



Field Test of a Factsheet for Assisted Reproductive Technology

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SUMMARY

Assisted Reproductive Technology (ART) has been used in the United States since 1981 to help women become pregnant, most commonly through the transfer of fertilized human eggs into a woman's uterus (*in vitro* fertilization). Connecticut now ranks fourth in the country in its *per capita* use of ART, with a 2010 rate of 5 per 1,000 women aged 15-44 years old. In the summer of 2014, a factsheet on ART usage in the State of Connecticut and its contribution to adverse birth outcomes was produced. The purpose of this study was to conduct a field test of the factsheet among ten participants of the general public, as well as among ten patients in the early stages of fertility treatment. The factsheet was tested among the general public at a public park in Hartford, Connecticut, as well as among patients at the Center for Advanced Reproductive Services. The factsheet was well-received by both groups, with limited negative responses. Feedback indicates that the factsheet was informative and helpful to both the general public and patients at the Center. Respondents from both the public and clinical setting found the factsheet to be easy to understand and pleasant to view, however only a majority of those in the clinic setting reported that the factsheet was also a good use of time. These results suggest that the existing factsheet may be more useful for people with an existing interest in the topic, and that a more general factsheet with less information and more graphics may be best for the general public.

Background

Although various definitions have been used for assisted reproductive technology (ART), it generally involves surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and then returning them to the woman's body, freezing them for later use or donating them to another woman. ART generally does NOT include treatments in which only sperm are handled (i.e., intrauterine—or artificial—insemination (IUI), or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved. The use of ART has been used in the United States since 1981 to help women become pregnant, most commonly through the transfer of fertilized human eggs into a woman's uterus (*in vitro* fertilization, or IVF). Connecticut now ranks fourth in the country in its *per capita* use of ART, with a 2010 rate of 5 per 1,000 women aged 15-44 years old.¹

Use of ART can significantly increase the likelihood of multiple births and low birth weight. In Connecticut during 2010, 43% of ART infants were born in a twin birth, compared to just 5% of all infants in the 2010 total cohort.¹ Only 2.8% of ART infants were born in a triplet birth,¹ and this relatively low percentage among other states in the country is linked to an insurance mandate that limits the number of embryos that can be transferred (Connecticut Public Act 05-196). An estimated 14% of low birth weight babies born in CT are the result of ART, due in part to the high percentage of twin births that result from ART.¹

¹ Sunderam, S, Kissin, DM, Crawford, S, Anderson, JE, Folger, SG, Jamieson, DJ, Barfield, WD (2013) Assisted reproductive technology surveillance – United States, 2010 MMWR Vol 62(ss09):1-24 (<http://www.cdc.gov/mmwr/pdf/ss/ss6209.pdf>), accessed on June 9, 2014.

The Centers for Disease Control and Prevention (CDC), Division of Reproductive Health (DRH), monitors all ART procedures performed in the U.S. using the National ART Surveillance System (NASS), a web-based ART reporting system (<http://www.cdc.gov/art/SMART.htm>). In 2001, CDC began to establish select partnerships with state health agencies through the States Monitoring Assisted Reproductive Technology (SMART) Collaborative. The Collaborative seeks to strengthen the capacity of states to evaluate ART-related maternal and perinatal outcomes and programs through state-based public health surveillance systems. The SMART Collaborative links information from ART surveillance with birth records, infant and fetal death records, hospital discharge registries, birth defects registries, and cancer registries. The linked data set creates a population-based data registry of ART and non-ART births that can examine and monitor ART pregnancy outcomes.

Connecticut joined the SMART collaborative of three other states (Massachusetts, Michigan, and Florida) in Spring, 2013, and recently received permission from both the CDC Internal Review Board and the DPH Human Investigations Committee to share record-level vital statistics and hospitalization records with CDC for linkage with its NASS database. Connecticut state records for 2000-2011 are in the process of being linked to the NASS database, with plans for future linkages. In this first phase, the Connecticut annual vital records data have been matched to create longitudinal files that identify each mother and also identify the delivery sets for each mother. Procedures for adding linked newborn hospitalization data are being evaluated, and the feasibility of adding newborn hearing screening records is also under review. These data, once linked to the NASS database, will provide a wealth of health information about mothers who have undergone ART, and their babies. The Connecticut SMART team is located within the Health Statistics and Surveillance Section of the DPH. For more information about public health surveillance of ART in the state, please see <http://www.ct.gov/dph/cwp/view.asp?a=3132&q=547044%20%20>.

Participation in the SMART Collaborative is part of a larger initiative within the state to reduce low birth weight and associated infant mortality. Over the past few years, DPH has built momentum and partnerships at the local, county and state levels, and is now working with a statewide multi-sector coalition to reduce low birth weight. Reduction of low birth weight is an objective in the State's Health Improvement Plan,² and was recently selected by the Commissioner of DPH as one of six priorities in the plan.³

The DPH is currently working with both the state March of Dimes, as well as the Medical Director for the state Medicaid program to understand the role of ART in poor maternal and infant outcomes. These partnerships will ensure that surveillance efforts are incorporated into consumer awareness strategies across the state to encourage the use of elective single embryo transfer (eSET), an ART technique with a high success rate and high percentage of single births. These partnerships will also allow the state to understand the degree to which families of all income levels access ART treatments, and to develop intervention strategies. The DPH is also working in partnership with CDC and a group of other states that offered questions in the state's adult health survey (<http://www.ct.gov/dph/BRFSS>) about reproductive health, family planning, and infertility. The results of these analyses will help DPH understand the magnitude of infertility in the state, and the choices families make when faced with infertility.

In the summer of 2014, a factsheet on ART usage in the State of Connecticut and its contribution to adverse birth outcomes was produced in partnership with the SMART team at CDC, the Center for Advanced Reproductive Services at the University of Connecticut Health Center, and In Vitro Sciences, Inc., a clinical management company that assists consumers and providers with financing and insurance reimbursement for ART (see **Appendix 1**). The factsheet was presented at the annual SMART meeting at CDC in August, 2014, in which additional input was provided by participants. No comments on the factsheet, however, were obtained from consumers, the audience intended for the factsheet.

² Connecticut Department of Public Health (2014) Healthy Connecticut 2020: State Health Improvement Plan, Hartford, Connecticut (http://www.ct.gov/dph/lib/dph/state_health_planning/sha-ship/hct2020/hct2020_state_hlth_impv_032514.pdf), accessed on June 10, 2014.

³ Connecticut Department of Public Health (2014) State Health Assessment and Plan Released at Meeting of Statewide Coalition (video) (<http://publichealth.mediastite.com/mediastite/SilverlightPlayer/Default.aspx?peid=08bf0be4d4b7449b902bacb05cbfe3351d>), accessed on June 10, 2014.

Although the factsheet has been posted on the DPH website (http://www.ct.gov/dph/lib/dph/hisr/pdf/art_factsheet_ct2014.pdf), it is not known what impact the factsheet may have on consumers, and what unintended consequences there might be among consumers who read the document.

The purpose of this study was to field test an existing factsheet among two subpopulations of state residents in Connecticut. The field test was studied among the general public, as well as among patients in the early stages of treatment for infertility, in partnership with the Center for Advanced Reproductive Services.

Methods

The factsheet field tested among consumers is posted on the DPH website (http://www.ct.gov/dph/lib/dph/hisr/pdf/art_factsheet_ct2014.pdf).

Ten patients at the early stages of IVF (in-vitro fertilization) treatment, both men and women, were recruited to provide anonymous assessment of the factsheet, from May 1, 2015 through May 13, 2015. Participants were recruited during clinic visits among those who have completed Part 1 and Part 2 of the IVF process. For more information on Part 1 and Part 2, please see <http://www.uconnfertility.com/treatments-services/in-vitro-fertilization>. Staff at the Center for Advanced Reproductive Services, an academic affiliate of UConn School of Medicine, recruited participants among patients as they finished with their appointments. Upon their consent, clients were escorted into a private room and were provided with a packet that contained an introductory letter, the factsheet, and feedback questionnaire. Each client was asked to review the introductory letter, and if they chose to continue, were additionally asked to review the factsheet and respond to the questionnaire (see **Appendix 2**). The questionnaire queried the degree to which they were more informed about ART after reading the factsheet, and how the factsheet impacted their understanding of ART. With the return of the completed questionnaire, each respondent received a \$10 Walmart gift card. An additional ten participants were recruited from among visitors to Bushnell Park in Hartford, Connecticut to represent the general public, on Friday, May 2, 2015, and a similar protocol was followed. This field test was offered to men and women at least 18 years of age who report English as their primary language.

Responses to the questionnaires were entered into an Excel worksheet. Summary-level quantitative and qualitative measures were created to assess the degree to which the factsheet raised awareness among participants, and how the factsheet might be improved to better resonate with consumers. Narrative responses were coded to develop themes for qualitative analysis. Coding for the general public and clinic setting were conducted independently to generate separate themes. All responses from participants were then classified into the themes.

This protocol was approved by the Human Investigations Committee at the DPH, and was determined to be exempt (Protocol number 71E). Gift cards were made possible through a contract with the Association of State and Territorial Health Officials. Partnership with the Center for Advanced Reproductive Services (Mr. Paul Verrastro, Chief Operating Officer) is greatly appreciated.

Results

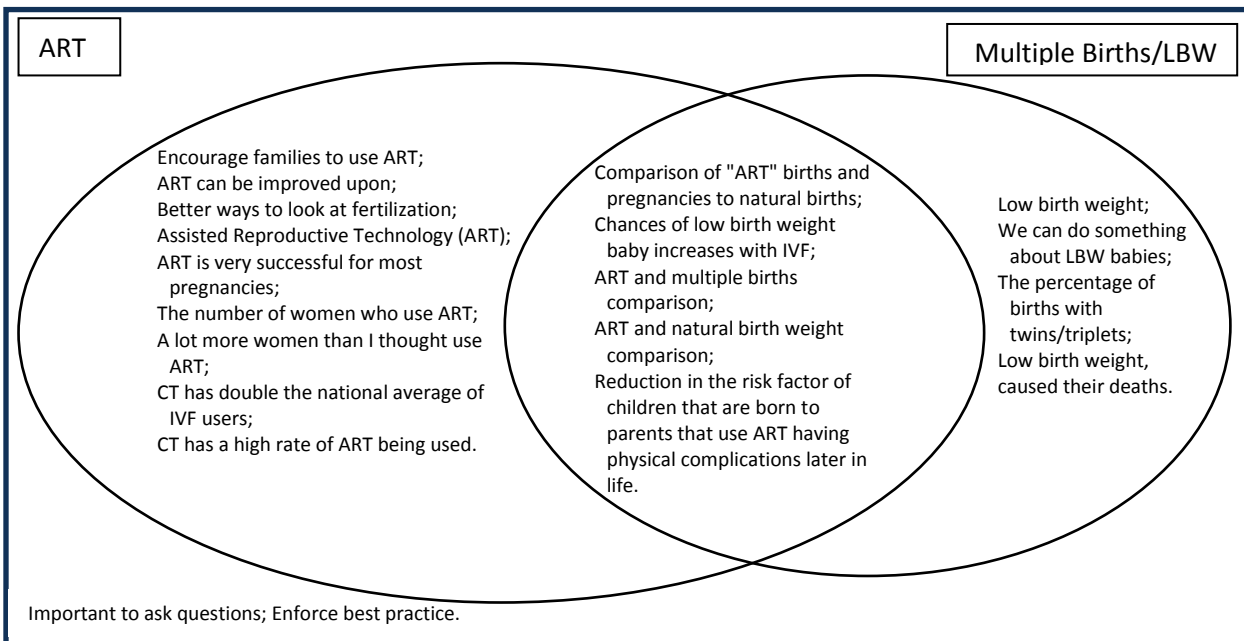
General Public

Among the total of ten responses obtained from the general public, responses were equally split between men and women; four respondents were 25-34 years old, two each were either 35-44 or 55-64 years old, and one each was

45-54 and 65 or more years old. Eight of the ten respondents reported being White, while one each reported being Black/African American or Hispanic. Overall, a majority of respondents reported that the factsheet was very informative and very helpful. The factsheet, however, was judged by the majority to be only moderately easy to understand, moderately pleasant to view, and a moderately good use of time.

The questionnaire first asked what two major points the respondent believed was being presented in the factsheet. Responses from the general public are summarized below, organized into three themes (**Figure 1**).

Figure 1. General Public: “What two major points do you believe are being presented in the factsheet?”



All but two responses could be categorized as either being about ART, LBW, or both. All respondents understood from the factsheet that ART was a primary topic, and a majority also understood the intended link between ART and LBW. Some reported that LBW was a primary topic. Two respondents reported either “Important to ask questions” or “Enforce best practice” as primary topics of the factsheet.

When asked, “What did you like about the factsheet?” respondents from the general public reported more positive aspects than negative, and whereas the positive aspects were generally related to data and graphs, the negative aspects were generally related to concern about the high number of ART and LBW that result from ART (**Table I**). Although respondents reported that the factsheet was informational with easy to understand statistics and graphics, two respondents reported being concerned about the twin birth rate or low birth weight. One respondent was alarmed by the “length some couples will go to start a family.” Four respondents reported being neither confused nor concerned.

When asked in what way the factsheet could be improved, responses fell into three themes. Three respondents felt the material was too dense and needed to be simplified. Another three respondents wanted more information. Three respondents provided suggestions that would help readability of the factsheet to the general public.

Table I. General Public Responses:	
“What did you like about the factsheet?”	“In what way did the factsheet confuse or concern you?”
Very informational. Charts backed up facts	A lot of text - more bullet points
Explains about ART and LBW	I'm alarmed at the high number of twins
Short and easy to understand	All the low rates of births
Good info and stats, is completely CT specific	Second page is clearer
Graphs are easy to read; source data/data sources are easily identified and well explained	It made me aware of the length some couples will go to start a family
The stats. Not too much info	The factsheet is easy to understand in my opinion
The embryo transfer	None
Presentation	None
The position the state is taking to improve this technology out of concern for the families	In no way

General public respondents provided positive advice when asked how the factsheet could be improved (**Table II**). Generally, respondents suggested that less writing and more graphs would be better. Although some wanted more information, others wanted the factsheet to be less “dense” with sentences. One respondent suggested that the first page needed a “hook” to capture the reader’s attention.

Table II. General Public: Advice for Improving the Factsheet

Less Information

Less information in paragraph form;

Too dense for general public;

Made more concise. The information is very valuable and surprising, but the presentation is very "busy." The dense blocks for text on the front side would be better presented like the shorter sentences on the back side.

More Information

Provide references to related factsheets, if any, and further breakouts of "ART" technologies;

List reasons that CT is more than twice that of the national average;

To talk about how many of the babies could live.

Layout

I think a better opening statement would help. Example - one or two sentences summarizing the point;

I would say only to find a way to be available to the public and couples who may be considering this method;

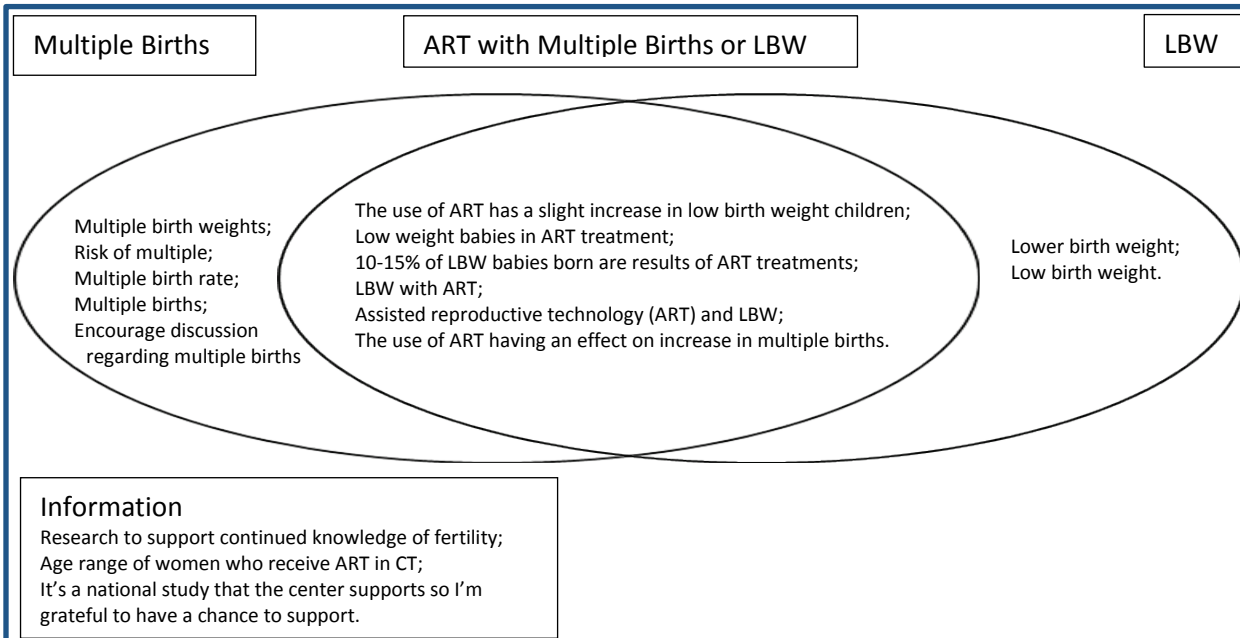
I thought if LBW said "Low Birth Weight" on the second page it would be easier for people to follow.

Clinic Patients

Among a total of ten respondents recruited from the Center for Advanced Reproductive Services, all but one was female. Six participants were 25-34 years old, and four were 35-44 years old. Six respondents reported being White, two reported being Black/African American, and one each reported being Hispanic or Asian. Overall, a majority of respondents reported that the factsheet was informative, pleasant to view, and a good use of time. All reported that the factsheet was easy to understand, and responses were equally split between very and moderately helpful.

When asked what two major points were presented in the factsheet, the majority of respondents from among clinic patients focused beyond the single topic of LBW, ART, or multiple births to understand the relationship between ART and either low birth weight or multiple births (**Figure 2**). Respondents from the clinic setting gathered general information about ART and were able to report specifics about ART, multiple births and LBW. Three respondents understood that the factsheet also encouraged ways to improve birth outcomes from ART.

Figure 2. Clinic Patients: “What two major points do you believe are being presented in the factsheet?”



When asked what they liked about the factsheet, four respondents from the fertility clinic reported liking its data, two reported liking the graphs, and three reported that they liked the simplicity or clarity of the factsheet (**Table III**). When asked in what way the factsheet either confused or concerned them, three respondents indicated that low birth weight associated with ART concerned them, and one respondent reported that the factsheet eased their concern about single embryo transfer. One respondent reported being confused about the age at which women undergo ART treatment, and the response of one patient suggested confusion about the questionnaire itself. One respondent reported that the large amount of data was confusing to them; three respondents reported being neither confused nor concerned.

When asked how the factsheet could be improved, eight of the ten respondents indicated that no improvements were needed (**Table IV**). One respondent reported the need for more statistics, and a second respondent reported that the data should be more current.

Table III. Clinic Patients Responses:	
What did you like about the factsheet?	In what way did the factsheet confuse or concern you?
Data	Concern
The comparative statistics	It concerned me given the rate of low birth weight in children conceived through ART
Percentage of all birthweights in CT	Low birth weight babies
Information and awareness	No confusion, slight concern about LBW in ART births
Information is stated clearly w/out too many medical terminology	It is always a concern when you think two is best to ensure pregnancy. But the factsheet helped overcome this concern
Discourages transfer of multiple embryos	
Graphs	Confusion
The graph	One thing that concerned me was that women 15 years of age were participating in the ART treatment
Graphs	It didn't confuse me at all. After what women go thru on this path, a blood draw is so simple
Simplicity/Clarity	Miscellaneous
Simplicity	Lots of numbers
Very clear	None
Easy to read/understand, also the comparison of ART to all births	None
	None

Table IV. Clinic Patients: Advice for Improving the Factsheet

Improvements

Provide more statistics
Updated to at least 2013

Nothing

Not applicable
Nothing, I almost said more color blue to ease the reading but not needed and may turn some patients away given the nature of the reason we are here
None
Not applicable
Very straight forward, no need for improvement
None
Not applicable
Pretty good!

Conclusions and Limitations

The results of the field test among the general population indicate that the factsheet is well-understood and informative for those with an interest in the topic of assisted reproductive technology. A simpler, more graphical, factsheet should be considered for the general public, however, or for those with little or no direct interest in the topic.

The factsheet was very well-understood, informative, as well as helpful and a good use of time for respondents at the Center for Advanced Reproductive Services, suggesting that the factsheet may be more appropriate for an audience with an existing interest in the topic of ART. The factsheet seems to be more appropriate for an audience that is already somewhat informed about ART; respondents from the clinic setting appeared to read the factsheet from a perspective of

one with knowledge of ART, and therefore were better able to understand the more difficult cognitive link between ART and either multiple births or LBW.

The authors noted that as the factsheet was being reviewed by the general public, it seemed that most took the task seriously and worked hard to understand the factsheet before completing the questionnaire. For some, this process took longer than expected, in one case over 30 minutes. Many engaged in a verbal conversation after reading the factsheet and completing the questionnaire, suggesting that the factsheet, once understood, was compelling enough for the reader to seek further information.

Similar observations were made from the patients at the Center. In addition, several of the respondents felt strongly in wanting to help other couples going through IVF treatment, and verbalized afterwards that not only was the factsheet helpful to them, but also felt convinced that others would benefit from the information presented on the factsheet. One respondent verbalized that the information on the factsheet gave her the necessary background information to better understand the clinic's concern about transferring multiple embryos.

Ten responses were solicited each from the public and clinic settings. Responses obtained from these participants were sufficient to develop themes from the narrative responses, suggesting that the degree of saturation was sufficient for this study. Although variation by sex, age, and race may, with a larger sample size, provide more detailed assessment of the factsheet, the themes developed with this sample were sufficient to discriminate between the general public and clinic patients in their response to the factsheet. Limitations related to descriptive validity were minimized by asking respondents to provide feedback in written format. Interpretive validity was not possible to assess, since there was no opportunity for follow-up among the respondents. Limitations related to theoretical validity were minimized by asking for only minimal responses that could be easily coded to develop themes.

Appendix 1: ART Factsheet (also located at http://www.ct.gov/dph/lib/dph/hisr/pdf/art_factsheet_ct2014.pdf)



Factsheet

Assisted Reproductive Technology (ART) in Connecticut

Summer, 2014

Health Statistics and Surveillance Section
Connecticut Department of Public Health

Significance for Connecticut

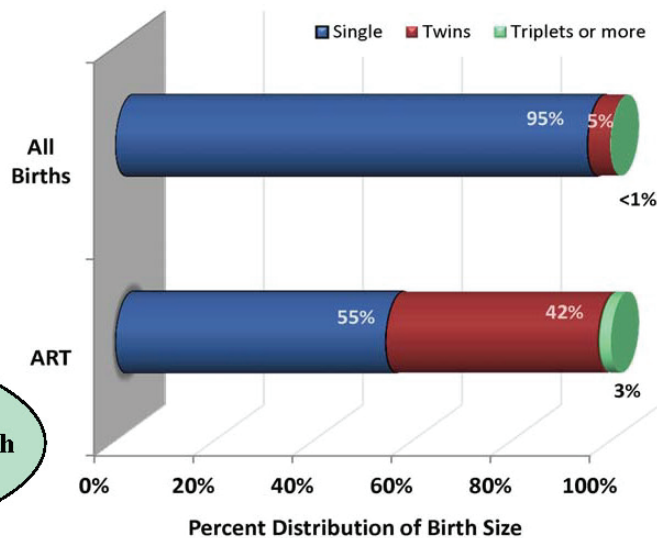
Assisted Reproductive Technology (ART) is a term used for a range of methods that are used to help women become pregnant. Techniques involve creating an embryo that is transferred into a woman's body. The rate of ART use in the State of Connecticut is more than twice that of the national average, a rate exceeded by only three other states in the country. Although Connecticut's infertility insurance mandate (PA 05-196) was an important step toward improving ART outcomes, births that result from ART now account for 10-15% of low birth weight babies born in the state.¹ New ART technologies show promise in reducing low birth weight outcomes, which are now often associated with twins, triplets, and higher order births that result from ART use.

ART and Multiple Births in Connecticut

5 in 1,000 women 15-44 years old in Connecticut have ART treatments in a single year.

10-fold: The increased risk of twins, triplets, or higher order births with ART treatment.

- Among all births in Connecticut during 2010, 95% were single, 5% were twin, and less than 1% were triplet or higher order.
- Among ART births in Connecticut during 2010, only 55% were single, while 42% were twin, and 3% were triplet or high order.



An ART technique called elective single embryo transfer (eSET) results in a single birth and is very successful for most pregnancies.²

Data Sources

Information on births in Connecticut during 2010 were obtained from vital records data within the Health Statistics and Surveillance Section, Connecticut Department of Public Health (DPH). Information about ART and associated birth outcomes were obtained courtesy of the ART team from the National ART Surveillance System (NASS), at the Centers for Disease Control and Prevention. This database is mandated by the Fertility Clinic Success Rate and Certification Act of 1992 (Public Law 102-493; <http://uscode.house.gov/statutes/1992/1992-102-0493.pdf>). Although the two databases were analyzed separately in this factsheet, plans to link the two databases are underway within DPH to study more fully ART usage in the state, as well as maternal and infant outcomes. This activity was made possible when DPH joined three other states in Spring, 2013 as a member of the SMART (States Monitoring ART) collaborative. For more information about the SMART collaborative, please go to <http://www.cdc.gov/art/SMART.htm>. The NASS database maintains information on ART methods such as *in vitro* fertilization, zygote intrafallopian transfer, tubal embryo transfer, gamete intrafallopian transfer, and intracytoplasmic sperm injection; use of fertility drugs such as Clomid, Serophene, or injectable hormones, and superovulation induction with inseminations are not maintained in the database.





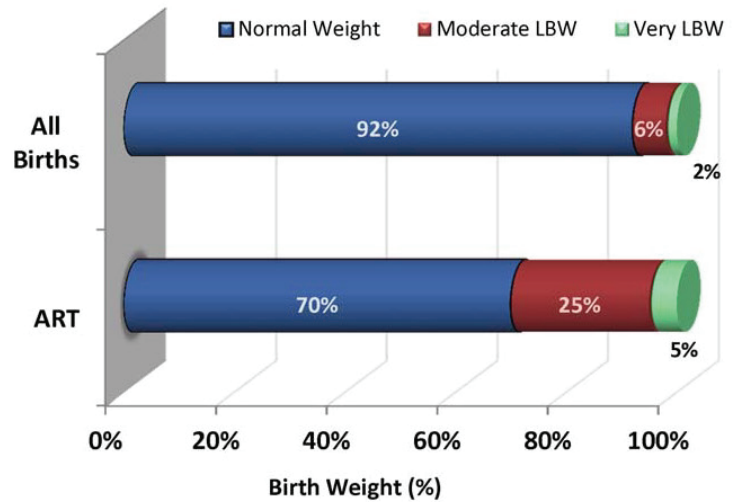
ART and Low Birth Weight (LBW)* in Connecticut

10-15% of LBW babies born in Connecticut are the result of ART treatments.

30% of ART treatments result in a LBW baby, compared to 8% of all births in the state.

1 in every 6 LBW babies born from ART treatments is very LBW.

Low birth weight babies have a higher risk of delayed childhood development, lower school achievement, and even medical complications or death during infancy.^{3,4}



*A low birth weight (LBW) baby has a birth weight less than 2,500 grams, or about 5.5 pounds. A very LBW baby has a birth weight less than 1,500 grams, or 3.3 pound, while a moderate LBW baby has a birth weight from 1,500 to 2,499 grams.

Strategies for Connecticut

Encourage families considering ART to consult with their fertility specialist about all methods of ART, and to consider eSET, when appropriate.⁵

Encourage best practice clinical guidelines that reduce the rate of twin births.

For additional information about infertility and ART, please see:

ART website at the Connecticut Department of Public health <http://www.ct.gov/dph/assistedreproductivetechnology>

Centers for Disease Control and Prevention <http://www.cdc.gov/art>

Society for Assisted Reproductive Technology <http://www.sart.org>

March of Dimes <http://www.marchofdimes.com/pregnancy/thinking-about-fertility-treatment.aspx>

The American Society for Reproductive Medicine <http://www.reproductivefacts.org>

References

¹ Sunderam, S, Kissin, DM, Crawford, S, Anderson, JE, Folger, SG, Jamieson, DJ, Barfield, WD (2013) Assisted Reproductive Technology Surveillance— United States, 2010, *MMWR* 62(ss09),1-24 (http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6209a1.htm?cid=ss6209a1_e), accessed on May 12, 2014.

² Kissin, DM, Kulkarni, AD, Kushnir, VA, Jamieson, DJ, for the National ART Surveillance System Group (2014) Number of embryos transferred after *in vitro* fertilization and good perinatal outcome. *Obstetrics and Gynecology* 123(2, Part 1): 239-247.

³ Pelletier, T, Maternal Substance Abuse and Child Development Project, Emory University School of Medicine, Department of Psychiatry and Behavioral Sciences, Atlanta, Georgia ([http://www.psychiatry.emory.edu/PROGRAMS/GADrug/Feature%20Articles/Mothers/Long%20term%20effects%20of%20Low%20Birth%20Weight%20\(mat08\).pdf](http://www.psychiatry.emory.edu/PROGRAMS/GADrug/Feature%20Articles/Mothers/Long%20term%20effects%20of%20Low%20Birth%20Weight%20(mat08).pdf)), accessed on May 12, 2014.

⁴ Low Birth Weight: March of Dimes Foundation, 2014 (<http://www.marchofdimes.com/baby/low-birthweight.aspx>), accessed on May 12, 2014.

⁵ Benadiva, C. (2012) Elective single embryo transfer. Center for Advanced Reproductive Services, University of Connecticut Health Center, Farmington, CT (<http://bit.ly/1oa4noD>), accessed on June 4, 2014.

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This factsheet can be viewed at: http://www.ct.gov/dph/lib/dph/nisr/pdf/art_factsheet_ct2014.pdf



Appendix 2: ART Questionnaire

ART Fact Sheet Feedback

First, please circle the response that best describes you.

Sex: M F

Age: 18-24 25-34 35-44 45-54 55-64 65 and over

Race/Ethnicity: White Black/African American Asian Hispanic Other

Is English your primary language? Yes No

Now, please answer the six (6) questions below after reading the fact sheet. Feel free to refer to the fact sheet as you answer the questions.

1) What two major points do you believe are being presented in the fact sheet?

1 -

2 -

2) What did you like about the fact sheet?

3) In what way, if any, did the fact sheet confuse or concern you?

4) In what way, if any, could the fact sheet be improved?

5) To what degree was the fact sheet:

Informative:	Not at All	Moderately	Very
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Helpful:	Not at All	Moderately	Very
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Easy to Understand:	Not at All	Moderately	Very
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Pleasant to view:	Not at All	Moderately	Very
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A good use of time:	Not at All	Moderate	Very
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6) Please provide us with any additional comments about the fact sheet.

Thank you!