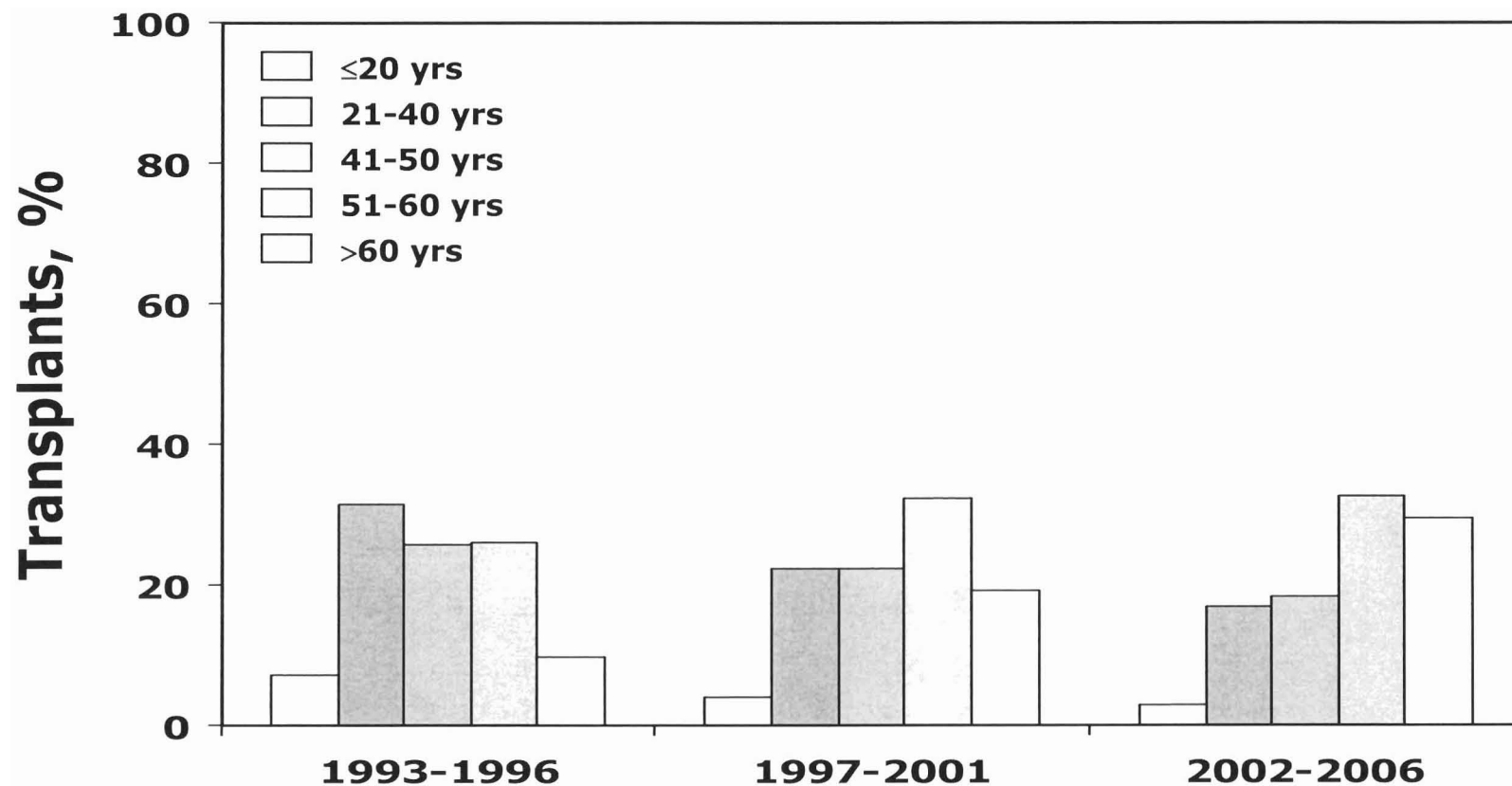
- Worldwide -



Autologous Stem Cell Sources by Recipient Age 1997-2006

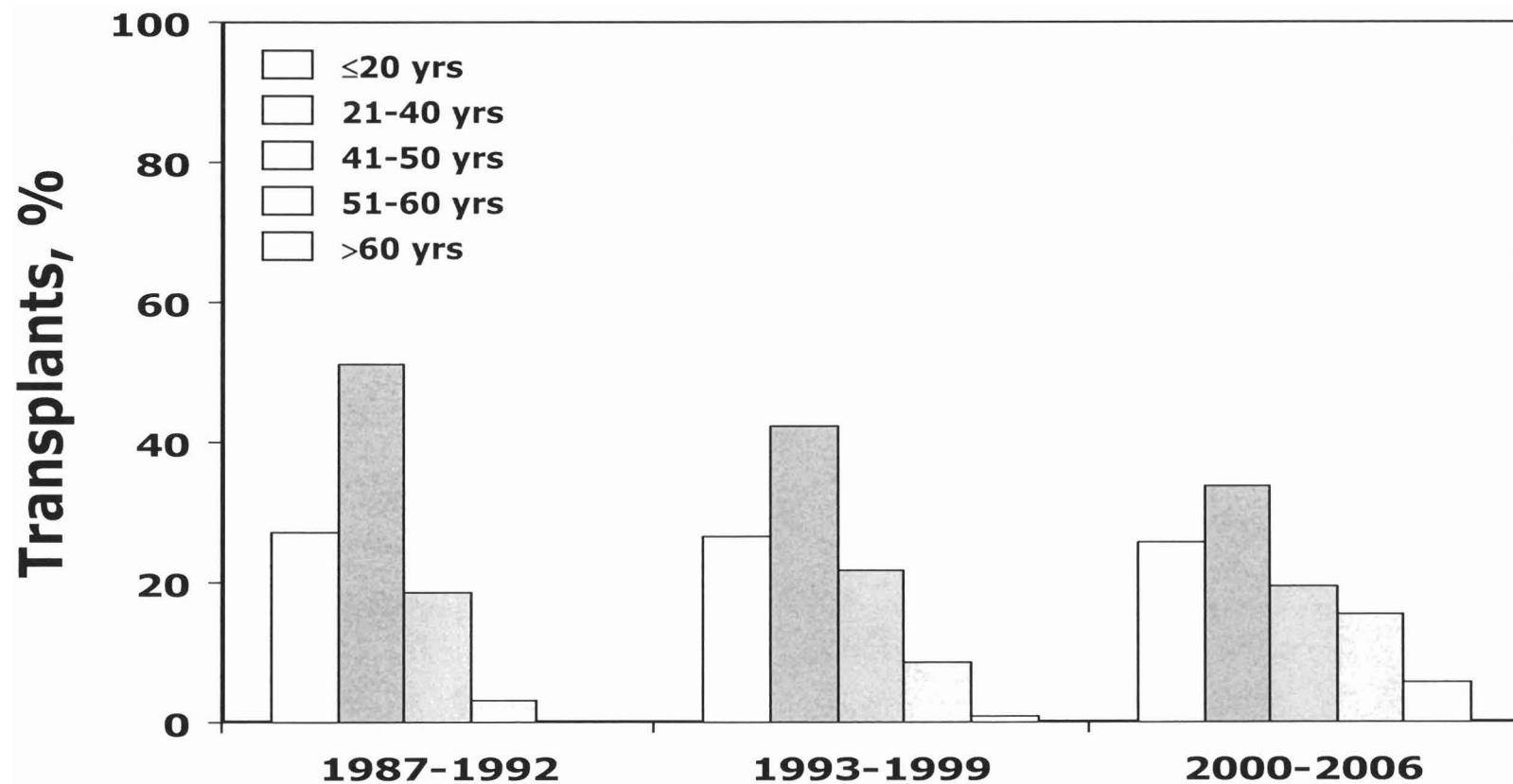


Trends in Autologous Transplantation Recipient Age* 1993-2006



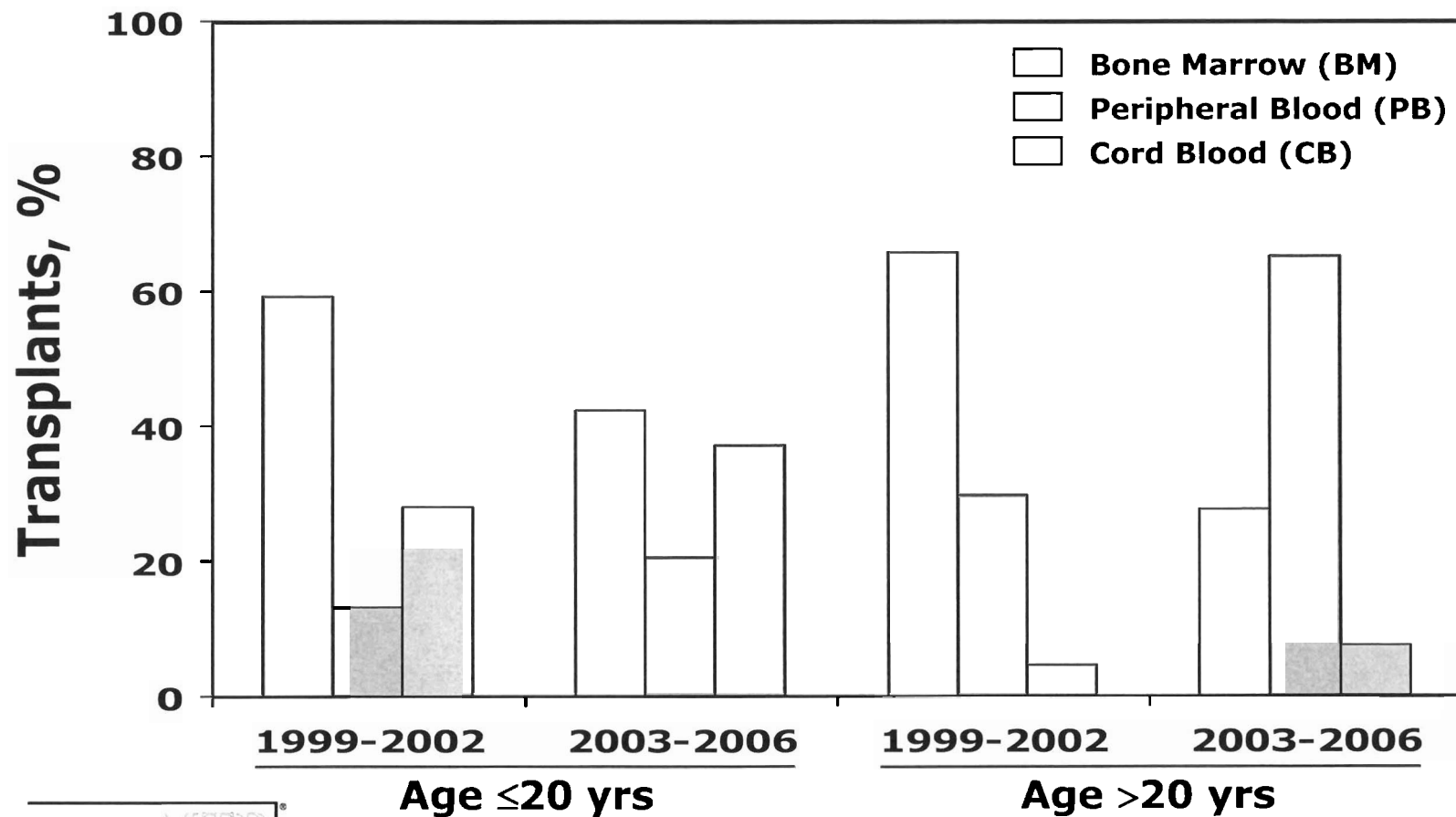
* Transplants for AML, ALL, NHL, Hodgkin disease, Multiple Myeloma

Trends in Allogeneic Transplantation Recipient Age* 1987-2006

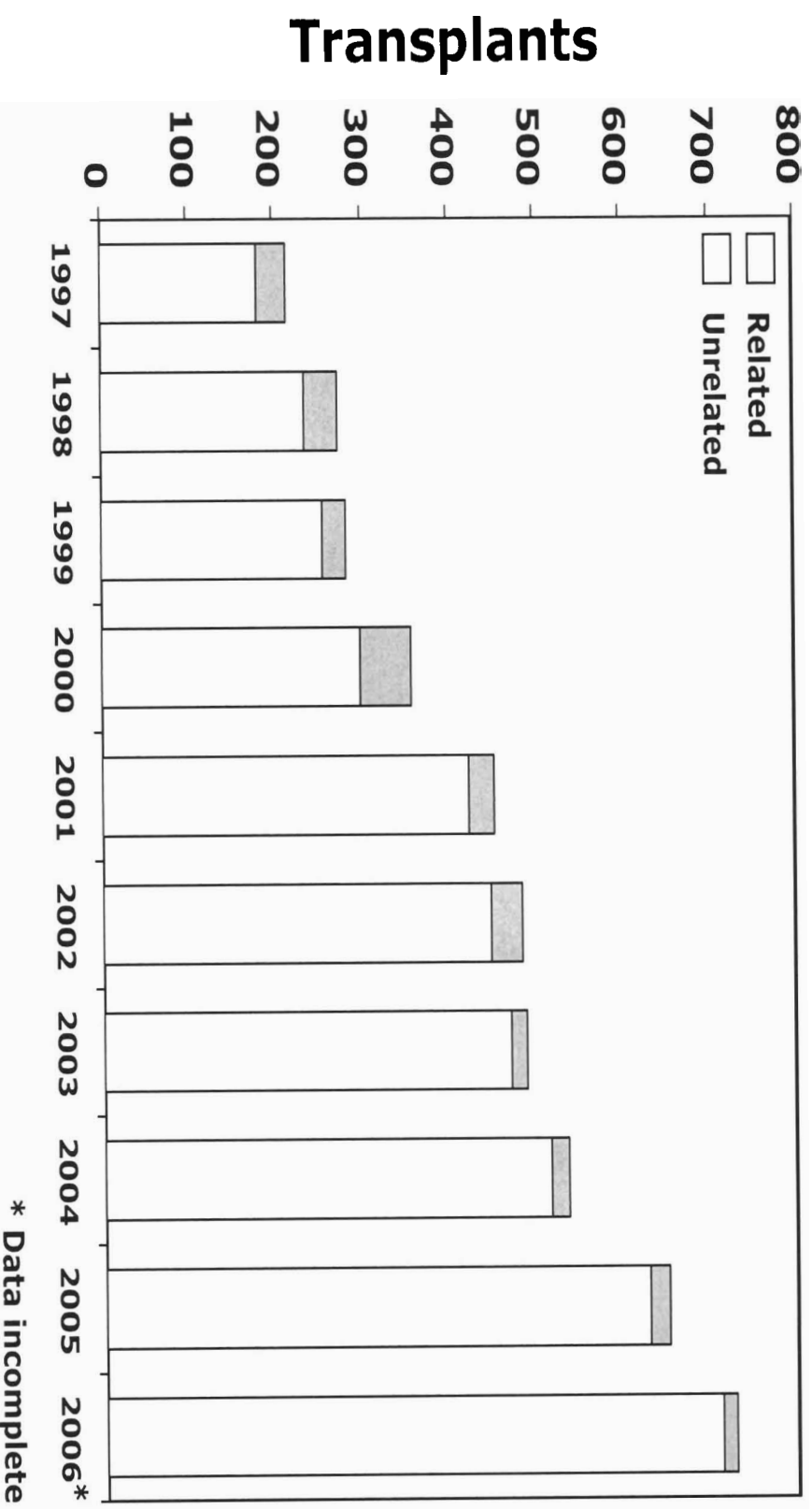


* Transplants for AML, ALL, CML

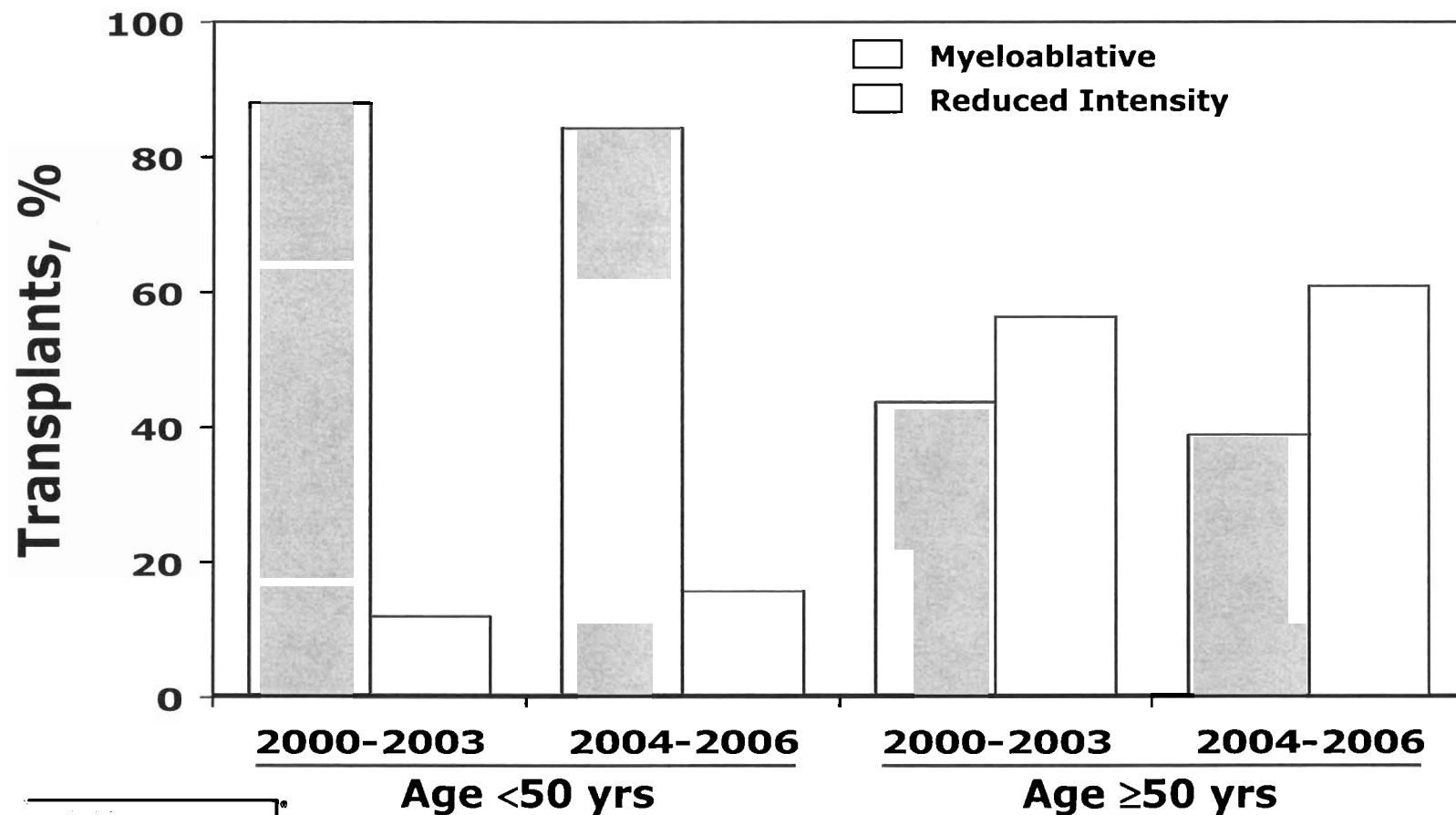
Unrelated Donor Stem Cell Sources by Recipient Age 1999-2006



Cord Blood Transplantations Registered with the CIBMTR, 1997-2006



Allogeneic Transplantations for AML by Conditioning Regimen Intensity and Age, Registered with the CIBMTR, 2000-2006



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October 16, 2008

Advancing medicine
Compassionate care

Mr. Edward B. Goldman, J.D.
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend Street, 7th Floor
Lansing, Michigan 48913

Dear Chairman Goldman,

On behalf of Oaklawn Hospital in Marshall, Michigan, we appreciate this opportunity to provide comments on the MRI standards up for review in 2009. Oaklawn Hospital is a 94-bed hospital with more than 800 employees and 90 active staff physicians providing 30 specialties. We have received the Governor's Award of Excellence, and we were recently named as one of the 100 Best Places to Work in Healthcare in the nation by *Modern Healthcare* magazine. In CMS' most recent release of patient satisfaction data, Oaklawn Hospital was above state and national averages in all ten categories.

Some of our recent clinical accreditations and recognitions include:

- Joint Commission, full, unconditional accreditation, June 2008
- Cardiopulmonary Services Department, Quality Respiratory Care Recognition by the American Association for Respiratory Care, a designation given to just 10% of hospitals nationally.
- Laboratory maintains accreditation by the Commission on Laboratory Accreditation of the College of American Pathologists (CAP), the most stringent accreditation available.
- Radiology Department maintains accreditation by the American College of Radiology.
- Oaklawn's joint replacement program has earned a 2009 Top 5% in the Nation designation by HealthGrades for clinical outcomes.

Oaklawn has been providing mobile MRI service since 1991. We currently receive mobile service five days per week and have considered increasing to seven days per week. However, in considering our options, it has become clear to us that our hospital needs a fixed MRI unit available 24 hours per day, not seven days per week of mobile service available only 12 hours per day.

Our Emergency Department sees more than 20,000 patients each year, with patients arriving during all hours of the day and night. From a practical standpoint, when we purchase mobile MRI service, it is available from 7:00 am to 7:00 pm, leaving our nighttime patients unserved by MRI until the next morning. Although we have a fixed CT scanner which provides us with a diagnostic tool to care for most of our emergency patients, there are still numerous patients who arrive at our Emergency area with conditions requiring MRI for optimum diagnosis and we are unable to provide that tool.

With recent literature confirming the superiority of MRI over CT in detecting acute strokes, especially in ischemic strokes which can be treated within the first three hours of symptoms with thrombolytic therapy resulting in improved patient outcomes, the need for a fixed MRI becomes even more apparent. (See attached article from The Lancet, January 27, 2007.) For example, when patients arrive who are exhibiting symptoms of stroke, we would be able to diagnose the stroke, analyze the size, and determine if the use of TPA is appropriate with an MRI scan. However, if that patient arrives when the mobile trailer is not parked at our facility, we must instead turn to other, less precise, methods of diagnosis.

Reducing exposure to radiation, especially in adolescent patients, is also a significant goal. While certain conditions require CT for diagnosis, there are many other conditions that could be diagnosed with MRI rather than CT as a way to reduce exposure to radiation. It is important to remember that MRI utilizes magnetic fields to create diagnostic images, whereas CT uses radiation. Exposure to radiation through the use of diagnostic CT was an issue raised at the CT Standards Advisory Committee last year. On October 10, 2007, Tom Slovis, MD, from the Detroit Medical Center, presented the SAC with evidence connecting pediatric exposure to CT with adult onset of cancer. Dr. Slovis' testimony reported that between 1 in 2,000 and 1 in 10,000 children receiving head or abdominal CT end up with cancer. He added, "Considering we are doing over 3 million CTs per year on children, this is a large public health problem."

Because *any* radiation exposure can cause cancer, according to Dr. Slovis, no dose of radiation can be considered safe, and therefore we must look for alternative modalities for diagnosing patients. Having these other modalities available is crucial. As Dr. Slovis put it, "If your only tool is a hammer, you use it for inserting nails, screws, or fixing things. If you only have CT available 24/7, then that's what you'll use when nothing else is available." This ever-increasing exposure to radiation

Mr. Edward B. Goldman, J.D.
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through diagnostic studies needs to be of major concern, and we must look for ways to reduce radiation exposure; utilizing MRI in place of CT as a diagnostic tool should be encouraged whenever it is appropriate.

We understand that the purpose of Certificate of Need is to ensure quality and access, while restraining the rising cost of health care. Having addressed safety, access and quality above, this leaves us only to look at cost. Based on our current costs for obtaining service from existing mobile MRI routes, we have determined that it would be less expensive for us to acquire a fixed MRI unit rather than pay for mobile service seven days per week.

More specifically, assuming the cost of mobile service stays consistent with current contracts and a \$2 million price tag for a fixed MRI unit, our hospital would save in excess of \$1 million in operating costs per year by replacing our mobile MRI service with a fixed MRI unit. Even when taking into consideration the capital expenses associated with a fixed MRI unit (i.e., construction/renovation costs and depreciation), the savings is still nearly \$500,000. Additionally, as already noted above, seven day per week mobile service would not give our patients round-the-clock access.

We do recognize that Michigan cannot afford for every hospital with an Emergency Department to have a fixed MRI. However, we do believe it is a vital diagnostic tool for an emergency department with significant volume that is located a fair distance from another emergency department with fixed MRI service. Since most hospitals with busy emergency departments already have fixed MRI service, this would only allow for those few hospitals that don't. Therefore, I am asking that the CON Commission modify the MRI standards to accommodate for these limited circumstances and have attached potential language modifications that would do so.

I appreciate your time in considering this matter and look forward to continued discussions as you review these standards early next year, and urge that you take up this matter in as expedited and efficient manner as possible. Please feel free to contact me directly at (269) 789-3924.

Sincerely,



Rob Covert
President and CEO

Magnetic resonance imaging and computed tomography in emergency assessment of...

Julio A Chalela; Chelsea S Kidwell; Lauren M Nentwich; Marie Luby; et al

The Lancet; Jan 27-Feb 2, 2007; 369, 9558; Research Library

pg. 293

Articles

Magnetic resonance imaging and computed tomography in emergency assessment of patients with suspected acute stroke: a prospective comparison

Julio A Chalela, Chelsea S Kidwell, Lauren M Nentwich, Marie Luby, John A Butman, Andrew M Demchuk, Michael D Hill, Nicholas Patronas, Lawrence Latour, Steven Warach

Summary

Background Although the use of magnetic resonance imaging (MRI) for the diagnosis of acute stroke is increasing, this method has not proved more effective than computed tomography (CT) in the emergency setting. We aimed to prospectively compare CT and MRI for emergency diagnosis of acute stroke.

Methods We did a single-centre, prospective, blind comparison of non-contrast CT and MRI (with diffusion-weighted and susceptibility weighted images) in a consecutive series of patients referred for emergency assessment of suspected acute stroke. Scans were independently interpreted by four experts, who were unaware of clinical information, MRI-CT pairings, and follow-up imaging.

Results 356 patients, 217 of whom had a final clinical diagnosis of acute stroke, were assessed. MRI detected acute stroke (ischaemic or haemorrhagic), acute ischaemic stroke, and chronic haemorrhage more frequently than did CT ($p < 0.0001$, for all comparisons). MRI was similar to CT for the detection of acute intracranial haemorrhage. MRI detected acute ischaemic stroke in 164 of 356 patients (46%; 95% CI 41–51%), compared with CT in 35 of 356 patients (10%; 7–14%). In the subset of patients scanned within 3 h of symptom onset, MRI detected acute ischaemic stroke in 41 of 90 patients (46%; 35–56%); CT in 6 of 90 (7%; 3–14%). Relative to the final clinical diagnosis, MRI had a sensitivity of 83% (181 of 217; 78–88%) and CT of 26% (56 of 217; 20–32%) for the diagnosis of any acute stroke.

Interpretation MRI is better than CT for detection of acute ischaemia, and can detect acute and chronic haemorrhage; therefore it should be the preferred test for accurate diagnosis of patients with suspected acute stroke. Because our patient sample encompassed the range of disease that is likely to be encountered in emergency cases of suspected stroke, our results are directly applicable to clinical practice.

Introduction

Magnetic resonance imaging (MRI) is generally thought to be better than computed tomography (CT) for the diagnosis of acute stroke, but this belief has never been substantiated for the full range of patients in whom this diagnosis is suspected. Patients who present to the emergency room with stroke-like symptoms might have cerebrovascular disease (ischaemic or haemorrhagic) or various other non-vascular disorders. The ideal imaging modality for assessment of patients with acute stroke should accurately detect both cerebral ischaemia and intracranial haemorrhage, and discriminate cerebrovascular causes from other causes. CT is the most common imaging modality used to assess patients with suspected stroke. This method is widely available, fast, easy, and less expensive than MRI. However, although CT is sensitive to acute intracranial haemorrhage, it is not sensitive to acute ischaemic stroke. Studies suggest that CT is insufficiently sensitive for the diagnosis of acute ischaemia, is subject to substantial inter-rater variability in interpretation, and might not be better than MRI for detection of acute intracranial haemorrhage.^{1–4}

MRI offers advantages for the assessment of acute stroke. Changes of acute ischaemic injury are detectable sooner with MRI than with CT, especially with diffusion-

weighted imaging, and ischaemic stroke diagnosis with MRI has greater interobserver and intraobserver reliability than CT, even in readers with little experience.^{5,6} Historical concerns that MRI is not sufficiently sensitive to detect acute intracranial haemorrhage in the earliest hours from onset have been addressed by studies that show gradient-echo MRI is as accurate as CT in patients with focal stroke symptoms within 6 h of symptom onset.⁷ However, the relative diagnostic yield of MRI and CT for routine emergency assessment of possible stroke, irrespective of time from onset, severity of symptoms, or ultimate diagnosis (cerebrovascular or otherwise), had not been investigated. We aimed to prospectively compare CT and MRI for the detection of acute stroke in the full range of patients who present for emergency assessment of stroke-like symptoms.

Methods

Study participants and clinical diagnosis

This study was a single-site, prospective comparison of CT and MRI for the assessment of acute stroke. It took place from Sept. 30, 2000, to Feb. 25, 2002, at Suburban Hospital, a community hospital in Bethesda, Maryland, USA, in accordance with the institutional review boards of both the hospital and the National Institute of Neurological

Lancet 2007; 369: 293–98

See Comment page 257

Medical University of South Carolina, Charleston, SC, USA (J A Chalela MD); Georgetown University, Washington Hospital Center, Washington DC, USA (C S Kidwell MD); Boston Medical Center, Boston, MA, USA (L M Nentwich MD); National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, MD, USA (M Luby MS, L Latour PhD, S Warach MD); National Institutes of Health Clinical Center, Bethesda, MD, USA (J A Butman MD, N Patronas MD); and University of Calgary, Alberta, Canada (A M Demchuk MD, M D Hill MD)

Correspondence to: Dr Steven Warach, Section on Stroke Diagnostics and Therapeutics, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 10 Center Drive, Rm B1D731, MSC 1063 Bethesda, MD 20892, USA (warachs@ninds.nih.gov)

Disorders and Stroke. A consecutive series of patients referred to the hospital's stroke team because of suspicion of acute stroke were eligible, irrespective of time from onset, symptom severity, or ultimate clinical diagnosis. The decision to use imaging was initiated by the emergency physician on suspicion of an acute stroke and before assessment by a stroke specialist. Emergency clinical assessment, including the National Institutes of Health stroke scale (NIHSS), was done by the stroke specialist according to the stroke centre routine. Assessments were typically made within an hour of one or both scans, although exact times of the clinical assessments were not routinely recorded, and the NIHSS might not have been used if the physician decided the diagnosis of stroke was unlikely. Patients were excluded from the present analysis if either CT or MRI was not done. Reasons for exclusions included contraindications to MRI, symptoms strongly suggestive of subarachnoid haemorrhage, initiation of antithrombotic or thrombolytic treatment before the completion of both scans, or inability to complete both scans in time to allow thrombolytic treatment within 3 h of the onset of symptoms. Results from a subset of these patients were previously reported in a multicentre comparison of MRI and CT for diagnosis of intracranial haemorrhage under 6 h.¹

The order of scanning was not randomised because such a requirement would have necessitated clinically unjustifiable delays in patient assessment and management. By design, MRI was to be done before CT, and the scans were to be initiated within 120 min of each other, but patients who did not meet this requirement were not excluded from the primary analysis.

The final clinical diagnosis was that documented in the patient's hospital record during the admission by the responsible stroke-team neurologist, on the basis of all available clinical information, including acute and follow-up brain imaging and ancillary testing. Patients with imaging evidence of cerebral infarction were given a final diagnosis of ischaemic stroke even if deficits were transient. The diagnosis of transient ischaemic attack was reserved for transient deficits (less than 24 h duration) without imaging evidence of infarction.

Imaging techniques and analysis

For MRI we used a 1.5 T scanner (GE Signa, General Electric, Milwaukee, WI, USA). Only patients for whom gradient-echo imaging and diffusion-weighted imaging sequences had been completed were eligible for enrolment. Gradient-echo imaging parameters were field of view 24 cm, repetition time (TR) 800 ms, echo time (TE) 20 ms, flip angle 30°, and acquisition matrix 256×192. Diffusion imaging parameters were field of view 24 cm, TR 6000 ms, TE 72 ms, acquisition matrix 128×128, and b values of 0 and 1000 s/mm² isotropically weighted. Both sequences yielded 20 contiguous slices that were 7 mm thick axial-oblique. Although other imaging sequences were also obtained, we did not assess them. For non-contrast CT we

used either a Somatom Plus scanner (Siemens, Iselin, NJ, USA) or a Lightspeed scanner (General Electric). Images were acquired in the orbitomeatal plane with 5 mm slice thickness from the skull base through the vertex.

Images were analysed by two expert neuroradiologists and two expert stroke neurologists, who were not connected with the care of patients and were unaware of all clinical information. Readers viewed the images independently, and were asked to record evidence of acute ischaemic stroke, acute haemorrhage, chronic haemorrhage, no acute stroke, or a combination of these.

Digital images were presented to readers with commercially available software that enabled readers to adjust the contrast, brightness, and size of the images. All images were devoid of patient identifiers. For MRI interpretation, readers were provided with images from the gradient-echo imaging and diffusion-weighted imaging sequences; diffusion-weighted imaging sequences included b=0, T2-weighted images. If the gradient-echo images were not interpretable because of motion artifact, readers were asked to use the b0 component of the diffusion-weighted images for haemorrhage detection. For CT interpretation, readers were provided with image sets adjusted for bone windows and conventional brain windows, and were allowed to adjust brightness and contrast on the displayed images. The CT and MRI images were randomly sorted, and pairs (CT and MRI) corresponding to each patient were presented on different days to avoid recognition of imaging findings by readers. For a case to be judged positive for the different variables of interest, the interpretation needed to be concordant for at least three of the four independent readers. The number of acute stroke diagnoses might be fewer than the sum of the subtypes if patients had both subtypes.

Statistical analysis

The primary hypothesis was that MRI is better than CT for the diagnosis of all forms of acute stroke. Secondary hypotheses were that MRI is better than CT for detection of acute ischaemic stroke, and that it is not worse than CT for detection of acute intracranial haemorrhage. We used McNemar's paired proportion test to measure the concordance between MRI and CT for each diagnosis. The hypothesis that was expected to show the smallest difference—comparison of MRI to CT for diagnosis of intracranial haemorrhage—was used to decide the target sample size. Therefore, the null hypothesis was that MRI was worse than CT for the detection of intracranial haemorrhage, and the alternative hypothesis was that MRI was not worse than CT for the detection of intracranial haemorrhage. On the assumption that MRI would be 2.5% more sensitive than CT, and that the proportion of discordant pairs would be 3.5%, with an 80% power, we decided that a sample size of 380 would be needed to reject the null hypothesis by the McNemar paired proportion test.

Sensitivity, specificity, and accuracy of blinded CT and MRI diagnosis obtained in this study were estimated in relation to final clinical diagnosis. The significance of correlated proportions was tested with the McNemar test. For this comparison, the diagnostic categories for the admission were acute stroke (acute ischaemic stroke, acute intracranial haemorrhage) or not acute stroke (including transient ischaemic attack). Logistic regression analysis was used to examine predictors of false-negative MRI outcomes.

Role of the funding source

The corresponding author is an employee of the funding source. The corresponding author had full access to all the data in the study and had final responsibility for the study design, data collection, data analysis, data interpretation, writing of the report, and decision to submit for publication.

Results

Over 18 months, 450 patients were screened and 94 were excluded—49 because of MRI contraindications (ie, electronic implants, severe patient agitation or claustrophobia, or medical instability); 34 because CT was not obtained because of failure to follow protocol or because treatment was initiated immediately after MRI; and 11 because CT was uninterpretable (ie, severe patient movement or failure to save scans). All MRIs were judged adequate for the panel of readers to make an interpretation of presence or absence of acute stroke, even if their quality was degraded by motion or other artifacts.

The study sample size was 356 patients. The median age of these patients was 76 years (range 21–100). The median time from symptom onset to MRI imaging was 367 min (range 36 min to 8 days; interquartile range 2 h 32 min to 8 h 34 min). The median time from symptom onset to CT imaging was 390 min (36 min to 8 days; 2 h 52 min to 8 h 51 min). The median difference in start time between MRI and CT imaging was 34 min earlier for MRI (236 min earlier to 212 min later; 26–41 min earlier). MRI was done before CT in 304 (85%) patients.

Table 1 shows that of the 356 patients referred because of clinically suspected stroke, acute stroke was the final clinical diagnosis for almost two-thirds. Acute stroke was detected in 185 of 356 (52%; 95% CI 47–58) with MRI and 59 of 356 (17%; 13–21) with CT. Table 2 shows that detection of all acute strokes (ischaemic or haemorrhagic) was more frequent with MRI than with CT ($p<0.0001$). The four readers unanimously agreed on the presence or absence of acute stroke in 286 cases (80%, 76–84%) with MRI and 207 (58%, 53–63%) with CT (table 3).

Ischaemic acute stroke was the final clinical diagnosis in more than half the study population. Table 1 shows that MRI detected ischaemic acute stroke in 164 of 356 patients and CT in 35 of 356. Table 2 shows similar detection rates in patients scanned within 3 h of symptom onset, acute ischaemic stroke was detected by MRI in

almost half of these 90 patients, and by CT in less than a tenth. In the 131 patients scanned between 3 h and 12 h of symptom onset, acute ischaemic stroke was detected by MRI in 53 (41%; 32–49%), and by CT in 16 (12%; 7–19%).

Table 2 shows that acute intracranial haemorrhage was detected by MRI in 23 of 356 patients (6%, 4–10%) and by CT in 25 (7%, 5–10%). For the detection of all forms of intracranial haemorrhage (acute or chronic), MRI was better than CT ($p<0.0001$). When only intraparenchymal

	CT	MRI	Clinical diagnosis
Acute stroke	59 (17%, 13–21%)	185 (52%, 47–58%)	217 (61%, 56–66%)
Acute ischaemic stroke	35 (10%, 7–14%)	164 (46%, 41–51%)	190 (53%, 48–59%)
Acute intracranial haemorrhage	25 (7%, 5–10%)	23 (6%, 4–10%)	27 (8%, 5–11%)
No stroke	297 (83%, 79–87%)	171 (48%, 43–53%)	139 (39%, 34–44%)

Data are number (% of total sample, 95% CI).

Table 1: Blinded imaging diagnosis compared to final clinical diagnosis

		Total sample		p value	<3 h from onset (n=90)		p value
		CT+	CT-		CT+	CT-	
Acute stroke	MRI+	56	129	<0.0001	16	33	<0.0001
	MRI-	3	168		1	40	
Acute ischaemic stroke	MRI+	32	132	<0.0001	6	35	<0.0001
	MRI-	3	189		0	49	
Intracranial haemorrhage (acute or chronic)	MRI+	23	66	<0.0001	10	18	<0.0001
	MRI-	2	265		1	61	
Acute intracranial haemorrhage	MRI+	21	2	ns	9	1	ns
	MRI-	4	329		2	78	
Acute haematoma or haemorrhagic transformation	MRI+	18	2	ns	7	1	ns
	MRI-	2	334		2	80	
Any haematoma or haemorrhagic transformation (acute or chronic)	MRI+	19	13	0.002	8	3	ns
	MRI-	1	323		1	78	
Chronic intracranial haemorrhage	MRI+	0	73	<0.0001	0	22	<0.0001
	MRI-	0	283		0	68	

CT=computed tomography. MRI=magnetic resonance imaging. MRI+=positive diagnosis with MRI. MRI-=negative diagnosis with MRI. CT+=positive diagnosis with CT. CT-=negative diagnosis with CT. Data are numbers of patients. P values calculated by McNemar's paired proportion test. NS=not significant.

Table 2: Paired proportion analysis of CT vs MRI for the diagnosis of stroke

	Yes	No	CT (n)	MRI (n)
Acute stroke	0	4	168	124
	1	3	96	30
	2	2	33	17
	3	1	20	23
	4	0	39	162
Acute ischaemic stroke	0	4	193	149
	1	3	97	32
	2	2	31	11
	3	1	17	20
	4	0	18	144
Acute intracranial haemorrhage	0	4	316	309
	1	3	35	13
	2	2	0	11
	3	1	4	6
	4	0	21	17

Table 3: Agreement between diagnoses by the four readers

	n	Acute stroke		Acute (ischaemic) stroke	
		CT	MRI	CT	MRI
Sensitivity					
All	356	26% (20-32)	83% (78-88)	16% (12-23)	83% (77-88)
>12 h	135	22% (14-33)	91% (82-96)	16% (9-27)	92% (83-97)
3-12 h	131	29% (19-41)	81% (70-89)	20% (12-33)	81% (69-90)
<3 h	90	27% (17-40)	76% (64-86)	12% (5-24)	73% (59-84)
Specificity					
All	356	98% (93-99)	97% (92-99)	98% (94-99)	96% (92-99)
>12 h	135	98% (89-100)	96% (86-99)	98% (90-100)	97% (88-99)
3-12 h	131	97% (87-99)	98% (90-100)	96% (87-99)	99% (91-100)
<3 h	90	100% (85-100)	96% (79-100)	100% (89-100)	92% (78-98)

Data in parentheses are 95% CI.

Table 4: Sensitivity and specificity of blinded imaging diagnosis by time from onset to scan

Data in parentheses are 95% CI.

Table 4: Sensitivity and specificity of blinded imaging diagnosis by time from onset to scan

haematoma or haemorrhagic transformation were considered (ie, aside from diagnoses of haemorrhage consisting of chronic microbleeds only) diagnosis of intracranial haemorrhage (acute or chronic) was more frequent by MRI than by CT ($p<0.002$). MRI was better for the detection of chronic haemorrhage ($p<0.0001$).

The relative sensitivity and specificity of CT and MRI were then assessed by comparison of blinded MRI and CT diagnoses with the final clinical diagnosis, as summarised in table 4. Acute stroke was the final diagnosis by treating physicians in 217 of 356 patients (61%), including acute intracranial haemorrhage in 27 (8%), and transient ischaemic attack in 50 (14%). In 89 of 356 patients (25%) the final diagnosis was not cerebrovascular disease. In 190 patients with a final clinical diagnosis of acute ischaemic stroke, the median severity by NIHSS score was 3 (range 0-37).

When compared with the final clinical diagnosis, MRI had a higher sensitivity than CT for all acute stroke and for acute ischaemic stroke ($p<0.0001$ by McNemar test). For diagnosis of acute intracranial haemorrhage, MRI had a sensitivity of 81% (95% CI 61-93%) and a specificity of 100% (98-100%), compared with 89% (70-97%) and 100% (98-100%), respectively, for CT. Relative to a final clinical diagnosis of acute stroke, MRI had an accuracy of 89% (85-92%) and CT of 54% (49-59%).

MRI was positive in 157 of 190 (83%; 77-88%) cases of acute ischaemic stroke, with a false-negative rate of 17% (12-24%). No cases of false-negative MRI were positive on CT. By stepwise multivariable logistic regression, false-negative MRI diagnoses of ischaemic stroke were associated with brainstem location (adjusted odds ratio 7.3, 95% CI 2.2-25.0), time from symptom onset to scan less than 3 h (5.8, 2.3-14.9), and NIHSS score of less than 4 (3.2, 1.3-7.9). Of the 31 ischaemic stroke patients with two or more predictors, the false-negative rate was 15 of 31 (48%; 31-67%), whereas the false-negative rate was 17 of 169 (10%; 6-16%) with either no predictor or only one. Two patients had all three predictors; both were false negatives.

The treating physicians with knowledge of clinical localisation and additional imaging data had identified an acute lesion at the time of the clinical event on diffusion-weighted imaging in 23 of the 32 masked false-negative cases.

Discussion

We report that MRI is more effective than CT for the diagnosis of acute stroke in a typical patient sample. Our sample was representative of the range of patients who are likely to present with a clinical suspicion of acute stroke, including patients who ultimately proved to have a different diagnosis. Therefore, our results are directly applicable to clinical practice.

The earliest comparisons of MRI to CT in the diagnosis of acute stroke, from the early 1990s, before clinical diffusion-weighted imaging and gradient-echo imaging were routine, showed that acute infarcts were visible more frequently on MRI than on CT and that these modalities were much the same for detection of intracranial haemorrhage.⁴² In the mid 1990s, diffusion-weighted imaging entered the clinic and showed promise of greater sensitivity for stroke diagnosis than conventional MRI, especially in the initial hours after stroke onset, and for the detection of small lesions.⁴³ Early reports that compared diffusion-weighted imaging MRI with CT estimated sensitivities of 86-100% for diffusion-weighted imaging and 42-75% for CT, but were limited by potential biases in patient selection and image assessment.⁴⁴⁻⁴⁶

The greater overall sensitivity of MRI for acute stroke in this study is attributable to its effectiveness for detection of acute ischaemic stroke. Diagnostic rates for acute intracranial haemorrhage were much the same for MRI and CT. MRI with diffusion-weighted imaging was both more effective within the critical first 3 h and in the entire sample. Acute ischaemic stroke was diagnosed with MRI in 46% of patients but with CT in only 10%. Of the 190 patients with final clinical diagnosis of ischaemic stroke, independent, blinded assessment with MRI diagnosed ischaemic stroke in 83% of patients, and in 16% with CT. This study accords with the reported difference between MRI and CT, but our rates of imaging diagnoses were lower in both modalities than those in previous studies.⁴²⁻⁴⁴

In our sample, 25% of the patients with suspected acute stroke had final diagnoses other than cerebrovascular; this rate is consistent with other samples of consecutive patients who present to emergency departments with the initial diagnosis of acute stroke.⁴⁷ Because the accuracies of diagnostic tests are overestimated in non-representative samples,⁴⁸ we would expect that the true accuracies of MRI and CT in acute stroke in this study would be lower than those previously reported. The addition of angiographic and perfusion acquisitions to CT might have increased the accuracy of this modality and made the results more similar to those of MRI.

False-negative diffusion-weighted imaging scans in ischaemic stroke do arise. We estimated the false negatives from such MRI scans at 17%. Two of the predictors of false-negative diffusion-weighted imaging—brainstem location and NIHSS of less than 4—could relate to small lesions that escape visual detection, especially in locations such as the brainstem, in which they might be difficult to distinguish from the hyperintensity of incompletely suppressed anisotropic diffusion or susceptibility artifacts. The practitioner must be cognisant of the possibility of false negatives with diffusion-weighted imaging for ischaemic stroke and note the presence of clinical factors that predispose to such stroke.

These results accord with our previous finding that MRI might be as accurate as CT for diagnosis of intracranial haemorrhage.¹ This expanded sample showed that MRI was not worse than CT for the detection of acute intracranial haemorrhage. These results are also consistent with previous reports that MRI can accurately detect acute intracranial haemorrhage.¹³⁻¹⁵ Thus, clinicians who use MRI as the sole imaging modality in acute stroke can be assured that a negative MRI excludes acute intracranial haemorrhage as effectively as does a negative CT. Since MRI was done before CT in most patients in our study (77% of cases of intracranial haemorrhage), the MRI signal changes associated with intracranial haemorrhage could have been less conspicuous than they would have been at a later stage. Nevertheless, the potential time bias did not seem to affect the rate of detection of intracranial haemorrhage by MRI in this cohort.

In this study neither MRI nor CT achieved 100% sensitivity for the diagnosis of acute intracranial haemorrhage. When compared with the final clinical diagnosis there were four cases of clinically confirmed acute intracranial haemorrhage that were misdiagnosed by the readers on MRI. In two cases readers erroneously classified acute haemorrhages as chronic; in another (in which the gradient-echo imaging scan was not available) readers missed an acute intracranial haemorrhage in their interpretation of the diffusion-weighted imaging MRI; and in a fourth case, a left frontal acute intracranial haemorrhage was not diagnosed by the readers. When detection by CT images was compared with the final clinical diagnosis there were three false-negative cases of acute intracranial haemorrhage: a subdural haematoma, a haemorrhagic metastasis, and a temporal lobe haematoma were not diagnosed by the readers. Previous studies have also noted that cases of acute haemorrhagic transformation could be seen on gradient-echo imaging but not on CT.¹

Although CT scanning has been the criterion that is standard for diagnosis of acute stroke, our study shows that use of CT is no longer justifiable on the basis of diagnostic accuracy alone. Logistical and financial arguments in favour of CT as the preferred emergency test can be made—non-contrast CT is generally more

accessible for emergency use, even in facilities at which MRI is available, and the fixed and variable costs of CT scanning are less than for the costs of MRI scanning. Would the improvement in diagnostic accuracy offered by MRI enhance patient outcomes and cost-effectiveness enough to justify the necessary increases in expense and effort? A comparison of immediate CT with delayed CT for acute stroke showed that correct early diagnosis by immediate CT scanning increased independent survival, informed subsequent treatment and management decisions, reduced costs, and increased quality-adjusted life-years.¹⁶ A similar analysis, comparing immediate CT with immediate MRI, would help to quantify the potential effect of increased early diagnostic accuracy of MRI on health-care costs and quality of stroke outcomes. Since immediate MRI allows more accurate diagnosis than immediate CT, it might increase the cost-effectiveness of stroke care, since definitive treatments and secondary prevention could be initiated sooner than with CT alone.

A potential bias was introduced by our decision not to randomise the order of scanning. However, since abnormalities become more conspicuous over time with both MRI and CT, the probability of detection of stroke was biased in favour of CT, which was done after MRI in our study. Therefore this bias cannot account for our results.

The selection bias against patients who were judged too medically unstable to undergo MRI probably eliminated severe strokes that would be readily detectable on imaging, and thus falsely decreased the sensitivity to some degree. Our study included the typical acute stroke population, and therefore skewed the distribution towards mild cases. This feature of our sample might explain why we recorded lower CT sensitivity and a greater difference between CT and MRI than studies that excluded cases less severe than a minimum criterion according to an established stroke diagnosis.⁸ This difference between our findings and other studies persisted at later times from onset.

Although the need for urgent management of patients with transient ischaemic attacks and mild stroke has been increasingly recognised,¹⁷⁻¹⁹ accurate diagnosis on the basis of clinical presentation and CT scanning can be especially difficult in these patients. MRI is more sensitive than CT for severe stroke, but the difference might not be clinically significant if a systematic method for CT reading is used.⁶ Nevertheless, because mild stroke and transient ischaemic attack make up most stroke admissions to a general hospital emergency department, our findings are directly applicable to real-world practice.

MRI can be used as the sole modality for the emergency imaging of patients with suspected acute stroke, whether ischaemic or haemorrhagic. The high diagnostic accuracy of MRI was the same for scans within the first 3 h as it was for the entire sample, and thus is relevant to patients who might be eligible for standard thrombolytic treatment of stroke. Many stroke centres use MRI as the basis of

thrombolytic treatment decisions,⁹ and where MRI is immediately available for emergency stroke diagnosis, initiation of thrombolytic treatment will not be substantially delayed.⁶

Since imaging studies in acute stroke are usually interpreted by non-specialists, the imaging modality with the highest sensitivity and the highest intra-rater and inter-rater reliability for diagnosis of ischaemic stroke by non-specialists—MRI—should be used.⁶ Because MRI is more effective for detection of acute ischaemia, and can detect acute and chronic haemorrhage, it should be the preferred test for accurate diagnosis of patients with suspected acute stroke.

Contributors

All authors participated in the data analysis and reporting stage of this manuscript, and have seen and approved the final version.

Conflict of interest statement

We declare that we have no conflict of interest.

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Section 3. Requirements for approval of applicants proposing to initiate an MRI service or mobile MRI host site

Sec. 3. (1) An applicant proposing to initiate a fixed MRI service shall demonstrate that 6,000 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section 15 of these standards.

(2)(a) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a mobile MRI unit shall demonstrate that a minimum of 5,500 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section 15 of these standards.

(b) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards, for each proposed host site that

(i) is not located in a rural or micropolitan statistical area county and

(ii) has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(c) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards for each proposed host site that

(i) is located in a rural or micropolitan statistical area county and

(ii) has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(3)(a) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site not in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards for that host site.

(b) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 15 of these standards for that host site.

(4) An applicant that meets all of the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is proposing to initiate a fixed MRI service.

(b) The applicant is currently a host site being served by one or more mobile MRI units.

(c) The applicant has received, in aggregate, the following:

(i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available or

(ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available, and the applicant meets all of the following:

(A) is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted;

(B) the nearest fixed MRI machine is located more than 15 radius miles from the application site;

(C) the applicant is a nonprofit licensed hospital site;

(D) the applicant certifies in its CON application, by providing a governing body resolution, that the board of trustees of the facility has performed a due diligence investigation and has determined that the fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access within the community hospital setting.

- (d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent 12-month period, referenced in (c) above, by each mobile MRI service/unit from which any of the MRI adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000 adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from network 18 do not need to be used to meet the 6,000 minimum.]
- (e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site or at the applicant's licensed hospital site as defined in these standards.

(5) AN APPLICANT THAT MEETS ALL OF THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1):

- (A) THE APPLICANT IS PROPOSING TO INITIATE A FIXED MRI SERVICE.**
- (B) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.**
- (C) THE HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AT LEAST 20,000 VISITS WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.**
- (D) THE NEAREST EMERGENCY ROOM WITH A FIXED MRI MACHINE IS LOCATED MORE THAN 10 RADIUS MILES FROM THE APPLICATION SITE.**

(56) Initiation of a mobile MRI host site does not include the provision of mobile MRI services at a host site if the applicant, whether the host site or the central service coordinator, demonstrates or provides each of the following, as applicable:

- (a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.
- (b) The addition of a host site to a mobile MRI unit will not increase the number of MRI units operated by the central service coordinator or by any other person.
- (c) Notification to the Department of the addition of a host site prior to the provision of MRI services by that mobile MRI unit in accordance with (d).
- (d) A signed certification, on a form provided by the Department, whereby each host site for each mobile MRI unit has agreed and assured that it will provide MRI services in accordance with the terms for approval set forth in Section 12 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, that are served by the mobile route as of the date of the signed certification or are committed in writing to be served by the mobile route.
- (e) The central service coordinator requires, as a condition of any contract with a host site, compliance with the requirements of these standards by that host site, and the central service coordinator assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

SOUTHGATE RADIOLOGY & CT / MRI

ACR Accredited in 1.5 Tesla MRI, 64 Slice CT, Mammography and Ultrasound: General, OB, Gynecological, and Vascular

Services include: Breast MRI, Cardiac and Peripheral Vascular CTA

15300 Trenton Road, Southgate, Michigan 48195
(734) 281-6600 Fax (734) 281-7481

Dennis P. Vollman, D.O. FAOCR
Robert Bixler, D.O. & Associates

Dear Anatomic MRI Committee;

September 18, 2008

This letter is to formally request that you consider an additional methodology or pathway to convert a mobile MRI service to a fixed MRI service. I am requesting that you consider adding a pathway based on economic and volume utilization methodology. I propose that a mobile MRI service can be converted to a fixed service if both of the following requirements are met.

- 1. An economic comparison between the costs of the fixed unit compared to the actual cost of the current mobile service be made. If a greater than 20 or 25% annualized savings can be realized by converting to a fixed unit, then the CON will be granted.**

AND

- 2. A mobile service attempting to convert to a fixed service has at least 4000 adjusted procedures being performed at their location over the past year.**

I am an owner of a diagnostic imaging center that provides MRI services utilizing two mobile MRI providers. I participated as a member of two of the prior Ad Hoc MRI sub-committees when the initial methodology for acquiring a fixed or mobile MRI service was developed in the mid 1990s. I am very aware of how the committee evaluated the CON process and know that your primary interest is in providing the best healthcare in the state of Michigan at the most economic cost. My interests coincide with yours and it is for this reason I am making this request.

I am sure you are aware that the reimbursement for MRI services have been decreasing over the past several years and that there is no incentive for the mobile MRI service providers to reduce their fees that they charge us. Most if not all of the service providers in southeastern Michigan have similar charges for there services. Most of the providers have not kept current on upgrading their technology so the patient's of Michigan often receive less than state of the art MRI imaging services. Many providers have units that are over 8 to 10 years old and have only received either one or no major upgrade. These same service providers are still charging the same daily rate to lease the unit to us. If this proposal is enacted then imaging centers and hospitals will have a bargaining capability with the MRI mobile service providers and will be able to negotiate a better lease rate.

The average cost for a 12 hour daily MRI unit lease is between \$5,000.00 and \$6,000.00 for weekdays and \$4,000.00 to \$5,000.00 for weekends. If you do the math for a 5 or 6 day lease the service will cost \$1,250,000.00 to \$1,500,000.00 per year. Because the technology is older the average exam time is about 45 minutes enabling about 15 exams to be done per day. The average reimbursement for a mix of 20% with an 80% without contrast is about \$500 if your practice is predominantly Medicare and Blue Cross but approximately \$350.00 - \$400.00 dollars for HMO's or Medicaid. Assuming a 10% no-show

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ACR Accredited in 1.5 Tesla MRI, 64 Slice CT, Mammography and Ultrasound: General, OB, Gynecological, and Vascular

Services include: Breast MRI, Cardiac and Peripheral Vascular CTA

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(734) 281-6600 Fax (734) 281-7481

Dennis P. Vollman, D.O. FAOCR
Robert Bixler, D.O. & Associates

or claustrophobic rate and a 5% bad debt rate the annual gross income for an MRI service is between 1.5 and 2 million dollars per year. Utilizing this scenario, the total number of adjusted procedures would be approximately 4500. As the revenues continue to decrease, it becomes plain to see that in a short time the cost of providing MRI services will be greater than the revenue generated by the service.

Hospitals with mobile MRI services and imaging centers with MRI services need a bargaining position that the additional pathway to converting a mobile service to a fixed service will provide. If I am unable to negotiate a lower price to lease a mobile service, there will come a time when I will no longer be able to provide outpatient MRI services. The ability of an imaging center to obtain over 6000 adjusted procedures annually is extremely difficult if not impossible. Hospitals are able to scan patients at night and if a patient is a no-show they can often image an in-patient in their place. Imaging centers are unable to do this.

The MRI mobile service providers have been granted a non-competitive service that allows them to keep cost to the lessee high and their profit substantial. Most of their units are paid off and the majority of costs are in transportation and service agreements.

The cost of converting a mobile service to a fixed service would also reduce the cost of providing MRI services. A new or fully upgraded refurbished MRI unit cost between 1 and 2 million dollars. The room preparation is about \$200,000.00. The annual maintenance agreement including cryogenics is between \$100,000.00 and \$150,000.00 per year. If this cost was capitalized over 5 years the annual cost would be between \$500,000.00 and \$700,000.00 per year. Room lease cost would be \$2000.00 per month or \$24,000.00 year. The technician cost would be approximately \$100,000.00 per year. It is plain to see that the cost of the fixed unit is significantly less than the cost to lease mobile services. By allowing the additional pathway the quality of MRI services will also improve because of the newer technology, more efficient scan time and improved patient comfort being in a fixed magnet with an open environment.

I hope you will consider this proposal and implement some version of it. If you have further questions please don't hesitate to contact me at Southgate Radiology 1-734-281-6600.

Sincerely Yours;

Dennis P. Vollman D. O. FAOCR
Co-owner Southgate Radiology.



MDCH CON POLICY

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
C/O Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing MI 48913

Dear Commissioner Goldman,

At present the State of Michigan has three Centers that perform solid organ transplantation under the current Certificate of Need. This certificate of need allows for the performance of heart, lung, and liver transplantation. All three of these programs are located on the East side of the state of Michigan. Our group on the West side of the state of Michigan at Spectrum Hospital believes that a review in the certificate of need policy should be entertained at this time. At present there are eight cardiothoracic surgeons located in Grand Rapids and Muskegon, performing over 1500 open heart surgery procedures each year. In 2005 the Meijer Heart Center opened as part of Spectrum Health Center which has 36 adult medical and 36 adult surgical critical care beds. Our plans are to develop a program using ventricular assist devices and hopefully transplantation in the future.

Our facilities on the West side of the state are ideally suited for a transplant program. Unfortunately, at present families on the West side of the state are not served by transplantation because of the necessity to travel a great distance. In addition, at Spectrum we are consistently providing organs for patients throughout the state of Michigan and the rest of the United States.

Currently in Grand Rapids there is rapid development of the medical community with the addition of Michigan State Medical School, the developing size of the VanAndel Research Institute, and the addition of the Helen DeVos Children's Hospital.

In summary, we are strongly encouraging the Commissioners to consider reviewing the certificate of need that limits the number of transplantation centers in the state of Michigan to three. In our minds it is time to have serious consideration given to the opening of a transplant program on the West side of the state. We appreciate your time and consideration.

Sincerely yours,

Lawrence H. Patzelt, MD

John C. Heiser, MD

Edward T. Murphy, MD

Robert L. Hooker, Jr., MD

Charles L. Willekes, MD

Theodore J. Boeve, MD

Eric M. Hoenicke, MD

Michael P. DeFrain, MD

LHP/sjg

Grand Rapids
Meijer Heart Center
100 Michigan St NE, Ste 8830
Grand Rapids, MI 49501
V 616.459.7258
F 616.459.5215

Lawrence H. Patzelt, MD
John C. Heiser, MD
Edward T. Murphy, MD
Robert L. Hooker, MD

Grand Rapids Mailing Address
100 Michigan St NE
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Grand Rapids, MI 49501-2005

Charles L. Willekes, MD
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2008 OCT 15 PM 2:15

616.752.2104
FAX 616.222.2104

cmccallum@wnj.com

October 15, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, Michigan 48913

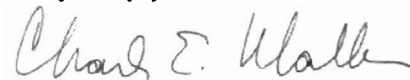
Dear Chairman Goldman:

I am a former Chairman of the Board of Butterworth Hospital (predecessor to Spectrum Health) and of Priority Health. I am writing to encourage you and the C.O.N. Commission to revise the C.O.N. review standards for heart/lung and liver transplantation services. Those standards provide for only three centers in the state, all of them located in Southeast Michigan. In order to assure reasonable access to such services for our citizens, it is important to have at least one center in West Michigan.

Transplants involve lengthy hospital stays followed by extended treatment periods and risk of re-hospitalization. To require West Michigan citizens and their families to travel to Southeast Michigan for such services subjects them to inconvenience and financial burden. West Michigan has highly sophisticated medical facilities, advanced health sciences research, and both undergraduate and postgraduate medical education, including a medical school. Such services can be safely and economically delivered in West Michigan.

I hope you and the Commission will give West Michigan citizens as well as the employers who fund their health care plans the opportunity for convenient local access to transplant services. I thank you in advance for your consideration of this request.

Very truly yours,



Charles E. McCallum

/blw
1593711



2008 OCT 23 PM 2:15

James P. Hackett
President and Chief Executive Officer

October 20, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman:

I am writing to encourage you to use the process established under Michigan law to review the standards for heart/lung/liver transplantation services. There is increasing concern that with only three centers, all located in Southeastern Michigan, that there are access and quality issues for residents of West Michigan. I am very mindful of our company's, and most other corporations in this nation, concerns with increasing health care costs.

I do believe however that these types of regulations and standards should be regularly reviewed—looking at cost, access and quality.

West Michigan has had tremendous population growth over the last two decades. In addition, we now have greatly expanded and sophisticated medical facilities, life sciences and cancer research, as well as a new medical school under construction. To put it mildly, West Michigan is a very different place since the standards for heart/lung and liver transplants were last reviewed. I believe that it is time for review.

Again, I trust this review will be done under the process established under Michigan law and Certificate of Need regulations and that the review will weigh and study the issues of cost, access and quality.

Good public policy in our state demands this type of review and a solid focus on reducing health care costs and increasing access and quality for all Americans.

Thank you for your consideration.

Regards,

A handwritten signature in black ink, appearing to read "J. Hackett", written in a cursive style.

James P. Hackett
President & CEO

JPH:mle

2008 OCT 15 PM 2:15

October 15, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

This letter is written to request that the CON Commission assess the CON Review Standards for Heart/Lung and Liver Transplantation Services, to assure access to organ transplant services for the residents of western Michigan.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all are currently located in Southeast Michigan. This situation leaves the residents of western Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, Western Michigan has the ability to develop advanced healthcare services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support your efforts to assist in these efforts.

Sincerely,



Thomas D. Kaufman
President



October 21, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Mr. Goldman,

This letter is written as formal testimony about the CON Review Standards for Heart/Lung and Liver Transplant Services which went into effect June 4, 2004. Spectrum Health appreciates the opportunity to comment on these Standards.

While the current Standards were approved four (4) years ago, the essential provisions have been in effect since 1986. The standards limit the number of organ transplantation services to three (3) transplant programs in Michigan. There are three (3) heart transplant programs currently in operation, and all are located in southeastern Michigan. Based on the current Standards, no additional programs can be approved. Three (3) may be the appropriate number of organ transplant centers for southeastern Michigan. However, the concentration of all programs in the same region of the state does not promote access to transplant services for the remainder of the state's population. Spectrum Health requests that the CON Commission open the CON Review Standards for Heart/Lung and Liver Transplantation Services for review during the current review cycle. We believe that access for residents of the western side of Michigan should be improved.

Containing nearly a third of the state's population, western Michigan includes the fastest growing counties in the state. The economy of western Michigan is increasingly enhanced by life sciences research and medical education, including the Van Andel Institute, the western campus of the MSU College of Human Medicine, a strong representation of the pharmaceutical industry, and the largest open-heart surgery program in the state. Clearly western Michigan has the necessary infrastructure to support development of advanced healthcare services, such as organ transplant.

At its Frederick and Lena Meijer Heart Center, Spectrum Health performs approximately 1200 open heart surgeries a year. In its heart and lung failure clinic, Spectrum Health maintains a caseload of more than 1,000 patients,

comprising approximately 4,600 visits each year. Referrals to the clinic come from throughout the western half of Michigan, the Upper Peninsula, and some parts of eastern Michigan. Over the last twenty (20) years, more than 250 patients have required referrals for heart transplant services. Under the present circumstances, these patients must be referred elsewhere in Michigan. Some even seek transplant services in other states. This situation is difficult for both patients and their families. It often requires disruption of their lives for long periods of time. Access to transplant services closer to home would lessen the burden on these western Michigan patients and families.

Clearly, the simplest way to address the issue of access on the western side of the state would be to create two (2) separate planning areas for organ transplantation services. Previously, this approach was incorporated into the bone marrow transplant standards for pediatric bone marrow transplant services. Establishment of an eastern and a western Michigan planning area for organ transplant services, and requiring at least one (1) transplant program in each planning area, would insure that all residents of the state would have reasonable access to these highly specialized services. By making such a change in the transplant standards, the western half of the state would then have access to the much needed transplant services currently provided only on the eastern side of Michigan.

To demonstrate broad support for the ability to establish organ transplantation services in western Michigan, we have enclosed letters of support from several legislative representatives from our area. In our conversations with legislators, Spectrum Health has reiterated our endorsement of the CON process and has emphasized that the regular review of the standards is a normal part of that process. They share our support for the activities of the Commission and endorse our request that you re-examine the organ transplant standards in the coming year.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for Heart/Lung and Liver Transplant Services, and we urge that the CON Commission initiate the appropriate process to revise these Standards to address access for outstate Michigan as soon as is possible. We will be pleased to participate in this process as appropriate.

Sincerely,

A handwritten signature in dark ink, reading "Robert A. Meeker". The signature is fluid and cursive, with the first name "Robert" being more prominent and the last name "Meeker" following in a similar style.

Robert A. Meeker
Strategic Program Manager

Enclosures



90TH DISTRICT
STATE CAPITOL
P.O. BOX 30014
LANSING, MI 48909-7514
PHONE: (517) 373-0830
TOLL-FREE: (866) 90TH-DIS
(866) 908-4347
FAX: (517) 373-7806
E-MAIL: billhuizenga@house.mi.gov
ONLINE: www.gophouse.com/huizenga.htm

MICHIGAN HOUSE OF REPRESENTATIVES

BILL HUIZENGA
STATE REPRESENTATIVE

COMMITTEES:
NEW ECONOMY AND
QUALITY OF LIFE,
MINORITY VC
COMMERCE
ENERGY AND TECHNOLOGY

October 8, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Chairman Goldman,

Please accept this letter as an indication of my support for Spectrum Health's request that the CON Commission open the review standards for heart/lung and liver transplantation services. This review is in order to assure access to these vital medical services, particularly for the residents of West Michigan, which includes my legislative district.

The current standards, which went into effect June 4, 2004, allow for only three (3) transplant centers in the state, all of which are currently located in Southeast Michigan. This fact unfairly places a burden on my constituents by forcing them to travel across the state, or out of state, for these services. The total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. Having to travel long distances for this service creates a significant hardship for transplant patients and their families.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplant services for residents outside of Southeastern Michigan. Thank you for your attention to this standard and for the role you play in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

Bill Huizenga
Michigan State Representative
90th District



BILL HARDIMAN

29TH DISTRICT
P.O. BOX 30036
LANSING, MICHIGAN 48909-7536
PHONE: (517) 373-1801
FAX: (517) 373-5801
www.senate.michigan.gov/hardiman

**THE SENATE
STATE OF MICHIGAN**

APPROPRIATIONS COMMITTEE, MEMBER

SUBCOMMITTEES:

CHAIR, COMMUNITY COLLEGES
CHAIR, DEPARTMENT OF HUMAN SERVICES
CHAIR, DEPARTMENT OF TRANSPORTATION
CAPITAL OUTLAY
HIGHER EDUCATION

**FAMILIES AND HUMAN SERVICES
COMMITTEE, VICE-CHAIR**

October 10, 2008

Mr. Edward B. Goldman
Chairman
Certificate of Need Commission
Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Goldman:

I am writing in support of Spectrum Health's request that the Certificate of Need Commission open the review standards for heart/lung and liver transplantation services. This request is prompted by a desire to ensure access to these services in west Michigan. My legislative district includes Grand Rapids and the surrounding area, and I am well aware of the concerns of local residents in this regard.

Current standards allow only three transplant centers in the state, and these are all located in southeast Michigan. Patients from west Michigan face an additional burden in treatment simply by having to travel across the state, or out of state, for their needed care. Of course, this is compounded by the total course of treatments lasting a year or more. The number and length of trips adds a significant complication to these patients in the midst of a serious medical situation.

On their behalf, I respectfully ask that you would use the Certificate of Need Commission's review process to improve access to organ transplant services for patients outside of southeast Michigan. Thank you for your consideration of this request and for your role in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

Bill Hardiman
State Senator
29th District



PHONE: 1-517-373-0846
TOLL-FREE: 1-877-328-3086
FAX: 1-517-373-8714
E-MAIL: rephildenbrand@house.mi.gov
ONLINE: www.gophouse.com/hildenbrand.htm

HOUSE OF REPRESENTATIVES
STATE OF MICHIGAN

DAVE HILDENBRAND
REPUBLICAN FLOOR LEADER

Committees:
Republican Vice Chair, Commerce
Insurance

86TH DISTRICT

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Goldman:

Please accept this letter as an indication of my support for Spectrum Health's request that the CON Commission open the review standards for heart/lung and liver transplantation services. This review is in order to assure access to these vital medical services, particularly for the residents of West Michigan, which includes my legislative district.

The current Standards, which went into effect June 4, 2004, allow for only three (3) transplant centers in the state, all of which are currently located in Southeast Michigan. This fact unfairly places a burden on my constituents by forcing them to travel across the state, or out of state, for these services. The total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. Having to travel long distances for this service creates a significant hardship for transplant patients and their families.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplant services for residents outside of Southeastern Michigan. Thank you for your attention to this standard and for the role you play in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

A handwritten signature in black ink, appearing to read "Dave Hildenbrand".

David Hildenbrand
State Representative
District 86



77TH DISTRICT
STATE CAPITOL
P.O. BOX 30014
LANSING, MI 48909-7514
PHONE: (517) 373-2277
TOLL-FREE: (866) KEVIN-77
FAX: (517) 373-8731

MICHIGAN HOUSE OF REPRESENTATIVES

KEVIN J. GREEN
STATE REPRESENTATIVE

COMMITTEES:
BANKING AND FINANCIAL SERVICES
HEALTH POLICY
SENIOR HEALTH, SECURITY
AND RETIREMENT

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Goldman:

Please accept this letter as an indication of my support for Spectrum Health's request that the CON Commission open the review standards for heart/lung and liver transplantation services. This review is in order to assure access to these vital medical services, particularly for the residents of West Michigan, which includes my legislative district.

The current Standards, which went into effect June 4, 2004, allow for only three (3) transplant centers in the state, all of which are currently located in Southeast Michigan. This fact unfairly places a burden on my constituents by forcing them to travel across the state, or out of state, for these services. The total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. Having to travel long distances for this service creates a significant hardship for transplant patients and their families.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplant services for residents outside of Southeastern Michigan. Thank you for your attention to this standard and for the role you play in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

Kevin J. Green
Michigan State Representative
77th District, Wyoming and Byron Township



30th DISTRICT
P.O. BOX 30036
LANSING, MI 48909-7536
TOLL-FREE: 1-877-KUIPERS
PHONE: (517) 373-6920
FAX: (517) 373-2751
E-MAIL: senwkuipers@senate.michigan.gov

MICHIGAN SENATE
WAYNE KUIPERS
STATE SENATOR

COMMITTEES:
EDUCATION, CHAIR
JUDICIARY, CHAIR
ADMINISTRATIVE RULES
ENERGY POLICY
GOVERNMENT OPERATIONS

October 16, 2008

Mr. Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Chairman Goldman:

Please accept this letter as an indication of my support for Spectrum Health's request that the CON Commission open the review standards for heart/lung and liver transplantation services. This review is to ensure that my constituents have access to these vital medical services.

The current standards, which went into effect June 4, 2004, allow for only three (3) transplant centers in a state, all of which are currently located in Southeast Michigan. This fact unfairly places a burden on the citizens I represent, by forcing them to travel across the state, or out of state, for these services. As you are aware, the total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. Having to travel long distances for this service creates a significant hardship for transplant patients and their families.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplant services for residents who live in West Michigan. Thank you for your attention to this standard and for the role you play in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

Wayne Kuipers
State Senator
30th District



Michigan Senate

MARK C. JANSEN

State Senator

28TH DISTRICT
520 FARNUM BUILDING
P.O. BOX 30036
LANSING, MI 48909-7536
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TOLL-FREE: (866) 305-2128
FAX: (517) 373-5236
senmjansen@senate.michigan.gov

ASSISTANT MAJORITY CAUCUS CHAIR

COMMITTEES:

FAMILIES AND HUMAN SERVICES, CHAIR
CAMPAIGN AND ELECTION OVERSIGHT
FINANCE

APPROPRIATIONS

SUBCOMMITTEES:

ECONOMIC DEVELOPMENT, CHAIR
RETIREMENT, CHAIR
DEPARTMENT OF HUMAN SERVICES

October 13, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
201 Townsend Street, Capitol View Building
Lansing, Michigan 48913

Dear Chairman Goldman:

Please accept this letter as an indication of my support for Spectrum Health's request that the Certificate of Need Commission open the review standards for heart/lung and liver transplantation services. This review is in order to assure access to these vital medical services, particularly for the residents of West Michigan, which includes my legislative district.

The current standards, which went into effect June 4, 2004, allow for only three transplant centers in the state, all of which are currently located in Southeast Michigan. This fact unfairly places a burden on my constituents by forcing them to travel across the state, or out of state, for these services. The total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. Having to travel long distances for this service creates a significant hardship for transplant patients and their families.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplant services for residents outside of Southeastern Michigan. Thank you for your attention to this standard and for the role you play in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

Mark C. Jansen
State Senator
28th District



87TH DISTRICT
STATE CAPITOL
P.O. BOX 30014
LANSING, MI 48909-7514
PHONE: (517) 373-0842
FAX: (517) 373-6979
E-MAIL: brianalley@house.mi.gov

MICHIGAN HOUSE OF REPRESENTATIVES

BRIAN CALLEY
STATE REPRESENTATIVE

COMMITTEES:
BANKING AND
FINANCIAL SERVICES
HEALTH POLICY
TAX POLICY

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Goldman:

As State Representative for the 87th District, I would like to take this moment to express my complete support for Spectrum Health's request that the CON Commission open the review standards for heart/lung and liver transplantation services. This review is in order to assure access to these -vital medical services, particularly for my constituency and all of West Michigan.

Standards effective July 4, 2004 place an unfair burden on my constituents by forcing them to travel across the state, or out of state, to enter a transplant center. The three (3) transplant centers allowed under the referenced standards are all located in Southeast Michigan - an extreme hardship for West Michigan transplant patients and their families. Furthermore, the total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplant services for residents outside of Southeastern Michigan. Thank you for your attention to this standard and for the role you play in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

A handwritten signature in black ink that reads "Brian Calley".

Brian Calley
State Representative
87th District



State Capitol
PO BOX 30014
Lansing, MI 48909
517-373-0838
888-238-1008
arlanbmeekhof@house.mi.gov

Arlan Meekhof
Michigan House of Representatives
89th District

October 14, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Goldman:

Please accept this letter as an indication of my support for Spectrum Health's request that the CON Commission open the review standards for heart/ lung and liver transplantation services. This review is in order to assure access to these vital medicine services, particularly for the residents of West Michigan, which includes my legislative district.

The current Standards, which went into effect June 4, 2004, allow for only three (3) transplant centers in the state, all of which are currently located in Southeast Michigan. This fact unfairly places a burden on my constituents by forcing them to travel across the state, or out of state, for these services. The total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. Having to travel long distances for this service creates a significant hardship for transplant patients and their families.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplant services for residents outside of Southeastern Michigan. Thank you for your attention to this standard and for the role you play in protecting access, quality and affordability of health care services in Michigan.

Sincerely,

A handwritten signature of Arlan Meekhof in black ink, written in a cursive style.

Arlan Meekhof
State Representative
89th District

PETE HOEKSTRA

SECOND DISTRICT

MICHIGAN

WORLD WIDE WEB

<http://hoekstra.house.gov>

110th Congress

Congress of the United States

House of Representatives

October 27, 2008

COMMITTEES:

HOUSE PERMANENT
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RANKING MEMBER

HOUSE COMMITTEE ON
EDUCATION AND LABOR

Edward B. Goldman, Chairman
Certificate of Need Commission
Michigan Department of Community Health
Certificate of Need Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman:

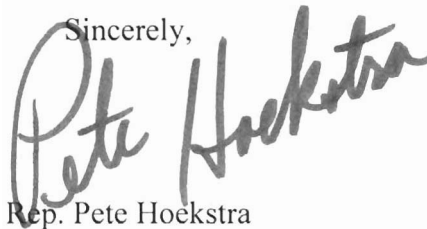
I request that the Certificate of Need (CON) Commission revise the CON Review Standards for Heart/Lung and Liver Transplantation Services, to ensure access to organ transplant serves for the residents of West Michigan.

It is my understanding that the current standards permit only three transplant centers in the state, and all are currently located in Southeast Michigan. Individuals who reside in West Michigan—as well as those in other areas of the state—are at a significant disadvantage in their ability to access transplant services. Residents are forced to travel significant distances either across the state or out-of-state to receive critical, life-saving transplant services. Since the total course of treatment for organ transplant can last for one year or more, traveling long distances can pose a significant hardship for patients and their families.

West Michigan includes five of the six fastest-growing counties in the state. West Michigan's economy continues to grow because of the life sciences research, nationally recognized health care systems and the expansion of Michigan State University's medical schools. This area of the state has the capacity and ability to provide advanced health care services such as organ transplants. I request that the CON Commission review its current CON standards governing transplant services and determine whether they can be offered to residents in other parts of Michigan.

Thank you for your consideration of this request. Should you have any questions, please do not hesitate to contact Katherine Haley of my staff.

Sincerely,



Rep. Pete Hoekstra
Member of Congress



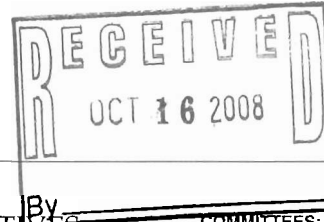
WASHINGTON OFFICE
2234 Rayburn House Office Building
Washington, DC 20515
(202) 225-4401
FAX: (202) 226-0779

DISTRICT OFFICE—HOLLAND
184 South River Avenue
Holland, Mich. 49423
(616) 395-0030
FAX: (616) 395-0271

DISTRICT OFFICE—MUSKEGON
900 3rd Street, Suite 203
Muskegon, Mich. 49440
(231) 722-8386
FAX: (231) 722-0176

DISTRICT OFFICE—CADILLAC
210-1/2 North Mitchell Street
Cadillac, Mich. 49601
(231) 775-0050
FAX: (231) 775-0298





74TH DISTRICT
STATE CAPITOL
P.O. BOX 30014
LANSING, MI 48909-7514
PHONE: (517) 373-8900
FAX: (517) 373-8697
E-MAIL: daveagama@house.mi.gov

MICHIGAN HOUSE OF REPRESENTATIVES

DAVE AGEMA
STATE REPRESENTATIVE

By _____
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SUBCOMMITTEES:
TRANSPORTATION
(MIN. VICE CHAIR)
COMMUNITY HEALTH
HIGHER EDUCATION

October 13, 2008

Edward B. Goldman, Chairman
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Chairman Goldman:

I ask that you please accept this letter as an indication of my fullest support for Spectrum Health's request that the CON Commission open the review standards for heart/lung and liver transplantation services. This review can assure access to vital, life-saving health care that all residents of West Michigan should have access to. This includes many of the constituents of my district.

Current standards from 2004 allow for only three transplant centers in the state of Michigan. They are all located in Southeast Michigan. This fact unfairly places a burden on my constituents on my constituents by forcing them to travel across the state, or even out of the state, for these services. The total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. As a result, many patients have to travel very long distances repeatedly and this creates significant hardships for patients and families.

Therefore, I am hopeful that the CON Commission's review will find a way to improve access to organ transplantation services for residents outside of Southeast Michigan. Thank you for your time and attention regarding this standard. Please continue to protect access, quality, and affordability of health care services in Michigan.

Sincerely,

David Agema
State Representative
74th District of Michigan

Richard M. DeVos

7575 Fulton Street East
Ada, Michigan 49355

Phone number: 616.787.8985
Fax number: 616.787.5695

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MDCH CON POLICY
2008 OCT 15 PM 2:15
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OWNER & CHAIRMAN

October 17, 2008

Edward B. Goldman, Chair
Certificate of need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

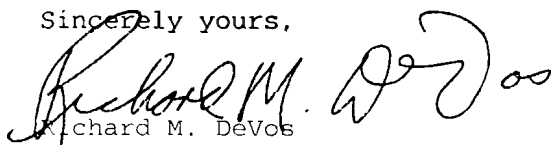
I would like to add my voice, as a long-term trustee of the largest hospital in Western Michigan, to those requesting that the Commission review current standards for heart, lung and liver transplant locations - to provide fair, efficient and cost-advantageous opportunities for West Michigan patients on the waiting list to obtain these health services.

A couple of years ago, Spectrum Health received State recognition for obtaining the largest number of organ donations over a twenty-year time span; Spectrum also obtained the second largest number of organ donors in the country per population. For quite a while, we have been performing adult (and now pediatric) kidney transplants in large numbers - right here in the city, with very good results and at low cost. Ours are modern, updated facilities with world class basic and translational research provided through the Van Andel Institute.

This year, the new Michigan State Medical School opened in Grand Rapids. Contrary to what is happening in the rest of the state, the population is growing in West Michigan, where the average income is higher than on the east side of the state. The rate of employment here has been higher than in the rest of the state - during good and bad economic times. The philanthropic support base provided by members of our community is one of the largest in the country, recently reflected in the phenomenal burst of construction on the "Medical Mile." The Cardiology and Cardiac Surgery Services of the Fred and Lena Meijer Heart Center are among the largest in the state, with mortality and morbidity consistently below the national average.

For all these reasons we believe that the regulation which awarded all three transplant centers to Eastern Michigan should be reviewed, allowing Western Michigan to have a Center in which to perform heart, lung and liver transplants, as well. I join the leaders of Western Michigan as we respectfully request that the committee review this provision and I appreciate the opportunity you have given me to express my views regarding to this matter.

Sincerely yours,


Richard M. DeVos

R.W. HAUENSTEIN

MDCH CON POLICY

2008 15 PM 2:15

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

St. Mary's and Spectrum Hospitals in Grand Rapids are delivering health care to our citizens with compassion and high quality at a reasonable cost. The facilities are modern with state of the art equipment. The doctors and staff meet the highest professional standards.

We now want to offer West Michigan citizens the opportunity for heart, lung and liver transplant services locally. Current C.O. N. rules allow only three approved locations all in Southeast Michigan. With the growth in our area the past 10 years, the need now exists here so our citizens do have the inconvenience of long travel.

Please have the C.O.N. Commission revise the C.O.N. Review Standards so we may position our hospitals to offer transplant services.

Thank you,


Ralph W. Hauenstein

Founder: Hauenstein Neurological Center – St. Mary's Hospital
12 year trustee – Van Andel Institute

Pennock

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October 15, 2008

Edward B. Goldman, Chair

Certificate of Need Commission

c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

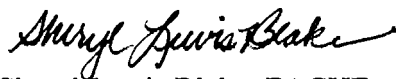
I recently learned that the CON Commission is assessing the CON Standards for Heart/Lung/Liver Transplantation Services in Michigan. Pennock Hospital is a small, independent and successful community hospital serving Barry County's population of 65,000 Michigan citizens. To assure access to organ transplant services for the residents of **western** Michigan, I request that the Commission re-evaluate the CON Standards.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all are currently located in southeast Michigan. This situation leaves the residents of Barry County at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

Barry County is a growing county situated between the cities of Kalamazoo and Grand Rapids. Our local economy is increasingly enhanced by life sciences research and medical education. Area hospitals are collaborating and we envision research centers and advanced healthcare services like organ transplant. As CEO of Pennock Health Services, I ask that the CON Commission revise the CON Standards governing organ transplant services to allow access of these services for Barry County residents.

Your thoughtful consideration of this request is appreciated. Please contact me if there is any additional information you need to support your efforts and this very important service.

Sincerely,



Sheryl Lewis Blake, FACHE
Chief Executive Officer
sblake@pennockhealth.com

2008 OCT 15 PM 2:15



*Advancing medicine.
Compassionate care.*

October 16, 2008

Mr. Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

This letter is written to request that the CON Commission assess the CON Review Standards for Heart/Lung and Liver Transplantation Services, to assure access to organ transplant services for the residents of western Michigan.

With the state's only three transplant centers all located in southeast Michigan, it places the residents of western Michigan at a disadvantage as they are forced to travel across the state or out of state when they need transplant services. Since total course of treatment for organ transplant can last a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy that is increasingly enhanced by life sciences research and medical education, western Michigan has the ability to develop advanced healthcare services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow closer access to these services for residents in population centers outside of southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support your efforts to assist in these efforts.

Sincerely,

Rob Covert, FACHE
President & CEO

MICHIGAN STATE
U N I V E R S I T Y

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing MI 48913

Dear Commissioner Goldman:

I am writing this letter to request that the CON Commission revise the CON Review Standards for Heart/Lung and Liver Transplantation Services, in order to assure access to organ transplant services for the residents throughout the state of Michigan.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all three are currently located in Southeast Michigan. This situation leaves the residents of the rest of that state at a disadvantage. Patients are forced to travel across the state or out of state when they need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan, in particular, includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, West Michigan has the ability to develop advanced healthcare services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you in advance for your consideration of this request. Please feel free to contact me if you should have any questions relative to my support for revision of the CON Review Standards for Heart/Lung and Liver Transplantation Services.

Sincerely,



Marsha D. Rappley MD
Dean



COLLEGE OF
HUMAN MEDICINE

Office of the Dean

Michigan State University
East Fee Hall
East Lansing, MI
48824-1316
517/353-1730
FAX: 517/353-9969

mmmc[®]
Michigan Medical, P.C.
"Putting Patients First"

MDC

JOY

2008 OCT 23 PM 2:15

October 21, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman:

This letter is written to request that the CON Commission assess the CON Review Standards for Heart/Lung and Liver Transplantation Services to assure access to organ transplant services for the residents of West Michigan. Michigan Medical, P.C. has over 200 physicians, 100 midlevel providers and 1400 employees with offices in Kent, Ottawa and Montcalm Counties. We are the largest multispecialty group (with over 35 specialties) in West Michigan. We do not have transplant specialists currently and are therefore advocating solely on behalf of our 250,000 patients (over 600,000 if one counts all patients seen by our specialists by referral from physicians outside our group).

It is my understanding that the current standards allow for only three (3) transplant centers in the state, with all currently located in Southeast Michigan. This situation leaves the residents of West Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, West Michigan has the ability to develop advanced healthcare services such as organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents of West Michigan. As West Michigan becomes a destination for health care, transplant services for those outside of Michigan will also enhance the overall economy of Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support this change.

Sincerely,

Edward J. Inman



Chief Executive Officer

4100 Lake Drive S.E., Suite 300

Grand Rapids, Michigan 49546
www.mmpc.com

(616) 974-4889 Fax: (616) 974-4887

Edward J. Inman
Chief Executive Officer

John M. MacKeigan, M.D.
Chief Medical Officer
Interim Chair of the Board

Allyn R. Lebster
Chief Operating Officer

Scott T. Harring, C.P.A.
Chief Financial Officer



October 17, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
C/O Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

I am writing this letter to request that the CON Commission revise the CON Review Standards for Heart/Lung and Liver Transplantation Services, in order to assure access to organ transplant services for the residents of West Michigan.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all are currently located in Southeast Michigan. This situation leaves the residents of West Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy that is increasingly enhanced by life sciences research and medical education, West Michigan has the ability to develop advanced healthcare services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of Southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything I can do to support your efforts to assist in these efforts.

Sincerely,

Roger Spoelman
President and CEO

HACKLEY CAMPUS

1700 Clinton Street • P.O. Box 3302
Muskegon, MI 49443-3302
231.726.3511 • (800) 825.4677

LAKESHORE CAMPUS

72 S. State Street
Shelby, MI 49455
231-861-2156

MERCY CAMPUS

1500 E. Sherman Blvd. • P.O. Box 358
Muskegon, MI 49443-0358
231-672-2000 • (800) 368-4125

MUSKEGON GENERAL CAMPUS

1700 Oak Avenue • P.O. Box 358
Muskegon, MI 49443-0358
231-672-2000 • (800) 368-4125



MDCH CON POLICY

2008 OCT 15 PM 2:15

October 15, 2008

Mr. Edward B. Goldman, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman:

As a citizen of the West Michigan community for the past 55 years, I have observed the growth of an outstanding health care system with a reputation surpassed by no system in the State.

However, we currently lack heart/lung and liver transplantation services which would be a tremendous benefit here to the patients and their families.

Given the approval for heart/lung and liver transplantation, we would be able to provide these critical services closer to the patient's home which is good for both the patient and their family. We can save all parties concerned considerable costs and we would be able to capitalize our skills and abilities on the largest open-heart program in the State as conducted by Spectrum Health.

We believe it is critical for the CON Commission to open the heart/lung and liver transplantation standards to provide these needed services in West Michigan.

Sincerely,

A handwritten signature in dark ink, appearing to read "Earl Holton". The signature is fluid and cursive, with a large initial "E" and a long, sweeping tail.

Earl Holton
President (Retired)



MDCH CON POLICY

2008 OCT 15 PM 2:15

October 15, 2008

Mr. Edward B. Goldman, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman:

West Michigan has five of the six fastest growing counties in Michigan with a corresponding growth for need of a comprehensive health system. We have most of the acute care facilities and services, but we are in need of heart/lung and liver transplantation services.

When we are able to provide these heart/lung and liver transplantation services, we will be in a position to save lives, provide a shorter travel distance for family and save all parties concerned a good deal of money.

Please have the CON Commission open the heart/lung and liver transplant standards to provide full access to these services in West Michigan.

Sincerely,

Fred Meijer
Chairman Emeritus

2008 OCT 15 PM 2:15

October 15, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,


This letter serves as a request that the CON Commission assess the CON Review Standards for Heart/Lung and Liver Transplantation Services, to assure access to organ transplant services for the residents of western Michigan.

The current Standards allow only three (3) transplant centers in the state, and all are currently located in Southeast Michigan. This situation leaves the residents of western Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, western Michigan has the ability to develop advanced healthcare services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support your efforts to assist in these efforts to reassess the organ transplant standards.

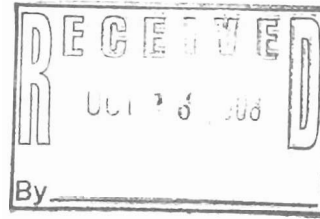
Sincerely,


Joseph A. Wasserman
President & CEO
Lakeland HealthCare

JAW:nh

J.C. HUIZENGA

3755 36TH STREET, S.E., SUITE 100
GRAND RAPIDS, MICHIGAN 49512-2913
PHONE: 616-957-9060 • FAX: 616-957-9002



October 14, 2008

Mr. Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

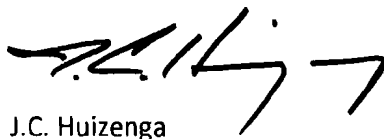
Dear Commissioner Goldman,

I understand that at the present time no C.O.N. exists for heart/lung and liver transplants for any hospitals in West Michigan. I have also been assured that there is capacity and technological capability to perform such transplants at certain hospitals in West Michigan.

Because of a desire to facilitate the needs of the people who live in West Michigan who require such surgery; because of the presence of medical research facilities, the Michigan State University School of Human Medicine, and various state of the art medical facilities; because transplant surgery requires extended recovery time during which access to the company of friends and relatives increases the probability of success for the operation, I wish to petition the C.O.N. Commission to revise its present policy to allow heart/lung and liver transplant procedures to occurring in West Michigan.

Thank you for your consideration.

Very truly yours,



J.C. Huizenga



October 16, 2008

Mr. Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

This letter is written to request that the CON Commission assess the CON Review Standards for Heart/Lung and Liver Transplantation Services, to assure access to organ transplant services for the residents of western Michigan.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all are currently located in Southeast Michigan. This situation leaves the residents of western Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, western Michigan has the ability to develop advanced health care services, like organ transplantation. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support your efforts to assist in these efforts.

Sincerely,

A handwritten signature in black ink, appearing to read "Dale Sowders".

Dale Sowders
President & CEO

DS/ch

Pediatric Nephrology

221 Michigan Street NE Suite 406 Grand Rapids MI 49503-2538
616 391 3788 fax 391 7930 devoschildrens.org

200 OCT 15 PM 2:15

October 14, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

I am the Director of Pediatric Nephrology, Dialysis and Transplantation at Helen DeVos Children's Hospital which is the pediatric hospital affiliated with the Spectrum Health system in Grand Rapids, Michigan. I came to this institution in 2003, in 2004 we became CMS certified to begin a pediatric dialysis unit, in 2005 as a UNOS certified physician I began a pediatric kidney transplant program at Butterworth Hospital for Helen DeVos Children's Hospital affiliated with Spectrum Health. Since 2005, we have successfully transplanted 25 children in a steroid free environment with 100% graft function and 100% patient survival. We have facilities within this institution at Butterworth Hospital of the Spectrum Health system for the following: drug monitoring, histological review, viral load monitoring, organ harvesting, organ procurement and an OR staff for transplantation.

We have begun a very unique process in this institution and are now serving the western part of Michigan that has never been served before. We have now prevented the need for children to travel 100 to 200 miles for dialysis as well as transplantation care. I will use an example of what needs to be done from our cardiac arena.

You may also be aware of the Spectrum Health system at Butterworth Hospital who continues to be of the top five hospitals in the country in terms of organ donation.

I am aware that presently there are three Certificates of Need available in the state for heart transplantation all of which are in the southeastern part of Michigan. While the need has been there and well fulfilled for years, there is clearly a large deficit of care for cardiac transplant in the western part of the state. The state of Michigan as we know economically has been very sluggish yet the western part of Michigan has had significant and ongoing growth.

Presently, patients who require heart transplants are required to travel hundreds of miles to the east side of the state or out of state for evaluation and ongoing care. Further these patients are kept on "on call" at the "availability of notification of heart transplant" and must drop all of their activities and immediately respond to their heart transplant institution.

While this has worked for years, we are now in a situation where we have a group of individuals with expertise and a patient population that could be taken care of locally.

In this situation, families of patients who are listed for heart transplant are at risk for the distance of travel especially during the winter months. Since there is a high need in this area, growth in our area, risk of patients for distance of travel, precedence on the pediatric transplant program, the infrastructure and expertise that currently exists, I believe it is time for consideration from the Michigan Department of Community Health to consider a Certificate of Need to help service the need of the population in need of cardiac transplantation in Western Michigan. This would allow for cardiac transplant in the western part of the state specifically at Butterworth Hospital in the Spectrum Health system. As a UNOS certified physician and a physician who has been in the transplant arena for over 20 years, this is a logical progression based on the expertise locally and the infrastructure that is in place.

I appreciate your efforts and the Commission's consideration into this matter. Thank you for your support.

Sincerely,

A handwritten signature in dark ink, appearing to read 'T. Bunchman', is written over a light blue horizontal line.

Dr. Timothy E. Bunchman
Professor and Director of Pediatric Nephrology, Dialysis and Transplantation
Member of the State of Michigan OPO for Solid Organ Transplantation

2008 OCT 23 PM 2:15

October 16, 2008

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Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

West Michigan includes the fastest growing counties in the State of Michigan and health care is an expanding part of the region's economic base. In light of this, I am writing this letter to request that the CON Commission revise the CON Review Standards for Heart/Lung and Liver Transplantation Services in order to assure access to organ transplant services for the residents of West Michigan.

The current Standards leave the residents of West Michigan at a real disadvantage, as the three transplant centers allowed in the state are currently located in southeast Michigan. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

With an economy which is increasingly enhanced by life sciences research and medical education, we feel the West Michigan community has the ability to provide specialized advanced healthcare services, like organ transplants. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you for your consideration of this request. Please feel free to contact me if I can provide additional support.

Sincerely,



Birgit M. Klohs
President & CEO

BMK/mam



MDCH CON POLICY

2008 OCT 23 PM 2:15

October 20, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman:

I write in support of revisions to the CON review standards that would permit heart/lung and liver transplantation services in west Michigan.

Current standards allow only three centers in the state, all in southeast Michigan. This is unfair to the families of west Michigan patients who find it difficult to support family members when they are hospitalized at great distance.

It is time to provide local transplantation services in west Michigan. I hope you can give this request serious consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. Haas', written over a circular stamp.

Thomas J. Haas
President

Thomas J. Haas
President

200 OCT 15 PM 2:15

October 16, 2008

Mr. Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

I'm writing today to request the Certificate of Need Commission open review standards for heart/lung/liver transplantation services to address equitable access in West Michigan.

Current standards, which only allow three centers in the State, are inadequate for West Michigan residents. All centers are currently located in Southeastern Michigan, putting our citizens at a significant disadvantage due to the hardships of travel. Transplantation services require a significant amount of time for pre and post-transplant care, perhaps as much as a full year. This burden to our residents is unacceptable and unnecessary.

Grand Rapids transfers an average 13 patients per year for heart transplants alone, a demand that justifies local services be available. Our population growth has outpaced other regions of the State for many years and five of the six fastest growing counties in Michigan are located in West Michigan.

A review will find that our economic and medical infrastructure is growing at an unprecedented pace with major investments by Spectrum Health, the Van Andel Institute and Michigan State University, who's Medical School is under construction in Grand Rapids. Yet with all this development, our medical costs are historically low, much lower than the eastern side of the State.

Western Michigan has a history of responsible use of its assets and is a good steward of opportunities that benefit a wide range of our residents. You may expect the same if you open access for transplantation services. Please consider this request at your earliest convenience.

Thank you for your consideration.

Very sincerely,



Danny R. Gaydou
Publisher



CON POLICY

2008 OCT 15 PM 2:15

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

This letter is written to request that the CON Commission assess the CON Review Standards for Heart/Lung and Liver Transplantation Services, to assure access to organ transplant services for the residents of western Michigan.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all are currently located in Southeast Michigan. This situation leaves the residents of western Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, western Michigan has the ability to develop advanced healthcare services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support your efforts to assist in these efforts

Sincerely,

A handwritten signature in cursive script, reading "Randall Stasik".

Randall Stasik
President/CEO
Gerber Memorial Health Services



MDCH CON POLICY

2008 OCT 15 PM 2:15

October 17, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
C/O Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman:

As a western Michigan business leader, access to exceptional health care is important to me. Currently, transplant patients need to travel to southeastern Michigan or out of state for services. This travel creates a significant hardship for patients and their families. This year, one of my employees passed away in an Ann Arbor hospital awaiting a lung transplant while his two young children and many other family members had to stay behind in Grand Rapids.

I respectfully request that the CON Commission open the heart/lung/liver transplant standards to address equal access in western Michigan. We have the medical infrastructure to effectively and safely handle these cases. Spectrum Health operates the largest open-heart program in the state and is the largest source of donated organs in Michigan. And, with the continued development of "Medical Mile", we only improve our capabilities.

Thank you for your consideration of this request.

Sincerely,

A handwritten signature in cursive script that reads 'Michelle Van Dyke'.

Michelle Van Dyke
President and CEO
Fifth Third Bank, Western Michigan



MDCH CON POLICY

2008 OCT 15 PM 2: 15

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

This letter is written to request that the CON Commission access the CON Review Standards for Heart/Lung and Liver Transplantation Services, to assure access to organ transplant services for the residents of western Michigan.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all are currently located in Southeast Michigan. This situation leaves the residents of western Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, western Michigan has the ability to develop advanced health care services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support your efforts to assist in these efforts.

Sincerely,

Craig P. Webb, Ph.D.
Senior Scientific Investigator
Director, Program of Translational Medicine

DAVID G. FREY
200 OTTAWA AVENUE, N.W.
GRAND RAPIDS, MI 49503 - 2405

MDCH COMM POLICY
200 OCT 15 PM 2:15

October 17, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

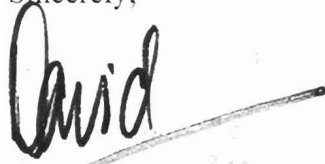
Dear Commissioner Goldman,

Given the dynamic demographic growth trends in West Michigan coupled with the extraordinary amount of private capital currently being invested in and by our three primary healthcare providers (Spectrum, St. Mary's and Metropolitan) it is appropriate for the C.O.N. Commission to revise its review standards for heart/lung and liver transplant services to ensure regional access for West Michigan citizens and many others who may select this site for these medical procedures.

The commitment to healthcare, medical education and medical research is perhaps unequalled for a metropolitan area and region of our size and profile anywhere in the country. Many believe that Grand Rapids and West Michigan represent the future for the state. We are in the process of creating an amazing medical consortium. We have the medical facilities and physician talent to compete with the best of the best! Now is the time for the above transplant services to be authorized and performed in West Michigan!

Your favorable consideration of this request will be greatly appreciated.

Sincerely,

A handwritten signature in dark ink, appearing to read "David", with a long horizontal stroke extending to the right.

David G. Frey



October 13, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

For more than forty years, I have served on the Board of Directors of Butterworth Hospital. The high quality of care at reasonable cost speaks to the dedication and professionalism of our doctors and support staff.

It is now time to provide transplant services in West Michigan. We have the facilities, professional staff and ability to bring this needed medical treatment to local citizens.

Please have the C.O.N. Commission revise the C.O.N. review standards for heart/lung and liver transplant services so that West Michigan citizens may have local access for transplants. Current rules only allow three centers for these transplants, all in Southeast Michigan.

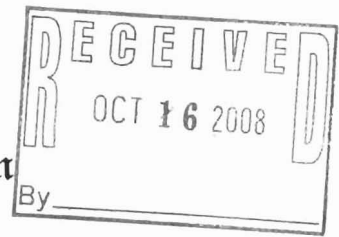
Thank you for considering this request.

Sincerely,

Peter C. Cook
Chairman



City of Grand Rapids, Michigan
OFFICE OF THE MAYOR



GEORGE K. HEARTWELL
MAYOR

October 16, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Goldman:

Please accept this letter as a formal request that the CON Commission open the CON Review Standards for Heart/Lung and Liver Transplantation Services, in order to assure access to these vital medical services for the residents of Grand Rapids and the entire region of West Michigan.

The current Standards allow only three transplant centers in the state, and all are currently located in Southeast Michigan. Residents of West Michigan are unfairly disadvantaged by having to travel across the state, or out of state for these services. The total course of treatment for a transplant patient, including patient care both before and after the organ transplant, can last for a year or more. Having to travel long distances for this service can be a significant hardship for transplant patients and their families from Grand Rapids and throughout western Michigan.

I respectfully request that the CON Commission find a way for access to organ transplant services be provided for residents outside of southeastern Michigan. Thank you for your consideration of this request.

Sincerely,


George K. Heartwell





October 20, 2008

Office of the President

Spoelhof Center

3201 Burton St. SE

Grand Rapids, MI 49546-4388

616-526-6100

Fax: 616-526-6577

www.calvin.edu

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

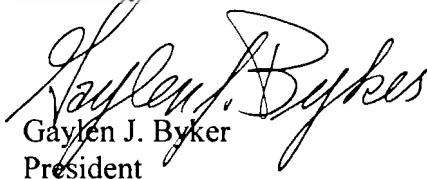
Dear Commissioner Goldman:

I have served on the Board of Directors for Priority Health since our move to Michigan fifteen years ago. The medical field is experiencing rapid growth in the West Michigan area with the sophisticated medical facilities, a state-of-the-art life sciences research facility, medical education and a medical school under construction. It is time to give West Michigan citizens local access to transplant services.

Please have the Certificate of Need Commission revise the C.O.N. review standards for heart/lung and liver transplant services so West Michigan citizens may have local access for transplants. Often transplants require extended time periods for treatment, and current rules place West Michigan citizens at a disadvantage with lengthy travel.

Thank you for considering this request.

Sincerely,


Gaylen J. Byker
President

GJB/sjc



C&H HOLDINGS, L.L.C., 618 KENMOOR AVENUE, SE, GRAND RAPIDS, MI 49546
PHONE: 616-949-7766 • FAX: 616-942-2175

October 13, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

Please have the C.O.N. Commission revise the C.O.N. review standards for heart/lung and liver transplantation services to assure local access for West Michigan citizens. Current standards allow only three centers in the state, all in Southeast Michigan.

West Michigan is a growth area with sophisticated medical facilities, enhanced life sciences research, medical education and a medical school under construction. It is time to give West Michigan citizens local access to transplant services. Often transplants require extended time periods for treatment, and current rules place West Michigan citizens at a disadvantage with lengthy travel.

Thank you for considering this request.

Sincerely,

Robert L. Hooker

2008 OCT 15 PM 2:15

October 15, 2008

Edward B. Goldman, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Goldman,

This letter is written to request that the CON Commission assess the CON Review Standards for Heart/Lung and Liver Transplantation Services, to assure access to organ transplant services for the residents of western Michigan.

It is my understanding that the current Standards allow only three (3) transplant centers in the state, and all are currently located in Southeast Michigan. This situation leaves the residents of western Michigan at a disadvantage. We are forced to travel across the state or out of state when we need transplant services. Since total course of treatment for organ transplant can last for a year or more, having to travel long distances can be a significant hardship for patients and their families.

West Michigan includes the fastest growing counties in the state. With an economy which is increasingly enhanced by life sciences research and medical education, Western Michigan has the ability to develop advanced healthcare services, like organ transplant. We ask that the CON Commission revise the CON Standards governing organ transplant services to allow access to these services for residents outside of southeastern Michigan.

Thank you for your consideration of this request. Please let me know if there is anything we can do to support your efforts to assist in these efforts.

Sincerely,



Thomas D. Kaufman
President