Assisted Reproductive Technology Program Reporting System

OMB No. 0920-0556

Public Comments and CDC Response

Federal Register Notice: A 60-day Notice was published in the *Federal Register* on July 21, 2014, Vol. 79, No. 139, pp. 42328-42329.

Seven public comments were submitted to CDC for consideration. This attachment includes all comments and a summary of actions taken by CDC in response to the comments.

Public Comment #1

From: Merritt, Thurman [mailto:TAMerritt@llu.edu]
Sent: Sunday, August 31, 2014 10:09 PM
To: Kissin, Dmitry (CDC/ONDIEH/NCCDPHP)
Cc: OMB-Comments (CDC)
Subject: RE: Response to request for Public Comment and in response to Federal Register (Vol 79, No. 139, July 21, 2014.

Thank you for providing me suggested changes in the NASS data collection variables. In response to your inquiry and the request for public comment in the Federal Register. Although the Assisted Reproductive Technology Team have provided an outstanding public service regarding documentation for consumers, researcher, and individual clinics within states and territories, I would to submit the following suggestions.

Because infant outcomes, in addition to, success or failure of IVF procedures and specific information being collected in the "Added Variables" it would be important for the NASS and Assisted Reproductive Technology Team to consider adding variables relating to infant outcomes (as listed below)

1. Use of traditional or gestational surrogate carriers:
   Surrogate age, numnber of prior pregnancies, number of previous live born infants, number of prior surrogaacy (either gestational carrier or traditional surrogate).

2. Maternal variables: occurrence of pregnancy induced hypertension, maternal diabetes and stage, hyperemesis gravidarium, fetal ultrasound results with special focus on fetal echocardiogram at 20-24 weeks

3. Placental examination: placental abnormalities, evidence of single umbilical artery, histologic chorioamnionitis, in twins or multiple gestations presence of twin to twin transfusion syndrome associated with artery-venous shunting in the placenta, placentation (diamniontic-dichorionic, monochorionic-diamniontic, and placentation of greater than twin).

4. Neonatal Variables Suggested to be added:

   A) Infant Weight, Length, and Head Circumference
   B) Infant Gestational age as determined by Ballard Physical and Neurodevelopment examination
   C) Admission to Neonatal Intensive Care Unit
   D)Specific Neonatal Variables:
      1. Apgar Scores as 1 and 5 minutes, requirement for resuscitation
      2. NICU admission,
      3. Length of Hospital Stay,
      4. Time (in days) to regain birth weight
      5. Specific Neonatal Morbilities:
         a. Occurrence of Respiratory Distress Syndrome,
         b. Presence of patent ductus arterioles,
         c. Hyperbilirubinemia requiring A) phototherapy and/or B) exchange transfusion and maximum total serum bilirubin,
         d. Occurrence of intraventricular hemorrhages by grade (Papille) i.e.. Grade I to IV,
         e. Occurrence of periventricular leukomalacia,
         f. Occurrence of necrotizing enterocolitis using the Bell scoring system,
         g. Occurrence of electrographic seizures,
         h. Did the infant pass the newborn hearing screen,

i. Abnormalities on the Newborn Metabolic Screen,

J. Results of the screen for congenital heart disease (Upper and Lower Sp02 after 24 hours),

k. Occurrence of minor and major phenotypic anomalies, occurrence of specific syndromes including imprinting disorders,

l. Karyotype results (if performed), results of chromosomal arrays (if performed).

I would be pleased to speak representative to the National ART Surveillance program or provide further comments if required.

Very sincerely,

T. Allen Merritt, MD MHA
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(909) 558-7448
909 362 3023 (mobile)

Public Comment #2

From: Ricardo Loret de Mola [mailto:rloretdemola@siumed.edu]
Sent: Tuesday, September 02, 2014 9:48 AM
To: OMB-Comments (CDC)
Subject: CDC addition of terms for ART Reporting

Leroy Richardson
1600 Clifton Rd, MS-D74
Atlanta, GA 30333
email: omb@cdc.gov

Dear Mr Richardson
The CDC's proposed changes in collection will result in the addition of 24 variables, deletion of 16, and modification of 47 variables. Only 33 currently collected data variables will remain unchanged. Each variable typically has several data field / input options. Based on the Office of Management and Budget (OMB) calculations this will increase burden per cycle reported which is not reimursable and feel that these changes are unnecessary. In addition rather than focusing on programs that are in compliance with reporting guidelines, I suggest that the agency focuses on clamping down on the dozens of programs that currently do not report and patients/consumers do not know the quality of care that is being provided.

Best wishes

J. Ricardo Loret de Mola MD
Medical Director, SIU Fertility and IVF

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Public Comment #3

From: Ajay Nangia [mailto:anangia@kumc.edu]
Sent: Friday, September 05, 2014 2:19 PM
To: OMB-Comments (CDC)
Subject: male data points on ART report - public comment period

Dear Mr Richardson,
in terms of the male data points planned can you please clarify these data points are included in the new planned data collection:

Reason for ART (Select all that apply): Male infertility (select all that apply)	
[SKIP IF MALE INFERTILITY NOT SELECTED]	☐ Medical condition ☐ Genetic or chromosomal abnormality Specify_____ ☐ Abnormal sperm parameters (select all that apply) Azoospermia, obstructive Azoospermia, non-obstructive Oligospermia, severe (<5 million/mL) Oligospermia, moderate (5-15 million/mL) Low motility (<40%) Low morphology (4%) ☐ Other male factor (not included above) Specify_____

Thank you for allowing us the opportunity to comment.

Sincerely
AN

Ajay K. Nangia MBBS, FACS
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Public Comment #4

From: Richard Sherbahn [mailto:rsherbahn@advancedfertility.com]
Sent: Friday, September 12, 2014 9:06 AM
To: OMB-Comments (CDC)
Subject: modification to annual data collection for ART clinics

In my opinion there is already too much data collected which requires too much time and money to collect and record. It is increasing endlessly over time and serves no legitimate purpose. There should be no further changes other than reducing (not increasing) data collection.

Richard Sherbahn

Richard Sherbahn MD
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http://www.advancedfertility.com

Public Comment #5

From: Forest Garner [mailto:forest@fertilitycenterlv.com]
Sent: Thursday, September 11, 2014 7:39 PM
To: OMB-Comments (CDC)
Subject: Attention Leroy Richardson: CDC Federal Register Notice for Reporting Changes for ART Reporting

Regarding proposed changes to the CDC's collection of information about Assisted Reproductive Technologies (ART):

I recommend the following added fields:

Method of delivery (Vaginal or C-section)
Indication for c-section (if c-section used) (Prior c-section, Overdue delivery, Medical complication, Non-medical indication/Patient preference)

This will take less than two additional minutes per cycle with live birth (zero for cycles without birth), as this information is almost always in the documents we routinely obtain.

Rationale:

Some reports indicate c-section delivery is more common with frozen-thawed embryo transfer. It is also reported that frozen-thawed embryo transfer is associated with larger birthweights. These two variables might be causally related, or might be confounded in assessments of perinatal outcomes. Consider that large infants can motivate a c-section, FET cycles often follow a fresh delivery that might have used a c-section and thus create an indication for c-section, and c-sections abbreviate a pregnancy so that birth by c-section occurs some hours or days earlier than otherwise would have.

Forest Garner
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Public Comment #6

From: John Frattarelli [mailto:jfrattarelli@armghawaii.com]
Sent: Thursday, September 11, 2014 8:24 PM
To: OMB-Comments (CDC)
Subject: modifications to annual ART data collections

To Whom It May Concern:

I am opposed to the current modifications for annual data collections. As a small business, the data collection is extremely burdensome to us. The increased cost and time is enormous. The estimated time of 39 minutes with an additional 1 minute added because of the modifications is extremely inaccurate. As a small practice that is run very efficiently, I can guarantee that each patient requires approximately 3 hours of time entering, checking, verifying and submitting our ART data. Yes –not 39 minutes but instead 180+ minutes! This is an added burden to the clinic and ultimately the cost is passed onto the patient. Since it is preached that these rates are not valid for comparing clinic, I would suggest that we curtail the data collection to a bare minimum in order to relieve the burden on the clinics and patients.

Sincerely,
John L. Frattarelli, M.D.

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Public Comment #7

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

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September 17, 2014

Leroy Richardson
Chief, Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Rd, MS-D74
Atlanta, GA 30333

Dear Mr. Richardson:

The American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) are writing to comment on proposed changes to the National ART Surveillance System (NASS) announced in the Federal Register on July 21, 2014. These proposed changes represent a significant modification to the annual data collection process required by law for ART clinics.

ASRM is a voluntary, non-profit organization devoted to advancing knowledge and expertise in reproductive medicine, including infertility, menopause, contraception, and sexuality. Founded in 1944, we are an organization of more than 8,000 physicians, researchers, nurses, technicians, and other professionals.

SART is an organization of nearly 400 member practices performing more than 95% of the assisted reproductive technology (ART) cycles in the United States. SART's mission is to set and help maintain the highest medical and professional standards for ART. SART works with the ASRM to create practice guidelines and minimum standards of care. SART is also actively involved in the collection of data outcomes from its member programs.

Our organizations are unwavering in our support of improving patient care. As the medical specialists who provide treatment options for patients and perform procedures during what is often an emotional time for them, we recognize how important it is that they have valid information about treatment outcomes. Indeed, it is the primary reason that we are involved in the collection and reporting of ART outcomes – we believe this reporting does improve care. SART has been collecting data on ART outcomes since 1985 and making that information available to the public. We feel very strongly about our contribution to this activity and intend to continue to collect this data and make it publicly available.

However, we are compelled to state that the collection of ART outcomes by the CDC is in fact duplicative of the work SART already does. We raise the

issue about the duplicative nature of this data collection process because it is important, and especially during this time of our nation's unacceptable debt levels, that needless and perhaps wasteful government spending be reduced or eliminated and certainly balanced against the additional value the duplication provides, if any. The additional expenditure by the CDC on the collection of data in 2012 only led to an increase of six percent in the total number of cycles reported. The cost of the collection to the federal government and taxpayers, compared to the yield, does not seem warranted. Moreover, this still does not capture all of the ART cycles performed in the U.S. It is in this context that we provide the following comments.

While a number of the changes in the data the CDC proposes to collect may be useful to know, several proposed data points we consider to go beyond the mandate established by the Fertility Clinic Success Rate and Certification Act of 1992, and its implementing regulations. For instance, fields related to quality assurance and diagnostic measures fall into a category that is ancillary to data about ART use and birth outcomes. Because the CDC is not tasked with collecting and reporting on measures beyond the national rates of pregnancy and live birth achieved using ART, as well as clinic specific live birth rates, we feel certain that these proposed data points potentially infringe on the manner in which this area of medicine is practiced and do not belong in this kind of reporting. Two examples of data collection that go beyond the CDC's mandate include information related to the quality of any embryo considered for transfer and prior ART cycles resulting in pregnancy. Again, while this information may be useful to know and can guide what occurs in the course of the medical treatment, this information is not about ART outcomes.

Further, ASRM and SART believe that the time burden for clinics, the majority of which are small businesses, is vastly underestimated by the CDC both in terms of fixed costs of personnel, as well as the costs of software modifications that will certainly be required. We object to the burden of time and expense the new NASS fields will impose on SART clinics. These changes will necessitate the creation or modification of bridge software so that the SART systems can speak to the NASS system. The changes may also require the redesign of practices' internal record-systems to facilitate the reporting. Personnel will certainly need additional training. The calculation that the proposed reporting requirements will only increase reporting time by a negligible amount is improbable.

SART is in the process of building an improved data collection system to make it easier for its member clinics to collect and report data to SART. We do not oppose the collection of many of the data points proposed by the CDC, and in fact, many are already collected by SART. Rather, our objections lie in the fact that the reporting itself is duplicative already, and to add additional data points that are outside the scope of the CDC's mandate is problematic and unjustified.

We appreciate the opportunity to comment on the proposed changes to the NASS Surveillance System and are open to further discussions on this matter.

Sincerely,

Rebecca Sokol, MD, MPH
President ASRM

Charles Coddington, MD
President SART

Summary of Public Comments and CDC Responses

Type of Comment	Comments	Draft ICR (Prepared for Public Comments)	Revised ICR and Response (Presented to OMB for review and approval)
Comments on burden estimate (From comment #2, #4, #6 & #7)	1. Burden underestimated 2. System implementation not included in total burden	The estimated burden for reporting one ART cycle (per response) is 40 minutes which is an average across clinics.	1. Increased the average burden to 43 minutes per response. 2. Added a one-time system implementation for each clinic (40 hours per each response) to update their data collection system to reflect the new platform and interface of the NASS web-application over a 3-year clearance period. The estimated annual burden to clinics is calculated using the average time required to answer the number of questions and possible responses to each question when applicable. We acknowledge that there is an additional burden for the first year of this transition associated with making the appropriate software modifications that was not represented in the Federal Register Notice published on July 21, 2014. In order to minimize the impact of this burden on clinic operations, clinics will have a full calendar year to implement changes, as the new data collection system will be implemented January 1, 2016. We have also recalculated the burden for the first year to include the fixed burden associated with changes to the data collection systems in each clinic.
Comments on proposed data elements (From comment #7)	Proposed data points were considered to go beyond the mandate established by the Fertility Clinic Success Rate and Certification Act of 1992, and it's	Changes to the NASS data elements are essential to keep pace with changes in medical practice, ensure that reported success rates reflect standardized definitions, and provide additional	Regards to the addition of variables such as embryo quality and the number of prior ART cycles, the NASS system collects information on ART outcomes as well as other patient and

	implementing regulations. Two examples of data collection that go beyond the CDC's mandate include information related to the quality of any embryo considered for transfer and prior ART cycles resulting in pregnancy. These variables not related to treatment outcomes.	insight into factors that may affect success rates.	procedure characteristics that may affect treatment outcomes. The reporting of success rates by patient and procedure factors allows consumers to see success rates for patients similar to themselves and undergoing procedures with similar characteristics. Presenting success rates without taking patient and procedural characteristics into account can produce misleading rates.
Comments on duplication of data collection (From comment #7)	The collection of ART outcomes by the CDC is in fact duplicative of the work SART already does. The issue about the duplicative nature of this data collection process is important, and especially during this time of our nation's unacceptable debt levels, that needless and perhaps wasteful government spending be reduced or eliminated and certainly balanced against the additional value the duplication provides, if any. The additional expenditure by the CDC on the collection of data in 2012 only led to an increase of six percent in the total number of cycles reported. The cost of the collection to the federal government and taxpayers, compared to the yield, does not seem warranted.	Not applicable	Section 2(a) of Public Law 102–493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a–1(a)), requires that each assisted reproductive technology (ART) program annually reports pregnancy success rates achieved by such ART program to the Secretary through the Centers for Disease Control and Prevention (CDC). The collection of ART outcomes by the Society for Assisted Reproductive Technology (SART) is not required by this law.
Request for additional data elements: Infant Outcomes (From comment #1)	1. Use of traditional or gestational surrogate carriers: Surrogate age, number of prior pregnancies, number of previous live born infants, number of prior surrogaacy (either gestational carrier or traditional surrogate). 2. Maternal variables: occurrence of pregnancy induced hypertension, maternal diabetes and stage,	The following infant outcome variables are included in the proposed NASS data elements: - Number of Infants Born - Birth Status (Live Birth, Stillbirth, Unknown) - Gender of Infant(Each Live-born and Stillborn Infant) - Birth Weight (Each Live-born and Stillborn Infant) - Birth Defect (Each Live-born and Stillborn	No changes were made Section 2(a) of Public Law 102–493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a–1(a)), requires that each assisted reproductive technology (ART) program annually reports pregnancy success rates achieved by such ART program to the Secretary through the Centers for Disease Control and Prevention (CDC). Many of the suggested data elements are only available through vital records

	hyperemesis gravidarium, fetal ultrasound results with special focus on fetal echocardiogram at 20-24 weeks 3. Placental examination: placental abnormalities, evidence of single umbilical artery, histologic chorioamnionitis, in twins or multiple gestations presence of twin to twin transfusion syndrome associated with artery-venous shunting in the placenta, placentation (diamniontic-dichorionic, monochorionic-diamniontic, and placentation of greater than twin). 4. Neonatal Variables Suggested to be added: A) Infant Weight, Length, and Head Circumference B) Infant Gestational age as determined by Ballard Physical and Neurodevelopment examination C) Admission to Neonatal Intensive Care Unit D)Specific Neonatal Variables: 1. Apgar Scores as 1 and 5 minutes, requirement for resuscitation 2. NICU admission, 3. Length of Hospital Stay, 4. Time (in days) to regain birth weight 5. Specific Neonatal Morbilities: a. Occurrence of Respiratory Distress Syndrome, b. Presence of patent ductus arterioles, c. Hyperbilirubinemia requiring A)	Infant) (i.e. Genetic Defect/Chromosomal Abnormality, Cleft Lip or Palate, Neural Tube Defect, Cardiac Defect, Limb Defect, Other Defect) Neonatal Death of Live-born Infants	(i.e. birth certificates, fetal death certificates) and NASS does not collect information from birth certificates. Collection of the additional variables suggested is not feasible as part of this effort.

	phototherapy and/or B) exchange transfusion and maximum total serum bilirubin, d. Occurrence of intraventricular hemorrhages by grade (Papille) i.e.. Grade I to IV, e. Occurrence of periventricular leukomalacia, f. Occurrence of necrotizing enterocolitis using the Bell scoring system, g. Occurrence of electrographic seizures, h. Did the infant pass the newborn hearing screen, i. Abnormalities on the Newborn Metabolic Screen, J. Results of the screen for congenital heart disease (Upper and Lower Sp02 after 24 hours), k. Occurrence of minor and major phenotypic anomalies, occurrence of specific syndromes including imprinting disorders, l. Karyotype results (if performed), results of chromosomal arrays (if performed).		
Request for additional data elements: Male Infertility (From comment #3)	In terms of the male data points planned can you please clarify these data points are included in the new planned data collection: • Medical condition • Genetic or chromosomal abnormality Specify_____ • Abnormal sperm parameters (select all that apply) Azoospermia, obstructive Azoospermia, non-obstructive	Suggested male data points are already in the proposed NASS data elements- see attachment C1	No changes were made- Suggested male data points are already in the proposed NASS data elements- see attachment C1.

	Oligospermia, severe (<5 million/mL) Oligospermia, moderate (5-15 million/mL) Low motility (<40%) Low morphology (4%) • Other male factor (not included above) Specify_____		
Request for additional data elements: Method of delivery (Vaginal or C-section) (From comment #5)	Method of delivery (Vaginal or C-section) Indication for c-section (if c-section used) (Prior c-section, Overdue delivery, Medical complication, Non-medical indication/Patient preference) This will take less than two additional minutes per cycle with live birth (zero for cycles without birth), as this information is almost always in the documents we routinely obtain. <u>Rationale:</u> Some reports indicate c-section delivery is more common with frozen-thawed embryo transfer. It is also reported that frozen-thawed embryo transfer is associated with larger birthweights. These two variables might be causally related, or might be confounded in assessments of perinatal outcomes. Consider that large infants can motivate a c-section, FET cycles often follow a fresh delivery that might have used a c-section and thus create an indication for c-section, and c-sections abbreviate a pregnancy so that birth by c-section occurs some hours or days earlier than otherwise would have.	Method of delivery is not listed in the proposed NASS data elements.	Added the variable 'Method of Delivery (Vaginal or C-section)' to the proposed data collection. CDC appreciates the suggestion to add 'Method of Delivery' to the data collection, and agree that this information could be reliably reported by the patient. However, 'Indication for C-Section' is usually only available through either the birth certificate or from the OB-Gyn care providers. CDC does not collection information directly from the OB-Gyns and NASS does not collect birth certificate information.