THE MICHIGAN ACTION PLAN FOR INFERTILITY AND ASSISTED REPRODUCTIVE TECHNOLOGY (ART)

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Michigan Department of Health and Human Services
Lifecourse Epidemiology & Genomics Division
States Monitoring Assisted Reproductive Technology (SMART) Collaborative Program

MDHHS
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Executive Summary

Infertility, or the inability to have one's own biological children, can be a devastating condition. Defined as not being able to get pregnant after one year of trying (or six months if a woman is over 35 years of age), infertility affects 7.3 percent of Michigan adults (10.1 percent of women and 4.8 percent of men) between the ages of 18 and 50 years.

Many known causes of infertility are public health issues. These include exposures to toxins, sexually transmitted infections, some chronic conditions, and behavioral factors (e.g. smoking, obesity). In addition, infertility can lead to stress and anxiety affecting quality of life and mental health. Currently, there are several viable treatments for infertility, including Assisted Reproductive Technology (ART), which includes in vitro fertilization (IVF) or any procedure where both eggs and sperm are handled. However, these treatments also have public health implications, such as the greater incidence of multiple gestation pregnancies (particularly twins), preterm birth, and low birthweight. These contribute to increased risks to mothers and infants including pregnancy complications, short- and long-term health issues, developmental disabilities, and maternal and infant mortality.

The World Health Organization (WHO) considers infertility to be a disease of the reproductive system, but to date the Centers for Disease Control and Prevention (CDC) has not designated infertility as a disease. Furthermore, many insurance companies and employers in Michigan do not cover infertility treatment or only offer limited coverage. Consequently, many people may not seek care for their infertility and those that do may pay large out-of-pocket expenses. This contributes to disparities in access to care and may lead patients to undergo procedures that may minimize their costs (e.g., use fertility drugs or transfer multiple embryos in one cycle), but increase health risks.

Reducing maternal and infant morbidity and mortality in addition to eliminating disparities are priorities in Michigan. Therefore, it is important to raise awareness of infertility treatments'--particularly ART's--contribution to multiple birth and preterm birth in Michigan; as well as find strategies to improve ART access and practices to ensure the birth of a healthy child. The Michigan Action Plan for Infertility and ART seeks to do both. The plan is the result of a statewide summit held on May 20, 2016, in which various stakeholders met to look at the contribution of ART to multiple birth and preterm birth, and develop recommendations for state action in the following areas: Provider Practice, Policy/Insurance Coverage, Patient Education, and Impact of Non-ART Treatments.

In addition, several cross-cutting recommendations are outlined in the plan. Successful implementation is dependent on ongoing dialogue and collaboration with new and existing partners throughout the state.

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Introduction

Public Health Importance of Infertility and ART

Infertility, defined as not being able to get pregnant after one year of trying (or six months if a woman is over 35 years of age), can be a difficult and devastating condition for individuals and couples who wish to have children.[1,2,3] Nationally, infertility affects six percent of married women aged 15-44 years and five percent of men aged 25-44 years.[4] In Michigan, 10 percent of women and nearly five percent of men aged 18-50 years report ever experiencing infertility.[5]

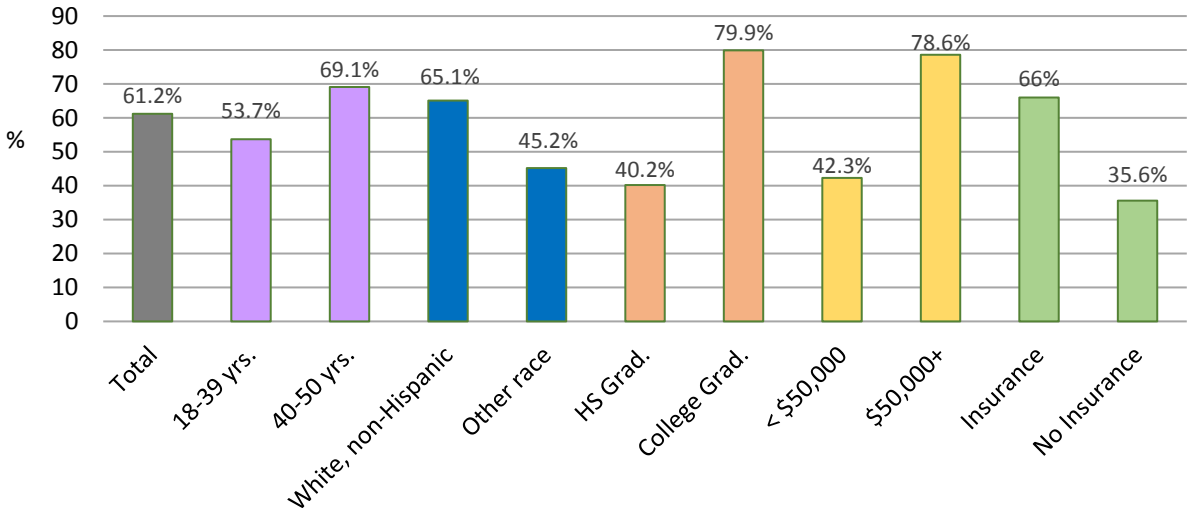
Acronyms	
ASTHO	Association of State and Territorial Health Officials
ART	Assisted Reproductive Technology
CDC	Centers for Disease Control and Prevention
ICSI	Intracytoplasmic Sperm Injections
IUI	Intrauterine Insemination
IVF	In Vitro Fertilization
MDHHS	Michigan Department of Health and Human Services
MIAdCO	Michigan Infertility Advisory Committee
OHSS	Ovarian Hyperstimulation Syndrome
PGS	Pre-Implantation Genetic Screening
SET	Single Embryo Transfer

Awareness of infertility as an important public health issue is increasing.[6] Infertility can affect anyone, both men and women. Furthermore, many of the known causes of infertility are public health concerns. These include exposure to environmental, occupational, and chemical toxins; sexually transmitted diseases and infections; chronic diseases and conditions; genetic and physical abnormalities; medications/iatrogenic factors (e.g., chemotherapy); and lifestyle behaviors (e.g., smoking, obesity).[7] Infertility or its treatment can lead to psychological stress, anxiety, and depression, not only affecting quality of life, but also contributing to mental health problems.[3] Furthermore, treatments for infertility can be physically invasive, cause discomfort, and may cause increased health risks for women and children.[3]

The WHO considers infertility to be a disease of the reproductive system,[8] but to date the CDC has not designated infertility as a disease. Many insurance and employer health plans in Michigan do not cover the costs of infertility treatment or have limited coverage. Thus, many people may not seek treatment for their infertility. In Michigan, close to 40 percent (38.8 percent) of those who report ever having experienced infertility noted that they did not receive treatment.[5] Those that do seek treatment often incur significant out-of-pocket expenses. This, in turn, may lead to use of less effective, but lower cost treatment methods.[7] In addition, to

decrease repeated procedures, patients--along with their physicians--may opt to have two or more embryos transferred, despite increased risks. Finally, cost barriers contribute to disparities in access to infertility care among various age, racial, ethnic, and socioeconomic groups.[3,7,9,10] In Michigan, those receiving treatment for their infertility are more likely to be age 40 to 50 years, White (non-Hispanic), college educated, earn an annual income of $50,000 or more, and have health insurance (Figure 1).[5]

Figure 1:
Demographics of Michigan Residents Receiving Infertility Treatment, MI BRFS, 2012-2014



Among those in Michigan who do receive treatment for their infertility, nearly 17 percent use ART.[5] ART is a type of infertility treatment in which both egg and sperm are handled outside the body to achieve a pregnancy.[11,12] Typical forms of ART include IVF and intracytoplasmic sperm injections (ICSI).[11] ART has been used successfully in the United States since 1981,[6,13-17] with its use steadily increasing over the years.[13] The number of ART procedures performed in the United States more than doubled between 1996 and 2006, and the number of children born through ART almost tripled.[11] In Michigan, the use of ART increased nearly eight percent from 3,197 cycles in 2009 to 3,442 cycles in 2013.[13-17]

Although ART enables people to have children who may not be able to otherwise, it is not without its risks. In particular, because more than one embryo is frequently transferred, ART can increase the chance of multiple gestation pregnancies, especially twins.[13-17] In 2013, nearly half (44.2%) of ART-conceived infants in Michigan were multiples, compared with 3.7 percent of all infants born in the state (Table 1).[17] Among ART-conceived multiples, 94.3 percent were twins.[17] Multiple gestations, including twins, carry risks to both the mother and baby, including pregnancy complications (e.g., high blood pressure, gestational diabetes, placental abnormalities, increased risk of surgical procedures, and hemorrhage) as well as preterm birth

(< 37 weeks) and low birth weight (< 2,500 grams), which can lead to acute and long-term health problems, developmental disorders, and infant mortality.[11,13-17]

While preterm births and low birthweight are common among all multiples, the incidence is higher with ART.[17] Among ART-conceived infants in Michigan in 2013, 37.4 percent were born preterm and 30.1 percent were low birthweight, compared with 11.6 percent and 8.2 percent of all infants born in Michigan respectively (Table 1).[17] The societal economic burden of preterm births among ART-conceived infants in Michigan was $32,525,386 in 2013, the 14th highest in the nation.[18]

Table 1
Percent of Multiple-Birth Deliveries, Preterm Births and Low Birth Weight Infants in MI by Type of Conception, 2013 (CDC Surveillance Summary)

	ART-Conceived Infants in Michigan	All Infants Born in Michigan
Multiple-birth deliveries	44.2%	3.7%
Preterm Births		
• <37 weeks	37.4%	11.6%
• <32 weeks	7.6%	2.2%
Low Birth Weight		
• <2,500 g	30.1%	8.2%
• <1,500 g	6.5%	1.6%

Reducing maternal and infant morbidity and mortality by preventing adverse pregnancy outcomes including preterm birth and low birth weight, and eliminating disparities are priorities in Michigan as outlined in the Michigan Infant Mortality Reduction Plan. Some strategies to reduce maternal morbidity and mortality include introducing safety bundles for the management of postpartum hemorrhage, hypertension, and venous thromboembolism in all birthing centers in the state. Current strategies to reduce premature birth and low birth weight focus on reducing early elective delivery and low-risk cesarean deliveries, ensuring at-risk women receive progesterone treatment when medically indicated, and promoting tobacco cessation among pregnant women. However, other opportunities to improve pregnancy outcomes and reduce preterm birth exist by reducing the incidence of twins and higher order multiples due to ART. Improving provider practice, patient education and counselling, and insurance coverage and policy to reduce the number of embryos transferred (when clinically appropriate) may help accomplish this goal. In addition, it is important to better understand the contribution of non-ART fertility treatments--primarily the use of fertility drugs--on the incidence of multiple birth, preterm birth, and low birthweight. Non-ART treatment methods are not systemically monitored at this time.

Michigan States Monitoring Assisted Reproductive Technology (MI SMART): Translating Data into Public Health Action Project

Since 2008, Michigan has been part of the SMART Collaborative. An initiative of the CDC Division of Reproductive Health, the SMART collaborative seeks to establish, evaluate, improve, and promote state-based surveillance of ART, infertility, and related activities, including ART-related maternal and infant health outcomes.[19]

The MI SMART project is a joint effort of the MDHHS Lifecourse Epidemiology and Genomics Division, and the Division for Vital Records and Health Statistics. The project consists of: 1) linking files of ART data with other state data sets to assess pregnancy outcomes and infants' health; 2) implementing a comprehensive surveillance plan; and 3) providing epidemiological and research consultation for the development of programs and policies to address the impact of ART and non-ART procedures on women's and infants' health in Michigan. In addition, the MI SMART project founded the Michigan Infertility Advisory Committee (MIAdCO), which includes reproductive endocrinologists/infertility and genetics specialists, embryologists, neo- and perinatologists, ethicists, genetic counselors, epidemiologists, public health administrators, health insurers, and community (i.e. March of Dimes) and national (i.e. CDC) partners. MIAdCO meets annually to give advice and quality assurance to the surveillance project, as well as help with the development of new and/or review of existing strategies and policies to assure continued improvement of efforts. While the MI SMART project has successfully broadened infertility and ART surveillance in Michigan, translating surveillance findings into action steps has been challenging.

In 2015, MDHHS received funding from the Association of State and Territorial Health Officials (ASTHO) for the MI SMART: Translating Data into Public Health Action Project. As part of a cooperative agreement with the CDC's, Division of Reproductive Health's *Building Capacity in Maternal and Child Health Programs*, the overarching purpose of the ASTHO funding was to promote leadership and build capacity in ART through enhancing the role of the state health department. The funding gave Michigan the opportunity to build on previous analytic work, MIADCO activities, and scientific research to raise awareness of the link between infertility treatments, ART, and premature birth; and to identify opportunities to improve ART practices with partner organizations moving forward. Consequently, funding was used to convene a state summit and develop a plan for state action around infertility and ART.

Development of the Infertility and ART Action Plan

The Michigan Assisted Reproductive Technology (MiART) Summit held on May 20, 2016, brought together diverse stakeholders to raise awareness about ART's contribution to twin/multiple birth and preterm birth in Michigan and develop recommendations for state

action to improve ART practices and birth outcomes to ensure the birth of a healthy child. Participants spent the morning learning from state and national experts about infertility, use of ART, and disparities in Michigan, as well as trends in multiple birth and preterm birth associated with ART and non-ART infertility treatments. Attendees also heard about patient/healthcare consumer needs and the first-hand experiences of ART users in Michigan. With this background, Summit participants took part in work groups to brainstorm recommendations for state actions in one of four key issue areas: 1) Provider Practice, 2) Policy/Insurance Coverage, 3) Patient Education, and 4) Impact of Non-ART Treatments.

In addition, three weeks before the Summit, a pre-Summit survey was administered, via an online portal, to various partners and stakeholders, including those who could, and could not, attend the Summit. The survey gave respondents the opportunity to contribute ideas to more than one work group issue area as well as allowed those who could not attend the Summit to provide input. Survey responses were shared with each respective work group during the Summit breakout session.

Information collected through the MiART Summit and pre-Summit survey was used to draft recommendations to address infertility and ART in Michigan. Recommendations were then circulated among key stakeholders for review and comment. This action plan is the result of this planning and review process. The recommendations presented in this plan outline strategies to improve ART access, practices, and outcomes in the state with the goal of helping couples achieve a safe pregnancy resulting in the birth of a healthy infant.

Recommendations

Addressing infertility and promoting access to treatments that reduce the risk of multiple birth—particularly twins, preterm birth, and low birth weight in Michigan is something no one agency, organization or discipline can do alone. In addition to medical and public health factors, there are societal, cultural, financial, physical, and emotional perspectives to consider.[20] This will take multiple partners working collaboratively across various sectors to effectively address issues of infertility—both female and male factor infertility— as well as promote greater access to care and use of ART best practices to help people experiencing infertility realize their dream of having children, while ensuring effective and safe outcomes that promote the birth of a healthy child.

The following recommendations and suggested action steps provide a platform for further discussion and collaborative action.[3] Recommendations/action steps are presented in four areas:

- ☐ Provider Practice
- ☐ Policy/Insurance Coverage
- ☐ Patient Education
- ☐ Impact of Non-ART Treatments

In addition, several of the work groups outlined cross-cutting recommendations.

Ongoing dialogue as well as nurturing existing and new partnerships will be critical to the successful implementation of the following recommendations to improve infertility and ART throughout the state.

Provider Practice (PP)

With ART becoming available in the United States starting in the early 1980s, the rate of US multiple births increased.[10] Although triplet and higher-order multiple rates have since decreased, the incidence of twin births among ART-conceived infants remains high.[10] Multiple gestation pregnancies, including twins, are at higher risk for adverse outcomes such as pregnancy complications and preterm birth, which may lead to greater morbidity and mortality among mothers and infants.[10, 13-17] However, clinicians can help to reduce twin and higher-order multiple births resulting from ART through prudent provider practices.

To begin to move forward the PP work group worked to identify actions to improve clinical practice and promote infertility and ART treatment options that could reduce the risk of

twin/multiple birth and preterm birth in Michigan. This encompassed exploring 1) the current context of infertility and ART treatment practices in Michigan (including successes, challenges, and needs), 2) opportunities for improvement, and 3) priorities for action.

There was general consensus that improvements could be made by enhancing efforts in four key areas:

- ☐ Increasing provider education;
- ☐ Promoting greater commitment among both providers and patients to single embryo transfers (SET);
- ☐ Ensuring greater continuity and coordination of care among all providers;
- ☐ Encouraging research in infertility and ART treatments.

Specific recommendations include the following:

PP-1) Increase education and training for general practitioners, primary care providers, and Ob/Gyns regarding fertility preservation, infertility diagnosis, safety and effectiveness of infertility treatment options, and referral to providers of infertility care such as urologists and reproductive endocrinology and infertility (REI) specialists. Strategies may include:

- ☐ Identifying and disseminating research, best practices, and guidelines for diagnosing, managing, counseling, and referring patients experiencing infertility.
- ☐ Enhancing fertility preservation education by offering more standardized education on fertility preservation options and the relative risks/safety of each.
- ☐ Providing training on the safety and effectiveness of various fertility treatments, as well as strategies to prevent iatrogenic multiple births.
- ☐ Educating providers about optimum consultation and management of medical disease and other high risk factors prior to initiating fertility treatment.
- ☐ Collaborating with professional societies and academic intuitions to provide continuing education programs and in-service trainings.
- ☐ Identifying resources and partnerships to sponsor regional meetings or seminars to enhance provider education.

PP-2) Promote greater commitment to and practice of SET, when medically appropriate. Strategies may include:

- ☐ Redefining success of fertility treatment as a balance between a successful pregnancy and safety concerns, with the goal of the birth of a healthy infant.
- ☐ Increasing professional education on the benefits of SET and how it may improve maternal and infant health outcomes by reducing the risk of multiple birth and preterm birth.

- ☐ Encouraging more research on the effectiveness of pre-implantation genetic screening (PGS), which may be used to identify "best candidate" embryos for SET (particularly for older patients or those with repeat failures).
- ☐ Enhancing patient education and counseling on SET, including potential success rate, how it may improve maternal and infant health outcomes by reducing multiple birth and preterm birth, and the full spectrum of potential risks from multiple birth/preterm birth (e.g. pregnancy complications, short- and long-term health problems, developmental disorders, physical/emotional toll, associated health care costs, etc.).
- ☐ Promoting insurance coverage for IVF with SET when medically appropriate (e.g., for patients less than 38 years of age, no prior failures); consider including frozen embryo transfers with coverage.

PP-3) Provide increased care coordination and psychosocial support for individuals/couples experiencing infertility and/or undergoing treatment. Strategies may include:

- ☐ Examining existing systems of communication and coordination among providers (i.e. primary care provider, Ob/Gyn, maternal fetal medicine specialist, urologist, REI specialist) in order to identify ways to promote referrals and improve communication.
- ☐ Encouraging utilization of electronic medical records (EMR) and/or care management database systems to ensure timely follow-up and coordination of care.
- ☐ Encouraging referrals to maternal fetal medicine specialists, internists and other healthcare providers to ensure patient safety and optimum maternal health prior to fertility treatment.
- ☐ Increasing patient referrals to mental health professionals, particularly those specializing in counseling patients with infertility issues.
- ☐ Collaborating with public health and community programs that provide assistance across various domains (e.g., social, emotional, financial) and linking patients to these resources.
- ☐ Encouraging referrals to, and participation in, patient support groups and other activities to address the psychosocial needs of patients and their families.

PP-4) Promote funding for rigorous research to better understand:

- ☐ Causes of male, female and a couples' infertility.
- ☐ Best practices for fertility preservation.
- ☐ Medical advancements and technologies in treating infertility.
- ☐ Successes, safety, outcomes, costs, and cost-effectiveness of various treatment options (both short- and long-term).
- ☐ Efficacy and effectiveness of medical guidelines and recommendations.
- ☐ Patient experience including barriers to access, burden of care, and psychosocial needs.

Policy/Insurance Coverage (P/I)

Currently, there is no state mandate requiring insurers to offer coverage for infertility or ART treatment in Michigan. In addition, employers may not recognize the need or potential benefits of providing coverage for infertility care to their employees. Consequently, relatively few people have insurance that lessens the financial burden of ART. This lack of coverage contributes to disparities in access to infertility care, as well as a tendency for patients who do seek treatment to undergo procedures that may result in multiple birth and preterm birth. Both carry the increased risk of adverse health outcomes leading to significant healthcare costs and economic burden.

The MiART Summit P/I work group was tasked with identifying policy and health insurance changes that are needed to improve access to infertility treatments/ART. Their goal was to ensure the implementation of best practices to reduce multiple birth and preterm birth resulting from infertility treatments in Michigan. While there was general agreement that increased insurance coverage for infertility treatment and ART is essential, the group concluded:

- ☐ Existing partnerships need to be expanded and strengthened;
- ☐ New relationships should be fostered and nurtured bringing insurers, health plans, employers, and policy makers together; and
- ☐ Access to infertility treatment should be expanded through more affordable coverage.

Specific recommendations include the following:

P/I-1) Engage and work with additional stakeholders including medical, public health, and healthcare consumer groups to raise awareness of infertility and ART issues; and develop a consistent, succinct, and unified message emphasizing the need for health care coverage to include ART. Stakeholders include (but are not limited to):

- ☐ Neonatologists;
- ☐ Maternal-fetal medicine specialist;
- ☐ Pediatricians;
- ☐ Medical geneticists;
- ☐ Maternal/child health specialists;
- ☐ Reproductive health specialists;
- ☐ Urologists;
- ☐ Specialists in sexually transmitted diseases/infections;
- ☐ Chronic disease professionals; and
- ☐ March of Dimes.

P/I-2) Form relationships and linkages with other key stakeholders including a) Insurers/health plans, b) Employers, and c) Legislators.

- ☐ Facilitate discussions to seek perspectives, foster open dialogue, and build bridges.
- ☐ Expand the understanding of why infertility/ART treatments may not be covered and what information, resources, and technical assistance they need to consider offering coverage.
- ☐ Encourage economic analysis of the role of insurance coverage for infertility treatment/ART on healthcare costs.
- ☐ Establish consensus of the overarching, common theme and goal: birth of a healthy child.

P/I-3) Convene another meeting/summit encompassing all stakeholder groups to keep the dialogue and momentum for action moving forward; let outcomes from this dialogue with stakeholders drive next steps for policy/insurance coverage.

Patient Education (PE)

Patient education and awareness are essential to improving ART practices and outcomes. When experiencing infertility, it is important for patients to understand the full spectrum of treatment options, including the specific procedures involved as well as the relative safety, risks, benefits, success rates, and costs of each. Information needs to be available from credible sources and presented in a clear, consistent, and accurate manner so that healthcare consumers struggling with infertility can make informed choices about how best to manage their condition. Factors such as out-of-pocket costs along with the physical and emotional toll of infertility treatment can further influence patient decisions, making them more likely to select procedures that seemingly increase their chance of having a child, while also potentially compromising their safety.

Given the role of PE in influencing infertility care decisions and potential health outcomes of ART treatments, the MiART Summit PE work group worked to identify actions to ensure patients/consumers have the information they need to make informed decisions about their infertility treatment, and options that may reduce their risk of multiple birth and preterm birth. Though the group discussed a wide range of ideas, several overarching themes emerged. These included: 1) the need to raise awareness among patients and the public at-large about reproductive health, infertility, prevention measures, fertility preservation options, infertility treatments, the burden of care, and the potential for adverse outcomes with certain treatments/procedures; 2) the importance of better understanding the patient experience and

providing credible and relatable information for patients on the risks of multiple births and the potential benefits of SET; and 3) the need to ensure that healthcare providers have adequate information, resources, and training to educate and counsel patients. Specific recommendations include the following:

PE-1) Develop and implement a Michigan-specific, statewide, comprehensive, and tailored public awareness and patient education campaign to increase understanding of infertility, treatment, and ART. This public awareness/education campaign should:

- ☐ Include multiple materials, mediums, communication channels, and points of access to accurate and credible information (e.g., centralized website, social media, printed materials/information graphics, videos, regional education seminars, science-based talk shows/Ted Talks/educational programs available through Internet channels, etc.).
- ☐ Provide information on general reproductive health, optimal age range for conceiving a child, and reproductive risks/protective factors for both men and women.
- ☐ Communicate that infertility is a disease and dispel myths, stereotypes, and social stigmas associated with infertility in order to promote understanding, empathy, and tolerance.
- ☐ Raise awareness of the mental and emotional toll of infertility, including the increased stress, anxiety, sense of loss, and potential for depression among those experiencing infertility.
- ☐ Increase understanding of the risks associated with twins and higher-order multiples, including pregnancy complications, preterm birth, low birth weight, short and long-term health problems, developmental issues, related costs, and emotional toll of having twins/multiples.
- ☐ Provide information about SET, including associated benefits, reduced risks, and factors that may increase its success.
- ☐ Ensure messages are culturally and linguistically appropriate.
- ☐ Feature regional education seminars for patients (that are science vs. commercial based).
- ☐ Provide patient education resources (e.g., where to go for accurate information, how to choose a provider, questions to ask a provider, what to expect during treatment, how to handle the mental/emotional stress, etc.).

PE-2) Work with patients, healthcare consumer organizations, and support groups to better understand the patient experience so that optimally effective and relatable patient education messages and materials can be developed about infertility treatment options, potential risks of multiple births, and the benefits of SET.

PE-3) Ensure that healthcare providers have adequate resources and training to educate and counsel patients about infertility assessment/diagnosis, male-factor infertility, fertility preservation options, and the benefits and risks of available infertility treatments.

PE-4) Disseminate to a wider audience existing patient education materials, and/or adapt materials for Michigan-specific use. Examples include:

- ☐ CDC – Having Healthy Babies: One at a time
  - https://www.cdc.gov/art/pdf/patient-resources/having-healthy-babies-handout-1_508tagged.pdf
  - https://www.cdc.gov/art/pdf/patient-resources/having-healthy-babies-handout-2_508tagged.pdf
- ☐ Resources from RESOLVE: http://www.resolve.org/
- ☐ Connecticut Department of Public Health's Factsheet: Assisted Reproductive Technology (ART) in Connecticut: http://www.ct.gov/dph/lib/dph/hisr/pdf/art_factsheet_ct2014.pdf

Impact of Non-ART Treatments (NA)

Non-ART treatments for infertility primarily consist of ovulation induction and ovarian stimulation through the use of pharmaceutical agents.[21] In ovulation induction, medications are used to induce ovulation in women who are unable to ovulate on their own.[21] In ovarian stimulation, drugs are administered to trigger multifollicular ovarian development and ovulation in women who are subfertile.[21] Both are coupled with timed intercourse or intrauterine insemination (IUI) to increase the chance of pregnancy.[21] However, each can carry health risks to the mother and child, such as ovarian hyperstimulation syndrome (OHSS), which results in enlargement of the ovary and buildup of abdominal fluid, or the increased risk of twin and higher-order multiple births.[3]

Currently, there is no national or state registry documenting the use and outcomes of non-ART fertility treatments.[21] This is despite the fact that non-ART treatments are estimated to account for more multiple births than ART.[21] Consequently, the Impact of Non-ART Treatments work group was tasked with identifying actions that are needed to better understand the use of non-ART therapies, their contribution to multiple birth and preterm birth in Michigan, and opportunities to prevent multiple birth due to these treatments.

While recognizing the value of non-ART treatments for certain infertility diagnoses and patient issues, there was general agreement that the risks associated with non-ART treatments could be averted through greater access to and use of IVF, which allows for more control over the

number of embryos conceived. When non-ART is utilized, then there is the need for more patient and provider education about its appropriate use, as well as greater monitoring of follicular development through routine ultrasound. Ultimately, there is the need to establish surveillance and tracking of the use of non-ART therapies and resulting birth outcomes in order to fully understand its contribution to multiple and preterm birth, and identify effective prevention strategies. Specific recommendations regarding non-ART include the following:

NA-1) Facilitate access--geographic and economic--to ART therapies by increasing the number of providers in certain areas of the state that administer ART/IVF and providing insurance coverage for ART/IVF so people are less likely to default to non-ART treatments or undergo repeated rounds of ovulation stimulation/IUI when not medically indicated.

NA-2) Increase healthcare provider and patient education regarding non-ART treatment, including the following:

- ☐ Types of treatments/medications available and the purpose, function, benefits, and risks of each.
- ☐ When non-ART therapies are most appropriate to use and how best to use various treatments.
- ☐ Effectiveness of non-ART treatments relative to ART/IVF.
- ☐ The importance of ultrasound monitoring during non-ART treatment.
- ☐ Potential for twins/higher-order multiples and the associated risks for adverse outcomes--e.g., pregnancy complications, preterm birth, low birth weight, stressors involved with NICU stays (e.g., financial, emotional, time requirements, etc.), short and long-term health effects, increased overall medical costs, etc.
- ☐ When to refer/seek the care of a specialist.
- ☐ When to move on from non-ART to ART/IVF.

NA-3) Develop and implement clearer guidelines for the administration of non-ART treatments. Considerations include the following:

- ☐ Conducting standard tests, including male partner evaluation and fertility analysis, to assess both male and female fertility prior to administering non-ART treatments.
- ☐ Limiting non-ART therapies by age.
- ☐ Administering medications and proper dosage.
- ☐ Importance of and protocols for ultrasound monitoring.
- ☐ When to cancel a cycle.
- ☐ When to consult or refer to a specialist.

NA-4) Increase ultrasound monitoring when administering non-ART therapies to determine number of follicles developing and if the cycle should be canceled due to this number. Potential strategies include:

- ☐ Increasing education and training for Ob/Gyns on proper use and monitoring.
- ☐ Increasing referral to a REI specialist for administering fertility medications.

NA-5) Establish surveillance of the use of non-ART therapies and resulting pregnancy and birth outcomes. Potential strategies include:

- ☐ Identifying data sources and tracking processes already in place such as pharmacy claims data, physician prescribing data, etc., that could be utilized to monitor use.
- ☐ Working with CDC and other partners to promote national surveillance of non-ART therapies and outcomes, which can be broken down into state-specific data.
- ☐ Exploring the potential to utilize an existing, or develop a new, database/registry to track ovulation induction/superovulation cycles performed in Michigan and resulting outcomes.

Cross-Cutting Recommendations (CC)

In addition to the numerous issue-specific recommendations outlined above, several cross-cutting recommendations emerged from MiART Summit and the pre-summit survey. These include the following:

CC-1) Raise public awareness of reproductive health and infertility in Michigan by promoting increased education among the general population about reproductive risk and protective factors, family planning considerations, infertility prevention, and infertility issues. Education should start at appropriate ages, increase awareness of infertility as a disease, and be integrated into broader reproductive health education programs and promotion campaigns.

CC-2) Define and officially recognize infertility as a disease in the United States. Strategies may include:

- ☐ Working with national and state agencies, medical associations, professional societies, and other partners to reach consensus on a nationally accepted, standard case definition of infertility.
- ☐ Promoting acceptance among national and state public health, health care, and medical institutions; along with providers, policy makers, insurers, and employers that infertility is a disease of the reproductive system.

CC-3) Educate legislators/policy makers about infertility as a disease and its health implications (e.g., host seminars for legislators/local representatives, participate in awareness-raising events at the Capitol, etc.) in order to make it less taboo to talk about, help guide the conversation publically, and encourage them to take action to address the needs of those with infertility.

CC-4) Promote better options to assist with access to infertility treatment and ART among Michigan insurers, health plans, and employers; and/or enact a state mandate for insurance coverage for ART. Considerations include:

- ☐ Providing coverage for ART procedures, medications, and related services, with incentives for SET (when medically appropriate) and reasonable restrictions to ensure adherence to best practices/guidelines based on a patient's age, infertility diagnosis, health status, and risk factors.
- ☐ Developing cost-effective, model coverage design plans for ART, and working with employers and insurers to add these coverage design plans to their benefit options.
- ☐ Exploring alternative options for infertility and ART coverage such as formation of "boutique" insurance policies that include coverage for specific professional groups.
- ☐ Accounting for diversity among individuals seeking ART in proposed or enacted coverage plans (e.g., fertile couples who may need to use ART due to genetic conditions or match-up issues among partners, cancer patients who may need to use ART to ensure a healthy pregnancy after treatment, same-sex couples wishing to have a family, etc.).

CC-5) Support efforts to better understand the male-factor side of infertility. In particular, explore and promote male-based interventions that could moderate the intensity of the treatment needed for couples to achieve a safe pregnancy and the birth of a healthy child.

CC-6) Expand and diversify research on infertility issues and outcomes in order to better inform state actions. Suggested research topics include:

- ☐ Stress, anxiety, depression, quality of life, and other mental health issues experienced by those struggling with infertility; as well as the use of medical and mental health services to address these.
- ☐ Patient perspective including specific barriers to care in Michigan (e.g., financial, geographical, job-related, medical--i.e. proper diagnosis) and the decision-making process of adults and couples trying to have children.
- ☐ The effect of twin/multiple gestation and adverse pregnancy outcomes on parents and children, including the short and long-term physical, mental, emotional, and financial toll.

- ☐ Environmental and occupational exposures (e.g., toxins, endocrine disruptors, etc.) associated with infertility to determine if there are any clusters and trends occurring in Michigan.
- ☐ Use of non-ART treatments (i.e. fertility medications) and their contribution to multiple birth and preterm birth in Michigan.
- ☐ Maternal complications among women undergoing ART and factors that increase their risk of adverse outcomes.
- ☐ Long-term effects of infertility treatment on adults undergoing treatment and children conceived through these treatments.

CC-7) Form partnerships and explore collaborative funding opportunities or availability of in-kind resources for infertility/ART research, educational programs, prevention initiatives, and awareness-raising efforts.

Next Steps

The Michigan Action Plan for Infertility and ART outlines multiple opportunities for state and local agencies, professional organizations, providers, health systems, insurers/health plans, policy makers, academic institutions, and consumer groups to take action. Specifically, the recommendations presented here provide direction for various partners and stakeholders to collaboratively address infertility and ART access, practices, and outcomes in Michigan, with the overarching goal of achieving the birth of a healthy child.

An essential first step in translating recommendations into action will be dissemination of this Action Plan to all potential partners throughout the state, followed by continued dialogue, discussions, and relationship building among key stakeholders. The next critical step will be to develop implementation guides that outline specific actions required to achieve the recommendations presented in this plan. As part of this process, Michigan partners will need to consider how these recommendations can be integrated into their current work as well as define and communicate their role to fellow partners. It is through collaboration that the fullest impact of the recommendations will be realized.

At times, state and local partners may need to work together to secure funding and other resources to implement this Action Plan. This includes identifying new federal funding opportunities, ways to tap into existing funding, and mechanisms to possibly secure corporate and/or foundation support. Other non-financial resources that can be instrumental in implementing the plan include already existing professional education curricula, patient educational materials, and public awareness campaigns that can be adapted for use in Michigan.

Finally, implementation of the recommendations and resulting outcomes must be monitored and evaluated on a routine basis. This may involve surveying partners about their individual and collaborative efforts; continuing to gather surveillance data; and possibly convening key stakeholders on a periodic basis to review recommendations, assess progress, and modify recommendations as needed.

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Appendix A

MiART Summit Agenda

8:00-9:00 a.m.	Registration & Networking/Light Breakfast
9:00-9:45 a.m.	Welcome and Opening Remarks • Michael Mersol-Barg, MD – Michigan Infertility Advisory Committee, Co-chair • Susan Moran, MPH – Michigan Department of Health and Human Services • Dmitry Kissin, MD, MPH - Centers for Disease Control and Prevention
9:45-11:00 a.m.	Key Note Address – The US Multiple Births Epidemic 1967-2014: Iatrogenic and Demographic Forces in Action. Dr. Eli Adashi, MD, MS, CPE, FACOG Professor of Medical Science Former Dean of Medicine and Biological Sciences The Warren Alpert Medical School, Brown University
11:00-11:15 a.m.	Break
11:15 a.m.-12:00 p.m.	Plenary Session – Consumer Needs Barbara Collura, President/CEO RESOLVE – The National Infertility Association
12:00 p.m.-1:15 p.m.	Consumer Panel/Lunch
1:15-3:15 p.m.	Breakout Work Groups • Provider/Clinical Practice – *Chestnut Ballroom* • Policy/Insurance Coverage – *Laurel Room* • Patient Education – *Maple Room* • Contributing Risks from Non-ART Treatments – *Chestnut Ballroom*
3:15-3:30 p.m.	Break
3:30-4:15 p.m.	Work Group Reports
4:15-4:30 p.m.	Closing Remarks/Adjourn - Michael Mersol-Barg, MD

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Appendix B

Pre-Summit Survey Responses

Q1. Provider Practice: What, if any, actions do you feel are needed to improve ART practices in Michigan, particularly those that may reduce the risk of twins/higher order multiples and preterm birth?

Answered: 21 Skipped: 0

Number	Response Text
1	In my experience, and the feedback I hear from others, there are still not enough physicians who push for a Single Embryo Transfer (SET). Many are still willing to, and easily agree to, transferring two embryos to patients whose medical history doesn't indicate they would benefit from transferring two embryos vs. doing an SET.
2	Education of the high costs and long term care and health issues related to multiple gestations and preterm deliveries. Incentives for practices to perform eSET. ??...
3	We feel that physicians should encourage the wide spread adoption of PGS (pre-implantation genetic screening) testing and this testing should be used to reduce the amount of embryos that are put back into the uterus for implantation. Also, if PGS is not to be used, to limit the amount of embryos put back into the uterus to no more than 2 embryos at a time. To advocate for FET cycles over fresh transfers for the ability to do PGS screening and then transfer one embryo at a time from the embryos deemed euploid.
4	Risk assessment of mom for prevention of conditions that would cause mom to conceive and subsequently have Preterm. Strict practice of not place multiple that increase rush of high order multiples
5	Implement regulations restricting the number of embryos transferred by age. Also, consider restricting the number of oocytes inseminated per cycle, which may discourage physicians from over medicating. Limit IUI's to clinics who are monitoring for follicular development (i.e. REI clinics).
6	Insurance coverage
7	Patient Education
8	Proper education of not only patients but the public in general regarding risks of multiple births and success rates with Single embryo transfers.

9	To ensure access to urologic care for male partners. Access to this care will allow for investigations to see if there are male-based interventions than can downgrade the intensity of intervention needed for the couple to achieve a safe pregnancy.
10	Women in their early childbearing years should have better information about the impact of postponing their pregnancies. Primary care as well as Ob/Gyn providers are best able to advise women of options, including banking of their own eggs in their early 20s. The public needs better information on standards of care related to IUI, IVF, PCOS and general health related contributions to fertility.
11	Consider transferring elective single embryo transfer at Blastocyst stage, especially in young patients and good prognosis older patients. For older patients, the option of PGS should be invariably offered, with possible multi-cycle package, so that they may have a good opportunity of few blastocysys available for biopsy from each cycle. This may help them to have couple of euploid blastocysts for transfer. For repeat failure cases, PGS should be offered, so that we may be able to transfer single euploid embryo.
12	the use of social media for quick and effective patient education and communication
13	Understand and consider the male contribution and access to state of the art testing.
14	Care coordination, assistance for women and couples in getting linked to public health and other community programs that provided needed support across multiple domains (social, emotional, financial) beyond medical.
15	More of a push for elective single embryo transfer and patient education as to why this will improve outcomes
16	Single embryo implantation. Proper stimulation protocols.
17	Follow ASRM guidelines
18	1. Single embryo transfer - Limitation: in the current "pay as you play" system, there is a cost to each transfer and as long as transfer of 2 excellent embryos maximizes the "per embryo transfer" pregnancy rate and some argue that one should transfer 3 or 4 lesser quality embryos, this strategy will be resisted. 2. Pre-implantation genetic screen will assist patients acceptance of single embryo transfer by now defining excellent as genetically normal (euploid) and not morphologically normal appearance.

19	Increase rates of single embryo transfers.
20	Single embryo transfers in most circumstances, especially with euploid embryos.
21	Encouragement and coverage for IVF with single blastocyst transfer.

Q2. Policy/Insurance Coverage: What, if any, policy and health insurance changes do you feel are needed to improve access to infertility treatments/ART and ensure the implementation of best practices to reduce multiple birth and preterm birth in Michigan?

Answered: 20 Skipped: 1

Number	Response Text
1	Four words. State mandated insurance coverage. Most people in Michigan are paying out of pocket for their health care related to infertility. There are people who don't even have coverage for their diagnosis, let alone the treatment of their disease. This is unacceptable! Many people feel pressured to get "more bang for their buck" and choose to transfer more than one embryo, hoping and praying that at least one will implant. This is especially true if they want more than one child and/or if someone who has been under the care of a physician for a long time. Many people start with lower cost treatment options, that aren't necessarily what a physician would determine the ideal treatment for their particular diagnosis, due to the fact that they are paying out of pocket. This results in emotional, physical, and financial burn out and multiple births when patients choose to transfer more than one embryo. Having embryos tested before transfer can eliminate the need to transfer more than one embryo, since it allows the ability to know an embryo is chromosomally sound and more likely to result in a successful pregnancy BEFORE transfer but again, the out of pocket cost of this is a barrier for patients.
2	Improve and refine guidelines for insurance coverage to incentivize programs to limit the number of embryo's to help limit multiple and preterm births. Requirements/guidelines approved by REI's for testing and workup's to determine the MOST practical infertility protocol based on patients age, infertility diagnosis, etc.

3	Insurance coverage is lacking in the state of Michigan for services provided for ART/infertility. Difficulty in having a child is due to a medical condition, and should therefore be a covered benefit under all insurance policies. Medical treatment for other medical conditions related to quality of life are covered under most insurance policies in Michigan. Also, there are several states in the US that mandate coverage for infertility and Michigan should be one of those, but is not. Prescriptions for other medical conditions are covered by insurance plans, but are not covered when receiving ART-related services. Also, when doing fertility treatments that are not considered ART, certain medications are covered by insurance, but when doing treatments that are considered ART, those same medications that are used for the same purpose (i.e. trigger shot to induce ovulation and maturation of oocytes) are not covered, only because the treatment is considered ART.
4	That they should be prior approval process to assure mom is not AMA and of good health to carry a baby to term
5	Put age restrictions for ART treatment, limit the number of embryos to be transferred& number to be inseminated. With these restrictions, then push for coverage. Also, limit IUI's to REI clinics, who are monitoring patients for the number of follicles, instead of Ob/Gyn clinics who are not and adding to the twin/higher order multiples.
6	Coverage for IVF procedures and medications. This would make it easier for patients in making difficult decisions regarding treatment. Many patients have limited access to treatment due to financial restraints. Patients may feel pressure to move forward with procedures against medical advice that may put them at high risk for a multiple birth because they cannot afford to try again.
7	Coverage of medications and treatments
8	I think that insurance coverage for IVF vs multiple IUIs would dramatically decrease the risk of twins/higher order multiples and preterm birth.
9	We need to frame the infertility around the concept that it is a disease, not a lifestyle choice. Policymakers and insurers should allow the same access to care for infertility that they allow for diabetes care.

10	Policies must be based on relevant evidence of best practice. Somehow we need financing of investigative research on current and proposed practice. Then, insurance and state oversight of insurance practices can set more appropriate standards when we begin to offer fertility treatment coverage. If we want to draw highly educated, productive women to the state of Michigan, we need to have these treatments supported by our health system and the insurance that drives it.
11	IVF procedure should be covered by insurance after careful evaluation that IUI has not worked and or it is not feasible, such as in severe male factor cases or blocked Fallopian tubes. There should be age limit for coverage for both male and female partners.
12	Regulations on gender selection needs to be discussed.
13	Need to also consider the male contribution.
14	Unsure.
15	More coverage of all aspects of infertility (diagnostic evaluation, medications, ultrasounds, procedures, including IVF) along with eSET
16	Health insurance universal coverage for infertility management
17	See 2 in Question 1 above. It is cheaper to pay for PGS than it is to pay for miscarriage when one adds up the costs of blood tests, ultrasound, out-patient suction D&C, and perhaps genetic testing of the recovered products of conception. Massachusetts heavily subsidizes IVF. A small number of states provide some support. The majority of states do not. Most private insurances do not pay for IVF. However, many support tubal reconstruction.
18	Coverage for patients doing IVF and especially coverage that promotes single embryo transfer. For patients that don't have the financial means to do repeat cycles, the patient prefers to transfer higher number of embryos with the belief it will increase their pregnancy rate.
19	Universal ART coverage, if standard SET was practiced. Total cost effectiveness is well demonstrated with this model.
20	Insurance coverage for IVF with restriction for embryo transfer number

Q3. Patient Education: What, if any, actions do you feel are needed to ensure patients/consumers have the information they need to make informed decisions about their infertility treatment options, particularly ART options that may reduce their risk of multiple birth and preterm birth?

Answered: 20 Skipped: 1

Number	Response Text
1	More and accurate information on the success rates of SET vs. transferring 2 or more embryos. Is there really that much of a difference? What are the differences in pregnancy rates vs. the rates of healthy babies being born? What are the risks of multiples and how can they affect both the short term and long term health of the child? I don't think enough attention is paid, by patients or physicians, to the long term (even pregnancy to birth) well-being of a child. There is so much focus on achieving pregnancy and unfortunately, pregnancy doesn't mean the birth of a baby.
2	Education, education, education. Discuss and clearly present to pt's the negative and long term effects and costs of multiple birth and preterm deliveries. Perhaps having insurance benefits for pt's that undergo elective single embryo transfer, etc.....
3	It is important for women to have more access to have ovarian reserve testing done early on in adulthood, at the latest, at or around age 30. There needs to be more education at the Ob/Gynecologist level in regard to available infertility treatments and on common infertility diagnoses and what that means in regard to medical treatment for those diagnoses. There needs to be more widespread adoption or buy-in for PGS testing with education to the risks of multiple births when not choosing to do the testing.
4	Have a class developed that covers not just the conception but all aspects of having multiples and risk benefits are all discussed
5	Physicians need to be firm re single embryo transfers. So often I hear, well the patient really wanted two transferred, then the ultrasound comes back and they have twins. Stand firm, be the doctor.
6	The media can be a positive and a negative... but more media public health knowledge regarding infertility treatments. There are a lot of misconceptions even within the Ob/Gyn physicians.

7	Educate PCP or Ob/Gyns on use of oral fertility medications.
8	Providing patients with not only success rates but explaining the whole process of IUI & IVF in detail could help explain not only greater chance of success but also decrease risks due to more control over cycle. Also explaining options available for financing for IVF or navigating insurance if applicable.
9	Patients need to understand the role that both partners can have in their subfertility.
10	There is a dearth of knowledge about best practices and the impact of a pregnancy of multiples and preterm birth. The stigmatization of reproductive failure leads often to self-blame, hidden grief, and stressed marriages. The public still often ascribes to a psychogenic explanation of infertility. People magazine seems to offer the most widely available information, as distorted as it is, to publicize ART, surrogacy, and reproductive challenges in general. Surely we can do a better job with evidence based research and reporting in an accessible format. Perhaps the use of social media by an authenticated source could provide balanced information.
11	There should be public seminars related to these issues. Couples should be encouraged to see proper physicians, such as REI physicians when the female partner is young and not able to conceive after couple of years of sincere attempts. Egg banking should be encouraged in professional, athletes, or in those serving in military. Cancer patients should be encouraged for egg and or sperm banking.
12	Understanding what is available now and tomorrow in terms of testing towards outcome
13	Unsure.
14	I think videos can be helpful. I also think it would be helpful to show them what a NICU looks like to help them understand better the risks involved in preterm delivery.
15	The flyers and patient clubs.
16	Patient brochures. Standard template counseling documents used by all providers to ensure consistency and ethical behavior
17	Access to REI care through telemedicine consultation.

18	Greater promotion of single embryo transfer. We often hear patients say "we could handle twins or even triplets..." but most patients are very poorly educated regarding the downside of multiples (long term health risks, additional costs, increased rate of divorce, etc.)
19	Clear and understandable risks of preterm and multiple births, and risk of those pregnancies by number of embryos transferred. Such educational tools are available or in development.
20	Sometimes the number of embryos transferred is more patient driven as they do not understand the risks associated with multi-fetal gestation. More patient education and transparency with regard to outcome should be done so that patients are truly aware of the risks. Cost is another factor, as some patients cannot afford IVF which could reduce the risk of multiples and would give them a higher success at pregnancy.

Q4. Contributing Risks of Non-ART Treatments: What, if any, actions do you feel are needed to better understand the use of non-ART/IVF treatments and their contribution to multiple birth and preterm birth in Michigan?

Answered: 16 Skipped: 5

Number	Response Text
1	I'm guessing you're referring to things like Clomid with timed intercourse or IUI? I always felt like I had a greater risk of having multiples while using these treatments. If you have multiple follicles/eggs released with one of these cycles, there's no way (or at least limited ways) of controlling the number of babies conceived, vs. IVF where you can transfer one embryo and lower your risk of multiples. I have heard of women in other states undergoing a follicle reduction with an IUI to decrease the number of eggs that could potentially be released and fertilize but I haven't heard of that being offered in Michigan. I haven't researched this to find out. I felt much safer once I moved to IVF. It's something that I likely would have done sooner based on my diagnosis if I had coverage for IVF. We were lucky and had coverage for IUIs but likely would have moved toward IVF sooner based on how we were feeling and my doctor's feedback based on diagnosis. By the time I got to IVF, I was really emotionally and physically burnt out and that ended up resulting in treatment not being successful for us because I wasn't willing to spend the emotional, physical, or financial resources that were needed to have a decent chance of IVF working for us.

2	Again, education. Guidelines...
3	People need to understand the purposes/benefits of non-ART treatments and for what diagnoses they are most beneficial to be used for. For example, if the medical condition being treated is endometriosis, non-ART treatments may not be beneficial. Also, education needs to be provided so that patients understand that it is most beneficial for proper ultrasound monitoring for a cycle with fertility medication used with timed intercourse and/or a cycle with intrauterine insemination (IUI) because of the risks of multiple births. Therefore, it is important for patients to seek a specialist when doing these type of treatments to ensure that proper care is received. People are reluctant to seek specialists (reproductive endocrinologists) because of the lack of insurance coverage that is anticipated and the financial strain that this causes, as when procedures are coded as ART or as infertility diagnosis, insurance typically does not pay for these services.
4	Ob/Gyn doctors giving medications, such as Clomid, without any ultrasound monitoring are adding to the problem. Any drug which causes the women to superovulate should be monitored by ultrasounds daily to make sure that there is only 1 or 2 follicles developing. So often this is not the case, and the pregnancies are higher order multiples.
5	Many patients move forward against medical advice when at high risk for multiple births during an OI cycles due to the cost of medication and financial restraints. If the patient has insurance coverage for medications they are more likely to follow medical advice, cancel the cycle and move forward with IVF procedures that will lower the risk of multiple births.
6	Physician education
7	Multiple Clomid/Femara/Letrazole cycles or multiple cycles of timed intercourse or IUIs without sufficient monitoring.
8	Better data tracking of both partners in all couples pursuing infertility evaluations. We need a better sense for the denominator of patients.
9	Education related to best health practices, particularly regarding the hormonal impacts of obesity and the pesticides, preservatives, and plastics in our food and environment, may help empower women to optimize their fertility options.

10	The seminars should include topics of adjunct non-ART treatments, so that patients understand their scientific values if any, and limits that one can depend on them. There should not be any exploitation of patients by such agencies who may offer such services.
11	Understanding Risk
12	Data collection, standardization.
13	It would be helpful to have a database like SART for gonadotropin treatments with OB outcomes. The more that IVF is accessible, the less people would do treatments like gonadotropins with an increased risk of multiple gestation.
14	Media talks and press news with accurate data using influential and well known spokesmen/women
15	Stimulated ovulation without monitor contributes to multiple pregnancy.
16	Databank of all ovulation induction/superovulation cycles performed, regardless of agent used.

Appendix C

Work Group Discussion Questions and Responses

Provider Practice

Discussion Questions/Responses:

1. What are we currently doing well with respect to promoting and implementing ART best practices in Michigan, particularly those that reduce the risk of twins/higher order multiples and preterm birth?

- ☐ Public funded insurance as well as employer sponsored insurance has made obstetrical care available more universally.
- ☐ Provide good quality ART.
- ☐ Working to reduce the stigma so that people are more willing to talk about it.

2. What are the opportunities for improving clinical/provider practice when it comes to infertility treatment and ART in Michigan, particularly practices that reduce the risk of twins/higher order multiples and preterm birth (what are the challenges, what needs our attention)? Please consider disparities in access, legal/ethical issues, as well as how the future of ART and the changing health care landscape could affect provider practice.

- ☐ Outcome based data needed.
- ☐ Single frozen embryo transfer.
- ☐ Psychological assessment/diagnosis – needed to qualify for insurance coverage.
- ☐ Patients and providers have different expectations.
    - Emotional/costs
    - Stress levels
- ☐ Misconception in mental health field about trauma.
- ☐ Represent outcomes to patients.
- ☐ Appropriate selection and optimization of the medical status of potential patients.

3. What are the essential needs--including both resources and actions—that are necessary to improve ART clinical/provider practices in Michigan, particularly those that reduce the risk of twins/higher order multiples and preterm birth?

- ☐ Cost reduction.
- ☐ Insurance coverage mandate.
- ☐ Professional political action group formation.
- ☐ Education (ASRM) materials.

4. Given the opportunities and essential needs described by the group, what recommendations do you have for state action to improve ART clinical/provider practices? In particular, consider recommendations that would be feasible to address in the next one to two years.

- ☐ Increase insurance coverage with single embryo transfer (SET).
  - Fresh #1 < 38 yr. old + 2 frozen (mandate SET for patients less than 38 years of age and include frozen embryo transfer).
  - Mandate SET.
- ☐ Encourage SET when it is likely to be successful – define success as well as balance safety.
- ☐ Encourage honest reporting and rewarding of clinics who encourage SET.
- ☐ Encourage infertility research and funding for this research.
  - Ensure research has valid control groups.
  - Include research on patient perceptions and needs/wants.
- ☐ Increase psychological support ($$) – ensure patients have the mental and emotional support they need.
- ☐ Enhance fertility preservation education.
  - More standardized education.
  - Provide education on fertility and fertility preservation options.
  - Enhance ASRM reproductive facts.
  - Counsel: Implantation rate equals success.

Policy/Insurance Coverage

Discussion Questions/Responses:

1. What, if anything, are we currently doing well with respect to ART policies and insurance coverage in Michigan, particularly policies/coverage that promote access and ensure the implementation of best practices to reduce the risk of multiple birth and preterm birth?

- ☐ Having a conversation about the issue.
  - The issue is on the table.
  - Continued conversations.
- ☐ Interest in the topic.

2. What are the opportunities for developing policies and promoting insurance coverage to improve ART access and best practices in Michigan (what are the challenges, what needs our attention)? Please consider disparities in access, legal/ethical issues, as well as how the future of ART and the changing health care landscape could affect policies and insurance coverage for ART.

- ☐ More coordination in relation to:
  - Players working together.
    - Also need to bring in neonatologists, MFMs (Maternal-Fetal Medicine), and pediatricians (lack of their presence at the Summit).
  - Formal mechanisms to keep momentum.
  - Michigan Alliance for Reproductive Technology and Sciences (MI-ARTS) – coordinate with them.
  - Learning from others.
  - One voice presented at once (all of the medical specialists).
  - Communicating the true benefit.
  - Numbers/clinical utility.
  - HCPs – continuity of care.
- ☐ Need to determine what is the message that advocates should present/demand/push for.
- ☐ Need to know what insurers need in order to cover treatment.
  - Conversations have not taken place on what is needed to cover treatment (data on what the benefit design should be).
  - Need to understand what the payers are afraid of.
  - Need to provide information to insurers regarding coverage needs for ART.
- ☐ Submit a claim even if it is not covered because it is tracked.
- ☐ Change infertility to fertility.
- ☐ Goal of a healthy child – use this as an incentive.

- ☐ Use eSET (elective single embryo transfer) as carrot/bait.
- ☐ Cover treatment when fertility preservation is needed due to cancer/chemo therapy.
- ☐ Canada – 1st free care; fertility switched to tax credit.

3. What are the essential needs--including both resources and actions—that are necessary to develop and implement ART policies and increase insurance coverage for ART in Michigan, particularly policies/coverage that ensure the implementation of best practices to reduce the risk of multiple birth and preterm birth?

- ☐ Birth of a healthy child.
- ☐ One voice for medical professionals (including OBGYNs/Neonatologists).
- ☐ One succinct message from ALL.
- ☐ Continuity of care.
- ☐ Massachusetts state demonstration.
- ☐ Education.
- ☐ Data on cost to payers/insurers that is persuasive.
- ☐ Data on cost to families/lost income to families.
- ☐ Money.
- ☐ How does pharma relate.

4. Given the opportunities and essential needs described by the group, what recommendations do you have for state action to improve ART policies and insurance coverage? In particular, consider recommendations that would be feasible to address in the next one to two years.

- ☐ Communicate why it is important/the ultimate goal: Birth of a healthy child.
- ☐ Need to account for diversity of those who seek ART (e.g. identify various groups seeking ART, couples with infertility, cancer patients, same sex couples who wish to have a family, etc.).
- ☐ Convene a second meeting/summit (MI ART take the lead) – Bring together more stakeholders not represented at the 1st Summit, get missing groups/partners to the table:
    - Insurers
    - Employers (particularly large, self-funded employers)
    - Other medical professionals
        - Neonatologists
        - Pediatricians
        - Medical geneticists (in particular for those couples who must use ART to conceive due to genetic issues or match up issues between the couple)
        - Maternal-Fetal Medicine practitioners
- ☐ Facilitate a meeting with insurers and 3rd party payers (MI ART take the lead):

- Seek perspective.
- Foster open dialogue on both sides.
- Form relationships.
- Build bridges.
- Find out why they do not cover ART and better understand what information they need to consider coverage.

☐ Facilitate discussion with largest employers in Michigan (MI ART take the lead):
- Seek perspective, foster dialogue, form relationships, build bridges.
- Find out why infertility treatments may not be covered in employee benefit packages and what they need to include this coverage.

☐ Let open dialogue drive/determine next steps for policy and insurance coverage.

☐ Additional notes:
- Create a benefit consulting firm that could be the expert on coverage design and inform insurers if they were interested in adding ART as a covered benefit.
- Look at "high uptake" groups on coverage and see what they used to get coverage for services.

Patient Education

Discussion Questions/Responses:

1. What are we currently doing well with respect to educating patients and consumers about infertility treatment options, specifically, options available through ART that may reduce the risks of multiple births and preterm birth?

- ☐ CDC's "Healthy Babies: One at a time" materials are a good resource.

2. What are the opportunities for improving patient education about infertility treatment and ART in Michigan (what are the challenges, what needs our attention)? Please consider disparities in access, legal/ethical issues, as well as how the future of ART and the changing health care landscape could affect ART patient education.

Provider-Focused Opportunities

- ☐ Provider education on infertility diagnosis, treatments, and ART.
    - Education for general practitioners, OBGYNs, Urologists.
        - Greater understanding of male/female reproduction.
        - Increased awareness of infertility.
    - Education on basic fertility treatment guidelines (especially for OBGYNs).
        - When to refer out.
        - How to monitor difference treatment plans (u/s with cc cycles).
    - Educate OBGYN offices about difference treatment options available:
        - IVF
        - IUI
        - Donor sperm
        - Donor egg
        - Gestational carrier
    - Education on the male factor side of infertility – include OBGYNs in education on the male factor side.
    - Getting the word out about latest techniques and technologies (address lack of updated information).
    - Better train and prepare providers for patient education.
        - Provide more standardized information about infertility and treatment options.
        - Provide standardized patient education materials.
        - Helps to ensure patients are receiving consistent information.
    - Encourage/support more time for providers to read latest medical journals that include information/studies on the most up-to-date science/technologies.
    - Hold regional educational seminars for general practitioners, OBGYNs, etc.

- Make it easier for clinic staff to attend conferences and continuing education programs.

- ☐ Create better working relationships among providers and specialists – general practitioners, OBGYNs, REIs, MFMs, etc. (better coordinated care, information sharing, cross-communication, knowledge of when to refer out and who to refer to).
- ☐ Encourage providers to spend more time with patients.
- ☐ Get more providers on-board with SET.

<u>Patient/Public-Focused Opportunities</u>

- ☐ Increase education to the public about fertility and infertility.
  - Start early – include education on infertility prevention and treatment during reproductive health/sex education classes in school.
  - Increase general/baseline knowledge about reproduction and reproductive health.
  - Increase general/baseline knowledge about infertility, pregnancy loss, and other reproductive risks.
  - Increase awareness of grief, loss, and stress experienced by those with infertility, as well as the overall mental/emotional toll of infertility.
  - Increase general knowledge about the risks of twins and multiple births to mothers and infants – both during and after pregnancy (e.g. increased risk for post-partum depression).
- ☐ Offer regional seminars for patients – ensure seminars are science-based vs. commercial-based (i.e. one practice promoting its own services).
- ☐ Provide education through scientific talk shows or Internet channels (e.g., YouTube videos, Ted Talks, etc.); though ensure patients/public know how to identify and access credible sources of information, especially on the Internet.
- ☐ Use science and knowledge as a tool to education patients.
- ☐ Provide better education about the mental and emotional toll of infertility.
- ☐ Provide standardized education information and materials, so that patients are receiving consistent information.
- ☐ Develop and implement a Michigan-specific, state-wide, comprehensive and consistent public awareness and patient education campaign about infertility, treatment and ART in Michigan.
  - Include multiple materials, medium, and points of access for reliable and credible information; ensure information/materials are designed for diverse audiences:
    - Infographics
    - Centralized, credible, quality website.

        - Credible social media.
        - Videos (including videos of personal stories).
        - Brochures.
        - Directory of resources.
        - Support groups.
        - Provider-driven channels.
        - Patient-driven channels.
        - Governor's Proclamation (recognizing those experiencing infertility – could be issued sometime between Mother's Day and Father's Day to help raise awareness of the issue).
    - Include information regarding:
        - Where to go for good/accurate information (reliable sources).
        - How to choose a provider/what to look for.
            - ☐ Education to the consumer/patient that they do have a choice where they get treatment.
            - ☐ Education to the patient on how to look at options for other clinics – such as CDC/SART data.
        - What patients can expect from providers and process of infertility diagnosis and treatment (e.g. time between IUI, IVF, etc.).
        - What providers may expect from patients/families.
        - What questions to ask during consultations/dr. visits.
        - What treatment options are available, how they differ, and why some options may be feasible/appropriate for some and not for others (e.g. IUI vs. IVF; fresh vs. frozen embryos; donor vs. own egg/sperm, etc.).
            - ☐ Include more education on how embryos fare through freezing, thawing, and refreezing (since they are stored more than one to a straw).
            - ☐ What embryos can go through with transplantation.
            - ☐ Education about PGS (Pre-Implantation Genetic Screening) in order to increase the incidence of eSET transfers in IVF.
        - Emotional and stress management
            - ☐ How to handle the mental/emotional toll.
            - ☐ How to deal with the stress of infertility and undergoing treatment (may help patients be more willing to go through multiple rounds of SET vs. less rounds of higher embryo transfers).
            - ☐ How to manage emotional burnout.
            - ☐ Mental health support resources.
    - More information/materials on the risk of twins/multiple births, including preterm birth and problems associated with multiple/preterm birth.

        - Include information on potential complications related to multiples/twins - many patients are not aware of the added risks, problems, long-term health effects, and costs of having twins or multiples; may be helpful to put this in relation to the costs of going through multiple cycles of IVF with SET (estimate the cost/benefit; return on investment).
        - Include stories on potential negative outcomes of twins/multiples; we often only hear the success stories of multiple births.
        - Need to think about how to get passed the "cloud of judgement" the patient may be experiencing when facing infertility and the burden of treatment (they either want a greater "bang for their buck" or can't face going through more cycles); may be helpful to highlight more long-term risks/costs in addition to immediate medical risks.
    - Include information on infertility/pregnancy loss rates so that those experiencing infertility/pregnancy loss don't feel so alone.
    - Include information and educational materials that address disparities, myths, stereotypes, and social stigmas associated with infertility; promote tolerance and understanding.
    - Promote more support groups.
    - Create more user-friendly and safe platforms that allow people to come together.

<u>Educating Legislators/Policy Makers</u>

- ☐ Educate legislators and policy makers about infertility and pregnancy loss; make it less taboo to talk about; help guide the conversation publically.
- ☐ Host seminars and invite local congressmen as guests.
- ☐ Educate politicians and encourage them to take action to address people's needs.

<u>General Opportunities</u>

- ☐ Provide more summits (or opportunities like the summit) to keep the conversation going.
    - Facilitates a lot of different ideas and perspectives coming together.
    - Allows for providers and patients/consumers to share information and experiences outside of individual clinics/visits or consults.
- ☐ Promote development of more education pieces and initiatives such as the CDC's *Healthy Babies: One at a time* materials.
- ☐ Raising awareness is #1 priority.

3. What are the essential needs--including both resources and actions—that are necessary to improve ART patient education in Michigan, particularly education about associated risks of multiple birth and preterm birth?

- ☐ Education for patients.
- ☐ Education for general physicians.
- ☐ Education for OBGYNs/Urologists.
- ☐ Politician/policy-maker education and involvement.
- ☐ State funding for pilot studies examining awareness of infertility compares to breast cancer or AIDS; use this to start a dialogue.
- ☐ More comprehensive reproductive health/sex education in schools.
- ☐ More education resources for patients so they can make better informed decisions.
- ☐ Funding.

4. Given the opportunities and essential needs described by the group, what recommendations do you have for state action to improve ART patient education? In particular, consider recommendations that would be feasible to address in the next one to two years.

- ☐ Education initiatives to improve widespread awareness of fertility, infertility, and impact of ART treatments on the health of women and infants.
    - In particular, develop and implement a Michigan-specific, state-wide, comprehensive and consistent public awareness and patient education campaign about infertility, treatment and ART in Michigan, as described under question 2 above.
- ☐ Better understanding of the patient experience so that more effective and relatable patient education initiatives, messages, and materials can be developed about potential risks of twin/multiple births and benefits of SET.
- ☐ Increased provider education (as described under question 2 above) to help facilitate improved patient education in the provider setting.
- ☐ Disseminate existing resources from RESOLVE and CDC (Having Healthy Babies: One at a time) to wider audiences.
- ☐ Physicians/providers need to get on board with SET. Too many are still recommending transferring more than one embryo when there is no reason to (e.g., patient is young, no previous losses, etc.).
- ☐ Physicians and patients come up with a treatment plan and stick to it.

Implementing top recommendations (if time allows, please discuss; otherwise note on ½ sheet handout):

a. What can MDHHS do specifically to address these recommendations and improve ART patient education in Michigan?
    - ☐ Convene nurse advisory board to work with OBGYNs/REIs to create education materials.
    - ☐ Bullet point educational guides that could be linked to by social media.
    - ☐ Education on social media with information on fertility and treatment options, choices.

b. What can your organization/institution do to help address the ART patient education recommendations identified by the group?
    - ☐ Participate on nurse advocacy groups/nurse advisory board.
    - ☐ We try to spend time (i.e. lunch, staff meetings) with referring practices to provide information about basic recommendations for treatment of infertility patients.
    - ☐ Providing the patient with education and resources to educate. Making sure our patients are making informed decisions.

Contributing Risks from Non-ART Treatments

Discussion Questions/Responses:

1. What, if anything, are we currently doing well with respect to understanding the use of non-ART/IVF treatments, their contribution to multiple birth and preterm birth in Michigan, and opportunities for prevention?

- ☐ Estimated contribution of non-IVF to multiple birth (nationally and in Michigan).
- ☐ Understanding the risk and lack of control with non-ART treatments.
- ☐ New technologies all the time; advancement of care and treatment options (i.e., testing with Ob/Gyn general list; with FP providers); may need preliminary documentation for referral to fertility clinic.
- ☐ Screening data available.
- ☐ Non-ART treatments are valuable when there are specific issues, including:
    - Financial barriers to IVF
    - Orthodox Jews - timing of fertility around menstrual cycle
- ☐ Industry: patient education materials (i.e. pharmaceutical industry creates good patient education materials).
- ☐ CDC – Singleton education materials.
- ☐ Studies that show non-ART contribution to multiples.
- ☐ Industry and insurance has data on number of patients with access to Femara and Clomid therapy.
- ☐ RE education to Ob/Gyn.
- ☐ Industry: education to Ob/Gyn.

2. What are the opportunities for improving our understanding of the use of non-ART/IVF treatments, their contribution to multiple birth and preterm birth in Michigan, and options to prevent multiple births due to these treatments (what are the challenges, what needs our attention)? Please consider disparities in access, legal/ethical issues, as well as how the future of ART and the changing health care landscape could affect our ability to understand the use, contribution, and prevention of non-ART/IVF on multiple birth/preterm birth.

- ☐ Education/information that takes patient psyche (psychological state) and information load into account.
- ☐ Health campaigns to provide education on infertility and treatments (public communication campaigns).
- ☐ Initial screening of male partners.
- ☐ Predictive modeling on individual patients.
- ☐ Family planning discussions – document on EMR/reproductive life plan.

- ☐ Advocate for children's health in addition to women's health.
- ☐ Statewide registry.
- ☐ Start collecting non-ART data in Michigan.
- ☐ Collect information about non-IVF treatments.
- ☐ Use predictive models to make better decisions regarding when to switch to IVF.
- ☐ Define non-IVF treatment.
- ☐ Better guidelines.
- ☐ Better patient education.
- ☐ CDC education on non-ART practices.
- ☐ Better non-ART data as it relates to multiples.
- ☐ More coverage for IVF in Michigan.
- ☐ Clearer Michigan state guidelines or state principles for non-ART fertility treatment:
    - Limit oral therapies by age.
    - Include analysis of male fertility prior to oral agents.
    - Standard test to assess fertility.
    - Provide family planning discussions at ages 29-34.
- ☐ Non-ART with lower dose of O1 – cycle cancelation of OHSS or multiple follicles, selected reduction of fetuses.
- ☐ Misuse of O1 medication and without monitoring, out of control.
- ☐ Patient's intention of having twins.
- ☐ Non-ART is much cheaper; if ART can be covered by insurance, then the situation will be changed.
- ☐ Would help to have evidence that ART is as safe as natural pregnancy to both maternal and infant.
- ☐ Rural areas and Upper Peninsula lack fertility providers; need to expand telemedicine
- ☐ Preconception education; prevention of STDs, early treatment.
- ☐ Educate providers – provider cultural issues – education for generalists and fertility specialists.
- ☐ Education regarding what happens with preterm birth – how there is an increased risk with increased number of babies.

3. What are the <u>essential needs</u>--including both resources and actions—that are necessary to better understand the use of non-ART/IVF treatments, their contribution to multiple birth and preterm birth, and options to prevent multiple births due to these treatments in Michigan?

- ☐ Data!!!
- ☐ Database (e.g. MICR) to include patient ID, non-IVF (need to explore whether this could be added to an existing database or if a new type of database/registry would need to be developed).

- ☐ Patient education on the risks and true implications/challenges of multiples and preterm birth.

4. Given the opportunities and essential needs described by the group, what recommendations do you have for state action to improve our understanding of the use of non-ART/IVF treatments, their contribution to multiple birth and preterm birth, and opportunities for prevention? In particular, consider recommendations that would be feasible to address in the next one to two years.

- ☐ Increase surveillance/data – increase state access to surveillance data (perhaps there are data sources and tracking processes already in place that can be leveraged).
- ☐ Provide more education, starting at younger ages.
    - Added concept of a "reproductive life plan" to health curricula starting in high school (or younger).
    - Included information on fertility and infertility.
    - Integrate into preconception education.
- ☐ Provide more education on the risks of higher order multiples and what to expect with preterm births, including the inherent stressors involved with NICU stays (e.g., financial, emotional, time requirements, etc.).
- ☐ Implement recommendations and/or guidelines for the administration of non-ART therapies/pharmaceutical agents.
- ☐ Use non-ART therapies less, if possible.
- ☐ Increase access (e.g. geographic, economic, etc.) to ART/IVF therapies; if there is more coverage for ART/IVF, people may use non-ART less.

Implementing top recommendations (if time allows, please discuss; otherwise note on ½ sheet handout):

a. What can MDHHS do specifically to address these recommendations and improve our understanding of the use of non-ART/IVF treatments, their contribution to multiple birth and preterm birth, and opportunities for prevention in Michigan?
    - ☐ Collect more data to show the advantages of ART.
    - ☐ Underwrite the medications used in ART.
    - ☐ Share state-level data for issue, or create a registry for surveillance; could help in making recommendations or developing education pieces.

b. What can your organization/institution do to help address these recommendations and improve our understanding of the use of non-ART/IVF treatments, their contribution to multiple birth and preterm birth, and opportunities for prevention in Michigan?

- ☐ Follow the indications of O1 and non-ART to reduce the side effects.
- ☐ Access to data already collected on products that contribute to non-ART cycles written by non-IVF providers.
- ☐ Models for insurance fertility benefit.

Appendix D

Michigan Infertility Advisory Committee Members

Voting members:

a) Five reproductive endocrinologists and infertility specialists:

1. Richard Leach, MD , FACOG, FACS
   Professor and Chair
   Obstetrics, Gynecology and Reproductive Biology
   College of Human Medicine
   Michigan State University

2. Michael Mersol-Barg, MD
   Medical and Laboratory Director
   Michigan Reproductive Medicine
   Associate Professor of Obstetrics & Gynecology
   Oakland University, William Beaumont School of Medicine and
   Wayne State University School of Medicine.

3. John Randolph, MD
   Professor, Obstetrics & Gynecology
   University of Michigan

4. Stephen A. Krawetz, PhD
   Professor of Obstetrics and Gynecology, and of Molecular Medicine and Genetics
   Charlotte B. Failing, Professor of Fetal Therapy and Diagnosis
   Associate Director, C.S. Mott Center for Human Growth and Development
   Wayne State University

5. -Vacant-

b) One embryologist:
   Gary Smith, PhD
   Professor, Molecular & Integrative Physiology
   Professor, Ob/Gyn
   Professor, Urology
   Director, MStem Cell Laboratories
   Co-Director, Reproductive Sciences Program
   University of Michigan

c) One ethicist or IRB member – academia:
Lance Adam Gable, MPH, JD
Associate Dean
Wayne State University School of Law

d) One genetic counselor:
Debra Duquette, MS, CGC
Adult Genetics/Genomics Coordinator
Michigan Department of Health and Human Services

e) Two perinatologists / Maternal Fetal Medicine specialists:
1. Federico Mariona, MD
Maternal/Fetal Medicine
Obstetrics/Gynecology
Beaumont (formerly Oakwood)

2. Dotun Ogunyemi, MD
Maternal Fetal Medicine
Obstetrics & Gynecology
Beaumont

f) Two neonatologists from a tertiary center (level three with NICU):
1. Robert Schumacher, MD
Professor, Neonatal-Perinatal Medicine
C.S. Mott Children's Hospital
University of Michigan

2. -Vacant-

g) One scientist/epidemiologist:
Galit Dunietz, PhD, MPH
Postdoctoral Research Fellow, Neurology
University of Michigan

h) One representative from MDHHS, Population Health Administration/Lifecourse Epidemiology & Genomics Division:
Patricia McKane, DVM, MPH
Director, Lifecourse Epidemiology & Genomics Division
Michigan Department of Health and Human Services

i) One representative from health insurance (BCBSM or Priority Health):
-Vacant-

Non-voting members:

a) One MDHHS IRB:
Ian Horste
Institutional Review Board Administrator and Chair
Michigan Department of Health and Human Services

b) One MDHHS Vital Statistics:
Glenn Copeland
Director, Division for Vital Records and Health Statistics
Michigan Department of Health and Human Services

c) One epidemiologist MDHHS:
-Vacant-

d) One program staff MDHHS:
Brenda Fink
Director, Family and Community Health Division
Michigan Department of Health and Human Services

e) One CDC representative – project officer:
Dmitry Kissin, MD
Epidemiologist
Division of Reproductive Health
Centers for Disease Control and Prevention

f) One representative from March of Dimes:
Kara Hamilton
State Director of Program Services and Advocacy
March of Dimes – Michigan Chapter

g) One infertile patient/couple:
-Vacant-

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For more information about this report, please contact:
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