

Reply of the Authors:

We thank Drs. Coulam and Clark for their comments on our paper.

Pregnancy rates after IVF-ET are significantly different between the United States and the United Kingdom because of different stimulation protocols used and the lower number of embryos that are transferred in the United Kingdom compared with the United States. The pregnancy rates achieved in our study are comparable with those of similar units in the United Kingdom (1).

The assay used for the detection of antiphosphatidylserine was performed in our own laboratories, which meet the standards of the United Kingdom National External Quality Assessment Survey (NEQAS) for the performance of antiphospholipid antibody (aPL) assays.

We concede that the sample size of our population was small and that consequently there is an increased probability of a type II error. However, we stand by our conclusion that routine screening of women undergoing IVF for aPL is not justified. This finding is supported by a recent meta-analysis of seven studies, published in this journal, which reported that there was no significant association between aPL and either clinical pregnancy or live birth rates (2).

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The Value of Laboratory Accreditation?

To the Editor:

This letter is in response to the article by Albert Smith, Ph.D., regarding the lack of correlation between College of American Pathologists/American Society for Reproductive Medicine (CAP/ASRM) laboratory accreditation and pregnancy rates (1). I am writing as an individual, but I am also Past President of the Society for Assisted Reproductive Technology (SART).

Constructive criticism of ART has led to many improvements in overall quality of patient care, and SART and ASRM have welcomed and demonstrated their responsiveness to many diverse opinions. Laboratory accreditation is a relatively recent improvement in the field of ART, and Dr. Smith's correspondence will contribute to its continued refinement. However, I would like to offer some additional perspectives concerning the value of accreditation of ART laboratories.

SART has always been committed to self-regulation and an oversight process developed by professionals practicing ART, and who are democratically nominated and elected by their peers. This will ensure the highest standards of care for our patients. The CAP/ASRM accreditation process was developed with significant laboratory professional participation and SART as advocated CAP/ASRM accreditation since the early 1990s. In 1999, accreditation became mandatory for SART membership. Currently, 201 programs are accredited by CAP, 58 certified or pending by JCAHO, 16 by state authority, and 76 have active applications for CAP/ASRM accreditation visits.

Although accreditation has not yet been shown to improve pregnancy rates, it may or may not be true that accreditation actually does improve pregnancy rates. Because mandatory accreditation became effective just last year, it is far too early to draw conclusions regarding its potential impact. Also, the process is constantly being improved as we gain experience. Additionally, pregnancy rates may not necessarily be the most germane measure of accreditation. Data currently available to us do not address potential differences in patient populations as well as other factors affecting pregnancy rates in accredited vs. nonaccredited laboratories. The presence of the accreditation process itself may have improved success rates in both accredited and nonaccredited laboratories.

Although live birth rates of singletons, and possibly twins, are undoubtedly the most important measure of our professional efforts, accreditation can bring value without directly increasing pregnancy rates. The standardization of definitions, procedures, systems, and outcome measures allows us to converse more efficiently, perform better research, compare results and eventually, we hope and expect, improve pregnancy rates. Accreditation also helps establish procedures to minimize laboratory errors that can have very serious ramifications for patients and professionals. The commitment to peer accountability through accreditation enables both embryologists and clinicians to continue to be self-regulated as opposed to having arbitrary and potentially inappropriate requirements set by those outside the ART profession. The government and public confidence in our services has unquestionably been increased by our accreditation efforts.

Further benefits of laboratory accreditation include increased recognition by SART of the need to develop clinical guidelines as well as laboratory guidelines. Requirements for

SART membership now include the need to follow guidelines regarding reporting results annually to SART, advertising, appropriate donor compensation, ethics codes, clinical care standards, laboratory-related practices such as the number of embryos to transfer, documentation of research cycles, and the need to participate in on-site validation visits. This year, for the first time, randomly selected SART programs will undergo on-site evaluation of their compliance with SART standards.

SART has long recognized the need for clinicians and laboratory professional to function as a team. SART has increased representation on its Executive Council to all professionals providing ART services, including two laboratory directors plus one representative from each of the Reproductive Biologists Professional Group (RBPG) and the Reproductive Laboratory Technologists Professional Group (RLTPG). These members have been selected by their laboratory colleagues and have been very active in representing laboratory interests and perspectives, and their contributions are highly regarded.

A legitimate concern regarding accreditation is its cost. Even though the overall cost of accreditation is much less than 1% of revenues, a small amount relative to the benefits and not high considering what is actually involved, SART is responding to cost concerns. SART is working with CAP and JCAHO to control costs. SART also accepts alternative accreditation from states that have equivalent standards.

In summary, the accreditation process is valuable for many reasons and may yet improve pregnancy rates. Significant benefits accrue through self-regulation, standardization, increased public confidence, enhanced clinical guidelines and collaboration between embryologists and clinicians—all consequences that directly benefit our patients. SART will continue to improve the accreditation process with the assistance of the ongoing active leadership of its laboratory representatives. It has in the past, and continues, to invite the constructive participation of all laboratory professionals.

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Reply of the Author:

I would like to thank Dr. Adamson for his comments on the dedication of the College of American Pathologists (CAP), the American Society of Reproductive Medicine (ASRM), and the Society of Reproductive Technology (SART) to the maintenance of self-regulation of the infertility industry, and

the role that lab accreditation may have in the maintenance of self-regulation. As pointed out by Dr. Adamson, the potential role of lab accreditation in the improvement of clinical pregnancy or take home baby rates has yet to be determined.

My personal feeling is that lab accreditation will, ultimately, have a negligible effect on the improvement of clinical pregnancy or take home baby rates. Improvement in clinical pregnancy or take home baby rates in the past decade are attributable to several factors: improved stimulation protocols, improved stimulation drugs, improved transfer techniques (ultrasound guided transfers), and improvements in lab procedures, such as intracytoplasmic sperm injection (ICSI), and the use of glucosephosphate free media. These recent innovations in the human field actually can be traced back to the 1970s for ICSI (1) and the 1980s for glucosephosphate free media (2) in animal species. Further improvement in the field of human embryology will undoubtedly stem from further application and incorporation of successful animal species techniques (hopefully without such extended lag times), not from lab accreditation per se.

If regulation of the infertility industry is forthcoming, it will certainly be due to excessively high multiple pregnancy or take home baby rates—43% for patients under the age of 35 in 1997 (3). Although not calculated in my original article (4) because of time limitations on my part, the multiple take home baby rates for CAP-accredited and non-CAP-accredited labs were not significantly different, as with all other parameters. Because there is no decrease in multiple take home baby rates associated with accreditation, lab accreditation will undoubtedly be a minor factor in the ultimate outcome of whether or not the infertility industry becomes regulated.

Although government regulation of the infertility industry seems heinous to most, it is already being regulated in labs. By requiring lab accreditation for membership in SART, labs are, by default, put under the jurisdiction of the Clinical Laboratory Inspection Agency (CLIA). Interestingly, in New York State, the only state in which SART allows accreditation by a state agency, 16 of 27 ART labs are accredited by the state agency. Does that mean government regulation is preferred as the best form of accreditation?

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