Dated: August 28, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Final Notice.

SUMMARY: This notice sets forth the requirements for Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs as required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). This notice describes who shall report to CDC, describes the reporting system, and describes the process for reporting by each assisted reproductive technology clinic. This notice incorporates comments received by CDC on the draft notice that was published in the Federal Register on September 3, 1999 (64 FR. 48402). This Announcement supersedes the previous notice that was published in the **Federal Register**, August 26, 1997 (62 FR. 45259).

FOR FURTHER INFORMATION CONTACT: Assisted Reproductive Technology Epidemiology Unit at (770) 488–5250.

SUPPLEMENTARY INFORMATION: Section 2(a) of Pub. L. 102–493 (42 U.S.C. 263a–1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention (1) pregnancy success rates achieved by such ART program and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under this act.

Pub. L. 102–493, Sec. 8 (42 U.S.C. 263a–7) defines ''assisted reproductive technology'' (ART) as ''all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any federal or other public agency).''

The Secretary is directed in Section 2(b) (42 U.S.C. 263a–1(b)) to define pregnancy success rates and ''make public any proposed definition in such a manner as to facilitate comment from any person during its development.''

Section 2(c) (42 U.S.C. 263a–1(c)) states ''the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies.''

Section 6 (42 U.S.C. 263a–5) states that the Secretary, through the CDC, shall annually ''publish and distribute to the States and the public, pregnancy success rates reported to the Secretary under section 2(a)(1) and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under each section, the name of each such program and each pregnancy success rate which the program failed to report.''

In developing the definition of pregnancy success rates, CDC has consulted with representatives of the Society for Assisted Reproductive Technology (SART, a national professional association of ART clinical programs), the American Society for Reproductive Medicine (ASRM, a national society of professional individuals who work with infertility issues), and RESOLVE, the National Infertility Association (a national, nonprofit consumer organization), as well as a variety of individuals with expertise and interest in this field.

The first **Federal Register** notice that outlined reporting requirements for ART programs was published August 26, 1997 (62 FR 45259) and solicited public comment. Because SART in conjunction with CDC made a number of revisions to the reporting process shortly after the publication of the first **Federal Register** notice, a second **Federal Register** notice was published on September 3, 1999 (64 FR 48402) that incorporated changes made to the reporting process. CDC also solicited public comment on this second draft document for the Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs. The current Announcement incorporates comments received by CDC on the September 3, 1999, draft notice and supersedes both the August 26, 1997, and the September 3, 1999, notices.

Reponse to Comments

In response to our request for comments to the September 3, 1999, draft document outlining reporting requirements, we received two letters, one from a laboratory professional organization, and one from an individual serving as the laboratory director of an ART clinic. These letters contained 15 separate comments. Responses to these comments are as follows:

1. There was concern that no consultation or communication had been conducted with the American Association of Bioanalysts (AAB) or its College of Reproductive Biology regarding the reporting requirements.

Response: The AAB was consulted early during the process in which CDC explored mechanisms to implement FCSRCA. Specifically, a representative of AAB attended a 1996 meeting convened by CDC to discuss issues related to the collection and reporting of ART clinic success rate statistics. Other professional organizations were represented as well. Although AAB did not participate in the most recent round of discussions on the clinic reporting requirements, a laboratory professional has been included in all discussions about reporting requirements.

2. There was an objection to the collection of data related to laboratory accreditation by the College of American Pathologists/American Society of Reproductive Medicine (CAP/ASRM) program.

Response: The 1992 Pub. L. 102–493 (42 U.S.C. 263a–1(a)), FCSRCA, requires CDC to report information on whether laboratories used by ART programs are certified under the CDC model state certification program. The model certification program was published in the **Federal Register**, July 21, 1999 (64 FR 39374). The model contained a set of quality standards for the performance of embryo laboratory procedures, maintenance of records, qualifications for laboratory personnel, and criteria for the inspection and certification of embryo laboratories. At this point, no state has adopted the model certification program, and thus no clinic is eligible for certification under the CDC model program. As a public service, CDC has agreed to include data on three non-federal laboratory accreditation programs in the annual ART Success Rates Reports. These are through the College of American Pathologists/ American Society for Reproductive Medicine (CAP/ASRM), Joint Commission on Accreditation of Healthcare Organizations (JACHO) and the New York State Tissue Bank

certification for ART laboratories (NYSTB). CDC consulted with ASRM and SART in gathering information on laboratory accreditation agencies that currently have systems for certifying embryo laboratories. CDC does not endorse these accreditation agencies, but rather is providing available accrediting information in response to public requests. This will be clearly stated in all Success Rates Reports that contain laboratory accrediting information.

3. There was concern that there would not be sufficient external validation of a laboratory's accreditation status.

Response: For an ART clinic's laboratory to be listed in the Success Rate Report as accredited by one of the three accrediting agencies (CAP/ASRM, JACHO, NYSTB) written documentation of such accreditation must be provided to SART concurrent with data collection.

4. Because of CDC's exclusive use of the SART database and CDC's reliance on SART for external validation of reporting activities, CDC appears to be ceding its regulatory authority to a private entity (SART). DHHS should establish very clear guidelines for selecting, reviewing, and evaluating any private entity that is given responsibility for evaluating these reporting activities.

Response: While the assisted reproductive technology programs are reporting their pregnancy success rate data to CDC through SART, CDC maintains ultimate control and authority over what information is contained in the annual pregnancy success rates report.

CDC's authority to publish and disseminate the annual report is not being ceded to SART, but rather SART is serving as a valuable resource from which CDC can obtain the necessary information to fulfill its statutory obligation.

SART has maintained a national database of ART cycle-specific data reported by each of its member clinics since 1986. Prior to the decision to partner with SART, CDC reviewed the SART reporting database and system and found that it provided the necessary information to publish an annual report as required by FCSRCA. Rather than duplicate SART's reporting system and thereby burden ART clinics, CDC has contracted with SART to annually obtain a copy of their clinic specific database. Notice of this contract was published in Commerce Business Daily Journal June 2, 1997. The decision to purchase the SART database was also published in the first **Federal Register** Notice detailing ART clinic reporting requirements (62 FR 45259). As a result of the contract with CDC, clinics that are not members of SART are now also eligible to submit data to the SART reporting system in order to meet their requirement to report data under FCSRCA. SART has agreed to accept data from non-SART member clinics without imposing membership requirements.

As part of its contract with CDC, SART is required to perform validation site visits for a portion of the clinics submitting data to its reporting system. CDC oversees and participates in all stages of the data validation process. CDC is present at meetings of the validation committee and maintains final approval of all validation materials. Additionally, a CDC representative attends approximately one-third of all validation site visits as an observer.

5. A separate comment on validation activities expressed further concern that CDC contracts with SART to perform external validation visits. There was a recommendation that a separate body be used because of SART's role in the reporting process.

Response: The SART validation committee is required to include at least one non-SART member at all times. Additionally, CDC attends all validation committee meetings and a proportion of validation site visits. Finally, CDC must approve SART's validation plan and retains ultimate authority over the validation process.

6. There was concern about the external validation procedure, namely that ART cycles for which social security number is not provided to the database will not be able to be validated.

Response: Even though specific identifiers are not submitted to CDC for any ART cycle, every clinic is required to maintain a copy of all information submitted to the reporting database and must be able to link each patient, cycle, and oocyte retrieved from the reporting database to the appropriate medical and laboratory records for external validation activities on site.

7. There was concern that informed consent was not mentioned in the **Federal Register** notice.

Response: Patients are not contacted directly during the data collection/validation process. The validation team does not collect personal identifying information when conducting validation visits.

8. There was an objection to reporting data related to SART membership.

Response: Consumers and consumer groups have indicated that such information is useful. CDC provides this information as a public service.

9. There was concern that an unreasonably short time frame was given for reporting, i.e., that SART need only provide the clinics with the required software 90 days prior to the deadline for reporting.

Response: CDC agrees that clinics should have as much lead time as possible. In the usual protocol, SART issues the data collection software and statistical tabulation program at the beginning of the reporting year, which is well in advance of the 90-day deadline. This deadline exists in the event that minor changes to the tabulation program are made. The revised software can then be reissued to clinics 90 days prior to the reporting deadline.

10. There was an objection to the requirement that clinics pay a fee to a private entity for data collection. There was a request that clarification on costs and cost justifications be provided.

Response: Fees are for the purposes of covering all cost associated with reporting information, including data collection, processing, analysis, publication, and administration. Additional fees may be charged if SART needs to provide technical assistance to clinics submitting a dataset with errors.

11. There was a recommendation that pregnancy outcomes should be reported separately for cycles using a combination of ART techniques, such as in vitro fertilization and gamete intrafollopian transfer.

Response: In the national section of each ART Report, success rates for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), and zygote intrafallopian transfer (ZIFT) are presented separately. Because the success rates are similar for each of the procedures and because there is often a small number of GIFT and ZIFT procedures at the individual clinic level, success rates for each type of ART procedure are not presented separately for each clinic.

12. There was concern about the definitions for preterm birth and stillbirth after ART.

Response: The decision to use date of transfer in defining gestational age was made by SART and CDC because date of transfer allows for a consistent definition for both fresh and frozen cycles. This issue will be discussed further and may be reconsidered at the next CDC–SART registry meeting.

13. There was an objection to reporting data related to whether ART services were available for single women.

Response: Consumers and consumer groups have indicated that such

information is useful. CDC provides this information as a public service.

14. There was an objection to the collection of ethnicity data.

Response: CDC collects data on demographics such as ethnicity in many surveillance systems. In this case, such information is intended to help describe groups that are using ART in the United States.

15. There was concern that too much information is being included in the reporting system.

Response: We have developed the ART report with consideration for the spirit of the 1992 FCSRCA (Pub. L. 102–493), consumer interests, and ART provider and clinic interests. Indeed, many providers and consumers have asked us to collect and report even more information than is currently included in the reporting system. Many providers have expressed concern that without consideration for many patient treatment factors the report will misrepresent clinic success rates. Of course, consumers are also very interested in a thorough and complete analysis, which will help in their goal of making an informed decision about ART.

Dated: August 28, 2000.

Candice Norwicki,

Acting Director, Executive Secretariat, Centers for Disease Control and Prevention (CDC).

Appendix—Notice for the Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs

Introduction

This notice includes four sections:

I. Who Reports * * * describes who shall report to CDC.

II. Description of Reporting Process * * * describes the reporting system and process for reporting by each ART clinic.

III. Data To Be Reported * * * describes the data items and definitions to be included in the reporting database.

IV. Content of the Published Report * * * describes terms, and how pregnancy success rates will be defined and reported, and outlines the topics that will be included in the annual published reports, using the data collected in the reporting database.

I. Who Reports

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires that each ART program shall annually report to the Secretary of the Department of Health and Human Services through the CDC.

The Society for Assisted Reproductive Technology (SART), an affiliate of the American Society for Reproductive Medicine (ASRM), maintains a national database of cycle-specific data reported by each of its members. CDC has reviewed the SART reporting database and system and finds that it provides the necessary information to publish an annual report as required by the FCSRCA. Rather than duplicate SART's reporting system, and thereby burden ART clinics and patients, CDC has contracted with SART to annually obtain a copy of their clinic specific database.

An ART program or clinic is defined as a legal entity practicing under State law, recognizable to the consumer, that provides ART to couples who have experienced infertility or are undergoing ART for other reasons. This can be an individual physician or a group of physicians who practice together and share resources and liability. This definition precludes individual physicians who practice independently from pooling their results for purposes of data reporting.

ART clinics that are participating in the ASRM/SART reporting system as described in this notice will be considered to be in compliance with federal reporting requirements of FCSRCA. Both SART and non-SART clinics shall contact SART for reporting information, instructions, and fees charged (fees are for the purposes of covering all costs associated with this activity, including data collection, processing, analysis, publication, and administration; additional fees may be charged if SART needs to provide technical assistance to clinics submitting a dataset with errors.) It is the responsibility of the practice director of each clinic performing ART to provide notification to SART of the clinic's existence and any changes in address, location, or change in key staff including the practice, medical, and lab director. Contact SART, telephone: (205) 978–5000, ext. 109.

The anticipated deadline for reporting is January 15 of the year 2 years subsequent to the reporting year in question. (For example, the anticipated deadline to report data on cycles initiated in 1999 is January 15, 2001.) The deadline will be published in Fertility and Sterility at least 90 days prior to the deadline. SART in conjunction with CDC may change the deadline if needed.

An ART clinic will be considered to not be in compliance with the federal reporting requirements of FCSRCA if the clinic was in operation in the full year that is being reported, *i.e.,* the clinic was in operation after January 1, and failed (a) to submit a dataset to SART in the required software by the reporting deadline or (b) the clinic table was not verified by signature of the medical director of the clinic by the same deadline.

The onus is on the clinic to confirm that SART has received the dataset. It is recommended that the clinic submit their data to SART as early as it is available so that any errors or reporting difficulties can be reconciled and verified before the reporting deadline which will be inflexible. In this respect, it would be prudent to submit data to SART at least 30 days in advance of the reporting deadline because errors or other problems in reporting may take up to 30 days to resolve. If problems cannot be resolved by the inflexible deadline of January 15, the clinic will be considered a non-reporter.

SART in conjunction with CDC will determine error rates for data submitted by clinics, and if data quality is deemed unsatisfactory, this finding may be published. Additionally, the program may be required to submit data 30 days prior to the deadline for the next reporting year. This requirement will allow for sufficient time to correct errors prior to the deadline for publication of the annual report. As noted earlier, additional fees may be charged if SART needs to provide technical assistance to clinics submitting a dataset with errors.

II. Description of Reporting Process

A. Reporting Activities

SART in conjunction with CDC will determine the required software for data submission. As noted above, to be in compliance with the law, a clinic must submit a dataset to SART in the required software by the reporting deadline, and verify, by signature of the medical director of the clinic, the clinic table by the same deadline.

Each year, SART will issue a unique clinic code, required computer software for their database reporting system, and all necessary reporting instructions at least 90 days in advance of the reporting deadline.

Currently, each patient receiving ART in a clinic is registered in the system with a unique, clinic-assigned code and should be entered into the reporting database when her cycle is initiated. Each cycle of each patient also receives a unique cycle code for that patient. In the reporting system, the patient is identified by the clinic code, the patient code, and the cycle code assigned by the clinic. The patient's name or other specific personal identifiers are not included in the reporting database. However, each clinic must maintain personal identifiers in the clinic database on site in order to be able to link every cycle reported to CDC to a specific patient (see below).

The following patients must be included in the reporting database: (1) All women undergoing ART, (2) all women undergoing ovarian stimulation or monitoring with the intention of undergoing ART; this includes women whose cycles are canceled for any reason, (3) all women providing donor oocytes, and (4) all women undergoing monitoring and/or an embryo thawing with the intention of transferring cryopreserved embryos.

It is anticipated that the reporting system may evolve such that data may be collected prospectively, *i.e.,* data submission will be required as cycles are initiated. (Currently data submission for all cycles is required at one time only.) Clinics will be provided at least 90 days advance notice of this or other changes in reporting requirements.

The CDC retains a copy of each of SART's annual data files. These will be maintained by CDC to be used for epidemiologic analysis and for the purpose of publishing an annual report as required by the law that includes national summary and clinic specific information.

B. External Validation of Clinic Data

Every clinic will maintain a copy of all information included in the reporting database and must be able to link each patient, cycle, and oocyte retrieved from the reporting database to the appropriate medical and laboratory records for external validation activities.

On a periodic basis, all ART clinical programs reporting their data (both SART and non-SART clinics) will be subject to external validation of their reporting activities, which will include review by appropriate professionals from outside the clinic staff. This review may include but not be limited to examination of medical and laboratory records and comparison of data in the reporting database with data in the medical record. CDC has contracted with SART to perform the validation site visits.

C. Updating of Reporting Requirements

The field of ART is a rapidly developing medical science. These reporting requirements will be periodically reviewed and updated as new knowledge concerning ART methods and techniques becomes available. Such review will include consultation with professional and consumer groups and individuals. Clinics will be notified in writing at least 90 days in advance of the reporting deadline of all changes to the reporting requirements.

III. Data To Be Reported

The current reporting system includes the following:

A. Clinic Information

Clinic name & address
Unique clinic ID number
Name(s) of embryo laboratory(s) used by clinic
Whether the laboratory is certified by a SART-accepted accrediting agency
Whether the clinic is a member of SART
Whether ART services are available for single women
Whether ART services include gestational carriers
Whether the clinic has a donor egg program, and if yes, if eggs from an individual donor are shared by multiple recipients
Whether the clinic has a donor embryo program
Whether the clinic has an embryo cryopreservation program
Total number of ART cycles performed during the reporting year

B. Patient Information

1. *Patient Demographic Information:*
   Ethnicity
   Date of Birth
   US Resident
   Zip Code
   City of Residence
   State of Residence
   Country of Residence (if not United States)
2. *Patient History:*
   Gravidity
   Prior Full-Term Births
   Prior Preterm Births
   Prior Spontaneous Abortions
   Surgical Sterilization—Patient or Partner
   Months of Infertility Since Last Live birth (if couple is not surgically sterile)
   Prior non-ART Gonadotropin Cycles
   Prior Thawed ART Cycles
   Prior Fresh ART Cycles
   Patient Maximum Follicle Stimulating Hormone (FSH) Level and Lab Upper Normal Limit for that FSH level
   Patient Maximum Estradiol Level and Lab Upper Normal Limit for that Estradiol Level
3. *ART Cycle Information:*
   Reason(s) for ART
   (Male Infertility, Endometriosis, Tubal Factor, Ovulatory Disorder/Polycystic Ovaries, Diminished Ovarian Reserve, Uterine Factor, Other, Unexplained Infertility)
   Cycle Start Date
   Suppression with Gonadotropin Releasing Hormone Analog (GnRHa)
   Ovarian Stimulation Medications Given to Patient (Clomiphene, FSH, Flare GnRHa) and Dosages
   Medications Given to Oocyte Donor and Dosages
   Intended ART Cycle Treatment Specifics:
   Oocyte Source
   (patient [autologous], donor oocyte, donor embryo)
   Oocyte/Embryo State
   (fresh, thawed)
   Intended Transfer Method(s)
   [In Vitro Fertilization (transcervical transfer); Gamete Intrafallopian Transfer; Zygote Intrafallopian Transfer/Tubal Embryo Transfer]
   Use of Gestational Carrier
   Cycle Initiated for Embryo Banking Only
   Cycle Meeting SART Criteria for Approved Research
   Did the Cycle Occur as Intended?
   Was the Cycle Canceled?
   Date of Cancellation
   Reason for Cancellation
   (Low Ovarian Response, High Ovarian Response, Failure to Survive Thaw, Inadequate Endometrial Response, Concurrent Illness, Patient Withdrawal from Treatment, Unable to Obtain Sperm Specimen)
   Complications Related to ART Treatment
   (Infection, Hemorrhage, Moderate Ovarian Hyperstimulation Syndrome, Severe Ovarian Hyperstimulation Syndrome, Medication Side Effect, Anaesthetic Complication, Psychological Stress, Death, Other Complication)
   Hospitalization for ART Complication
   Date of Oocyte Retrieval (from patient and/or from donor)
   Number of Oocytes Retrieved (both from patient and/or from donor)
   Were Oocytes Derived from the Donor Used by More Than One Recipient?
   Number of Embryos Thawed for Transfer in a Frozen Cycle
   Semen Source
   (Partner, Donor, Mixed)
   Semen Collection Method
   (Ejaculation, Epididymal Aspiration, Testicular Biopsy, Electroejaculation, Retrograde Ejaculation)
   Use of Intracytoplasmic Sperm Injection
   Use of Assisted Hatching
   Was Oocyte or Embryo Transfer Attempted?
   Transfer Date
   Number of Fresh Embryos Transferred to Uterus
   Number of Fresh Embryos Transferred to Fallopian Tubes
   Number of Oocytes Transferred to Fallopian Tubes
   Number of Fresh Embryos Cryopreserved
   Number of Thawed Embryos Transferred to Uterus
   Number of Thawed Embryos Transferred to Fallopian Tubes
   Number of Thawed Embryos Re-Frozen
4. *Outcome Information:*
   Outcome of Treatment
   (Not Pregnant, Biochemical Pregnancy, Ectopic Pregnancy, Clinical Intrauterine Gestation, Heterotopic Pregnancy, Unknown)
   Was an Ultrasound Performed?
   Ultrasound Date
   Maximum Number of Fetal Hearts Observed on Ultrasound
   Was a Medically Induced Fetal Reduction Performed?
   Induced Reduction Date
   Outcome of Pregnancy
   (Live birth, Stillbirth, Spontaneous Abortion, Induced Abortion, Maternal Death Prior to Birth, Unknown)
   Date of Pregnancy Outcome
   Source of Information for Outcome of Pregnancy
   (Verbal Confirmation Patient, Written Confirmation Patient, Verbal Confirmation Physician or Hospital, Written Confirmation Physician or Hospital)
   Number of Infants Born
   Birth weight for Each Live-born and Stillborn Infant
   Birth Defects Diagnosed for Each Live-born and Stillborn Infant
   (Genetic Defect/Chromosomal Abnormality, Cleft Lip or Palate, Neural Tube Defect, Cardiac Defect, Limb Defect, Other Defect)
   Neonatal Death of Live-born Infants

C. Definitions

The following definitions provide clarification for data included in the current reporting system:

ART—Assisted reproductive technology, defined as all treatments or procedures that include the handling of human oocytes and sperm or embryos for the purpose of establishing a pregnancy. This includes, but is not limited to in vitro fertilization and transcervical embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, embryo cryopreservation, oocyte or embryo donation, and gestational surrogacy. ART does not include assisted insemination using sperm from either a woman's partner or sperm donor.

ART cycle—ART Cycles can be stimulated (use of ovulation induction) or unstimulated (natural cycle). An ART cycle is considered any cycle in which (1) ART has been used, (2) the woman has undergone ovarian stimulation or monitoring (*i.e.* performance of sonogram, serum estradiol or LH measurements) with the intent of undergoing ART, (3) in the case of donor oocytes, a woman began medication for endometrial preparation with the intent of undergoing ART, or (4) in the case of cryopreserved embryos, a woman began medication for endometrial preparation with the intent of undergoing ART and/or embryos were thawed with the intent of transfer.

ART program or clinic—A legal entity practicing under state law, recognizable to the consumer, that provides assisted reproductive technology to couples who have

experienced infertility or are undergoing ART for other reasons. This can be an individual physician or a group of physicians who practice together, and share resources and liability. This definition precludes individual physicians who practice independently from pooling their results for purposes of data reporting.

ASRM—American Society for Reproductive Medicine.

Autologous cycle—Intent to transfer embryos derived from patient oocytes fertilized with either partner or donor sperm OR in cases of GIFT, patient oocytes transferred with either partner or donor sperm.

Birth defect—Anomalies diagnosed within the first two weeks of life that result in death or cause a serious disability requiring surgical and/or medical therapy. Specific anomalies to be identified include genetic defect/chromosomal abnormality, cleft lip or palate, neural tube defect, cardiac defect, limb defect, or other defect.

Biochemical pregnancy—A positive serum pregnancy test (Beta-hCG) without ultrasound confirmation of a gestational sac within the uterus.

Canceled cycle—An ART cycle in which ovarian stimulation or monitoring has been carried out with the intent of undergoing ART but which did not proceed to oocyte retrieval, or in the case of thawed embryo cycles, to the transfer of embryos. Reasons for cancellation include low ovarian response, high ovarian response, failure of embryo to survive thaw; inadequate endometrial response, concurrent illness, patient withdrawal from treatment, and unable to obtain sperm specimen.

Clinic ID number—An identification number assigned to each ART clinical program by the reporting database operator.

Clinical pregnancy/Clinical intrauterine gestation—An ultrasound-confirmed gestational sac within the uterus or the documented occurrence of a birth, spontaneous abortion, or induced abortion in cases of missing ultrasound data. Clinical pregnancies include all gestational sacs regardless of whether or not a heartbeat is observed or a fetal pole is established. This definition excludes ectopic pregnancy but includes pregnancies which end in live birth, stillbirth, spontaneous abortions, and induced abortions.

Clomiphene citrate—An ovulation induction medication with the trade name of Clomid® or SeroPhene®.

Complication—A medical complication for the woman related to ART procedures. Specific complications to be identified include infection, hemorrhage, moderate ovarian hyperstimulation syndrome, severe ovarian hyperstimulation syndrome, medication side effect, anaesthetic complication, psychological stress requiring intervention, and death.

Cryopreservation—A technique used in ART to preserve sperm and embryos through freezing.

Cycle start date (cycle initiation date)—The cycle start date is (1) the first day that medication to stimulate follicular development is given to a patient in a stimulated fresh, non-donor cycle, or (2) the first day of natural menses or withdrawal bleeding in an unstimulated cycle or (3) the first day the recipient (patient or gestational carrier) receives exogenous sex steroids to prepare the endometrium in a fresh donor cycle, or (4) the first day the recipient (patient or gestational carrier) receives exogenous sex steroids to prepare the endometrium in a thawed embryo cycle.

Diminished ovarian reserve—A condition of reduced fecundity related to diminished ovarian function; includes high FSH or high estradiol measured in the early follicular phase or during a clomiphene challenge test, reduced ovarian volume related to congenital, medical, surgical or other causes, or advanced maternal age (>40 years).

Donor embryo cycle—Intent to transfer donated embryos, that is, embryos derived from oocytes previously fertilized for another couple's ART therapy that were subsequently donated.

Donor oocyte cycle—Intent to transfer oocytes, or embryos derived from oocytes that were retrieved from a woman serving as an oocyte donor (sperm source may be either the patient's partner or a sperm donor selected by the patient).

Ectopic pregnancy—A pregnancy in which the fertilized egg implants outside the uterine cavity.

Embryo—The normally (2 pronuclei) fertilized egg that has undergone one or more divisions.

Embryo banking cycle—A cycle initiated with the intent of cryopreserving all fertilized embryos for later use. (This does not apply to cycles initiated with the intent to transfer embryos but for which all embryos were subsequently cryopreserved regardless of the reason.)

Embryo transfer—Attempt to introduce embryos into a woman's uterus after in vitro fertilization or attempt to introduce embryos or gametes (oocytes and sperm) into a woman's fallopian tubes; a transfer procedure is considered to have been carried out, if attempted, even if no embryos or gametes were successfully transferred.

Endometriosis—The presence of tissue resembling endometrium in locations outside the uterus such as the ovaries, fallopian tubes, and abdominal cavity; a history of all stages of endometriosis (minimal to severe) whether treated or not may be a reason for ART.

Endometrium—The lining of the uterus that is shed each month as the menstrual period. As the monthly cycle progresses, the endometrium thickens and thus provides a nourishing site for the implantation of a fertilized egg.

Estradiol (E2)—The predominant estrogen hormone produced by the ovary that has several activities important for reproduction. An elevated serum Estradiol level in the early follicular phase of a woman's menstrual cycle (day 2, 3, or 4) may indicate diminished ovarian reserve.

Fecundity—The ability to conceive.

Fertilization—The penetration of the egg by the sperm and fusion of genetic materials to result in the development of a fertilized egg (or zygote).

Fetus—The developmental stage during pregnancy from the completion of embryonic development at eight weeks of gestation until delivery.

Flare protocol—Use of a GnRH analog to directly stimulate follicle development.

Follicle—A fluid-filled sac located just beneath the surface of the ovary that contains an oocyte and cells that produce hormones.

Fresh oocyte or embryo cycle—Intent to transfer oocytes or embryos derived from oocytes retrieved during the current cycle (either from the patient or donor), *i.e.*, not thawed embryos retrieved during a previous cycle.

FSH—Follicle stimulating hormone. A gonadotropin hormone produced and released from the pituitary that stimulates the ovary to ripen a follicle for ovulation. An elevated serum FSH level in the early follicular phase of a woman's menstrual cycle (day 2, 3, or 4) or during a clomiphene challenge test (day 10 of the cycle) may indicate diminished ovarian reserve. FSH, either alone or with luteinizing hormone (LH), is also included in gonadotropin drug preparations used to stimulate follicular development during an ART cycle.

Full-term birth—A birth that reached 37 completed weeks gestation. This includes both live births and stillbirths. For the purpose of reporting prior full-term births, births are counted as birth events (*e.g.*, a triplet birth is counted as one).

Gamete intrafallopian transfer (GIFT)—An ART procedure that involves removing oocytes from a woman's ovary, combining them with sperm, and immediately transferring (via a catheter) the eggs and sperm into the fallopian tube. Fertilization takes place inside the fallopian tube.

GnRHa-Gonadotropin—releasing hormone analog (agonist or antagonist); medications used to suppress natural FSH and LH production to allow greater control when using follicle stimulation medications.

Gestational carrier (sometimes referred to as a gestational surrogate)—A woman who gestates an embryo that did not develop from her egg with the expectation of returning the infant to its intended parents.

Gestational sac—A fluid-filled structure surrounding an embryo that develops within the uterus early in pregnancy.

Gonadotropin—Hormones having a stimulating effect on the gonads (ovaries and testes). Two such hormones are secreted by the anterior pituitary: follicle stimulating hormone (FSH) and luteinizing hormone (LH). Gonadotropins (FSH, either alone or with LH) are also included in drug preparations used to stimulate follicular development during an ART cycle.

Gravidity—Total number of prior pregnancies a woman has had. This includes ectopic pregnancies, and pregnancies that ended in therapeutic abortion, spontaneous abortion, stillbirth, or live birth.

Hatching (Assisted)—A micromanipulation technique that involves making a small opening in the zona wall of the embryo in an effort to enhance implantation; various methods of assisted hatching have been utilized including chemical, laser, and mechanical methods.

Heterotopic pregnancy—A clinical intrauterine gestation in combination with an ectopic pregnancy.

Hydrosalpinx—Accumulation of watery fluid in a fallopian tube that usually results from damage to the tube.

Hypothalamus—A gland at the base of the brain that controls many functions of the body, regulates the pituitary gland, and releases gonadotropin releasing hormone (GnRH).

Induced abortion—Operative procedure to electively terminate the entire pregnancy (no gestational age limit).

Induced fetal reduction—A procedure in which the number of fetal sacs is reduced by direct medical intervention. Termination of an ectopic gestation or a heterotopic pregnancy is not considered an induced reduction. Induced reduction is used in women with multiple gestations, usually three or more, to decrease the number of fetuses a woman carries, usually to two.

Insemination—Injection of sperm into the uterus or cervix for the purpose of producing a pregnancy. Insemination cycles are not considered ART for the purposes of this notice.

Intracytoplasmic sperm injection (ICSI)—The placement of a single sperm into the ooplasm of an oocyte by micro-operative techniques.

In vitro fertilization (IVF)—A method of assisted reproduction that involves removing oocytes from a woman's ovaries, combining them with sperm in the laboratory, and after fertilization is confirmed, replacing the resulting embryo into the woman's uterus.

Live birth—A birth (delivery) in which at least one fetus was live born, *i.e.,* showed signs of life after the complete expulsion or extraction from its mother. Signs of life include breathing, beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles. Any birth event in which an infant shows signs of life should be counted as a live birth, regardless of gestational age at birth. Live births are counted as birth events (*e.g.,* a triplet live birth is counted as one).

Male infertility—Infertility due to abnormal semen parameters or abnormal sperm function.

Neonatal death—Death of a live-born infant before completion of the 28th day of life.

Oocyte—The female reproductive cell, also called an egg.

Oocyte donor—A woman who undergoes an oocyte retrieval procedure with the intent of donating the oocytes retrieved to a couple(s) undergoing an ART donor oocyte cycle (see donor oocyte cycle). The donor relinquishes all parental rights to any resulting offspring, while the recipient woman retains all parental rights of any resulting offspring.

Oocyte retrieval—A procedure to collect the eggs contained within the ovarian follicles. This definition includes procedures in which oocyte recovery was attempted but not successful.

Oocyte transfer—In GIFT (see definition), transfer of retrieved eggs into a woman's fallopian tubes. Includes attempted transfers, whether or not the transfer was successful.

Ovarian monitoring—Monitoring the development of ovarian follicles by ultrasound and/or blood or urine tests.

Ovarian stimulation—Use of one or more follicle stimulation medications to stimulate the ovary to develop follicles and oocytes.

Ovarian hyperstimulation syndrome—A possible complication related to medically induced ovulation. Moderate ovarian hyperstimulation syndrome is characterized by abdominal distension and discomfort as well as nausea, vomiting and/or diarrhea; ovaries enlarged 5–12 cm; and ultrasound evidence of ascites. Severe ovarian hyperstimulation syndrome is characterized by features of moderate ovarian hyperstimulation PLUS: clinical evidence of ascites (fluid in the abdominal cavity) and/or hydrothorax (fluid in the chest) or breathing difficulties; change in blood volume, increased blood viscosity due to hemoconcentration, coagulation abnormalities, and diminished kidney perfusion and function.

Ovulatory disorder/polycystic ovaries (PCO)—One or more disorders causing reduced fecundity that is associated with structural, anatomic, or functional impairment of one or both ovaries; includes multiple ovarian cysts affecting fertility, oligo-ovulation (<6 cycles per year), anovulation (of hypothalamic or non-hypothalamic causes).

Ovulation induction—See stimulated cycle.

Pituitary—A small gland just beneath the hypothalamus in the brain which controls other hormone producing glands such as the ovaries, thyroid, and adrenal glands. Ovarian function is controlled through the secretion of follicle stimulating hormone (FSH) and luteinizing hormone (LH) from the pituitary.

Pregnancy test—A blood test that determines the level of human chorionic gonadotropin (hCG), a hormone produced by the placenta; if it is elevated, this confirms a pregnancy, which may be biochemical only, ectopic, or clinical intrauterine gestation (normally developing pregnancy).

Preterm birth—Birth at least 20 but less than 37 completed weeks gestation. This includes both live births and stillbirths. For the purposes of reporting prior preterm births, births are counted as birth events (*e.g.* a triplet birth is counted as one).

Recipient—In an ART cycle, the woman in whom embryos or oocytes are transferred; includes the female patient or a gestational carrier for the patient.

SART—Society for Assisted Reproductive Technology.

Semen—Fluid discharged at ejaculation in the male, consisting of spermatozoa in their nutrient plasma which includes secretions from the prostate, seminal vesicles, and various other glands.

Sperm—The male reproductive cell that has completed the process of meiosis and morphological differentiation.

Sperm donor—A man providing sperm for the fertilization of oocytes of a woman other than his sexual partner.

Spontaneous abortion (miscarriage)—A clinical pregnancy ending in spontaneous loss of the entire pregnancy prior to completion of 20 weeks of gestation (or 18 weeks from the date of transfer if the pregnancy was achieved using ART).

Stillbirth—Birth (delivery) at 20 weeks of gestation or later (or 18 weeks or later from the date of transfer if the pregnancy was achieved using ART) in which no fetus showed signs of life after the complete expulsion or extraction from the mother. Stillbirths are counted as birth events (*e.g.* a triplet stillbirth is counted as one).

Stimulated cycle—An ART cycle in which a woman receives medication to stimulate follicular development including the use of clomiphene citrate, follicle stimulating hormone (FSH), or follicle stimulating hormone and luteinizing hormone (FSH and LH).

Surgical sterilization—An operative procedure for the purpose of termination of fertility without reversal. Surgical sterilization includes tubal ligation, vasectomy and hysterectomy.

Thawed cycle— Intent to transfer embryos that were cryopreserved during a previous cycle and will be thawed for transfer during the current cycle (pertains to both donor and non-donor embryos).

Tubal embryo transfer (TET)—Transfer of an early stage embryo to the fallopian tube.

Tubal factor—A factor causing reduced fecundity that is associated with structural, anatomic, or functional injury of one or both fallopian tubes; the following are included: (1) Tubal ligation, not reversed, (2) hydrosalpinx (in place), and (3) any other tubal disease including but not limited to pelvic or peritubal adhesive disease, prior tubal surgery, prior ectopic pregnancy, or tubal occlusion (partial or complete without hydrosalpinx).

Ultrasound—A technique for visualizing the follicles in the ovaries and the gestational sac or fetus in the uterus, allowing the estimation of size.

Unexplained infertility—Infertility in which no etiology (male infertility, endometriosis, tubal factor, ovulatory disorders/PCO, diminished ovarian reserve, uterine factor, or other factors (such as immunologic, chromosomal, cancer chemotherapy or other systemic disease) has been identified.

Unstimulated cycle—An ART cycle in which the woman does not receive medication to stimulate follicular development such as clomiphene or follicle stimulating hormone. Instead, natural follicular development occurs.

Uterine factor—A factor causing reduced fecundity that is associated with structural, anatomic, or functional injury to the uterus whether repaired or not; includes septum, myoma, Diethylstilbestrol (DES) exposure, intrauterine adhesions, congenital anomalies.

Zygote—A normal (2 pronuclei) fertilized egg before cell division begins.

Zygote intra fallopian transfer (ZIFT)—Eggs are collected and fertilized, and the resulting zygote is then transferred to the fallopian tube.

D. Updating Data To Be Reported

Specific data items and definitions will be provided to clinics each year along with all other reporting requirements at least 90 days in advance of the reporting deadline. Data items and definitions will be periodically reviewed and updated. Such review will include consultation with professional and consumer groups and individuals.

IV. Content of Published Reports

The data reported will be used to provide a picture of the national rates of pregnancy and live birth achieved using ART as well as clinic-specific, live-birth rates. The annual report will have four components:

(A) A national component, which will provide a comprehensive picture of success rates given a variety of factors including age, reason for ART, type of ART procedure, number of embryos transferred etc. This is possible because the large number of cycles at the national level allow accurate statistical reporting of success rates that is not possible with the smaller number of cycles carried out in individual clinics.

(B) A clinic-specific component which will provide success rates for all ART cycles using fresh, non-donor embryos, success rates for ART cycles using thawed embryos, and success rates for ART cycles using donor oocytes or embryos.

Success rates will be reported by specific age groups. In addition, the clinic-specific component will provide other information that may be useful to the consumer such as types of services the clinic offers (*e.g.,* gestational surrogacy, single women), the number of cycles carried out, the percent distribution of types of ART, the types of infertility problems the clinic sees, the frequency of cancellations, the average number of embryos transferred per cycle and the percentage of multiple pregnancies and births (twins and triplets or greater).

Pregnancy and live birth success rates will be defined and characterized as described below.

For fresh, non-donor cycles, success rates will be defined as

1. The rate of *pregnancy* after completion of ART according to the number of:

a. All ovarian stimulation or monitoring procedures.

2. The rate of *live birth* after completion of ART according to the number of:

a. All ovarian stimulation or monitoring procedures.

b. Oocyte retrieval procedures.

c. Embryo (or zygote, or oocyte) transfer procedures.

For cycles using thawed embryos and cycles using donor oocytes or embryos success rates will be defined as

1.The rate of *live birth* after completion of ART according to the number of:

a. Embryo (or zygote, or oocyte) transfer procedures.

(C) An appendix containing a consumer-oriented explanation of all medical and statistical terms used in the report.

(D) An appendix containing a list of all reporting clinics and a list of all clinics that did not report data (See above, **Who Reports** section, for a full description of clinics that will be considered to not be in compliance with the federal reporting requirements of FCSRCA; such clinics will be listed as non-reporters in the published report.) This appendix will contain the names, addresses, and telephone numbers for all reporting and non-reporting clinics. It will also contain information on the laboratories used by reporting clinics.

The entire annual report will be available to the general public. As resources allow, additional information may also be published.

[FR Doc. 00–22425 Filed 8–31–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[PA #00130 et al.]

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: HIV/AIDS Prevention Program Development and Technical Assistance Collaboration With Countries Targeted by the Leadership and Investment in Fighting the Epidemic (LIFE) Initiative, et al.

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: HIV/AIDS Prevention Program Development and Technical Assistance Collaboration with Countries Targeted by the Leadership and Investment in Fighting the Epidemic (LIFE) Initiative, PA #00130; Prevention Program Development and Technical Assistance to Improve Blood Safety and Reduce the Impact of HIV/AIDS in Countries Targeted by the LIFE Initiative, PA #00133; LIFE—Global AIDS Activity, PA #00134; HIV/AIDS Prevention Program Development and Technical Assistance Collaboration for Faith Communities in Countries Targeted by the LIFE Initiative, PA #00137; Youth-Focused HIV/AIDS Prevention Program Development and Technical Assistance Collaboration with Countries Targeted by the LIFE Initiative, PA #00138; and HIV/AIDS Prevention Program Development and Technical Assistance Collaboration for Public Health Laboratory Science with Countries Targeted by the LIFE Initiative, PA #00139.

Times and Dates: 10:00 a.m.–Noon, September 13, 2000 (Open); Noon–4:30 p.m., September 13, 2000 (Closed); 8:30 a.m.–4:30 p.m., September 14, 2000 (Closed).

Place: Centers for Disease Control and Prevention, 12 Corporate Square Boulevard, Building 12, Conference Rooms 1203 and 1307, Atlanta, GA 30329.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to P. L. 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcements 00130, 00133, 00134, 00137, 00138, 00139.

This notice is published less than 15 days prior to the meeting due to administrative delays.

Contact Person for More Information

Chad Martin, Special Assistant to the Director on Youth and HIV Prevention, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 8 Corporate Square Boulevard, M/S E35, Atlanta, Georgia 30329, telephone 404/639–5217, e-mail cmartin@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for the both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 29, 2000.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–22599 Filed 8–30–00; 12:58 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interim Hepatitis B Vaccine Information Materials

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: A hepatitis B vaccine has recently been approved for administration in a two dose schedule to adolescents 11 to 15 years of age as an alternative to the three dose schedule. This additional schedule necessitates a revision of the vaccine information statement entitled, ''Hepatitis B Vaccine: What You Need to Know'' (dated December 16, 1998), which was developed by the CDC as required by the National Childhood Vaccine Injury Act of 1986 (NCVIA). To ensure that up-to-date information is