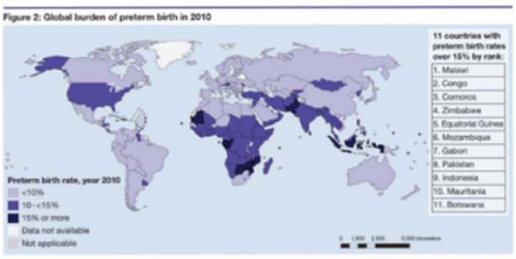
Perinatal Regionalization
Birth Hospitals Level of Care
Certificate of Need

May 2012
Updated December 2012
Workgroup Meeting – March 7, 2013

Agenda

1. Infant Mortality – Statistics – MDCH Dashboard
2. History of Perinatal Regionalization
3. Perinatal Guidelines
   - *Perinatal Regionalization: Implications for Michigan* (2009)
4. Birth Hospitals - Levels of Care – Issues
5. CON involvement
6. Designation – Verification – Certification of Birth Hospitals
   - Workgroup process
   - Flow Chart
   - Key Points of Application, Verification, Review Team, Corrective Action Plan, Appeal, Annual Report
7. Questions and Discussion

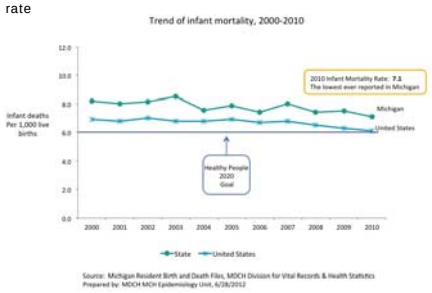
U.S. Has Comparatively High Rate Of Babies Born Early Report: Born too Soon. Global Action Report on Preterm Birth - 2012



Kaiser Health News Blog (2012, May 2) **Report: U.S. Has Comparatively High Rate Of Babies Born Early**
http://capsules.kaiserhealthnews.org/index.php/2012/05/report-u-s-has-comparatively-high-rate-of-babies-born-early/

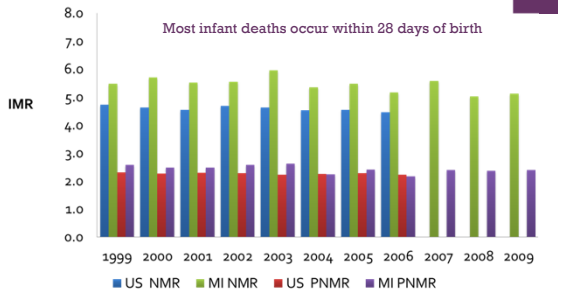
Public Health Crisis: Too Many Michigan Infants are Dying

Michigan's Infant Mortality Rate has not changed significantly in the past 10 years and remains higher than the US rate



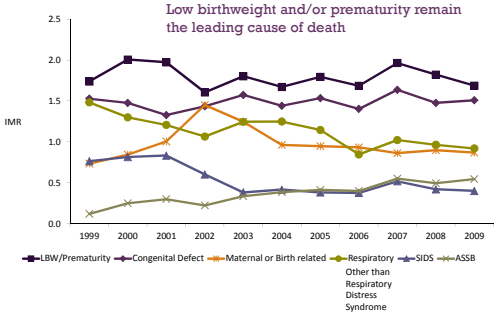
Source: Michigan Resident Birth and Death Files, MDCH Division for Vital Records & Health Statistics
Prepared by: MDCH MCH Epidemiology Unit, 6/28/2012

Neonatal and Post Neonatal Mortality Michigan and United States



Michigan Infant Mortality Rate by Cause

Low birthweight and/or prematurity remain the leading cause of death



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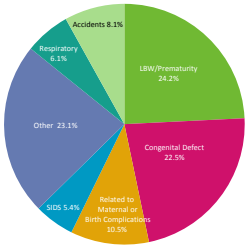
Distribution of infant mortality by cause, MI 2010

Low birth weight and/or prematurity remain the leading cause of death



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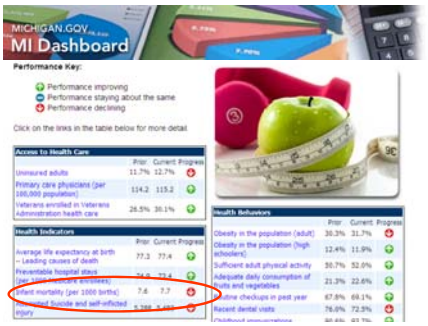
+ Govenor Synyder Dashboard



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Infant Mortality Reduction Plan August 1, 2012

http://www.michigan.gov/documents/mdch/MichiganIMReductionPlan_UPDATED_395151_7.pdf

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Infant Mortality Reduction Campaign

Targeted evidence based strategies to reduce and prevent infant mortality:

1. Implement Regional Perinatal System
2. Promote statewide adoption of policies to eliminate medically unnecessary deliveries before 39 weeks gestation
3. Promote adoption of progesterone protocol for high risk women
4. Promote safer infant sleeping practices to prevent accidental suffocation
5. Expand home-visiting programs to support vulnerable women and infants
6. Support better health status of women and girls
7. Reduce unintended pregnancies
8. Weave the social determinants of health into all targeted strategies to promote reduction of racial and ethnic disparities in infant mortality

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Historical Perspective of Regionalization in Michigan

- Development of effective newborn intensive care in the late 1960s and 1970s
- 1976: NCPH recommended a regionalized system for perinatal care (*"Toward improving the Outcomes of Pregnancy"*): focused to inpatient care
- Implemented further by most state health departments
- Authority for health department to designate levels of care was contained in Administrative Rules promulgated on 2/21/76
- The MI State Medical Society developed its own guidelines for perinatal care in 1982 – closely paralleled the March of Dimes TIOP I
- Regionalization crumbled in the 90's when funding was cut

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Literature Review and National Experts

- Indicate that states with a regionalized and coordinated perinatal system of care better assure that pregnant women and babies are more likely to deliver in an appropriate hospital setting and receive appropriate services to meet their needs.

- Healthy People 2020
  - MICH-33 Increase the proportion of very low birth weight (VLBW) infants born at level III hospitals or subspecialty perinatal centers

Perinatal Guidelines - 2009

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- The Michigan Legislature asked the Department of Community Health:

  "Convene appropriate stakeholders to determine the efficacy and impact of restoring a statewide coordinated regional perinatal system in Michigan."

- The Michigan Perinatal Level of Care Guidelines are based on AAP/ACOG Level of Care Guidelines modified to reflect Michigan's standards.

2012 Release of Perinatal Levels of Care Guidelines – AAP/ACOG

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- NOTE: AAP/ACOG have released NEW Perinatal Level of Care Guidelines
  - Level I
  - Level II
  - Level III (NICU)
  - Level IV (NICU)

Perinatal Regionalization

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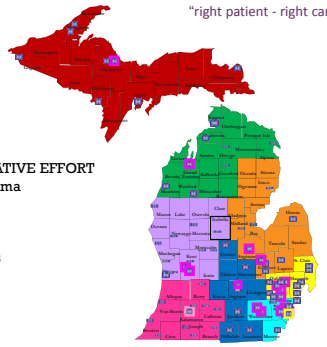
TIME DEPENDENT EMERGENCY SYSTEM

"right patient - right care - right time."



Time Dependent Emergencies Regions

Region 1
Region 2S
Region 2N
Region 3
Region 5
Region 6
Region 7
Region 8

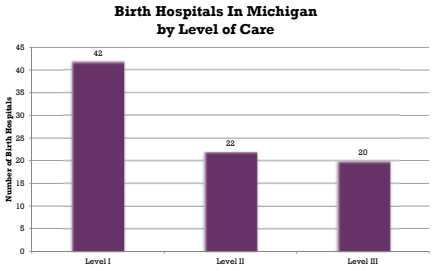
COLLABORATIVE EFFORT
- EMS/Trauma
- Stroke
- Stemi
- Perinatal
- Pediatrics

DRAFT

Birth Hospitals in Michigan

83 Total (Plus Detroit Children's NICU)

16



Perinatal Guidelines - 2009
NICU - Level IIIA, B, C

NOTE: 2012 will have Level III and Level IV

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- Level IIIA (Subspecialty)
  - Perinatal Care Center and Neonatal Intensive Care Unit
  - > 28 weeks gestation and weight > 1,000 gm
  - At least 15 VLBW infants born per year
  - CPAP and conventional mechanical ventilation
  - Minor surgery, central line and hernia repair
  - Women without significant co-morbidities

- Level III B (Subspecialty)
  - Perinatal Care Center and Neonatal Intensive Care Unit with Neonatal Subspecialty Service
  - < 28 weeks gestation and weight < 1,000 gms or with complex illnesses
  - At least 70 VLBW infants per year
  - High frequency ventilation, Inhaled nitric oxide
  - Pediatric surgery (except cardiac)
  - All maternal conditions

- Level III C (Subspecialty)
  - Perinatal Care Center or Freestanding Pediatric Hospital with Neonatal Subspecialty Service
  - < 28 weeks gestation and weight < 1,000 gms or with complex illnesses
  - At least 70 VLBW infants per year
  - Infants with ECMO or open cardiac surgery
  - All maternal conditions

Perinatal Guidelines - 2009
Level I and Level II

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- Level I (Basic) [Unchanged for 2012]
  - Community-Based Maternal-Newborn Service
  - ≥ 35 weeks gestation
  - Care if uncomplicated births

NOTE: 2012 Guidelines eliminate the A & B – will be Level II

- Level II A (Subspecialty)
  - Community-Based Maternal-Newborn Service with a Special Care Nursery
  - > 32 weeks gestation
  - > 1,500 gm
  - Uncomplicated preterm infant with problems that are expected to resolve rapidly
  - Stabilization of sick newborn infants until transfer only
  - No surgery

- Level II B (Subspecialty)
  - Community-Based Maternal-Newborn Service with a Special Care Nursery
  - > 32 weeks gestation
  - > 1,500 gm
  - Uncomplicated preterm infant
  - CPAP and mechanical ventilation for less than 24 hours
  - No surgery

Level II is NOT regulated!

CON Regulates NICUs (Level III)

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[Level III and Level IV with the 2012 Guidelines]

State of Michigan - Birth Hospitals with NICU

April 2012

County	HOSPITAL	Level of Care (Not Verified)	CON NICU	# NICU Beds	OTHER BEDS
Genesee	Hurley Medical Center	Level III B	44	44	NICU only, NO SCN - all beds on one unit
Grand Traverse	Munson Medical Center	Level III A	12	12	4 step down beds - same unit
Ingham	Sparrow Health Systems	Level III B	33	33	In addition to 33 NICU beds, they also have 2 unlicensed beds
Kalamazoo	Bronson Methodist Hospital	Level III B	45	45	They use 1/2 their beds as NICU and 1/2 their beds as SCN. NICU on 4th floor, SCN 3rd floor
Kent	Spectrum/DeVos Health Systems	Level III C	67	72	They have 113 beds - 72 licensed beds and 36+ unlicensed beds (SCN capacity)
Kent	St. Mary's Mercy Medical Center	Level III	15	15	NICU only, no alternative beds
Marquette	Marquette General Hospital	Level III A	10	10	Also have 4 sick beds in same unit
Oakland	Providence Hospital	Level III	15	15	NICU only, no alternative beds
Oakland	St. Joseph Mercy, Pontiac	Level III	29	29	NICU only, NICU is in 2 locations with 3 pods
Oakland	Beaumont, Royal Oak	Level III B	38	38	They have a total of 50 beds in the NICU - 38 licensed and 12 unlicensed with flexible use of space on unit
Oakland	Beaumont, Troy	Level III A	15	15	Has 15 licensed beds and 28 bed capacity with SCN (i.e. 13 unlicensed beds)
Saginaw	Covenant Hospital	Level III B	40	40	40 NICU beds with 15 bassinettes on the same unit
St. Clair	Port Huron Hospital	Level 2	4		
Washtenaw	St. Joseph Mercy, Ypsilanti	Level III	15	15	Unit has 30 beds - 15 NICU beds and 15 SCN beds
Washtenaw	University of Michigan Health System	Level III C	40	41	New unit has 41 beds with capacity for 46 (5 other beds)
Wayne	Children's Hospital - DMC	Level III C	45	40	I was told there are 32 beds and 40 if needed
Wayne	Henry Ford Health System	Level III B	35	35	Felt not represented at table when transfers of NICU beds occurred in region with UofM
Wayne	Hutzel - DMA	Level III B	36	37	Have a separate unit for SCN with 43 bassinettes
Wayne	Oakwood Hospital	Level III B	30	30	NO extra beds or SCN
Wayne	Sinai Grace	Level III	20	20	Has 4 virtual beds
Wayne	St. John Hospital	Level III B	35	35	Have a separate unit for SCN with 13 bassinettes

Issues

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- There is NO regulation for Level II hospitals or Special Care Nurseries in the state
- Wide variation in level of care provided in Level II –
  - some will only care for babies > 35 weeks (the same as a Level I hospital)
  - some push the limits with the length of time babies are on ventilators
- 50% of the NICUs in the state have "unlicensed beds" in the same unit as the NICU
- "Teeth" are needed to enforce the recommendations from "Perinatal Regionalization: Implications for Michigan" (2009) and the Levels of Care that are recommended (based on ACOG and AAP standards)

Why CON?

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- CON already provides the type of service needed for Level III nurseries
- Addendum for NICU standards seems logical for Level II regulation
- A service to provide at hospitals

Why regulate?

22

- Literature and evidence indicate that states with a regionalized and coordinated perinatal system of care better assure that pregnant women and babies are more likely to deliver in an appropriate hospital setting and receive appropriate services to meet their needs.
- Healthy People 2020
  - MICH-33 Increase the proportion of very low birth weight (VLBW) infants born at level III hospitals or subspecialty perinatal centers

Workgroup #1: Designation, Verification and Certification

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- Purpose:

Utilizing the Perinatal Guidelines Levels of Care as a foundation, determine how birth hospitals will be designated, verified and certified.

Workgroup #1 Members

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- MDCH (Division of Family and Community Health, Children Special Health Care Services, Medicaid Actuarial, Certificate of Need, Licensing and Certification)
- Level III hospitals
- Michigan Health and Hospital Association
- Blue Cross/Blue Shield of Michigan
- Michigan State University

Perinatal Guideline Recommendations that apply

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- Develop a method of authoritative recognition of levels of NICU care and establish a statewide mechanism to oversee and enforce adherence to the Michigan guidelines to ensure that hospitals and NICUs care for only those mothers and neonates for which they are qualified
- The Guidelines should be periodically reviewed and updated as new data occur and recommendations from national groups are made.
- If the authoritative recognition of levels of care is through the Certificate of Need process, create a provision to retrospectively change a hospital's perinatal level of care designation

Why Is The Process Needed?

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- Quality
- Consistency
- Safety
- Education
- Structure (Capacity and Support)
- Data
- Cost Containment

Workgroup Process: Survey

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- Survey conducted of all members on key components of designation, verification and certification process to determine the strategy.
- Out of 16 members at that time, 12 responded.
- Consensus was obtained on areas of application, how to designate, who conducts reviews, authoritative body, noncompliance and an Advisory Committee.
- Positive responses to questions ranged from 64% to 100% for the process discussed.

Visual Confirmation

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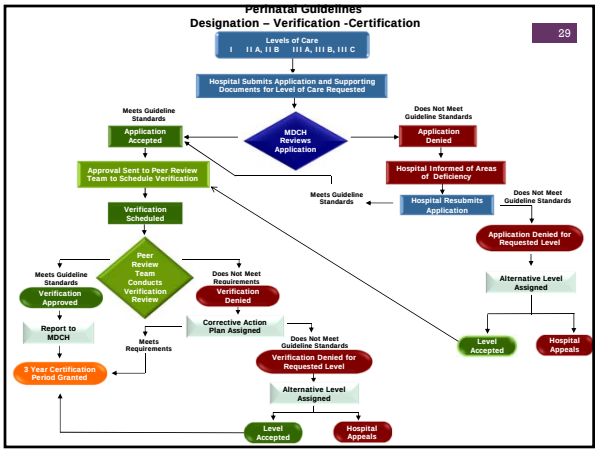
- Flow chart of process
- Draft Administrative rules
- Draft processes of each major activity
- Workgroup modification and final concurrence on each document occurred from January – May 2012.



Application Process- Key Points

- All hospitals will apply for their desired designation. If the level desired is regulated by CON, the hospital must meet all the requirements in their Standards.
- The application process and verification process will be conducted over a 3 year time frame.
- One third of each level of hospital (I, II, and II) will apply and have a verification review each year.
- By the end of year three all hospitals will have completed the designation and verification process.

Application Acceptance – Key Points

- A hospital will be notified of the acceptance of their application for the designation requested. A formal letter from MDCH will be sent to the hospital and to Certificate of Need and licensing.
- The hospital will be informed of the preliminary designation until they have their on site verification review can be accomplished.
- The hospital will be put into the schedule for a verification review and will be provided the approximate date that it will occur.

Application Denial-Key Points

- If a hospital's application is not accepted for the designation applied for either due to lack of supporting documentation or incompleteness of the application, MDCH will send a formal letter to the hospital with the application deficiencies.
- The hospital may resubmit the application for the same designation with a complete application and supporting documentation.
- The hospital may resubmit for a different designation Level with a complete application and supporting documentation.
- This resubmission must be completed within 60 days of the notification of denial.

Verification Review- Key Points

- Once the hospital's application has been approved for the requested designation, the hospital will be scheduled for their on-site verification review.
- The verification tool will be developed by MDCH with the assistance of individuals representing all three levels of care hospitals.
- The hospital will be provided the time line for the "Peer Review Team's" report to MDCH.

Review Team- Key Points

- Comprised of individuals representing the Designation Level from other hospitals outside of the applying hospitals service area. Called "Peer Review Teams".
- The "Peer Review Team" would require hospital to provide in kind (approved time to help in the review process) support to allow one or more of their employees/staff to serve.
- The "Team" would be multidisciplinary and would include physicians and nurses. Additional team members may include a Respiratory Therapist and Pharmacist.
- Training for all reviewers would be developed by MDCH for consistency of reviews and adherence to MDCH requirements.

Certification- Key Points

- Based on the recommendation and results of the review, MDCH will send a formal response to the hospital within 30 days from the conclusion of the review.
- The response will notify the hospital of: approval of their designation and those deficiencies requiring a Corrective Action Plan or disapproval of their designation and deficiencies that require a Corrective Action Plan.

Corrective Action Plan-Key Points

- A satisfactory Corrective Action Plan will result in the hospital receiving their applied for designation as a formal certification. This certification will be good for 3 years.
- A needs modification Corrective Action Plan will be sent back to the hospital with the areas that need to be corrected or changed.
- A hospital with an unsatisfactory Corrective Action Plan to meet the desired designation that they have requested will be provided with a written denial with two options: alternative level designation, if appropriate, or no level of designation and not certified.

Appeal-Key Points

- Hospitals that are not satisfied with the Certification given to them by MDCH or want to appeal the non-certification of their facility may do so according to the Appeal Process that is currently in effect.

Annual Report-Key Points

- The annual report will be required of all hospitals for non-verification review years.
- The report format will be developed by MDCH but will include a narrative report on the previous year and the current year activities.
- MDCH will evaluate the feasibility of incorporating this report into existing required reports already being submitted.

Questions?

Healthy Mothers and Health Babies

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Thanks

- The following people contributed slides, information, data or maps in this presentation
  - Patti McKane
  - Rose Mary Asman
  - Trudy Esch