Michigan's Surveillance Plan for the States Monitoring Assisted Reproductive Technology (SMART) Collaborative

FY 2010-2012
Michigan Department of Community Health

Rick Snyder
Governor, State Of Michigan

Olga Dazzo
Director, Michigan Department of Community Health

Corinne E. Miller, PHD
Director, Bureau of Disease Control, Prevention, and Epidemiology
Michigan Department of Community Health

Janice V. Bach, MS, CGC
Acting Director, Division of Genomics, Perinatal Health and Chronic Disease Epidemiology
Michigan Department of Community Health

Patricia McKane, DVM, MPH
MCH Epidemiologist/SSDI Coordinator/SMART Coordinator
Michigan Department of Community Health

Questions regarding the content of this report can be directed to the Michigan Department of Community Health, SMART Project at 517-335-9456 or mckanep@michigan.gov

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I. Introduction

Infertility, defined as not being able to get pregnant after one year of trying (or 6 months if a woman is over 35 years of age), and sub-fecundity (not being able to stay pregnant) affects an estimated 10% of women ages 15-44 years in the United States[1]. Additionally, survey results indicate that 7.5% of sexually active men in the United States reported a visit to address infertility [2]. Awareness of infertility and impaired fecundity as an important public health problem has increased. For purposes of this discussion, the term infertility will refer to both infertility and sub-fecundity, as this gives a broader definition to observe the wide-range of fertility problems, thus presenting a more complete estimate of the true prevalence, as well as the potential demand for medical services. Within the context of specific surveillance systems, the two measures will be analyzed separately where statistically feasible.

Many conditions have been associated with infertility including genetic abnormalities, infectious disease, environmental agents, behavioral risk factors and the natural aging process. Because social and racial disparities exist in health status and some risk factors, preventable causes of infertility disproportionately affect the less privileged. Thus, the prevalence of infertility in some groups may be underestimated as financial barriers limit access to diagnostics, evaluation and treatment [3]. Alternatively, high income groups may be more apt to delay childbearing, making them more likely to have infertility (estimated to be one-third of couples in which the woman is older than 35 years) [4]. Yet, only 50% of infertile women seek medical advice or testing, and fewer receive treatment [1]. Approximately 12% of women of childbearing age in the United States have ever received infertility services [1]. One barrier to treatment is lack of insurance coverage, meaning patients are financially responsible for the costs associated with consultation, medical and/or surgical treatment, which contribute to economic and racial disparities.

Assisted reproductive technology (ART) has been used in the United States since 1981 and although many definitions have been used, the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) defined ART to include all infertility treatments where egg and sperm are

handled. Further, the act mandated The Centers for Disease Control and Prevention (CDC) to publish an annual report of pregnancy success rates and embryo laboratory certification status.

Congress directed:

1) All ART clinics to report medical information on each patient; and

2) The CDC to analyze cycle specific clinic data and to provide consumers with an annual report that contains the information needed to make informed decisions regarding ART usage.

To meet the FCSRCA requirements, the CDC conducts surveillance of ART procedures performed in the United States. From 1995 to 2003, the CDC purchased ART outcome data from the Society for Assisted Reproductive Technology (SART) and since 2004 from Westat, Inc. The CDC has developed and maintained a database, the National Assisted Reproductive Technology Surveillance System (NASS) and published the annual report: ART Success Rates – National Summary and Fertility Clinic Reports since 1997.

The intent of the annual report is to publish information to the public concerning the success rates for individual fertility clinics providing ART. This information can be used by consumers to make an informed decision as to whether ART is best for them. However, this report is limited in that it provides little information regarding the potential of adverse consequences for women who used ART and their infants. To date, studies of adverse outcomes associated with ART have mainly been conducted in small clinical settings. Thus, evaluation of potentially adverse short-term perinatal outcomes has been hampered by small sample sizes, lack of appropriate comparison groups and the inability to adequately control for confounding variables.

To address these limitations and to provide a population-based resource the CDC worked with the state of Massachusetts on a medical record linkage project combining information from their ART data base with Massachusetts birth certificates and infant death records to research the effects of ART use on maternal and infant outcomes. This project was approved by the CDC Institutional Review Board (protocol number 5556, expiration 1/8/2010) and Massachusetts Department of Public Health (Project # 2000025, expiration 9/29/2009). The results of the project

indicate that systematic assessment of certain adverse outcomes is feasible through linkage of existing systems.

The CDC expanded this project with contract number 200-2008-M-28096 to the state of Michigan Department of Community Health (MDCH) since Michigan performs a large number of ART procedures (19,802 from 2001 to 2006). Michigan ranks fourteenth when compared to all U.S. states and territories in number of ART procedures performed (3,264 in 2006). The large number of Michigan ART procedures resulted in 1,390 infants born in 2006. Based on the current trends, the number and proportion of Michigan infants conceived using ART is expected to increase. On the other hand, Michigan continues to have poor pregnancy outcomes and increasing risk behaviors, obesity and morbidities in women of reproductive age. Based on the current trends, the number and proportion of Michigan infants conceived using ART is expected to increase due to the increasing prevalence of chronic diseases and other risk factors that lead to infertility. With continued economic challenges barriers to access are likely; however ovarian stimulation protocols alone may be used at a much lower cost compared to other ART procedures. The concern is that these protocols are either not reported or accurately monitored meaning that complications during pregnancy and delivery, poor pregnancy outcomes and impact on offspring's health are more difficult to measure, assess and monitor for further improvement. Therefore, the CDC is interested in expanding the scope of the Michigan project to include linkage with birth defects database, the cancer registry database and developing a state surveillance plan.

Linkage of ART surveillance data with the Michigan live births and linked birth-death certificates data would provide detailed information on both the circumstances surrounding conception and the short-term maternal and infant and maternal outcomes, including infant morbidity infant mortality, maternal morbidity and maternal mortality. Michigan's linked birth-death certificate data files include data for all infants born in the state and information relating to infant deaths during the first year of life. In addition to birthweight, gestational age at delivery, and neonatal conditions, the data collected include maternal characteristics, maternal complications and complications of labor and delivery. Besides these basic data resources, Michigan operates statewide population-

based cancer and birth defects registries. Furthermore, the linkage with other statewide databases such as hospital discharge, birth defects and cancer registries will lead to a better understanding of other infertility related outcomes. Finally, MDCH has considerable experience and expertise in the analysis and interpretation of their vital statistics and other health records which are essential for the expansion of this linkage project.

Definition of Surveillance

Michigan's SMART project utilizes the CDC definition of public health surveillance: The ongoing systematic collection, analysis, and interpretation of health data essential to the planning, implementation of health data essential to the planning, implementation and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know.

II. Objective/Rationale of the Infertility Surveillance Plan

The objective of the Michigan SMART project is to create a statewide system to serve as a model for surveillance of infertility, ART, and non-ART. This surveillance system will provide evidence-based support to providers, researchers and clients; develop educational and awareness resources to enhance provider and client knowledge; improve overall health and quality of life of Michigan residents affected by infertility, ART or non-ART.

Target Populations

While the Michigan SMART project will benefit all Michigan residents, certain groups have been identified as being underrepresented in current infertility surveillance and therefore will be targeted by the SMART project.

Groups to be targeted by the surveillance plan:

- Non-ART users
- ART or non-ART users that were unable to conceive or to maintain a pregnancy
- Individuals or couples with infertility who have not sought medical treatment

- People of lower socioeconomic status
- Men

III. Structure of the Infertility Surveillance Plan

Goals

The three main goals of the Michigan SMART surveillance plan are listed below:

1. Develop linked files of ART data with other Michigan datasets to assess pregnancy outcomes as well as children's health
2. Develop a comprehensive surveillance plan to inform planning, implementation, evaluation and policy development of the need for continued assessment and improvement of ART and non-ART outcomes
3. Provide epidemiological leadership and research consultation into development of the public health efforts to address the impact of ART and non-ART procedures on women's and children's health in Michigan

Major Objectives

Successful achievement of the Michigan SMART surveillance plan will be evaluated by the following objectives:

1.0 Perform linkages of different files (i.e. live birth, MIDB, Cancer registry, Birth defects)

1.1 Complete validation studies

2.0 Assemble epidemiological and infertility expertise

2.1 Develop a model for a comprehensive surveillance system for ART and non-ART procedures in Michigan

2.2 Develop new data collection tools and quality improvement methods

2.3 Assessment of the reporting and data systems

3.0 Epidemiological studies, presentations and publications

3.1 Inform advisory committee, stakeholders and other partners

Activities and Program Timeline

See Appendix A for a comprehensive list of the activities and timeline planned to meet the project goals and objectives

Surveillance Logic Model

Monitoring the status of infertility, ART, non-ART and related health outcomes in Michigan's population is essential for setting achievable objectives, as well as for planning, implementing and evaluating Michigan's SMART surveillance program. Moreover, it is imperative to demonstrate the burden and impact of infertility in the state to gain support and secure resources for SMART surveillance.

The logic model on the following page illustrates surveillance inputs, activities, outcomes and goals.

INPUTS Partners & Resources	OUTPUTS Activities	PUBLIC HEALTH & CLINICAL RELEVANCE Outcomes	Goals
Staff • Bureau of Epidemiology Director • Genomics, Perinatal Health & Chronic Disease Epidemiology Division Director • Vital Records and Health Statistics Division Director • Reproductive Health Epidemiologist/Project coordinator • Vital Records Statistician/Data analyst • Researcher/Epidemiologist • BRFSS Coordinator /Epidemiologist • PRAMS Coordinator /Epidemiologist • IT Support • Collaborating Partners (CDC, MA, FL) **Data Sources** • National data sources • State data source • New data sources **Other** • Michigan Infertility Advisory Committee (MiAdCo) • Funding • Stakeholders/Partner-ships	• Identify current national, state and other data sources • Prepare Vital Records file and data dictionary for linkage • Develop strategies to identify unmatched records • Identify and prepare additional files for linkage o MBDR o Cancer (expanded) • Continue validation study of MI vital records National ART linked file • Prepare final report of validation study	• Enhanced communication within MDCH and with external partners • Increased understanding of existing literature, data sources, resources and partnerships • Ongoing monitoring of prevalence of infertility, ART, non-ART and related outcomes • Documentation of trends in infertility, its treatment and outcomes	**Goal #1** **Develop linked files of ART data with Michigan Vital records data to assess pregnancy outcomes and children's health**
	• Assemble meeting of core team staff to confirm and implement management and staffing plan and to assign specific tasks • Participate in meetings and calls with CDC and other partners o Steering committee o Research committee o Other committees relevant to the MI SMART project • Conduct professional/provider key informant interviews (MiAdCo) and meet with stakeholders to identify research needs and project goals and objectives • Create a needs assessment summary document of the priorities identified from the stakeholders and articulate program goals and objectives • Include infertility module on MIBRFSS 2012 and identify other potential new data sources • Develop plan and Inform stakeholders, partners and providers of plan	• Advisory group and others informed of SMART surveillance plan, research plan and the impact on MCH outcomes • Model for comprehensive ART and non-ART surveillance procedures in MI • New data collection tools • Assessment of reporting and data systems • Surveillance plan modified based on evaluation	**Goal #2** **Develop a comprehensive surveillance, research and evaluation plan to inform planning, implementation, evaluation and policy development for improvement of ART and non-ART outcomes**
	• Develop timeline for studies and products • Conduct studies in collaboration with project partners, stakeholders • Data analysis and interpretation • Ensure data security & confidentiality per HIPAA • Develop a communication plan • Report the statewide impact of the program • Develop a summary document of the project and disseminate project findings through multiple venues • Attend state, national and subject matter conferences and meetings	• Epidemiological studies, publications and presentations • Summary report of infertility, ART, non-ART and MCH outcomes • Increase in evidence-based interventions, planning, evaluation and policies	**Goal #3** **Provide epidemiological and research consultation into the development of public health efforts to address the impact of ART and non-ART procedures on women's and children's health in Michigan**

Ultimate Impact: **Create a statewide system to serve as a model for infertility, ART and non-ART surveillance which will: provide evidence-based support to providers, researchers and clients; develop educational and awareness resources to enhance provider and client knowledge; improve overall health and quality of life of Michigan residents affected by infertility, ART or non-ART.**

IV. Sustainability of the Infertility Surveillance Plan

To be sustainable, a public health surveillance system relies on consistent data collection, adaptability and simplicity. A mature system consists of multiple years of data which provides the ability to examine at-risk populations, promote policy changes and evaluate the impact of those changes. Moreover, the Michigan SMART surveillance system data collection must be consistent, reliable and allow comparisons with other states within the collaborative and national indicators. The surveillance system relies on data from existing national and state data sources (i.e. NASS and MI Vital Records), which are/will be linked to additional data sources (e.g. MI hospital discharge, MI birth defects, MI cancer registry, etc). In addition, the inclusion of an infertility module in existing surveys (i.e. BRFSS) will expand the population measured beyond women who had live birth and ART to a representative sample of men and women ages 18 years and older.

A list of data sources and proposed years to be used for Michigan SMART surveillance are listed in the tables below and on the following page.

Michigan SMART Surveillance System Data Source

Data Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
MEBR	X	X	X	X	X	X	X	X	X	X	X	X	X
MI Fetal Deaths					X	X	X	X	X	X	X	X	X
MIDB	X	X	X	X	X	X	X	X	X	X	X	X	X
MI Mortality	X	X	X	X	X	X	X	X	X	X	X	X	X
NASS	X	X	X	X	X	X	X	X	X	X	X	X	X
MBDR	X	X	X	X	X	X	X	X	X	X	X	X	X
MCR	X	X	X	X	X	X	X	X	X	X	X	X	X
BRFSS											X	X	X
HOPS*								X	X				
PRAMS										X	X	X	X

Michigan SMART Surveillance System Linked Files

Data Source	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
MEBR/Newborn Discharge	X	X	X	X	X	X	X	X	X	X	X	X	X
MEBR/Maternal Discharge	X	X	X	X	X	X	X	X	X	X	X	X	X
Maternal Registry	X	X	X	X	X	X	X	X	X	X	X	X	X
MEBR/ MBDR	X	X	X	X	X	X	X	X	X	X	X	X	X
MEBR/Mortality	X	X	X	X	X	X	X	X	X	X	X	X	X
MEBR/MCR	X	X	X	X	X	X	X	X	X	X	X	X	X
MEBR/NASS	X	X	X	X	X	X	X	X	X	X	X	X	X

Acronyms used in these tables

BRFSS: Behavioral Risk Factor Surveillance System

HOPS: Health Outside Pregnancy Survey (sampled 2007 & 2008 live births)

MBDR: Michigan Birth Defects Registry

MCR: Michigan Cancer Registry

MEBR: Michigan Electronic Birth Record

MIDB: Michigan Inpatient Database

NASS: National Assisted Reproductive Technology Surveillance System

PRAMS: Pregnancy Risk Assessment Monitoring System

Infertility Surveillance Data Collaboration/Integration Efforts

The MI Infertility/SMART Surveillance program seeks, collaborates and coordinates opportunities to collect infertility burden and outcome data through the integration and linkage of existing datasets and surveys.

Partnerships have been established to leverage resources for data collection, analysis and dissemination, including the:

- Michigan Department of Community Health, MCH epidemiologist
- Michigan Department of Community Health, Division for Vital Records and Health Statistics
- Centers for Disease Control and Prevention, Division of Reproductive Health
- Michigan Department of Community Health/Michigan State University Department of Epidemiology, male infertility epidemiologist
- Michigan Department of Community Health, BRFSS coordinator/epidemiologist
- Michigan Department of Community Health, PRAMS coordinator/epidemiologist
- Michigan Infertility Advisory Committee
- Michigan Department of Community Health, Birth Defects program
- Michigan Department of Community Health, Cancer Genomics program

Michigan Infertility Data Advisory Committee

The Michigan SMART Surveillance project founded the Michigan Infertility Advisory Committee (MIAdCo) to be a part of the process, providing comment and quality assurance to the project. The committee is comprised of reproductive endocrinologists, infertility specialists, embryologist, genetic counselor, ethicist, scientists, neonatologists, and other stakeholders (see Appendix B). The purpose of MIAdCo is to critique infertility assessment and monitoring as described in the

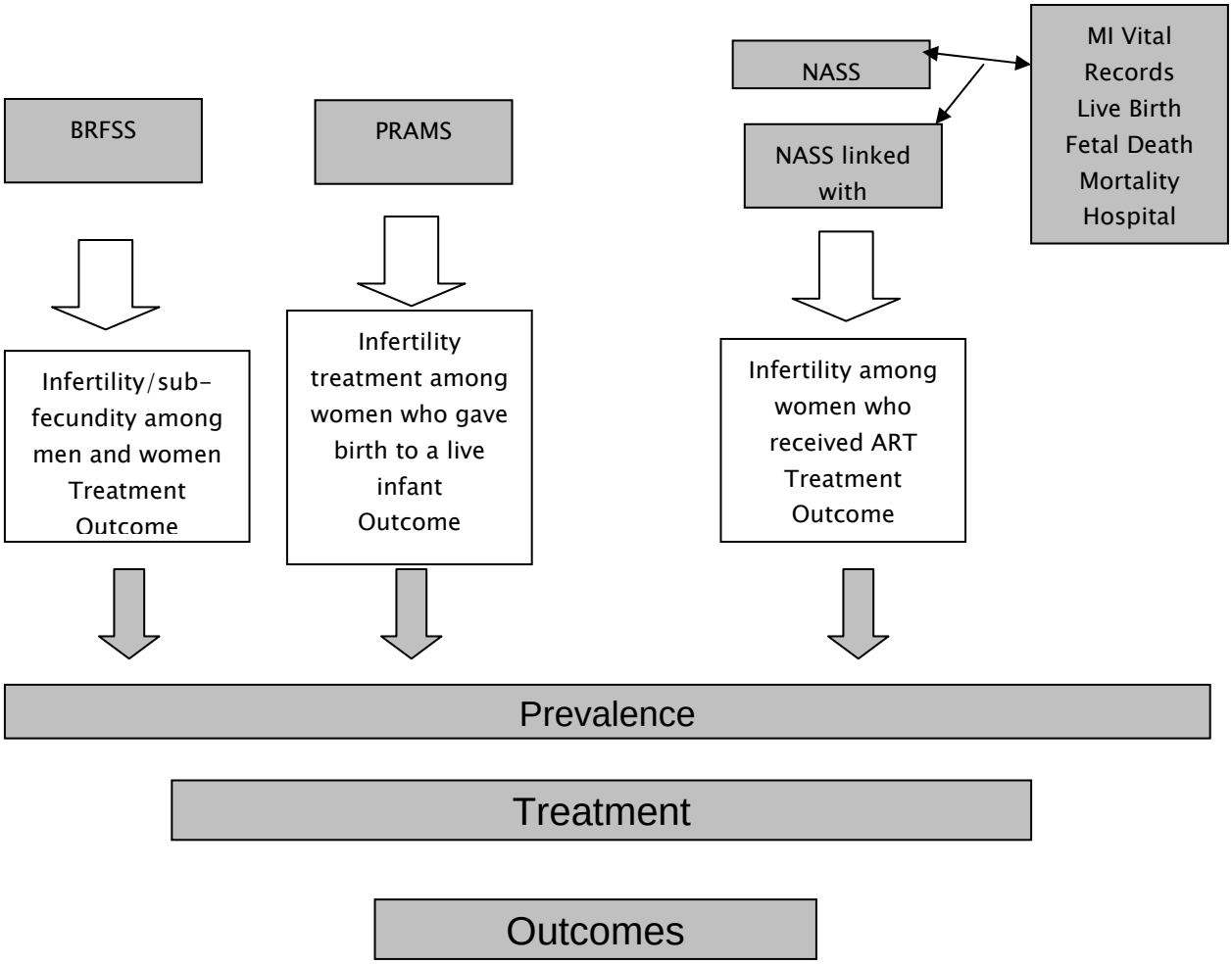
surveillance plan, as well as to assist with development of new and/or review of strategies and policies to assure continued improvement.

MIAdCo has the following responsibilities:

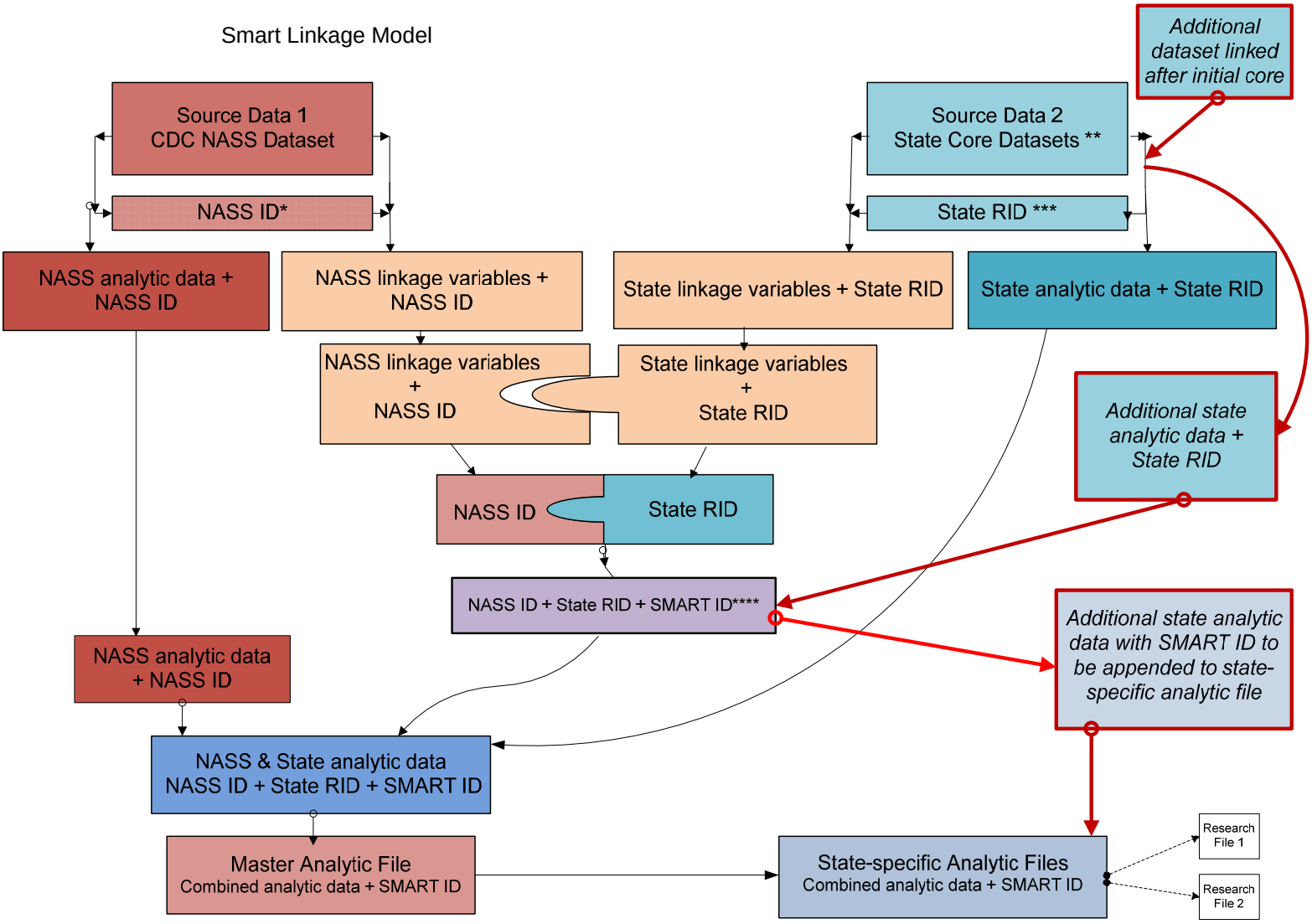
- Review and discuss the existing strategies and policies related to infertility from data collection to clinical services and quality assessment/improvement
- Review and discuss the strategies for collecting information related to infertility prevalence, services and treatment
- Review and discuss any proposed strategies and policies related to infertility
- Develop recommendations for new strategies and policies to address any identified issues related to assessment and monitoring of infertility and the corresponding outcomes
- Designate working subcommittees of individuals, members and non members of the Committee based on the emerging needs. The subcommittee will report to the MIAdCo scheduled meetings, as necessary.

V. Components of the Infertility Surveillance Plan

Infertility Surveillance Model



Smart Linkage Model



Notes:
* Randomly assigned identification number by the National ART Surveillance System (NASS), CDC; ** The contents of State Core Datasets would be determined by a separate Working Group; linkage of core datasets should take place in each state; *** State assigns a random ID (RID); **** SMART ID is randomly assigned by CDC
Linkage dictionary file, which includes NASS ID, State RID, & SMART ID, is kept at CDC in a secure location.
The Master Analytic File includes NASS & States' analytic data and the SMART ID
The Master Analytic File and the State Analytic Files have confidential information that could potentially lead to identification. Processes should be developed by CDC and each state to address this risk.

Indicators related to Infertility

Selection of Indicators/Measures

The purpose of infertility surveillance is to identify significant concerns related to infertility, its treatment and outcomes. The National Centers for Disease Control and Prevention, Division of Reproductive Health leads and supports the identification of data resources and appropriate indicators. To develop an expedient infertility surveillance system, it is essential to assess currently available assets, such as a data sources which include an infertility module, as well as other state resources and capacities that can be leveraged to inform infertility research. Initially, the CDC collaborated with Massachusetts to pilot enhanced infertility surveillance. Linkage of the ART surveillance data with the Massachusetts linked birth-death certificate data, 1997-2000, proved feasible and provided detailed information on both the circumstances surrounding conception and the short-term maternal and infant outcomes, including infant mortality [5-7]. In 2008, Michigan and Florida joined the collaborative and Investigators from the three states and from CDC held meetings to coordinate and synchronize the linkage projects and agreed that a desirable core of information linking the circumstances of conception with the maternal and child health outcomes would include data from the following sources: 1) CDC ART surveillance system; 2) live birth record; 3) fetal death record; 4) hospital discharge summaries for the mother (hospital stays during 9 months preceding and 12 months following delivery); 5) hospital discharge summaries for the infant (hospital stays during 12 months following delivery); and 6) birth defect registry. An inventory of available data sources is outlined in Appendix C.

Expanding the linkage of the ART surveillance data with the Michigan data would provide further detailed information on maternal and infant outcomes of ART patients. As the use of ART continues to increase, and more states consider legislation that mandates insurance coverage of infertility treatment, including ART, assessing the impact of ART on maternal and child health has become an increasingly important priority for both public health and health care policy.

Furthermore, the CDC-Michigan linked dataset would provide the following: 1) Identification of a population-based birth cohort of infants conceived using ART in the US; 2) Linkage of ART births directly with maternal, birth and neonatal data; 3) Identification of appropriate comparison group of non-ART births; 4) Control of confounding factors such as maternal age and socioeconomic status in all studies comparing ART births and non-ART births; and 5) ability to combine data linkages from several states and further examine trends in adverse maternal and infant outcomes.

In addition, the Michigan Infertility Surveillance Program will use existing surveys such as the Michigan Behavior Risk Factor Survey (MIBRFS) and the Pregnancy Risk Assessment Monitoring Surveillance (PRAMS). In 2010 and 2011, two questions regarding infertility were placed on the MIBRFS and in 2012 the module will be expanded to 4 questions. PRAMS initiated an infertility question as part of the national survey beginning in 2009 and plans to continue the module until 2015. Text of MIBRFS and PRAMS questions are included in the data inventory found in Appendix C

These data sources will provide indicators which represent:

- Risk factors and co-morbidities associated with infertility/impaired fecundity
- Access, utilization and performance of services
- Maternal and infant outcomes of ART and non-ART

A list of variables from each of the proposed data sources is included in Appendix D.

Infertility Data Analysis Plan

The Michigan Infertility Surveillance Program utilizes data from multiple sources. Some of these sources are maintained within the MDCH and others reside in external agencies. The Michigan SMART Surveillance Program will calculate trends for all indicators, including analysis by major demographic groups. Certain datasets (i.e. BRFSS) will allow analysis of infertility, treatment and outcome by co-morbid conditions (e.g. cancer, obesity) or access to health care (e.g. health insurance coverage, primary care provider) among a cohort that has been excluded in previous surveillance in Michigan. Prior efforts used the live birth record as the sampling frame, which restricts the population to women who gave birth to a live infant, ignoring men, and women who either were unable to become pregnant or to carry an

infant to term. By using the MIBRFSS data to supplement the NASS/Vital Records dataset Michigan aims to provide a more comprehensive depiction of infertility, its treatment and outcomes among Michigan residents. Data analysis will include the conduct of analyses for both CDC and the MDCH as decided upon by investigators. It is likely that the initial analyses will focus on data quality and validation as well as the utility of the linked dataset and it is expected that CDC and MDCH investigators will have an equal number of analyses to be conducted in a given year. We anticipate that 2 to 3 analyses will be conducted (and corresponding manuscripts and reports prepared) in which a CDC person assumes the lead role, and 2 to 3 analyses will be conducted in which a MDCH person assumes the lead role. A list of potential analyses can be found in Appendices E and F. These include studies assessing the impact of ART on the population of births in MI and comparisons between ART births and non-ART births.

Dissemination of SMART Surveillance Program Information

The Michigan SMART Surveillance Program disseminates infertility prevalence, treatment and outcome data to inform policymakers, medical professionals, the public and other stakeholders with regard to the burden and implications of infertility. The audiences for these data include: public health practitioners, health care providers, infertility specialists, professional organizations, policy makers, potential funding partners, the media and the public.

Options for disseminating data and information include:

- Publication of articles in scientific, peer reviewed journals;
- Presentations at state and national professional meetings; and
- Electronic publication of fact sheets, briefs, annual reports or other types of reports.

As the Michigan SMART Surveillance Program evolves, the indicators, and analyses will be refined and improved based on a surveillance evaluation plan.

Confidentiality of Infertility Surveillance Program Data

Management of all health-related data meets HIPAA standards for patient privacy, data confidentiality and data management. Protected health information (PHI) is maintained and de-identified and stored securely at MDCH (MI Vital Records data) or CDC (NASS, NASS/MI Vital records linked files).

With regard to the NASS/MI Vital Records liked files: All analyses will be conducted on site at DRH or via data access from the Research Data Center (RDC). This is because of contractual limitations and confidentiality restrictions in releasing the ART surveillance system data. The contractual limitations result because CDC purchased the ART surveillance dataset from SART under contract for the years 1995 through 2003. As a part of the contractual agreement, CDC has the right to use the dataset for epidemiologic analyses; however, CDC is restricted from distributing the dataset outside of CDC. Confidentiality restrictions result from the sensitive and potentially identifying nature of the data. The ART surveillance data is sensitive because it contains information about topics such as medically induced fetal reduction and the use of donor eggs, sperm, and embryos, and it is potentially identifying because it contains variables such as city, state, zip code, and birth date of both the women undergoing ART and resultant infants. The CDC received approval for an Assurance of Confidentiality (308(d)) to protect the confidentiality of the persons in the ART surveillance database as well as the clinics whose data makes up the surveillance database. Data on ART cycles performed during 2004 or later are no longer collected under contract with SART and are the property of the U.S. government. Thus, they are not subject to the contractual restrictions mentioned above limiting data release. They are, however, subject to the same restrictions imposed by the Assurance of the Confidentiality covering all ART data, and we do not expect that our data release policy will be different.

The restrictions mentioned above limit the ability of Michigan investigators to use the data. We intend to use the RDC's facilities of remote data access which will allow Michigan researchers to perform analyses. RDC is a data enclave hosted by the National Center for Health Statistics (NCHS) that allows researchers to access restricted data in a secure environment. The CDC ART team will provide RDC with a copy of the linked ART-state data set with original indirect identifiers (such as mother and infant date of birth). This data set will contain no direct identifiers such as names or social security numbers. The RDC will host this linked data set and provide two options for access to researchers from the states who wish to perform their own analyses. First, remote access will be provided to the data set via an automated system. Researchers will be able to remotely access the data from any computer at any time to conduct their own analyses. At no time will researchers be able to see individual data records (microdata).

Researchers will send SAS/SUDAAN code via e-mail and receive their output via e-mail, without direct access to the data. Additionally, researchers can also access the data on site at the NCHS RDC centers located in NCHS in Hyattsville, Maryland and in the Rhodes Building, University Office Park, in Atlanta, Georgia. Admittance to the RDC is limited to pre-approved researchers listed on the Research Proposal.

General Requirements

- Researchers must work under the supervision of an RDC Analyst during normal business hours (Monday-Friday, 9:00 a.m. – 5:00 p.m.).
- Admittance to the RDC is limited to the researchers listed on the Research Proposal.
- Researchers must show photo identification to be admitted to the research facilities.
- Researchers are not permitted to bring in documents, manuals, books, etc., that they could use to identify or disclose confidential information that they access in the RDC.
- Cell phones, pagers, or other communication devices are not allowed in the research facilities.
- On-site appointments can be scheduled in increments ranging from a minimum of 2 consecutive days to a maximum of 10 consecutive days. Researchers can request more time if workstations are available.

Workstation Requirements

- A maximum of three collaborating researchers can sit at a computer workstation at the same time.
- Only approved datasets will be available on the workstation.
- Researchers must conduct their analyses with the software specified in the research proposal.
- The RDC will retain and archive all program files the researcher writes.

Primarily, ART Epidemiology Unit staff will conduct the analyses on site at CDC. Only the aggregated findings of the analyses will be released to MDCH staff. MDCH researchers involved with this project may visit DRH periodically as contractors to provide input into or partake in ongoing analyses. Any contractor

working with this project will be required to sign confidentiality pledges and will be allowed to work only with the de-identified data, only on site at CDC.

Infertility Surveillance Publication Distribution List

State of Michigan Agencies

Department of Community Health

Medical Services Administration, as needed

Public Health Administration

- Epidemiology

- Environmental Epidemiology

- Genomics

- Maternal & Child Health

- Chronic Disease

- CVD, Obesity, & Nutrition

- Primary Care Initiative

- Disparities Reduction Program

- STD and HIV

Family, Maternal and Child Health

-Perinatal Health

-Infant Health

-Reproductive Health

Preconception Health Work Group

Life Course Indicator Work Group

Michigan Public Health Institute

State Governmental Libraries

Local Public Health

Local health officers/ Medical Directors/Epidemiologists

Local liaison report

Professional Organizations

Michigan Infertility Advisory Committee (listerv, biannual meetings)

Michigan Medical Society

Michigan SART

Federal and State Collaborators

CDC Division of Reproductive Health

State of Massachusetts SMART program

State of Florida SMART program

VI. References

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Appendices

Appendix A Goals, Objectives and Activities of the Michigan Plan

1. Develop linked files of ART data with other Michigan datasets to assess pregnancy outcomes and children's health
   Outcome: ART data linked with vital records
   Outcome: ART data linked with birth defects, CSHCS, NBS and cancer registry

Objective 1.0: Perform linkages of different files by August 31, 2009

Item Underway	Item Planned	Activities	Target Date	Completed
x		1.0.1 Prepare vital records file/Glenn Copeland (Years 2000-2004)		10/31/2008
x		1.0.2 Perform the linkage/CDC team (preliminary linked file)		07/31/2009
x		1.0.3 Develop strategies to find unmatched records		07/31/2009
x x x x	 x	1.0.4 Prepare other files for linkage/Glenn Copeland Michigan Hospital Discharge file Birth Defects Cancer Registry CSHCN		08/31/2009

Objective 1.1: Develop and conduct validation studies (under CDC leadership) by December 31, 2009

Item Underway	Item Planned	Activities	Target Date	Completed
x		1.1.1 Cases Selected /CDC		X
x		1.1.2 Plan developed		X
x		1.1.3 Prepare draft of report/manuscript		X
	x	1.1.4 Review manuscript for possible publication (date contingent on release of manuscript from CDC)	12/2011	

2. Develop a comprehensive surveillance plan to inform planning, implementation, evaluation and policy development of the need for continued assessment and improvement of ART and non-ART outcomes
   Outcome: Engage and inform stakeholders regarding ART, non-ART and the impact on MCH outcomes
   Outcome: New data sources and findings used in planning, implementation and evaluation of interventions, systems and policy

Objective 2.0: Assemble epidemiological and infertility related expertise by March 31, 2009

Item Underway	Item Planned	Activities	Target Date	Completed
x		2.0.1 Engage epidemiologist/researcher (Julie Wirth)		03/31/2009
x		2.0.2 Develop charter for and form Advisory Committee		01/31/2009

x		2.0.3 Create Advisory committee agenda and schedule twice yearly meetings		Ongoing
x	x	2.0.4 Engage Advisory Committee on topics of interest i.e. Review BRFS questions, validation study, cancer and ART Study		Ongoing
Objective 2.1: Develop a model for a comprehensive surveillance system for ART and non-ART procedures in Michigan by August 31, 2009				
Item Underway	**Item Planned**	**Activities**	**Target Date**	**Completed**
x		2.1.1 Review existing surveillance models at federal, state and local levels*		12/31/2008
x		2.1.2 Develop the surveillance plan and share with Advisory Committee for comments*		08/31/2009
x		2.1.3 Revise and evaluate the model every year	09/30/2011	
x		2.1.4 Revise plan to meet CDC guidelines	09/30/2011	
Objective 2.2: Develop new data collection tools and quality improvement methods by August 31, 2010				
Item Underway	**Item Planned**	**Activities**	**Target Date**	**Completed**
x		2.21 Develop and conduct a survey to estimate the overall prevalence of causes of infertility (HOPS)		09/30/2009
x		2.22 Develop and conduct a survey with perinatalogists and neonatalogists*		03/31/2010
Goal 2 continued				
Objective 2.2 continued				
x		2.23 Develop and conduct a survey with reproductive endocrinologists and infertility specialists		03/31/2010
x		2.2.4 Develop and insert questions in BRFSS		06/30/2010
x		2.2.5 Revise BRFSS questions	10/15/2011	
x x x x x		2.2.6 Analyze findings from all surveys and prepare reports BRFSS Brief on Infertility published (C.Fussman) HOPS Summary prepared (C. Larder) Abstracts Summary Report on Infertility	 08/31/2012	Ongoing 08/15/2011 08/15/2011 Ongoing
x		2.2.7 Explore collaboration with Neonatology Vermont Oxford Network*		Ongoing
x		2.2.8 Explore collaboration with infertility clinics and providers		Ongoing
Objective 2.3: Conduct assessment of the reporting and data systems by August 31, 2012				
Item Underway	**Item Planned**	**Activities**	**Target Date**	**Completed**
	x	2.3.1 Gather credible evidence regarding performance of surveillance system		

		components		
	x	2.3.2 Perform evaluation of the surveillance system using CDC guidelines	08/01/2012	
	x	2.3.3 Share preliminary findings with Advisory committee and MDCH SMART managers	08/15/2012	
	x	2.3.4 Prepare final report and submit to CDC	08/30/2012	

3. Provide Epidemiological leadership and research consultation into development of the public health efforts to address the impact of ART and non-ART procedures on women's and children's health in Michigan

   Outcome: Epidemiological studies, publications and presentations

Objective 3.0: Develop epidemiological studies and publications by September 30, 2012

Item Underway	Item Planned	Activities	Target Date	Completed
x		3.0.1 Develop timeline for epidemiological studies and publications	12/31/2011	
x		3.0.2 Develop research studies in collaboration with other researchers	12/31/2011	
	x	3.0.3 IRB application (verify expiration and reapply)	10/31/2011	
	x	3.0.4 Conduct analysis		Ongoing
	x	3.0.5 Prepare presentations for state, national and stakeholder meetings		
	x	3.0.6 Write manuscript		

Objective 3.1: Communicate the findings to the Advisory committee, stakeholders and other partners by September 30, 2010

Item Underway	Item Planned	Activities	Target Date	Completed
x	**x**	3.1.1 Develop a communication plan*		09/30/2009
x	**x**	3.1.2 Present at the MSMS Perinatal committee meeting (V Grigorescu)*		03/31/2009
x		3.1.3 Attend annual CDC meeting	08/30/2012	08/17/2011
x		3.1.4 Attend monthly SMART conference calls		Ongoing
x		3.1.5 Attend semi-annual Advisory Committee meetings		Ongoing
	x	3.1.6 Report findings to MDCH managers	09/30/2012	
x		3.1.7 Attend state and national meetings as they pertain to infertility, ART and non-ART (two per calendar year)		

Appendix B – Michigan Infertility Data Advisory Committee

Participating (voting) members:

a. Five reproductive endocrinologists and infertility specialists
   Douglas Daly
   Richard Leach
   Michael Diamond
   Michael Mersol-Barg
   John Randolph

b. One embryologist
   Gary Smith

c. One ethicist or IRB member – academia
   Lance Adam Gable

d. One genetic counselor
   Debra Duquette

e. Two perinatologists / Maternal Fetal Medicine specialists
   Federico Mariona
   Marjorie Treadwell

f. Two neonatologists from a tertiary center (level three with NICU)
   Padmani Karna
   Robert Schumacher

g. One scientist/epidemiologist
   Julie Wirth

h. One representative from MDCH, Public Health Administration/DGPHCDE
   Patricia McKane

i. One representative from health insurance (BCBS or Priority Health)
   - vacant -

Participating (non-voting) members:

a. One MDCH IRB
   -vacant-

b. One MDCH Vital Statistics
   Glenn Copeland

c. One epidemiologist MDCH
   Cristin Larder

d. One program staff MDCH
   Alethia Carr

e. One infertile patient/couple
   Lisa Westbrook

f. One CDC representative – project officer
   Dmitry Kissin

g. One representative from March of Dimes
   Kara Hamilton

Appendix C – Minimum Infertility Data Source Inventory

Minimum Required Core Data Sets

1. Michigan Live Birth File
2. MI Fetal Death File
3. MI Inpatient Database
4. MI Mortality File (Michigan Death Certificates)
5. MI Birth Defects Registry
6. Michigan Cancer Registry
7. National Assisted Reproductive Technology Surveillance System (NASS)
8. MI Behavior Risk Factor Surveillance System
9. Pregnancy Risk Assessment Monitoring System

1. Michigan Live Birth File

What is the basic purpose and use of these data?
The birth certificate database is a high quality computerized data set containing demographic information, maternal health and health behavior, birth outcome, and delivery complications for all Michigan residents (out of state births included) and non-Michigan residents born in Michigan. Birth certificates are one of public health's vital records for monitoring the health of citizens. Originally, these data were collected for demographic and legal purposes. The Division for Vital Records and Health Statistics (DVRHS) in the Michigan Department of Community Health uses Birth certificate data, along with data related to population, deaths, fetal deaths, marriages, divorces, induced abortions, and communicable diseases to develop extensive statistical tabulations.

What organization is responsible for maintaining these data?
Michigan Department of Community Health
Bureau of Local Health and Administrative Services
Division for Vital Records and Health Statistics

Who is the contact person responsible for maintaining these data?
Name: Michael Beebe
Division for Vital Records and Health Statistics
Michigan Department of Community Health
Telephone Number: (517)-335-8715
Email Address: BeebeM@Michigan.gov

How will this data set contribute to infertility surveillance?
Birth certificates will be used as the source of demographic information, maternal health and health behavior, birth outcomes and delivery complications for the NASS/MIEBR linked dataset.

Are there separate local data sets that are maintained?
Yes, data exist for Michigan counties and minor civil divisions (MCD).

Are these local data sets included in the statewide data set?
Yes, county and MCD data are included in the statewide data set.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
Yes. The National Center for Health Statistics maintains the National Vital Statistics System.

Data Collection

Is there a legal mandate to collect these data? If so, please cite and summarize the specific statue or Public Health Code that mandates data collection.
Section 2821 of Public Health 368 of 1978 requires birth registration for each individual born in the state. A record of live birth is to be filed at the office of the local registrar not more than 5 days after the birth.

Are there any legal protections to the data that have been collected? If so, cite and summarize the specific law or code that protects these data.
Birth certificate data are available for what is considered appropriate research. Interested parties must make an application to the Department for these data. This application includes the signing of an agreement of confidentiality and a data use agreement. The Department strives to ensure the validity and advisability of research based on its death certificates. These data can be accessed via CDC's WONDER on-line database as well.

What are the criteria for including a record in this data set?
All instate occurrences regardless of the state of residence and all Michigan residents regardless of location of birth.

Is this a system designed to collect information on all events or a sample of events?
This database includes all births in Michigan and births to Michigan residents where the delivery occurred out-of-state.

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
No, physicians, other individuals who attended the birth, father, mother and individuals in charge of the institution where the birth occurred (if applicable) or their designated representatives complete the birth certificates.

What is the data collection process?
If a live birth occurs in an institution or en route to an institution, the individual in charge of the institution or their designated representative obtain personal data, prepare the certificate of birth, secure required signatures and file the certificate of birth with the local registrar or as otherwise directed by the state registrar within 5 days after the birth. The physician or other individual in attendance provide the medical information required by the certificate and certify to the facts of birth not later than 72 hours after the birth.

Description of the Data

How long has this dataset existed?
Birth certificates have been collected in Michigan since 1867. Currently used statistical birth files date back to 1970.
The birth certificate was revised mid-2007.

How many variables are in each record?
The number of variables has varied as the birth certificate has undergone revisions. The current master birth file has 262 variables, with many of those for statistical use only. The variables collected and the coding schemes are standard statewide. Not all the data collected on the birth certificate are entered into the database.

Are there any personal identifiers on each record and, if so, which ones?

Name:	Yes
Birth Date:	Yes
Birth Year:	Yes
Resident Street Address:	Yes
Social Security Number:	Yes (parents and child)

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes

Race:	Yes
Ethnicity:	Yes
Age:	Yes
Resident City:	Yes
Residence County:	Yes
Residence Zip Code:	Yes
Income:	No
Education:	Yes
Usual Occupation:	No
Industry of Occupation:	No
Marital Status:	Yes

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
No

What proportion of events is reported?
Nearly 100% with some delay in home birth registration and rare infanticides

What is the length of time between an event and entry to the computerized data set?
Web based reporting with final data completed in 7 -10 months.

What quality assurance procedures are performed?
Vital records staff conducts extensive and ongoing quality assurance procedures including: real time editing of data entry and manual review of documents.

What are the biases/limitations of these data?
Generally there are no known biases limitations to the data.

Are there any data quality issues related specifically to the data?
No known data quality issues, the reporting of live births is believed to be very accurate. However, medical information within the data can be very poor.

2. Michigan Fetal Death File

What is the basic purpose and use of these data?
The fetal death report database is a high quality computerized data set containing demographic information, maternal health and health behavior, delivery complications, and causes/conditions contributing to fetal death. These reports serve to provide valuable information essential to the measurement of perinatal health, the development and evaluation of programs to improve pregnancy outcomes and other important uses. Originally, these data were collected for demographic and legal purposes. From 1978 until June, 2003, the fetal death reports were reports used only for medical and health purposes and were not retained nor made available as official records of these events. Effective June 1, 2003, Michigan adopted changes to reporting based upon a revised national standard form for reporting fetal death. The Division for Vital Records and Health Statistics (DVRHS) in the Michigan Department of Community Health uses Birth certificate data, along with data related to population, deaths, fetal deaths, marriages, divorces, induced abortions, and communicable diseases to develop extensive statistical tabulations.

What organization is responsible for maintaining these data?
Michigan Department of Community Health
Bureau of Local health and Administrative Services
Division for Vital Records and Health Statistics

Who is the contact person responsible for maintaining these data?
Name: Michael Beebe
Division for Vital Records and Health Statistics
Michigan Department of Community Health
Telephone Number: (517)-335-8715
Email Address: BeebeM@Michigan.gov

How will this data set contribute to infertility surveillance?
Fetal Death Certificates will be used as the source of demographic information, maternal health and health behavior, delivery complications and causes/conditions associated with death for the NASS/MIVR linked dataset.

Are there separate local data sets that are maintained?
Yes, data exist for Michigan counties and minor civil divisions (MCD).

Are these local data sets included in the statewide data set?
Yes, county and MCD data are included in the statewide data set.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
Yes. The National Center for Health Statistics maintains the National Vital Statistics System.

Data Collection

Is there a legal mandate to collect these data? If so, please cite and summarize the specific statue or Public Health Code that mandates data collection.
Michigan law defines when the delivery of a stillbirth is reportable. The definition of a fetal death contained in section 333.2803 MCL is: The death of a fetus which has completed at least 20 weeks of gestation or weighs at least 400 grams. The fetus must be separated from the mother i.e. delivered, to be reported. The fetal death reporting law amended by ACT 562 of 2002 is effective for fetal death reports filed on and after June1, 2003. The reports will be retained in the state vital records repository as a permanent legal record of the event. A fetal death report is to be filed with the Michigan Department of Community Health not more than 5 days after the birth.

Are there any legal protections to the data that have been collected? If so, cite and summarize the specific law or code that protects these data.
Fetal death data (from 2004 forward) are available for what is considered appropriate research. Interested parties must make an application to the Department for these data. This application includes the signing of an agreement of confidentiality and a data use agreement. The Department strives to ensure the validity and advisability of research based on its death certificates. These data can be accessed via CDC's WONDER on-line database as well.

What are the criteria for including a record in this data set?
All instate occurrences regardless of the state of residence and all Michigan residents regardless of location of birth.

Is this a system designed to collect information on all events or a sample of events?
This database includes all fetal deaths in Michigan and fetal deaths to Michigan residents where the delivery occurred out-of-state.

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
No, the facility where the delivery occurred or if the delivery occurred in en route to the facility is responsible to report the event. If the fetal death occurs outside a facility and isn't attended to shortly after delivery within a facility then the physician in attendance at the delivery is responsible. If the attendant isn't a physician, arrangements for the reporting of the fetal death must be made with the medical examiner of the county where the delivery occurred. Section 333.2834(5) requires that if a fetal death occurs without medical attendance at or after the delivery, the attendant, the mother or other persons

having knowledge of the fetal death shall notify the medical examiner of the county where the delivery occurred.

What is the data collection process?
See above

Description of the Data

How long has this dataset existed?
Death certificates have been collected in Michigan since 1867. Statistical death files date back to 1970, which noted fetal deaths. The Fetal Death File, which can be linked to other vital records files, can be used from 2004 forward.

How many variables are in each record?
The number of variables has varied as the fetal death certificate has undergone revisions. The current master fetal death file has 261 variables, with many of those for statistical use only. The variables collected and the coding schemes are standard statewide. Not all the data collected on the death certificate are entered into the database.

Are there any personal identifiers on each record and, if so, which ones?

Name:	Yes
Birth Date:	Yes
Birth Year:	Yes
Resident Street Address:	Yes
Social Security Number:	Yes

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes
Race:	Yes
Ethnicity:	Yes
Age:	Yes
Resident City:	Yes
Residence County:	Yes
Residence Zip Code:	Yes
Income:	No
Education:	Yes
Usual Occupation:	No
Industry of Occupation:	No
Marital Status:	Yes

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.

What proportion of events is reported?

What is the length of time between an event and entry to the computerized data set?

What quality assurance procedures are performed?

What are the biases/limitations of these data?

Are there any data quality issues related specifically to the data?
No known data quality issues, the reporting of fetal deaths is believed to be very accurate.

The Michigan Vital Records staff conducts extensive data quality assurance procedures and can provide more information regarding these procedures, data quality and variable validity.

3. Michigan Inpatient Database (MIDB)

What is the basic purpose and use of these data?
These data are collected for use in developing information important to hospital administration and are used by facilities themselves for internal evaluation. The data are obtained by the state from the Michigan Health and Hospital Association to help support the State health planning activities. At MDCH, the Division for Vital Records and Health Statistics develop annual library tables, containing discharge rates and length of hospital stay for various ICD-9-CM groupings, by age, sex, and county. Reports cannot be published that identify individual hospitals. Individual hospitals can access and evaluate data pertaining to their facility.

What organization is responsible for maintaining these data?
Michigan Health and Hospital Association

Who is the contact person responsible for maintaining these data?
Glenn Copeland
Michigan Department of Community Health
Division for Vital Records and Health Statistics
Telephone Number: (517) 335-8677
Email Address: copelandg@michigan.gov

How will this data set contribute to infertility surveillance?
The MIDB will be used to provide prevalence estimates of maternal and infant hospitalizations for Michigan residents and to provide procedures and discharge diagnostics for Michigan born deliveries.

Are there separate local data sets that are maintained?
Locally, each hospital is responsible for collecting data at their facility. Data are sent to the Michigan Health and Hospital Association (MHHA), where the database is constructed.

Are these local data sets included in the statewide data set?
There is a standard statewide data set. Data are aggregated at the MHHA. While hospitals do not use a standard coding scheme, these coding differences are reconciled at MHHA when the data are aggregated.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
Yes. There is data available from the National Hospital Discharge Survey (NHDS) which has been conducted annually since 1965. NHDS is a national probability survey designed to meet the need for information on characteristics of inpatients discharged from non-Federal short stay hospitals in the United States. The NHDS collects data from a sample of approximately 270,000 inpatient records acquired from a national sample of about 500 hospitals. Another source of national hospitalization data is the Nationwide Inpatient Sample (NIS) sponsored by the Health Care Utilization Project. NIS contains all discharge data from 994 hospitals located in 28 states, approximating a 20% stratified sample of U.S. community hospitals.

Data Collection

What are the criteria for including a record in this data set?
A case, or record, is defined as a discharge from any of Michigan's acute care hospitals or Michigan residents discharged from acute care hospitals in contiguous and several other, (e.g. CO, MO, FL) states. Note that hospitals use differing criteria to define a hospital admission.

Is this a system designed to collect information on all events or a sample of events?
All hospital discharges are collected.

Is there staff that is dedicated to obtaining records, i.e. conducting active surveillance?
No, MDCH does not have staff that obtains records. Trained hospital staff collects clinical and administrative information.

What is the data collection process?
Data are collected throughout a patient hospital stay by clinical and administrative staff and filed within a medical record. Hospital medical record personnel ascertain and keypunch information from these records. Some small hospitals complete data collection forms and send these directly to MHHA for processing. Depending on the facility, data are submitted monthly, quarterly, or annually to MHHA. Because data formats often differ by hospital, all coding is converted into standard formats at MHHA. Data files are developed based on date of discharge.

Description of the Data

How long has this dataset existed?
MDCH has purchased data since 1982. Before then, a maximum of 40% of the hospitals were reporting in a given year.

How many variables are in each record?
The number of variables in each record varies by year. Those consistently available include:

County of residence	Discharge Diagnoses, 1-34
Zip code of residence	Procedures, 1-30
Race	Primary payer
Sex	Secondary payer
Date of birth	Length of stay
Age	Hospital identification number
Admission date	Disposition at discharge
Discharge date	Readmission
DRG	Medical record number (1996 – present)
Admission Diagnoses, 1	Total Charges
Admission Source	Admission Type

Are there any personal identifiers on each record and, if so, which ones?

Name:	No
Birth Date:	Yes
Birth Year:	Yes
Resident Street Address:	No
Social Security Number:	No

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes
Race and/or ethnicity:	Yes
Age:	Yes
Resident City:	No
Residence County:	Yes
Residence Zip Code:	Yes
Income:	No
Education:	No
Occupation:	No

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
Mandatory variables are nearly all complete upon submission to MHHA. Voluntary items, such as race can be quite incomplete with approximately 25% of the discharges missing data on race. With 2003 hospitalizations onward, when this field is missing, Division for Vital Records and Health Statistics staff utilizes links to other datasets (birth certificates, death certificates, etc.) to ascertain race. For remaining missing cases, the patient's race is assigned using an algorithm based on the racial distribution of the total hospitalized population for that year. Hospitalizations occurring between 1990 through 2002 with missing data for race were assigned a race based on the 1990 census population for Michigan, using the patient's zip code. Also, injury or "E-Codes" are missing for approximately 15-20% of hospitalizations. E-coding rates vary greatly by hospital and thus, county of residence.

What proportion of events is reported?
All acute care hospitals submit inpatient data to MHHA. In addition, coverage is excellent regarding Michigan resident discharges from hospitals in Indiana, Ohio, and Wisconsin. Each year, a few hospitals do not submit all their discharges – about 10,000 records or 1% is not submitted each year. To ensure a database representing all discharges, Statistical Studies Section staff selects a random sample of submitted discharges and duplicates data from these records.

What is the length of time between an event and entry to the computerized data set?
This depends on each individual hospital; some submit monthly, quarterly and annually. The length of time it takes for MDCH to receive the latest year of complete data is 12 months after the year end.

What quality assurance procedures are performed?
Hospitals utilize facility-specific data for internal evaluation and therefore stress accuracy in their submissions. MHHA performs quality assurance checks on the data. When hospitals receive the aggregated database, they evaluate the data and flag errors for correction.

What are the biases/limitations of these data?
As mentioned previously, before 2003, for records that were missing data on race, a race value was assigned to missing fields using an algorithm based on the 1990 census. From 2003 onward, for records that were missing data on race, a race value was assigned to missing fields using an algorithm based on the racial distribution of hospitalizations. The readmission variable in the data set is unreliable. The charges variable is consistently unpopulated. The medical record number in the data file is specific to an individual within a single hospital and, in some hospital systems, to a specific year. The medical record number cannot be used to track a specific person between hospitals or over time. Also, if a hospital did not submit their data for all or part of a given year, records within the data set are duplicated. It is unknown whether the field designating a record as a duplicate is reliable. Data from the MIDB represent counts of hospitalizations, not individuals. Therefore, incidence rates cannot be calculated, just hospitalization rates. Finally, the lack of standardized E-code inclusions in the hospitalization records makes comparisons of injury causes, such as those related to alcohol, difficult.

4. Michigan Death Certificates

What is the basic purpose and use of these data?
The death certificate database is a high quality computerized data set containing demographic and cause of death information for all Michigan residents (out of state deaths included) and non-Michigan residents dying in Michigan. Death certificates are one of public health's vital records for monitoring the health of citizens. Originally, these data were collected for demographic and legal purposes. The Division for Vital Records and Health Statistics (DVRHS) in the Michigan Department of Community Health uses death certificate data, along with data related to population, births, fetal deaths, marriages, divorces, induced abortions, and communicable diseases to develop extensive statistical tabulations.

What organization is responsible for maintaining these data?
Michigan Department of Community Health
Bureau of Local health and Administrative Services
Division for Vital Records and Health Statistics

Who is the contact person responsible for maintaining these data?
Name: Michael Beebe
Division for Vital Records and Health Statistics
Michigan Department of Community Health
Telephone Number: (517)-335-8715
Email Address: BeebeM@Michigan.gov

How will this data set contribute to infertility surveillance?
Death certificates will be used to determine the prevalence of infertility treatment-related mortalities in the State of Michigan.

Are there separate local data sets that are maintained?
Yes, data exist for Michigan counties and minor civil divisions (MCD).

Are these local data sets included in the statewide data set?
Yes, county and MCD data are included in the statewide data set.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
Yes. The National Center for Health Statistics maintains the National Vital Statistics System.

Data Collection

Is there a legal mandate to collect these data? If so, please cite and summarize the specific statue or Public Health Code that mandates data collection.
Section 2843 of Public Health 368 of 1978 requires a funeral director to initiate the gathering of information for the death certificate, the attending physician to complete and sign the medical information within 48 hours of death, and the death record to be filed with the local registrar within 72 hours of death.

Are there any legal protections to the data that have been collected? If so, cite and summarize the specific law or code that protects these data.
Death certificate data are available for what is considered appropriate research. Interested parties must make an application to the Department for these data. This application includes the signing of an agreement of confidentiality. The Department strives to ensure the validity and advisability of research based on its death certificates. These data can be accessed via CDC's WONDER on-line database as well.

What are the criteria for including a record in this data set?
All instate occurrences regardless of the state of residence and all Michigan residents regardless of location of death.

Is this a system designed to collect information on all events or a sample of events?
This database includes all deaths in Michigan and deaths of Michigan residents where the death occurred out-of-state.

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
No, funeral directors, physicians, and medical examiners complete the death certificates.

What is the data collection process?
A funeral director, or another individual responsible for disposing of the body, completes the demographic and disposition components of the death certificate. When applicable, an attending physician or other hospital medical staff completes the portion of the death certificate describing the death (time, date,

place, and immediate/underlying cause). A county medical examiner completes this section in all unexpected deaths including fatal injuries. The death certificate is then sent to the local registrar who verifies that the document has been properly filled out. If not, it is returned to the appropriate person for revision. Certificates for Michigan residents dying out-of-state are provided by those states (primarily Indiana, Ohio, and Wisconsin). Instructional materials to complete the death certificate are available at the state and local level for doctors, hospitals, medical examiners, and funeral directors. Michigan funeral director training also includes an annual seminar on death certificate completion.

Description of the Data

How long has this dataset existed?
Death certificates have been collected in Michigan since 1897. Statistical death files date back to 1970.

How many variables are in each record?
The number of variables has varied as the death certificate has undergone revisions. The current master death file has 197 variables, with many of those for statistical use only. The variables collected and the coding schemes are standard statewide. Not all the data collected on the death certificate are entered into the database.

Are there any personal identifiers on each record and, if so, which ones?

Name:	Yes
Birth Date:	Yes
Birth Year:	Yes
Resident Street Address:	Yes
Social Security Number:	Yes

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes
Race:	Yes
Ethnicity:	Yes
Age:	Yes
Resident City:	Yes
Residence County:	Yes
Residence Zip Code:	Yes
Income:	No
Education:	Yes
Usual Occupation:	Yes
Industry of Occupation:	Yes
Marital Status:	Yes

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
There are no missing values in the database. Death certificates that do not contain certain required information are returned to the person responsible for completing that item.

What proportion of events is reported?
According to the DVRHS, death certificates are submitted for more than 98.5% of deaths.

What is the length of time between an event and entry to the computerized data set?
For most cases, death certificates are completed within a week after death. Local registrars submit death certificates monthly to the Division for Vital Records and Health Statistics for processing. The length of time it takes for a death certificate from filing with the funeral director to MDCH vital record's statistical file is about 90 days.

What quality assurance procedures are performed?
Some samples of computerized records are checked against the original death certificate. If accuracy for a given data entry person does not meet a specified standard, all records entered by that person are re-entered. In addition, the National Center for Health Statistics (NCHS) checks submitted data for accuracy.

What are the biases/limitations of these data?
There is no law in Michigan specifying the scope to which county medical examiners investigate cases. Therefore, the accuracy of attributing cause of death may vary by county. Death certificates for Michigan residents dying out-of-state may not be received in time for inclusion in the statistics tabulated annually, but almost all are eventually received.

Are there any data quality issues?
No known data quality issues, the reporting is believed to be very accurate.

5. Michigan Birth Defects Registry (MBDR)

What is the basic purpose and use of these data?
The Michigan Birth Defects Registry maintains a file of case reports on children diagnosed with a reportable condition at birth to two years of age born in Michigan or to Michigan residents and diagnosed with a reportable condition in the state of Michigan. Originally, these data were collected for publish health disease surveillance purposes. The Division for Vital Records and Health Statistics (DVRHS) and the Division of Genomics, Perinatal Health and Chronic Disease Epidemiology at the Michigan Department of Community Health compute baseline birth defects incidence and mortality rates analyze trends; identify and investigate clusters; plan and develop programs; and evaluate programs and services. These activities seek to improve knowledge of birth defects prevention.

What organization is responsible for maintaining these data?
Michigan Department of Community Health
Bureau of Local health and Administrative Services
Division for Vital Records and Health Statistics

Who is the contact person responsible for maintaining these data?
Name: Glenn Copeland
Division for Vital Records and Health Statistics
Michigan Department of Community Health
Telephone Number: (517)-335-8677
Email Address: copelandg@Michigan.gov

How will this data set contribute to infertility surveillance?
Birth Defects Registry will be used to determine the prevalence of birth defects among infants born to parents who used ART or non-ART in the state of Michigan.

Are there separate local data sets that are maintained?
Yes, data exist for Michigan counties.

Are these local data sets included in the statewide data set?
Yes, county data are included in the statewide data set.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
No. There is currently no source for national surveillance data on the prevalence of birth defects.

Data Collection

Is there a legal mandate to collect these data? If so, please cite and summarize the specific statue or Public Health Code that mandates data collection.

Section 5721 and 5805 of Public Health 368 of 1978 established the MBDR. Section 5721 of Part 57 stipulates that "(1) Each diagnosed incidence of a birth defect, including a congenital or structural malformation, or a biochemical or genetic disease and any information relevant to incidents of birth defects, shall be reported to the department. (2) The department shall maintain comprehensive statewide records of all information reported to the birth defects registry." Public Act 236 of 1988 amended the public health code and directs MDCH to establish a comprehensive birth defects registry and improving statewide identification of children with birth defects and facilitating the assessment of service and referral needs for these children.

Are there any legal protections to the data that have been collected? If so, cite and summarize the specific law or code that protects these data.
Confidentiality of all data is required by law and strictly maintained by the Health Department staff. Section 2631 of the Public Health Code regulates procedures protecting confidentiality and regulating disclosure of data and records.

What are the criteria for including a record in this data set?
A registrant is defined as "a child age birth to 2 years who is diagnosed with a reportable birth defect in the state of Michigan." Any child or stillborns who were born in the state of Michigan to mothers who were residents of the state are included in the registry.

Is this a system designed to collect information on all events or a sample of events?
This database is intended to collect information on all events.

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
No, an administrative officer for a health care facility where the child was diagnosed and clinical laboratory directors that conducts postmortem examinations or cytogenetic tests shall report to the department.

What is the data collection process?
A responsible individual completes the form approved by MDCH or submits an electronic case report through the Web EBC or using existing hospital information systems. The report is to be submitted to within 30 days. Case report data are augmented from various sources including newborn screening data, Children's Special Health Care and vital records data.

Description of the Data

How long has this dataset existed?
Formal surveillance of birth defects began in 1987. Statewide case reporting began in 1992.

How many variables are in each record?
The birth defects report includes 24 items with additional data merged into the registry from linked live birth and mortality files.

Are there any personal identifiers on each record and, if so, which ones?

Name:	Yes
Birth Date:	Yes
Birth Year:	Yes
Resident Street Address:	Yes
Social Security Number:	Yes

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes
Race:	No
Ethnicity:	No
Age:	Yes
Resident City:	Yes

Residence County:	Yes
Residence Zip Code:	Yes
Income:	No
Education:	No
Usual Occupation:	No
Industry of Occupation:	No
Marital Status:	No

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
No.

What proportion of events is reported?
Based upon audit findings, the registry is believed to be 97% complete but the level of completion does vary by birth defects type and severity.

What is the length of time between an event and entry to the computerized data set?
Complete data for 1st year diagnoses is available within 12 months of the end of an incidence year. Full two year diagnoses data takes an additional year.

What quality assurance procedures are performed?
Retrospective facility audits are conducted periodically to assess statewide performance in the reporting of birth defects and to identify opportunities for improvement. In the most recent audit (2009- 2010) 71.6% of sampled reports were accurate, but most errors were due to demographic discrepancies. A total of 33 false positives were found for a false detection rate of 6%.

What are the biases/limitations of these data?
The reporting mechanism is facility based which means that conditions not evident at birth and not requiring hospitalizations are more likely to go unreported.

Are there any data quality issues?
As a passive registry, there is always some element of concern with regard to completeness and diagnostic accuracy. From most purposes, the data are sufficiently reliable for statistical analyses.

6. Michigan Cancer Registry

What is the basic purpose and use of these data?
The registry was established to provide statistical information on cancer incidence, enable surveillance of cancer and facilitate research into the causes and control of cancer. A state wide population based cancer registry is the only means whereby state wide incidence data for cancers by type and by area of residence can be developed. The registry is of value in examining the frequency of cancer by demographic characteristics such as age, race and sex and is of significant value to researchers in epidemiological case control studies.

What organization is responsible for maintaining these data?
Michigan Department of Community Health
Bureau of Local health and Administrative Services
Division for Vital Records and Health Statistics

Who is the contact person responsible for maintaining these data?
Name: Glenn Copeland
Division for Vital Records and Health Statistics
Michigan Department of Community Health
Telephone Number: (517)-335-8677

Email Address: CopelandG@Michigan.gov

How will this data set contribute to infertility surveillance?
Cancer registry data will be useful for surveillance of infertility and birth outcomes among cancer survivors and analyzing the incidence of cancer among women who underwent infertility treatment and their offspring.

Are there separate local data sets that are maintained?
Michigan hospitals operate 37 ACOS approved cancer registries collecting data on all cancer patients touched by specific facilities or groups of facilities. The Detroit Metropolitan Cancer Surveillance System operates a Surveillance Epidemiology End Results (SEER) registry which reports for all hospitals and most laboratories within Oakland, Macomb and Wayne counties. Other regional registries include the West Michigan Cancer Center in Kalamazoo and the cancer registry at Marquette General Hospital in Marquette.

Are these local data sets included in the statewide data set?
Yes, regional data are included in the statewide data set.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
Yes, data on cancer incidence is collected by the CDC National Program of cancer Registries as is included in the national cancer surveillance system database.

Data Collection

Is there a legal mandate to collect these data? If so, please cite and summarize the specific statue or Public Health Code that mandates data collection.
Act 82 of 1984, effective July 1, 1984 mandates MDCH to establish a registry to record cases of cancer and other specified tumorous and precancerous diseases that occur in the state. Reporting of diagnosed cancers is effective for those cases diagnosed on or after January 1, 1985.

Are there any legal protections to the data that have been collected? If so, cite and summarize the specific law or code that protects these data.
Cancer incidence reports and data files on cancer cases are afforded confidential handling as required by Act 82 of 1984 which amended section 2631 of Act 368 of 1978. Information may be provided to a researcher conducting approved research, following specific protocol based upon the nature of the research. Further protection of the data is afforded by sections 2632 and 2633 of Act 368 of 1978 and privacy within the Michigan Administrative Code.

What are the criteria for including a record in this data set?
All in situ or invasive cancers are reportable including carcinoma in situ of the uterine cervix but excluding basal or squamous cell cancers in non-genital skin. The residence of the patient is not a factor. Since 2004, benign lesions of the central nervous system are also reportable.

Is this a system designed to collect information on all events or a sample of events?
This database includes all diagnosed cancers in Michigan and cancer diagnoses of Michigan residents where the diagnosis occurred out-of-state. Michigan currently has resident data exchange agreements with twenty other states concerning resident cancer case exchange.

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
No, reports of diagnosed cancers are required of a facility diagnosing and/or treating a cancer patient. All hospitals, clinical laboratories, physician offices, dentists and clinic directors who have knowledge of a cancer case report the case to MDCH.

What is the data collection process?
Facilities report cancer diagnoses, diagnoses of benign brain-related tumors and any tumorous and precancerous diseases to the state central cancer registry either manually on paper or automated with computer data files within 180 days of a diagnosis.

Description of the Data

How long has this dataset existed?
Cancer reporting in Michigan dates back to 1947 when an administrative rule was enacted to require reporting of cancer cases. This rule was never effectively enforced until 1978. In 1980 a pilot project was initiated and by 1984, fifty two hospitals were reporting cancer cases each year. On April 17, 1984, a bill to mandate state wide reporting was signed into law. In 2009, changes to the information reported for 2010 cancer cases were initiated. The new dataset conforms to recommendations of the North American Association of Central Cancer Registries (NAACCR) and nearly conform to the National Program for Cancer Registries (NPCR).

How many variables are in each record?
The number of variables has varied as the registry has undergone revisions. The current cancer registry file has 108 variables, with many of those for statistical use only. The variables collected and the coding schemes are standard statewide and satisfy the requirements of the CDC NPCR program.

Are there any personal identifiers on each record and, if so, which ones?

Name:	Yes
Birth Date:	Yes
Birth Year:	Yes
Resident Street Address:	Yes
Social Security Number:	Yes

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes
Race:	Yes
Ethnicity:	Yes
Age:	Yes
Resident City:	Yes
Residence County:	Yes
Residence Zip Code:	Yes
Income:	No
Education:	No
Usual Occupation:	Yes
Industry of Occupation:	Yes
Marital Status:	Yes

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
Ethnicity data and occupational data are poorly reported and unreliable.

What proportion of events is reported?
It is estimated that the registry collects 98% of all diagnosed cases within months of the end of a diagnoses year.

What is the length of time between an event and entry to the computerized data set?
24 months for the complete case information

What quality assurance procedures are performed?

Each reporting entity will be subject to inspection every 5 years to assess quality and completeness of the reporting; they shall allow the department to inspect part of a patient's medical record necessary to verify the accuracy of the submitted data. Quality control field projects carried out within Michigan have been designed to measure the completeness and accuracy of the cancer data as well as timeliness of reporting. Internal quality control relates to the process that is established to check for errors and discrepancies as reports come into the registry. External quality control is a method that checks for errors and discrepancies at the reporting facility.

What are the biases/limitations of these data?

Are there any data quality issues?
No known data quality issues, the reporting is believed to be very accurate.

7. National ART Surveillance System

What is the basic purpose and use of these data?
The National ART Surveillance System (NASS) is a web-based ART data reporting system supported by the CDC and in large part based on data collected by SART. The data collected include information the client's medical history (such as infertility diagnoses), clinical information pertaining to the ART procedure, and information on resulting pregnancies and births. The data file is organized with one record per ART procedure performed. Multiple procedures from a single patient are not linked. It is estimated that the ART surveillance system captures over 95% of the ART procedures performed each year in the U.S. Despite its completeness and the rich database, the ART surveillance system is intrinsically limited in its ability to follow up mothers and their ART-conceived infants. In particular, data about specific obstetric, perinatal, and neonatal complications and outcomes cannot reliably be collected with the current ART surveillance system because ART providers don't typically care for patients beyond their first trimester of pregnancy. The CDC has developed collaborative projects with three state health departments (Florida, Massachusetts and Michigan) to link the existing ART surveillance data for infants born to resident women with data obtained from the state birth, death, fetal death and hospital discharge file for both the mother (one year prior to after delivery) and the infant (after delivery).

What organization is responsible for maintaining these data?
Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Division of Reproductive Health

American Society for Reproductive Medicine
Society for Assisted Reproductive Technology

How will this data set contribute to infertility surveillance?

NASS data linked to MI vital records data will the source of pre-pregnancy health, treatment modality and treatment frequency variables

Are there separate local data sets that are maintained?
Yes, for each clinic

Are these local data sets included in the statewide data set?
Yes, clinic data are included in the statewide data set.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
Yes, NASS is a national data collection system.

Data Collection

What are the criteria for including a record in this data set?
Each clinic submits data electronically either to SART or to Westat for each ART cycle initiated during a given reporting year. A reporting year is defined from January 1 through December 31 of the calendar year when the cycle was initiated. The reporting process has incorporated a nine month lag time in order that all pregnancies achieved using ART can be followed up for birth outcome

Is this a system designed to collect information on all events or a sample of events?
Yes, this system is designed to collect information on all ART cycles initiated from January 1 through December 31

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
Clinics have staff dedicated to report the data.

What is the data collection process?
Each ART clinic is assigned a unique numeric clinic code, appropriate computer software, and reporting instructions. Each patient receiving ART in a given clinic is assigned a unique code by the participating clinic and entered into that clinic's reporting data file when her treatment cycle is initiated. Each cycle of each patient is also assigned a unique code. Therefore, within a clinic, the clinic code, patient code, and cycle code from the reporting system can be linked back to a clinic record. All cycles must be reported. This includes (1) all women undergoing ART with fresh, cryopreserved and/or donor embryos or oocytes (2) all women undergoing ovarian stimulation or monitoring with the intention of undergoing ART, including women whose cycles are canceled for any reason.

Description of the Data

How long has this dataset existed? How long has infertility related information been collected?
The dataset has existed since 1984. CDC does not collect infertility-related information. However, MI has been collected infertility-related information on the state questionnaire in 2010 through BRFSS. Florida and Massachusetts will start collecting similar information through the state BRFSS questionnaires. Data collected and submitted to CDC include general patient information such as date of birth, patient history and infertility diagnoses, information pertaining to the current ART cycle (which includes information on the donor, if a woman does not utilize her own oocytes), and information on resultant pregnancies and births. A complete list of data currently collected and submitted to CDC is available upon request.

What data is collected with regard to Infertility?
NASS collects information on reasons for infertility.

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
Smoking, race, weight (all missing approximately 50%)

What is the length of time between an event and entry to the computerized data set?
Each patient receiving ART in a given clinic is assigned a unique code by the participating clinic and entered into that clinic's reporting data file when her treatment cycle is initiated. The reporting process has incorporated a nine month lag time in order that all pregnancies achieved using ART can be followed up for birth outcome.

What quality assurance procedures are performed?
Once submitted, data are reviewed and processed at SART and each clinic is sent an aggregate report of their data and required to verify that the data being reported are correct. A cumulative data file is then created which combines data from all ART clinics that report and verify their data for a given reporting

year. This data file is then forwarded to the CDC. The data file is organized with one record per cycle. The CDC reviews these data further and if inconsistencies between key variables are discovered, the CDC generates a list of records with inconsistent data and works with SART to contact the individual clinics and resolve discrepancies.
To have their success rates published in this annual report, clinics have to submit their data in time for analysis and the clinics' medical directors have to verify by signature that the tabulated success rates are accurate. Then, Westat conducts an in-house review and contacts the clinics if corrections are necessary. After the data have been verified, a quality control process called validation begins. This year, 35 of 436 reporting clinics were randomly selected for site visits. Members of the Westat Validation Team visited these clinics and reviewed medical record data for a sample of the clinic's ART cycles. For each cycle, the validation team abstracted information from the patient's medical record. The abstracted information was then reviewed on-site and compared with the data submitted for the report. CDC staff members participated as observers in some of the visits. For each clinic, the sample of cycles validated included all cycles that were reported to have multiple-fetus pregnancies and a random sample of up to 50 additional cycles. In almost all cases, data available in the medical records on pregnancies and births were consistent with reported data. Validation primarily helps ensure that clinics are being careful to submit accurate data. It also serves to identify any systematic problems that could cause data collection to be inconsistent or incomplete.

What are the biases/limitations of these data?
A small proportion of clinics do not submit their data to CDC each year. Information on embryo quality and donor history are not collected.

Are there any data quality issues related specifically to the infertility data?

8. Michigan Behavioral Risk Factor Surveillance System (BRFSS)

What is the basic purpose and use of these data?
The Michigan BRFSS is the only source of population-based estimates of the prevalence of certain health behaviors, chronic conditions, and preventive practices among the Michigan adult population.

What organization is responsible for maintaining these data?
Michigan Department of Community Health, Bureau of Disease Control, Prevention, and Epidemiology

Who is the contact person responsible for maintaining these data?
Name: Chris Fussman
Michigan Department of Community Health
Division of Genomics, Perinatal Health and Chronic Disease Epidemiology
Telephone Number: 517-335-8144
Email Address: fussmanc@michigan.gov

How will this data set contribute to infertility surveillance?
The BRFS will be used to determine the prevalence of infertility and impaired fecundity; infertility treatment; and outcome of most recent infertility among Michigan residents.

Are there separate local data sets that are maintained?
Some Michigan counties conduct local surveys that are not included in Michigan or national BRFS data.

Are these local data sets included in the statewide data set?
No

Is there a national data set that is a natural comparison to this data set? If so, what is it?
Yes, the National Behavioral Risk Factor Surveillance Survey. CDC provides state and national level prevalence data on their web site. However, infertility questions will only be asked in 3 states: Michigan, Massachusetts and Florida.

Data Collection

What are the criteria for including a record in this data set?
A record is a completed telephone interview. The CDC develops approximately 80 questions each year. Some of these are core questions asked each year, and some are rotating core questions asked every other year. There is also CDC supported modules that address specific topics that states can use. States also develop additional questions to supplement the core questions. The selected respondent must be a Michigan resident, 18 years of age or older who lives in a private residence and has a telephone. One randomly selected adult from a household is interviewed.

Is this a system designed to collect information on all events or a sample of events?
This is a statistical sampling of Michigan residents. The data are weighted to represent estimates for the general adult population. The most recent (2010) CASRO response rate was 56.91% compared to the national average of 54.60%.

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
Yes, data are collected for the Michigan BRFSS by the Michigan State University, Institute for Public Policy and Social Research, Office for Survey Research (MSU OSR). MSU OSR sets a quota for interviews to be completed on a quarterly basis based on the proposed sample size.

What is the data collection process?
Estimates are based on data collected from a random-digit dial telephone survey of Michigan households annually. BRFSS interviewers use the Computer Assisted Telephone Interviewing (CATI) system, which provides the interviewer with prompts. Different answers to questions activate different prompts. The interviewer types the respondent's responses directly onto the computer screen, providing quality control and minimizing interviewer error. The target sample size for 2011 is 10,080 respondents (8,400 landline and 1,680 cell phone respondents). The proposed sample size for 2012 is 10,000 respondents (8,000 landline and 2,000 cell phone respondents).

Description of the Data

How long has this dataset existed? How long has infertility related information been collected?
The dataset has existed since 1984; infertility-related information has been collected on the state questionnaire in 2010 and 2011.

What data is collected with regard to Infertility?
In 2010 and 2011 the Michigan BRFSS included the following two questions:
1. Have you or your wife/partner (husband/partner) ever had any medical procedures for infertility, taken infertility medications, or had some other form of infertility treatment?
2. What type of treatment did you or your wife/partner have? Was it....
   1 A medical procedure such as In Vitro Fertilization or Intracytoplasmic Sperm Injection
   2 Infertility medication only
   3 Both a medical procedure and medication, or
   4 Something else **[specify]**

In 2012 the infertility module will be expanded to 4 questions included below:

Please read: The next questions are about infertility and pregnancies not ending in a live birth. This means that after a year of trying to do so, a couple is unable to become pregnant or carry a pregnancy due to miscarriage or stillbirth.

24.1 *If Q7.6 = 1 or 6:*
Have you or your spouse/partner ever experienced infertility or difficulty carrying a pregnancy due to miscarriage or stillbirth?

Interviewer Note: If Q7.6 = 1 or 6 and response is "Yes", probe with "Was it you, your partner, both you and your partner, or was it undetermined?"

Interviewer Note: If Q7.6 = 1 or 6 and response is "No", probe with "Is this because you have never tried to get pregnant?"

If Q7.6 = 2, 3, 4, 5 or 9 and Q7.22 = 2:
Have you ever experienced infertility or difficulty carrying a pregnancy due to miscarriage or stillbirth?

Interviewer Note: If Q7.6 = 2, 3, 4, 5, or 9 and Q7.22 = 2 and response is "No", probe with "Is this because you have never tried to get pregnant?"

If Q7.6 = 2, 3, 4, 5 or 9 and Q7.22 = 1:
Have you ever experienced infertility?

()

1	Yes, I have	**[Go to CATI Note before Q24.2]**
2	Yes, my partner has	**[Go to Q24.2]**
3	Yes, we both have	**[Go to Q24.2]**
4	Yes, but undetermined	**[Go to Q24.2]**
5	No	**[Go to Q24.3]**
6	Never tried to get pregnant	**[Go to next section]**
7	Don't know / Not sure	**[Go to next section]**
9	Refused	**[Go to next section]**

CATI NOTE: If Q7.6 = 2, 3, 4, 5 or 9 and Q7.22 = 1, code "1" for Q24.2. Otherwise, continue.

24.2 Was it infertility, difficulty carrying a pregnancy due to miscarriage or stillbirth, or both?

()

1	Infertility
2	Difficulty carrying a pregnancy due to miscarriage or stillbirth
3	Both
7	Don't know / Not sure
9	Refused

24.3 *If Q7.6 = 1 or 6:*
Which of the following treatments have you or your spouse/partner received?

If Q7.6 = 2, 3, 4, 5 or 9:
Which of the following treatments have you received?

()

Interviewer Note: Allow for up to six responses.

Please read:

0 1 Drugs to improve or stimulate ovulation (such as Clomid ®, Serophene ®, or Pergonal ®)
0 2 Artificial insemination or intrauterine insemination (treatments in which sperm, but NOT eggs, are collected and medically placed into a woman's body)
0 3 Assisted reproductive technology (treatments in which BOTH a woman's eggs and a man's sperm are handled in the laboratory, such as In Vitro Fertilization, Intracytoplasmic Sperm Injection, frozen embryo transfer, or donor embryo transfer)
0 4 Another type of surgical treatment for infertility
0 5 A consultation with an infertility specialist
0 6 Something else **[specify]**, or
0 7 You have not received medical consultation or treatment for infertility
[Go to next section]

Do not read:

7 7 Don't know / Not sure
8 8 No additional responses
9 9 Refused

24.4 What was the result of the most recent treatment? Did you or your spouse/partner…
()

Please read:

1 Become pregnant and are still pregnant
2 Become pregnant and had a baby
3 Become pregnant, but the pregnancy was not maintained
4 Did not become pregnant, but are still trying
5 Did not become pregnant and have stopped trying, or
6 You are currently receiving infertility treatment

Do not read:

7 Don't know / Not sure
9 Refused

How many variables are in each record?
There are approximately 200 core and optional module variables.

Are there any personal identifiers on each record and, if so, which ones?

Name:	No
Birth Date:	No
Birth Year:	Yes – for randomly selected child only
Resident Street Address:	No
Social Security Number:	No

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes
Race:	Yes

Ethnicity:	Yes
Age:	Yes
Residence County:	Yes
Residence Zip Code:	Yes
Income:	Yes
Education:	Yes
Occupation:	No
Marital Status:	Yes

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
All BRFSS responses are voluntary. Respondents are free to choose which questions they would like to respond to and can refuse to answer any question within the survey. With that being said, there is intermittent missing data throughout the survey, but no variables have even close to 20% missing data.

What is the length of time between an event and entry to the computerized data set?
The data is entered into the data set as it is collected. The resulting data is coded, cleaned, and submitted to the Centers for Disease Control and Prevention (CDC) on a quarterly basis.

What quality assurance procedures are performed?
10% of calls are verified. Quality control computer programs are written to check the raw data for values out of range. CDC writes a program to check the data quality for core questions administered by every state and Michigan State University writes a program to check Michigan specific questions. Additionally, interviewers are monitored during the annual questionnaire pilot period and intermittently during the data collection period to determine whether any interviewer bias exists and to correct any bias that might be found.

What are the biases/limitations of these data?
There is an overall moderate response rate; although Michigan's response rate is higher than the national median response rate for all states (2010). Prior to 2011, the sample represented only Michigan adults living in a private residence with a landline telephone, but starting in 2011, the sample also includes data from respondents living in cell phone-only households. The survey adjusts for non-response so responders do not differ from non-responders. There is an assumption that may introduce further error. Even though the participants interviewed do not represent the state of Michigan in terms of age, sex and race distribution, it is believed that weighting the data corrects for this potential bias. Since estimates are based on self-report data, they may over- or underestimate the actual prevalence of a particular risk factor in the population. The annual sample size is too small to compute precise estimates at the county level. The child prevalence data are reliant on proxy report from the adult respondent to the BRFSS and may be subject to misclassification related to this method.

Are there any data quality issues related specifically to the infertility data?
This is a new module and data quality has not been determined.

9. Pregnancy Risk Assessment Monitoring System (PRAMS)

What is the basic purpose and use of these data?
PRAMS was initiated in 1987 to reduce infant mortality and low birth weight. The program has since been expanded to support CDC's Safe Motherhood initiative to promote healthy pregnancies and the delivery of healthy infants. It is an ongoing population-based surveillance system designed to identify and monitor selected maternal experiences and behaviors that occur before and during pregnancy and during the child's early infancy.

What organization is responsible for maintaining these data?
Michigan Department of Community Health, Bureau of Disease Control, Prevention, and Epidemiology

Who is the contact person responsible for maintaining these data?
Name: Cristin Larder
Michigan Department of Community Health
Division of Genomics, Perinatal Health and Chronic Disease Epidemiology
Telephone Number: (517)-335-9509
Email Address: LarderC@Michigan.gov

How will this data set contribute to infertility surveillance?
This data set will be used to assess the prevalence of infertility treatment among women who had a live birth. .

Are there separate local data sets that are maintained?
Some individual counties in Michigan collect their own local PRAMS date.

Are these local data sets included in the statewide data set?
Local datasets are not currently included in the statewide dataset.

Is there a national data set that is a natural comparison to this data set? If so, what is it?
The CDC keeps a combined dataset with information from all participating PRAMS states, which represents approximately 87% of all live births in the United States. CPONDER is a Web-based query system created to access data collected through Pregnancy Risk Assessment Monitoring System (PRAMS) surveys.

<u>Data Collection</u>

Is there a legal mandate to collect these data? If so, please cite and summarize the specific statue or Public Health Code that mandates data collection.
The Health Care and Education Affordability Reconciliation Act of 2010 specifically requests that states collect data on the oral health status of pregnant women using the PRAMS surveillance system, although PRAMS itself is not legally mandated.

Are there any legal protections to the data that have been collected? If so, cite and summarize the specific law or code that protects these data.
The CDC obtains approval for the overall project from its IRB, and MDCH obtains approval for Michigan's methodology through its own IRB. All materials including the questionnaire, protocol, cover letter, etc. are presented to the MDCH IRB. Informed consent is required from all participants before data collection is allowed. In order to protect the privacy of the data collected, the CDC requires all states to adopt the following policies: 1) All information collected shall be held in confidence to the extent allowed by law. All state staff and contractors involved in PRAMS shall be trained concerning procedures and practices to ensure privacy of data and shall sign a confidentiality pledge. 2) No individually identifiable information will be provided to persons other than state PRAMS staff, contractors working on the PRAMS state project, or CATI system administrators as they maintain the Web-based CATI system for all states. 3) No information, including the fact that the woman recently gave birth, will be released to a woman's friends or family. Individually identifiable information may be released only if authorization is explicitly granted by the

affected individual or legal guardian. 4) No individually identifiable information will be presented in any reports arising from analysis of data collected as part of PRAMS. 5) Completed questionnaires and any files with personal identifiers must be kept in a locked file cabinet or locked room: access to these files must be limited to authorized personnel. 6) All electronic files will have restricted access. 7) Only a few individuals from CDC and the CDC contractor may have access to identified data. In all other cases, data sent to CDC will be de-identified. 8) States must decide on a policy regarding the archival and destruction of PRAMS questionnaires. 9) States must ensure that any contractors who may be responsible for any portion of the PRAMS operations also follow all policies described above.

What are the criteria for including a record in this data set?
The inclusion requirements for including a record in the PRAMS sample are as follows: 1) Birth must be to a MI resident. 2) Birth must occur in MI. 3) Mother's last name must be documented in the birth file. 4) Birth certificate must be processed within six months of the birth. 5) Only one infant from multiple gestations can be included in sample. 6) Infant must not be adopted. 7) Infant must not have a surrogate mother or gestational carrier.

Is this a system designed to collect information on all events or a sample of events?
Information is collected on a sample of events.

Is there staff that is dedicated to obtaining records, (i.e. conducting active surveillance)?
An MDCH Vital Records staff member serves 35% of time on PRAMS (creating sampling frame, drawing sample, and generating monthly sampling files). Michigan State University's Office for Survey Research is responsible for receiving monthly samples from Vital Records, conducting the mail survey, coding and entering data on completed and returned questionnaires, searching for telephone numbers of non-responders to facilitate telephone interviewing attempts, conducting the telephone interviews, mailing out incentives, maintaining PRAMTrac records and samples, and outputting and processing final datasets to meet CDC specifications.

What is the data collection process?
PRAMS is a mixed-mode surveillance system: it combines mail and telephone surveillance. Data collection procedures are as follows: 1) When the sample is received from vital records (Day 1), a pre-letter is sent to sampled women to notify them that they have been selected and that a questionnaire will arrive in the mail shortly. 2) One week after the pre-letter (on Day 7), the first mail questionnaire is sent. 3) A tickler is sent to remind women to return the questionnaire on Day 14. 4) On Day 28, a second questionnaire is sent to women who have not returned their first questionnaire. 5) A third questionnaire is sent on Day 42 to women who have not returned one. 6) On Day 56, all women who have not returned a questionnaire move to the telephone phase, and interviewers begin calling. 6) On Day 91 or when an infant reaches 9 months of age (whichever comes first), telephone contact attempts end.

Description of the Data

How long has this dataset existed? How long has infertility related information been collected?
MI has collected PRAMS or PRAMS related data since the program began its first year of data collection in the fall of 1988 (Phase 1). Infertility related information has been collected beginning in 2009 and is planned through 2015

What data is collected with regard to infertility?
The Phase 6 questionnaire (2009-2015), which is the questionnaire used in the latest available data, contains the following questions related to infertility:
- Did you take any fertility drugs or receive any medical procedures from a doctor, nurse or other health care worker to help you get pregnant with your new baby? This may include infertility treatments such as fertility-enhancing drugs or assisted reproductive technology.

How many variables are in each record?
Six variables are included in each record.

Are there any personal identifiers on each record and, if so, which ones?
No, the analytic data set is de-identified.

Is socio-demographic information collected on each record, and, if so, what information?

Sex:	Yes
Race and/or ethnicity:	Yes
Age:	Yes
Resident City:	No
Residence County:	No
Residence Zip Code:	No
Income:	Yes
Insurance Status:	Yes

Data Quality

Are there any variables for which there are a large proportion of missing data (e.g. > 20%)? If so, identify which variables and estimate the percent missing.
No.

What proportion of events is reported?
Each year's sample is weighted to represent all births that meet the inclusion criteria before reporting.

What is the length of time between an event and entry to the computerized data set?
The length of time between an event and entry into the computerized data set is typically two to nine months.

What quality assurance procedures are performed?
Ten percent of all mail questionnaires are double entered, and interviewers are monitored on the telephone 10% of the time that they are making calls for quality control purposes. Data files are cleaned and edited for data entry errors before being sent to CDC. CDC checks each monthly batch with an automated system once submitted by the state.

What are the biases/limitations of these data?
Some bias may occur due to self-reporting. Data does not include information on abortions, miscarriages, or stillbirths. Recall bias is a possibility since the data is collected retrospectively.

Are there any data quality issues related specifically to the infertility data?
The quality of the infertility data is unknown as this is a new module.
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Appendix D – Variables

Variables included in the NASS data set

System Clinic Code
System Patient Code
System Cycle Code

Patient History
Patient Date of Birth
Patient Race
Patient City of Residence
Patient State of Residence
Patient Zip Code of Residence
Number of Prior Pregnancies
Number of Prior Live births
Infertility Diagnosis/Reason for ART
Number of Prior ART Procedures
Number of Prior ART Procedures Since Last Birth

Current Cycle Information
Date Cycle Started
Ovarian Stimulation Medication Used
Source of Semen (partner, donor, or combination of partner and donor)
Method Used to Collect Semen (ejaculation, aspiration, biopsy, other)
Gestational Carrier Used (also known as surrogate)
Type of ART Cycle
(in vitro fertilization with fresh oocytes, gamete intrafallopian transfer, zygote intrafallopian transfer, frozen embryo transfer, fresh donor oocyte transfer, fresh donor embryo transfer, frozen donor embryo transfer)
Was the Cycle Canceled?
Date of Cancellation
Reason for Cancellation
Medical Complication Related to Procedures
Hospitalization as a Result of Complication(s)
System Donor Identification Number (for donor procedures)
Ovarian Stimulation Medication Used for Donor
Were the Donor's Oocytes Shared?
Number of Oocytes Retrieved (from patient or donor in cases of donor cycle)
Date of Oocyte Retrieval
Use of Intracytoplasmic Sperm Injection (ICSI)
Use of Assisted Hatching
Number of Fresh Embryos Transferred to Uterus
Number of Fresh Embryos Transferred to Fallopian Tubes
Number of Oocytes Transferred to Fallopian Tubes
Number of Embryos That Were Cryopreserved for Later Use
Number of Embryos That Were Thawed
Date Thawed Embryos Had Been Frozen
Number of Thawed Embryos Transferred to Uterus
Number of Thawed Embryos Transferred to Fallopian Tubes
Date of Embryo (or Gamete) Transfer to Uterus and/or Fallopian Tubes

Pregnancy Information
Date of Pregnancy Test
Result of Pregnancy Test
Type of Pregnancy (biochemical, clinical intrauterine gestation, ectopic, heterotopic)

Was Ultrasound Performed?
Ultrasound Date
Number of Sacs Detected
Number of Fetal Hearts Detected
Was the Pregnancy Aborted?
Date of Abortion
Type of Abortion (spontaneous, therapeutic)
Was the Pregnancy Reduced?
Date of Reduction
Number of Sacs Before Reduction
Number of Sacs After Reduction
Reason for Pregnancy Reduction (spontaneous, therapeutic)

Birth Information
Did a Birth Occur?
Date of Birth
Number Live born
For Each Infant Born (up to 6):
Was the Infant Live born?
Birth weight

Variables included from the Michigan hospital discharge summaries

Sex
Race
Number of days in hospital
Source of patient admission
Date of hospital admission
Outcome of hospitalization
Sources and types of hospital expense reimbursement (type of insurance coverage)
Diagnostic codes for all events, conditions and complications related to the patient hospitalization
Codes for specific procedures performed during hospitalization (length of stay in hospital,newborn birth weight)
Codes for specific services received (obstetrics, pediatrics, psychiatry, hospice, detoxification, oncology, rehabilitation, nursery, neonatal ICU)
Chronic conditions
Subacute conditions
- medical
- surgical ICU
- pediatric ICU
- psychiatric ICU
- post-care ICU
- burn unit
- trauma ICU
- other special care ICU
- coronary care unit
- pulmonary care unit
- major complication co-morbidity indicators

Variables from Michigan linked live birth/fetal, infant and child mortality file

VARIABLE NAME	CODING STRUCTURE
YEAR OF DEATH	YEAR OF DEATH CONTAINS LAST DIGIT OF CENTURY + DECADE YEAR (I.E. 1989 WOULD BE 989) UNKNOWN OR BLANK CODED 000
DEATH CERTIFICATE NUMBER	000000 = OUT-OF-STATE UNNUMBERED, 999999 = NOT AVAILABLE
YEAR OF BIRTH	YEAR OF BIRTH CONTAINS LAST DIGIT OF CENTURY + DECADE YEAR (I.E. 1989 WOULD BE 989) UNKNOWN OR BLANK CODED 000
BIRTH CERTIFICATE NUMBER	000000 = OUT-OF-STATE UNNUMBERED, 999999 = NOT AVAILABLE
MONTH OF DEATH	SELF-EXPLANATORY
DAY OF DEATH	SELF-EXPLANATORY
MONTH OF BIRTH	SELF-EXPLANATORY
DAY OF BIRTH	SELF-EXPLANATORY
LAST MENSES YEAR	YEAR OF LAST MENSES CONTAINS LAST DIGIT OF CENTURY + DECADE YEAR (I.E. 1989 WOULD BE 989) UNKNOWN OR BLANK CODED 000
LAST MENSES MONTH	MONTH OF LAST MENSES, SELF EXPLANATORY UNKNOWN OR BLANK CODED 00
LAST MENSES DAY	DAY OF LAST MENSES, THREE SPECIAL CODES MAY BE USED WHEN THE FOLLOWING RESPONSES APPEAR ON THE CERTIFICATE 'BEGINNING OF MONTH' = 32 'MIDDLE OF MONTH' = 33 'END OF MONTH' = 34 SET 35-99 = 00
LAST LIVE BIRTH YEAR	3 DIGIT YEAR OF LAST LIVE BIRTH, CONTAINS LAST DIGIT OF CENTURY + DECADE YEAR (I.E. 1989 WOULD BE 989) UNKNOWN OR BLANK CODED 000
LAST LIVE BIRTH MONTH	MONTH LAST LIVE BIRTH,SELF EXPLANATORY UNKNOWN OR BLANK CODED 00
LAST LIVE BIRTH DAY	DAY LAST LIVE BIRTH, FILLED WITH 0'S
LAST FETAL DEATH YEAR	3 DIGIT YEAR OF LAST FETAL DEATH, CONTAINS LAST DIGIT OF CENTURY + DECADE
LAST FETAL DEATH MONTH	MONTH LAST FETAL DEATH,SELF EXPLANATORY UNKNOWN OR BLANK CODED 00

LAST FETAL DEATH DAY	DAY LAST FETAL DEATH, FILLED WITH 0'S
BIRTH RESIDENCE STATE	STATE OF RESIDENCE AT BIRTH.
BIRTH RESIDENCE COUNTY	COUNTY OF RESIDENCE AT DEATH. MUST BE PAIRED WITH STATE OF RESIDENCE TO BE MEANINGFUL.
BIRTH RESIDENCE MCD	MINOR CIVIL DIVISION OF RESIDENCE. MUST BE PAIRED WITH COUNTY OF RESIDENCE AND STATE OF RESIDENCE TO BE MEANINGFUL.
BIRTH RES.CENSUS TRACT	NOT APPLICABLE
DETROIT RES. CENSUS AREA	NOT APPLICABLE
DEATH RESIDENCE STATE	STATE OF RESIDENCE AT DEATH
DEATH RESIDENCE COUNTY	COUNTY OF RESIDENCE AT DEATH. MUST BE PAIRED WITH STATE OF RESIDENCE TO BE MEANINGFUL.
DEATH RESIDENCE MCD	MINOR CIVIL DIVISION OF RESIDENCE. MUST BE PAIRED WITH COUNTY OF RESIDENCE AND STATE OF RESIDENCE TO BE MEANINGFUL.
DEATH RES.CENSUS TRACT	NOT APPLICABLE
DETROIT RES. CENSUS AREA	NOT APPLICABLE
BIRTH OCCURRENCE STATE	STATE OF OCCURRENCE AT BIRTH.
BIRTH OCCURRENCE COUNTY	COUNTY OF OCCURRENCE. MUST BE PAIRED WITH STATE OF OCCURRENCE TO BE MEANINGFUL.
BIRTH OCCURRENCE MCD	MINOR CIVIL DIVISION OF OCCURRENCE. MUST BE PAIRED WITH COUNTY OF OCCURRENCE AND STATE OF OCCURRENCE TO BE MEANINGFUL.
HOSPITAL OF BIRTH	MUST BE PAIRED WITH COUNTY OF OCCURRENCE TO BE MEANINGFUL. CERTAIN LOCATIONS HAVE A COMMON NUMBER WITHIN EACH COUNTY: 990 = ENROUTE TO THE HOSPITAL IF A HOSPITAL IS NAMED 991 = ENROUTE TO THE HOSPITAL IF NO HOSPITAL IS NAMED 992 = HOSPITAL WITH NO MATERNITY WARD 994 = OTHER - HOTEL, DOCTOR'S OFFICE, YWCA 998 = PRIVATE HOME (INCLUDING GARAGE), CABIN 999 = UNKNOWN
DEATH OCCURRENCE STATE	STATE OF OCCURRENCE.
DEATH OCCURRENCE COUNTY	COUNTY OF OCCURRENCE. MUST BE PAIRED WITH STATE OF OCCURRENCE TO BE MEANINGFUL.
DEATH OCCURRENCE MCD	MINOR CIVIL DIVISION OF OCCURRENCE. MUST BE PAIRED WITH COUNTY OF OCCURRENCE AND STATE OF OCCURRENCE TO BE MEANINGFUL.
HOSPITAL OF DEATH	MUST BE PAIRED WITH COUNTY OF OCCURRENCE TO BE MEANINGFUL. CERTAIN LOCATIONS HAVE A

	COMMON NUMBER WITHIN EACH COUNTY: 990 = ENROUTE TO THE HOSPITAL IF A HOSPITAL IS NAMED 991 = ENROUTE TO THE HOSPITAL IF NO HOSPITAL IS NAMED 992 = HOSPITAL WITH NO MATERNITY WARD 994 = OTHER - HOTEL, DOCTOR'S OFFICE, YWCA 998 = PRIVATE HOME (INCLUDING GARAGE), CABIN 999 = UNKNOWN
NCHS PLACE OF ACCIDENT	0 = HOME, 1 = FARM, 2 = MINE AND QUARRY, 3 = INDUSTRIAL PLACE AND PREMISES, 4 = PLACE FOR RECREATION OR SPORT, 5 = STREET AND HIGHWAY, 6 = PUBLIC BUILDING, 7 = RESIDENT INSTITUTION, 8 = OTHER SPECIFIED PLACES, 9 = PLACE NOT SPECIFIED, 99 = NOT APPLICABLE
MICHIGAN PLACE OF ACCIDENT	0 = HOME, 1 = FARM, 2 = MINE AND QUARRY, 3 = INDUSTRIAL PLACE AND PREMISES, 4 = PLACE FOR RECREATION OR SPORT, 5 = STREET AND HIGHWAY, 6 = PUBLIC BUILDING, 7 = RESIDENT INSTITUTION, 8 = OTHER SPECIFIED PLACES, 9 = PLACE NOT SPECIFIED, 99 = NOT APPLICABLE
SEX AT DEATH	1 = MALE 2 = FEMALE 9 = UNKNOWN
RACE AT BIRTH	0 = OTHER ASIAN OR PACIFIC ISLANDER 1 = WHITE 2 = BLACK 3 = AMERICAN INDIAN 4 = CHINESE 5 = JAPANESE 6 = FILIPINO 7 = HAWAIIAN 8 = OTHER NONWHITE 9 = UNKNOWN, NOT STATED/NOT CLASSIFIABLE
RACE AT DEATH	0 = OTHER ASIAN OR PACIFIC ISLANDER 1 = WHITE 2 = BLACK 3 = AMERICAN INDIAN 4 = CHINESE 5 = JAPANESE 6 = FILIPINO 7 = HAWAIIAN 8 = OTHER NONWHITE 9 = UNKNOWN, NOT STATED/NOT CLASSIFIABLE
AGE UNIT AT DEATH	AGE AT DEATH UNIT 0 = 100 YEARS AND OVER 1=YEARS 2 = MONTHS 3=DAYS 4=HOURS 5 = MINUTES 9=UNKNOWN
AGE AT DEATH	AGE AT DEATH NUMBER. SELF EXPLANATORY. MUST BE PAIRED WITH UNIT TO BE MEANINGFUL. COMBINED UNKNOWN AGE CODE

	IS 900. UNKNOWN AGE FOR NEWBORNS (WHERE DATE OF BIRTH IS NO MORE THAN 1 DAY EARLIER THAN DATE OF DEATH) IS CODED 400 (HOURS, UNKNOWN NUMBER).
AGE GROUP	COMPUTER GENERATED FIELD FROM AGE AT DEATH UNIT AND NUMBER. 01 = UNDER 1 DAY, 02 = 1 DAY, 03 = 2 DAYS, 04 = 3-6 DAYS, 05 = 7-13 DAYS, 06 = 14-20 DAYS, 07 = 21-27 DAYS, 08 = 1 MONTH, 09 = 2 MONTHS, 10 = 3 MONTHS, 11 = 4 MONTHS, 12 = 5 MONTHS, 13 = 6 MONTHS, 14 = 7 MONTHS, 15 = 8 MONTHS, 16 = 9 MONTHS, 17 = 10 MONTHS, 18 = 11 MONTHS, 19 = 1 YEAR, 20 = 2 YEARS, 21 = 3 YEARS, 22 = 4 YEARS, 23 = 5 YEARS AND OVER, 24 = UNKNOWN.
AUTOPSY	1 = PERFORMED (INCLUDING PARTIAL) 2 = NO 9 = UNKNOWN
UNDERLYING CAUSE PREFIX	0 = DISEASE 1 = EXTERNAL (FILLED WITH 9'S STARTING IN 1999)
UNDERLYING CAUSE OF DEATH	UNDERLYING CAUSE OF DEATH THE 9TH REVISION OF THE INTERNATIONAL CLASSIFICATION OF DISEASES IS USED FOR YEARS 1989-1998. THE 10TH REVISION IS USED FOR YEARS 1999-PRESENT. CODES ARE EITHER DISEASE OR EXTERNAL. THE NATURE OF INJURY CODES MAY NEVER BE AN UNDERLYING CAUSE OF DEATH. THE (EB) MAY BE USED TO ACCEPT ANY COMBINATION OF UNDERLYING CAUSE, SEX AND AGE WITHOUT QUESTION IF VERIFIED AS CORRECT.
282 CODE	282 CODE FOR UNDERLYING CAUSE OF DEATH COMPUTER GENERATED GROUPINGS FROM THE UNDER-LYING CAUSE. THE MODIFIED LIST OF 282 SELECTED CAUSES OF DEATH FOR USE IN MICHIGAN DIFFERS FROM NCHS LIST OF 282 CAUSES. THIS FIELD IS ZERO FILLED STARTING IN 1999.
REL CAUSE1 LINE NUMBER	13 FIELDS OF 1 DIGIT EACH. INDICATES ON WHICH LINE THE RELATED CAUSE APPEARED. 1=PART I, LINE A OF DEATH CERTIFICATE, 2=PART 1, LINE B, 3=PART 1, LINE C, 4 AND 5=CONTINUATION OF LINE C IN PART I OF DEATH CERTIFICATE, 6=PART II, 0 AND 9=BLANK.

REL CAUSE2 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE3 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE4 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE5 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE6 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE7 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE8 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE9 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE10 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE11 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE12 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
REL CAUSE13 LINE NUMBER	SEE RELATED CAUSE 1 LINE NUMBER
RELATED CAUSE1	RELATED CAUSE OF DEATH. THE 9TH REVISION ICD CODES ARE USED FOR 1989-1998. THE FIELD IS 5-DIGITS PREFIXED BY A 0 FOR DISEASE(1-799), 1 FOR EXTERNAL CAUSES (E800-E999), OR 2 FOR NATURE OF INJURY CODES (800-999). THE 10TH REVISION CODES ARE USED FOR 1999-2001. THE FIELD IS 4-DIGITS. UNUSED FIELDS CONTAIN ZEROS.
RELATED CAUSE2	SEE RELATED CAUSE 1
RELATED CAUSE3	SEE RELATED CAUSE 1
RELATED CAUSE4	SEE RELATED CAUSE 1
RELATED CAUSE5	SEE RELATED CAUSE 1
RELATED CAUSE6	SEE RELATED CAUSE 1
RELATED CAUSE7	SEE RELATED CAUSE 1
RELATED CAUSE8	SEE RELATED CAUSE 1
RELATED CAUSE9	SEE RELATED CAUSE 1
RELATED CAUSE10	SEE RELATED CAUSE 1
RELATED CAUSE11	SEE RELATED CAUSE 1
RELATED CAUSE12	SEE RELATED CAUSE 1
RELATED CAUSE13	SEE RELATED CAUSE 1
PLURALITY	1 = SINGLE 2=TWIN 3=TRIPLET 4 = QUADRUPLET 5=QUINTUPLET OR MORE 9 = UNKNOWN, NOT STATED, X, CHECK
SEX AT BIRTH	1 = MALE 2 = FEMALE 9 = UNKNOWN
BIRTHWEIGHT POUNDS	NOT UNIQUE. MUST BE PAIRED WITH OUNCES TO BE MEANINGFUL. EDIT CUT-OFF IS 13 POUNDS. IF THE NUMBER IS 14 OR OVER, THE EDIT BYPASS MAY BE USED TO ACCEPT UP TO 20 POUNDS - 15 OUNCES
BIRTHWEIGHT OUNCES	NOT UNIQUE. MUST BE PAIRED WITH POUNDS TO BE MEANINGFUL.
BIRTHWEIGHT GRAMS	COMPUTER GENERATED FROM POUNDS AND OUNCES; (POUNDS X 16 + OUNCES) X 28.35. WEIGHT WAS ROUNDED TO THE NEAREST

	WHOLE GRAM. TREAT 0 AND 9498-9999 AS UNKNOWN.
WEIGHT INDICATOR	1=GRAMS 2=POUNDS & OUNCES BLANK=POUNDS & OUNCES 9=UNKNOWN
ATTENDANT AT BIRTH	1=M.D. 2=D.O. 3=NURSE 4=MID-WIFE 5=NURSE MID-WIFE 6=HUSBAND 7=PHYSICIAN'S ASSISTANT 8=OTHER 9=UNKNOWN 0=NO ATTENDANT
AGE OF MOTHER	ACCEPTABLE RANGE = 7-62, 99=UNKNOWN
RACE OF MOTHER	0 = OTHER ASIAN OR PACIFIC ISLANDER 1 = WHITE 2 = BLACK 3 = AMERICAN INDIAN 4 = CHINESE 5 = JAPANESE 6 = FILIPINO 7 = HAWAIIAN 8 = OTHER NON-WHITE 9 = UNKNOWN, NOT STATED/NOT CLASSIFIABLE
EDUCATION OF MOTHER	00 = NONE, NO SCHOOLING 01-11 = FIRST THROUGH ELEVENTH GRADE 12 = HIGH SCHOOL OR GENERAL EDUCATION TEST PASSED 13 = ONE YEAR OF COLLEGE 14 = TWO YEARS OF COLLEGE, LPN, RN, 2-RN 15 = THREE YEARS OF COLLEGE, 3-RN 16 = BA, BS OR BBA DEGREE AT COLLEGE UNDERGRADUATE LEVEL, 4-RN, BS-RN 17 = FIVE(+) YRS OF COLLEGE, MS DEGREE, LAW DEGREE, DO, PHD, MD, DDS 99 = UNKNOWN, NOT SPECIFIED
AGE OF FATHER	ACCEPTABLE RANGE - 10-90, 99=UNKNOWN
RACE OF FATHER	0 = OTHER ASIAN OR PACIFIC ISLANDER 1 = WHITE 2 = BLACK 3 = AMERICAN INDIAN 4 = CHINESE 5 = JAPANESE 6 = FILIPINO 7 = HAWAIIAN 8 = OTHER NON-WHITE 9 = UNKNOWN, NOT STATED/NOT CLASSIFIABLE
EDUCATION OF FATHER	00 = NONE, NO SCHOOLING 01-11 = FIRST THROUGH ELEVENTH GRADE 12 = HIGH SCHOOL OR GENERAL EDUCATION TEST PASSED 13 = ONE YEAR OF COLLEGE 14 = TWO YEARS OF COLLEGE, LPN, RN, 2-RN 15 = THREE YEARS OF COLLEGE, 3-RN 16 = BA, BS OR BBA DEGREE AT COLLEGE UNDERGRADUATE LEVEL, 4-RN, BS-RN 17 = FIVE(+) YRS OF COLLEGE, MS DEGREE, LAW DEGREE, DO, PHD, MD, DDS

	99 = UNKNOWN, NOT SPECIFIED
PREVIOUS CHILDREN BORN NOW LIVING	VALID RANGE=0-25 77=BLANK 99=UNKNOWN
PREVIOUS CHILDREN BORN NOW DEAD	VALID RANGE=0-15 77=BLANK 99=UNKNOWN
PREVIOUS CHILDREN BORN DEAD	VALID RANGE=0-15 77=BLANK 99=UNKNOWN
MONTH PRENATAL CARE BEGAN	MONTH PRENATAL CARE BEGAN 10 = NO CARE 1 = FIRST MONTH 2 = SECOND MONTH 3 = THIRD MONTH 4 = FOURTH MONTH 5 = FIFTH MONTH 6 = SIXTH MONTH 7 = SEVENTH MONTH 8 = EIGHTH MONTH 9 = NINTH MONTH 99=UNKNOWN
NUMBER OF PRENATAL VISITS	PRENATAL VISITS 00-49 = NUMBER OF VISITS TO DOCTOR, 99 = UNKNOWN THE EDIT BYPASS MAY BE USED TO ACCEPT A NUMBER OF VISITS UP TO 98
CALCULATED WEEKS OF GESTATION	CALCULATED WEEKS OF GESTATION, COMPUTER GENERATED. VALID RANGES - 16-52, 99 = UNKNOWN. TREAT UNDER 16 WEEKS AND OVER 52 WEEKS AS UNKNOWN.
MOTHER'S ZIP CODE	MOTHER'S 5 DIGIT ZIP CODE
MULTIPLE BIRTH ORDER	MULTIPLE BIRTHS, IF NOT A SINGLE BIRTH, CODES 1,2,3,4 & 5 INDICATE ORDER OF BIRTH
ESTIMATED WEEKS OF GESTATION	ESTIMATED WEEKS GESTATION. REFERS TO NUMBER OF WEEKS FROM THE BEGINNING TO THE END OF THE PREGNANCY, AS ESTIMATED BY THE PHYSICIAN, 99 = UNKNOWN.
1 MINUTE APGAR SCORE	APGAR SCORE 1 MINUTE, VALID RANGE 00-10, 99 = UNKNOWN
5 MINUTE APGAR	APGAR SCORE 5 MINUTE, VALID RANGE 00-10,

SCORE	99 = UNKNOWN
NAMED PARENTS	1=ONE 2=TWO 9=UNKNOWN
PATIENT STATUS - HOSPITAL DEATHS	1=DOA 2=EMERGENCY ROOM/OUTPATIENT 3=INPATIENT 4=DOA IF NO HOSITAL IS NAMED 8=OTHER 9=UNKNOWN
MEDICAL EXAMINER REFERRAL	1=YES 2=NO 9=UNKNOWN
ACTUAL PLACE OF DEATH	1=HOSPITAL 2=NURSING HOME 3=EXTENDED CARE 4=HOME 5=OTHER INSTITUTION 6=AMBULANCE 8=OTHER 9=UNKNOWN
MEDICAL EXAMINER CERTIFICATION	1=NOT A MEDICAL EXAMINER CASE 2=IS A MEDICAL EXAMINER CASE 9=BLANK
STATE OF BIRTH	STATE OF BIRTH DECLARED ON DEATH CERTIFICATE
REV UNKNOWN DELIVERY METHOD	0=NO 9=YES
REV VAGINAL	1=YES 0=NO 9=UNKNOWN
REV VAGINAL AFTER PREV C-SEC	1=YES 0=NO 9=UNKNOWN
REV C-SEC PRIMARY	1=YES 0=NO 9=UNKNOWN
REV C-SEC REPEAT	1=YES 0=NO 9=UNKNOWN
REV FORCEPS	1=YES 0=NO 9=UNKNOWN
REV VACUUM	1=YES 0=NO 9=UNKNOWN
DECEDENT'S ANCESTRY	DECEDENT'S ANCESTRY; SEE ATTACHMENT
MOTHER'S ANCESTRY	MOTHER'S ANCESTRY; SEE ATTACHMENT
FATHER'S ANCESTRY	FATHER'S ANCESTRY; SEE ATTACHMENT
MOTHER'S ZIP +4	LAST FOUR DIGITS OF MOTHER'S ZIP
BIRTH SOURCE OF PAYMENT	SOURCE OF EXPECTED PAYMENT 1 = PRIVATE INSURANCE 2 = MEDICAID 3 = SELF PAY 8 = OTHER 9 = UNKNOWN, N/A
MOM TRANSFERRED?	MOTHER TRANSFERRED PRIOR TO DELIVERY? 1 = YES 2 = NO 9 = UNKNOWN, BLANK OR N/A

FACILITY MOTHER TRANSFERRED	2 DIGIT COUNTY CODE + 3 DIGIT HOSPITAL CODE
CHILD TRANSFERRED?	CHILD TRANSFERRED? 1 = YES 2 = NO 9 = UNKNOWN, BLANK OR N/A
FACILITY CHILD TRANSFERRED	2 DIGIT COUNTY CODE + 3 DIGIT HOSPITAL CODE
BIRTH PLACE TYPE	PLACE OF BIRTH 1 = HOSPITAL 2 = FREE STANDING BIRTHING CLINIC 3 = CLINIC/DOCTOR'S OFFICE 4 = RESIDENCE 5 = OTHER 0 = NONE
NICU ADMISSION	WAS CHILD WAS TRANSFERRED TO NEONATAL INTENSIVE CARE UNIT 1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - NONE	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - ANEMIA	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - CARDIAC DIS.	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - LUNG DISEASE	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - DIABETES	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - GENIT. HERPES	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - OLIGO/HYDRAM	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - HEMOGLOBIN	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - CHRONIC HYPER	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - PREG HYPER	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - ECLAMPSIA	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK - INCOMP CERVIX	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK PREV LRG BABY	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK PREV SML BABY	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK RENAL DISEASE	1=YES 2=NO 9=UNKNOWN

MEDICAL RISK RH SENSITIVITY	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK UTERINE BLEED	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK OTHER	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK DRUG ABUSE	1=YES 2=NO 9=UNKNOWN
MEDICAL RISK HIV	1=YES 2=NO 9=UNKNOWN
TOBACCO USE	1 = YES 2 = NO 9 = UNKNOWN
CIGARETTES/DAY	AVERAGE NUMBER OF CIGARETTES PER DAY 00-98 = CIGARETTES SMOKED 99 = UNKNOWN OR BLANK
ALCOHOL USE	1=YES 2=NO 9=UNKNOWN
DRINKS/DAY	AVERAGE NUMBER OF DRINKS PER WEEK 00-98 = NUMBER OF DRINKS 99 = UNKNOWN OR BLANK
WEIGHT GAIN DURING PREGNANCY	00=NO GAIN OR LOSS, 1-98 LBS, 99=UNKNOWN
OBSTET PROC NONE	1=YES 2=NO 9=UNKNOWN
OBSTET PROC AMNIOCENTESIS	1=YES 2=NO 9=UNKNOWN
OBSTET PROC ELEC FET MON	1=YES 2=NO 9=UNKNOWN
OBSTET PROC INDUC OF LABOR	1=YES 2=NO 9=UNKNOWN
OBSTET PROC STIM OF LABOR	1=YES 2=NO 9=UNKNOWN
OBSTET PROC TOCOLYSIS	1=YES 2=NO 9=UNKNOWN
OBSTET PROC ULTRASOUND	1=YES 2=NO 9=UNKNOWN
OBSTET PROC OTHER	1=YES 2=NO 9=UNKNOWN
COMP PREG NONE	1=YES 2=NO 9=UNKNOWN
COMP PREG FEBRILE	1=YES 2=NO 9=UNKNOWN
COMP PREG MECONIUM	1=YES 2=NO 9=UNKNOWN
COMP PREG PREM RUPTURE	1=YES 2=NO 9=UNKNOWN

COMP PREG PLAC ABRUPT	1=YES 2=NO 9=UNKNOWN
COMP PREG PLAC PREVIA	1=YES 2=NO 9=UNKNOWN
COMP PREG EXCESS BLEED	1=YES 2=NO 9=UNKNOWN
COMP PREG SEIZURES	1=YES 2=NO 9=UNKNOWN
COMP PREG SHORT LABOR	1=YES 2=NO 9=UNKNOWN
COMP PREG LONG LABOR	1=YES 2=NO 9=UNKNOWN
COMP PREG DYSF LABOR	1=YES 2=NO 9=UNKNOWN
COMP PREG BREECH/MALP	1=YES 2=NO 9=UNKNOWN
COMP PREG CEPH DISPROP	1=YES 2=NO 9=UNKNOWN
COMP PREG CORD PROLAPSE	1=YES 2=NO 9=UNKNOWN
COMP PREG ANESTH COMP	1=YES 2=NO 9=UNKNOWN
COMP PREG FETAL DISTRESS	1=YES 2=NO 9=UNKNOWN
COMP PREG OTHER	1=YES 2=NO 9=UNKNOWN
DEL METHOD VAGINAL	1=YES 2=NO 9=UNKNOWN
DEL METHOD VAGINAL AFTER C	1=YES 2=NO 9=UNKNOWN
DEL METHOD PRIMARY C-SEC	1=YES 2=NO 9=UNKNOWN
DEL METHOD REPEAT C-SEC	1=YES 2=NO 9=UNKNOWN
DEL METHOD FORCEPS	1=YES 2=NO 9=UNKNOWN
DEL METHOD VACUUM	1=YES 2=NO 9=UNKNOWN
ABNORMAL CONDITIONS NONE	1=YES 2=NO 9=UNKNOWN
AB COND ANEMIA	1=YES 2=NO 9=UNKNOWN
AB COND BIRTH INJURY	1=YES 2=NO 9=UNKNOWN
AB COND FETAL ALCOHOL SYN	1=YES 2=NO 9=UNKNOWN
AB COND HYALINE MEM DIS	1=YES 2=NO 9=UNKNOWN
AB COND MECONIUM ASPIR SYN	1=YES 2=NO 9=UNKNOWN

AB COND ASSIS VENT <30 MIN	1=YES 2=NO 9=UNKNOWN
AB COND ASSIS VENT >30 MIN	1=YES 2=NO 9=UNKNOWN
AB COND SEIZURES	1=YES 2=NO 9=UNKNOWN
AB CONDITIONS OTHER	1=YES 2=NO 9=UNKNOWN
CONGENITAL ANOMALY NONE	1=YES 2=NO 9=UNKNOWN
ANENCEPHALUS	1=YES 2=NO 9=UNKNOWN
SPINA BIFIDA	1=YES 2=NO 9=UNKNOWN
HYDROCEPHALUS	1=YES 2=NO 9=UNKNOWN
MICROCEPHALUS	1=YES 2=NO 9=UNKNOWN
OTHER CNS	1=YES 2=NO 9=UNKNOWN
HEART MALFORMATION	1=YES 2=NO 9=UNKNOWN
OTHER CIRCULATORY	1=YES 2=NO 9=UNKNOWN
RECTAL ATRESIA	1=YES 2=NO 9=UNKNOWN
TRACHEO/ESOPH	1=YES 2=NO 9=UNKNOWN
OMPHAL/GASTRO	1=YES 2=NO 9=UNKNOWN
OTHER GASTRO	1=YES 2=NO 9=UNKNOWN
GENITAL MALFORMATION	1=YES 2=NO 9=UNKNOWN
RENAL AGENESIS	1=YES 2=NO 9=UNKNOWN
OTHER UROGENITAL	1=YES 2=NO 9=UNKNOWN
CLEFT LIP/PALATE	1=YES 2=NO 9=UNKNOWN
POLYDCTYLY/SYNDACTYLY	1=YES 2=NO 9=UNKNOWN
CLUB FOOT	1=YES 2=NO 9=UNKNOWN
DIAPHRAGMATIC HERNIA	1=YES 2=NO 9=UNKNOWN
OTHER MUSCULO ANOM	1=YES 2=NO 9=UNKNOWN
DOWNS SYNDROME	1=YES 2=NO 9=UNKNOWN

OTHER CHROMOSOMAL ANOM	1=YES 2=NO 9=UNKNOWN
OTHER ANOMALY	1=YES 2=NO 9=UNKNOWN
REVISED KESSNER INDEX	1=ADEQUATE 2=INTERMEDIATE 3=INADEQUATE 9=UNKNOWN

SOURCE: VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, MDCH.

Variables included from the Michigan Birth Defects Registry

Congenital Anomaly Diagnosis Codes

Variable name - ICD9COD1, ICD9COD2,...ICD9COD15

Medical Procedures Codes

Variable name - PROC1, PROC2, PROC3,.....PROC15

Congenital Syndrome Code

Variable name - SYNDROM1

Cytogenetics testing

Variable name - CYTOGEN1

Cytogenetics Diagnostic code

Variable name - CYTOCOD1

Condense Diagnoses

Variable name – CONDENSEDX

Condense Procedures

Variable name - CONDENSEPX

Variables from the Michigan Cancer Registry

Key:

- Items in bold in data set every diagnostic year
- Highlighted items are of interest for this proposed linkage

Requirements Legend	
R	Required
R*	Required when available
R^	These text fields may be met by one or several text block fields
R+	Required by diagnosis year
RH	Historically collected, transmitted
RH*	Historically collected, transmitted when available
RS	Required, site specific
D	Derived value
O	Optional
S	Supplementary/recommended
#	May code using SEER or CoC data item and associated rules
.	Not in data set

Table 3.3.1
NPCR Required Data Items (NAACCR Record Layout)

DIAGNOSIS YEAR		**2008**	**2007**	**2006**
Item #	**Item Name**	**Collect**	**Collect**	**Collect**
70	**Addr at DX--City**	R	R	R
2330	**Addr at DX--No & Street**	R	R	R
100	**Addr at DX--Postal Code**	R	R	R
80	**Addr at DX--State**	R	R	R
2335	Addr at DX--Supplemental	R	R	R
230	**Age at Diagnosis**	R	R	R
430	**Behavior (92-00) ICD-O-2**	RH	RH	RH
523	Behavior Code ICD-O-3	R	R	R
240	**Birth Date**	R	R	R
250	**Birthplace**	R*	R*	R*

1910	**Cause of Death**	R	R	R
120	**Census Cod Sys 1970/80/90**	RH*	RH*	RH*
364	Census Tr Cert 1970/80/90	RH*	RH*	RH*
365	Census Tr Certainty 2000	R	R	R
110	**Census Tract 1970/80/90**	RH*	RH*	RH*
130	Census Tract 2000	R	R	R
610	Class of Case	R	R	R
200	Computed Ethnicity	R	R	R
210	Computed Ethnicity Source	R	R	R
90	County at DX	R	R	R
2810	CS Tumor Size	R	.	.
2810	CS Extension	R	R	R
2820	CS Tumor Size Ext/Eval	R	.	.
2830	CS Lymph Nodes	R	R	R
2850	CS Mets at DX	R	R	R
2880	CS Site-Specific Factor 1	RS	RS	RS
2900	CS Site-Specific Factor 3	RS	RS	RS
2935	CS Version 1st	R	R	R
2936	CS Version Latest	R	R	R
2110	Date Case Report Exported	R	R	R
2112	Date Case Report Loaded	R	R	R
2111	Date Case Report Received	R	R	R
580	Date of 1st Contact	R	R	R

1270	Date of 1st Crs RX--COC	R#	R#	R#
390	Date of Diagnosis	R	R	R
1260	Date of Initial RX--SEER	R#	R#	R#
1750	Date of Last Contact	R	R	R
2113	Date Tumor Record Availbl	R	R	R
2380	DC State File Number	R	R	R
3020	Derived SS2000	D	D	D
3050	Derived SS2000--Flag	D	D	D
490	Diagnostic Confirmation	R	R	R
1790	Follow-up Source	R*	R*	RH
1791	Follow-up Source Central	R	R	R
366	GIS Coordinate Quality	R*	R*	R*
440	Grade	R	R	R
522	Histologic Type ICD-O-3	R	R	R
420	Histology (92-00) ICD-O-2	RH	RH	RH
1920	ICD Revision Number	R	R	R
2116	ICD-O-3 Conversion Flag	R	R	R
192	IHS Link	R*	R*	R*
280	Industry Code--Census	R*	R*	R*
300	Industry Source	R*	R*	R*
410	Laterality	R	R	R
2352	Latitude	R*	R*	R*
2354	Longitude	R*	R*	R*
2300	Medical Record Number	R	R	R
470	Morph Coding Sys--	R	R	R

	Current			
2280	Name--Alias	R	R	R
2240	Name--First	R	R	R
2230	Name--Last	R	R	R
2390	Name--Maiden	R	R	R
2250	Name--Middle	R	R	R
191	NHIA Derived Hisp Origin	D	D	D
45	NPI--Registry ID	.	.	.
545	NPI--Reporting Facility	R*	R*	.
330	Occup/Ind Coding System	R*	R*	R*
270	Occupation Code--Census	R*	R*	R*
290	Occupation Source	R*	R*	R*
1990	Over-ride Age/Site/Morph	R	R	R
2040	Over-ride Histology	R	R	R
2060	Over-ride Ill-define Site	R	R	R
2070	Over-ride Leuk, Lymphoma	R	R	R
2050	Over-ride Report Source	R	R	R
2000	Over-ride SeqNo/DxConf	R	R	R
2071	Over-ride Site/Behavior	R	R	R
2074	Over-ride Site/Lat/Morph	R	R	R
2010	Over-ride Site/Lat/Seq No	R	R	R
2030	Over-ride Site/Type	R	R	R
2020	Over-ride Surg/DxConf	R	R	R
20	Patient ID Number	R	R	R
1940	Place of	R	R	R

	Death			
630	Primary Payer at DX	R*	R*	R
400	Primary Site	R	R	R
160	Race 1	R	R	R
161	Race 2	R	R	R
162	Race 3	R	R	R
163	Race 4	R	R	R
164	Race 5	R	R	R
1570	Rad--Regional RX Modality	R	R	R
1340	Reason for No Surgery	R	R	R
10	Record Type	R	R	R
40	Registry ID	R	R	R
540	Reporting Facility	R	R	R
3300	RuralUrban Continuum 1993	D	D	D
3310	RuralUrban Continuum 2003	D	D	D
1460	RX Coding System--Current	R	R	R
1410	RX Summ--BRM	R	R	R
1390	RX Summ--Chemo	R	R	R
1420	RX Summ--Other	R	R	R
1292	RX Summ--Scope Reg LN Sur	R	R	R
1294	RX Summ--Surg Oth Reg/Dis	R	R	R
1290	RX Summ--Surg Prim Site	R	R	R
1380	RX Summ--Surg/Rad Seq	R	R	R
1639	RX Summ--Systemic/Sur Seq	R	R	R
3250	RX Summ--Transplnt/Endocr	R	R	R
2660	RX Text--BRM	R^	R^	R^

2640	RX Text--Chemo	R^	R^	R^
2650	RX Text--Hormone	R^	R^	R^
2670	RX Text--Other	R^	R^	R^
2620	RX Text--Radiation (Beam)	R^	R^	R^
2630	RX Text--Radiation Other	R^	R^	R^
2610	RX Text--Surgery	R^	R^	R^
760	SEER Summary Stage 1977	RH	RH	RH
759	SEER Summary Stage 2000	RH	RH	RH
380	Sequence Number--Central	R	R	R
220	Sex	R	R	R
450	Site Coding Sys--Current	R	R	R
2320	Social Security Number	R	R	R
190	Spanish/Hispanic Origin	R	R	R
2550	Text--DX Proc--Lab Tests	R^	R^	R^
2560	Text--DX Proc--Op	R^	R^	R^
2570	Text--DX Proc--Path	R^	R^	R^
2520	Text--DX Proc--PE	R^	R^	R^
2540	Text--DX Proc--Scopes	R^	R^	R^
2530	Text--DX Proc--X-ray/Scan	R^	R^	R^
2590	Text--Histology Title	R^	R^	R^
2580	Text--Primary Site Title	R^	R^	R^
2600	Text--Staging	R^	R^	R^
320	Text--Usual Industry	R*	R*	R*
310	Text--Usual	R*	R*	R*

	Occupation			
500	Type of Reporting Source	R	R	R
1760	Vital Status	R	R	R

Appendix E – SMART Project Research Plan

Analyses to be conducted using linked ART surveillance and Michigan birth/death dataset:

1) Validating data quality on ART surveillance data base and on birth certificates.

   We will examine agreement of variables the two datasets have in common, including plurality, gravidity, parity, birth weight, adverse outcomes (birth defects), neonatal death, and gestational age.

   We also will examine the validity of a new variable Michigan has added to their birth certificates on whether ART was used to conceive the pregnancy.

2) Examine outcomes associated with ART.

   We will describe the prevalence of maternal and infant outcomes associated with ART in the state of Michigan. Examples include low birthweight, preterm delivery, multiple birth, maternal complications, and infant mortality.

3) Characterize populations who give birth using ART.

   We will describe the population of ART users in Michigan on variables such as socioeconomic status, age, and race/ethnicity.

4) Compare ART users to matched non-ART users.

   We will compare these groups in various outcomes - for example, are small-for-gestational-age babies more likely the result of ART after controlling for numerous factors?

5) Assessing the impact of ART on adverse outcomes.

   We will calculate population attributable risk of the impact of ART on outcomes such as low birth weight, infant mortality, small for gestational age, multiple births, C-sections, and perinatal mortality.

Appendix F – SMART Project Action Plan 2011-2012

Activities	Responsible Person(s)	Deadline	Comments/Current Status
General			
Maintain the list of Guidance and Recommendations from professional associations that SMART can inform	CDC	Revise by Sep 26	Document created and discussed by SC on Aug 29, 2011. Need to add more guidance documents (ACOG, SART) and bullets for each document.
Create and use group authorship as "SMART Collaborative" for all future papers	CDC, each state	Revise by Sep 26	Discussed by SC on Aug 29, 2011. Each state will provide names of collaborators to include.
Create SMART webpage on CDC website	CDC	Draft outline by Oct 1, 2011	Draft SMART summary will be circulated for comments.
States to develop impact summaries (surveillance summaries) for each of the states and disseminate to stakeholders	Each state	Draft by Nov 1, 2011	Summary may include data from NASS, BRFSS, BC. Patti will resend Violanda's summary.
States to develop surveillance plans	Each state	Oct 1, 2011	
Adding questions on infertility and fertility treatments to 2012 BRFSS	Each state	Finalize questions by Sep 26	Discussed questions by SC on Aug 29, 2011. Patti drafted questions for further discussion. Patti will revise questions
Make Research Data Center option available	CDC, each state	Draft MOU by Oct 1	Draft MOU
Explore Guest Researcher option	CDC	Nov 1, 2011	Explore: (1) guest researcher with remote access; (2) CDC researcher (e.g. EIS officer) with remote access
Linkage			
Prepare core analytic files for 2000-2008	FL	FL: TBD	Lori will send CDC data use agreement forms. Florida is waiting for CDC to submit a Vital Statistics data use agreement,

Activities	Responsible Person(s)	Deadline	Comments/Current Status
			requesting 2007-2008 birth, infant death, fetal death, maternally linked, and birth facility data files. The birth, infant death, and fetal death files will be sent in NCHS de-identified interjurisdictional format, unless requested in a different format.
Birth data 2000-2003 Birth data 2004-			
Hospital discharge data 2000-2003 Hospital discharge data 2004-			
Fetal death data 2000-2003 Fetal death data 2004-			
Linked infant death data 2000-2003 Linked infant death data 2004-			
Birth defects registry data 2000-2003 Birth defects registry data 2004-			
Prepare core analytic files for 2000-2008	MA	MA:TBD	Bruce will prepare list of files to be included in the core analytic files.
Birth data 2000-2003 Birth data 2004-			
Hospital discharge data 2000-2003 Hospital discharge data 2004-			
Fetal death data 2000-2003 Fetal death data 2004-			
Linked infant death data 2000-2003 Linked infant death data 2004-			
Birth defects registry data 2000-2003 Birth defects registry data 2004-			

Activities	Responsible Person(s)	Deadline	Comments/Current Status
Prepare core analytic files for 2000-2008	MI	MI:TBD	
Birth data 2000-2003 Birth data 2004-			
Hospital discharge data 2000-2003 Hospital discharge data 2004-			
Fetal death data 2000-2003 Fetal death data 2004-			
Linked infant death data 2000-2003 Linked infant death data 2004-			
Birth defects registry data 2000-2003 Birth defects registry data 2004-			
Link core analytic files for 2000-2008 from each state to NASS	CDC, each state	Within *** after receiving the files	
Refine linkage methodology using validation study results	Linkage WG (Bruce - lead, Russ, Yujia, Aniket, James, Glenn, Karen, Patti)	TBD	Not the first priority
Figure out the system of maternal, infant, and delivery IDs	Linkage WG (Bruce - lead, Russ, Yujia, Aniket, James, Glenn, Karen, Patti)	TBD	Florida is adding a delivery ID. A Florida workgroup will need to review and approve the methodology for generating the delivery ID. It will take at least a month to complete this work and the workgroup review. Bruce needs a co-lead for the WG.
Review and amend CDC IRB protocols and state IRB protocols: (a) to include core analytic files up to 2008, (b) to include RDC data hosting option	CDC, each state	FL: TBD MA: TBD MI: 10/6/2011	FL: MA: MI: CDC IRB protocol continuation will be submitted by 10/6/2011 (Due for renewal by 11/20/2011)
Publications			

Activities	Responsible Person(s)	Deadline	Comments/Current Status
Probabilistic Linkage of Assisted Reproductive Technology Information with Vital Records, Massachusetts, 1997 - 2000	Yujia Zhang et al.	DONE!	Published ahead of print
Obesity, Assisted Reproductive Technology, Early Preterm Birth – Florida, 2004-2006	Erin Sauber-Schatz et al.	In clearance. Plan to submit AJE by Dec 2011.	Tier 1. Manuscript is in clearance.
Can Birth Certificate Data be Used to Assess Assisted Reproductive Technology? The Florida and Massachusetts Experience, 1997 - 2000	Bruce Cohen et al.	Draft by Dec 31, 2011.	Tier 1.
Differences in pregnancy outcomes for ART by infertility diagnosis	Violanda Grigorescu et al.	Draft by …	Tier 1.
Maternal Demographic Characteristics for State-specific ART – Vital Records linked file	Lori Westphal et al.	Draft by …	Tier 1.
MI linkage validation study	Patti, Yujia, others	Report to the group by …	Tier 2? Explore the possibility of publishing validation study; review Maurizio's draft.
Literature review on association of birth defects with ART (framing as SMART Collaboration)	Lewis and Russell	Report to the group by Oct-Nov 2011	Tier 2. High interest.
Compare embryo transfer practices and delivery outcomes in MA (where insurance pays for ART) and other two states (where it doesn't)	Dmitry, others	Report to the group by Nov 1, 2011	Tier 2? High interest. Can use ART-live birth linkage.
Prevalence of infertility/ART by causes and corresponding demographic characteristics – comparing the three states	Violanda?	Bike rack	Linkage of ART-live births
Fetal and Infant mortality in ART conceived – is it different than in non-ART	TBD	Bike rack	High interest. Requires linkage to infant mortality data.

Activities	Responsible Person(s)	Deadline	Comments/Current Status
and why?			
Maternal mortality in women with infertility and successful ART - case review	TBD	Bike rack	Medium interest. Can be a special project.
Chronic diseases and infertility by specific cause/type (demographic and pregnancy characteristics): diabetes, cardiac diseases, endocrine disorders (thyroid related)	TBD	Bike rack	High interest. Requires hospital discharge data.
Hospitalizations during pregnancy and postpartum (differences by state): admission diagnostics, procedures, complications, length of stay, hospital charges	TBD	Bike rack	High interest. Can be combined with previous paper? Can be a special project. Requires ART-live birth-hospital discharge data.
Assessing the congenital malformations and other birth defects in children conceived through ART. Are there differences by cause of infertility and so the treatment received?	TBD	Bike Rack	High interest. Requires linkage ART-live births-BDR.
What is the prevalence of hereditary disorders diagnosed through NBS in ART conceived newborns? Are there difference by cause of infertility and so the treatment received?	TBD	Bike Rack	Low interest. Requires linkage ART-live births-NBS.
Cancer survivors and ART (pilot)	TBD (someone from MI?)	Bike rack	Can use MI data which is already linked to live-birth data. Need to explore literature. Can be a good doctoral student project.
Cancer after ART (pilot)	TBD	Bike rack	Requires linkage of ART-live births-cancer registry. Need to explore literature. Can be a good doctoral student project.

Activities	Responsible Person(s)	Deadline	Comments/Current Status
Cancer in children conceived through ART (pilot)	TBD	Bike rack	Requires linkage of ART-live births-cancer registry. Need to explore literature. Can be a good doctoral student project.
Overall prevalence of infertility and differences between ART and non ART in demographic characteristics and other health related issues (including the access to primary care provider and health insurance status)	TBD	Bike rack	MI BRFSS data can be used? MA and FL are exploring option of adding questions to BRFSS.
Assessment of preconception health: ART versus non-ART (preconception indicators could be measured)	TBD	Bike rack	Linkage of ART-live births-PRAMS. Possibly using BRFSS data.
Ovarian stimulation protocols and ART procedures - differences by cause of infertility	TBD	Bike rack	Linkage of ART-live births-claims (health insurance) data.
Male infertility and environmental exposure	Julie	Bike rack	No data currently. Literature review can be conducted and reported to the group.
STD and infertility	TBD	Bike rack	No data currently.

SC=Steering Committee; TBD=To be determined