Validation of prognosis-based in vitro fertilization grant selection criteria

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Objective: To validate a prognosis-based scoring system for in vitro fertilization (IVF) grant allocation.
Design: Retrospective cohort study.
Setting: A 501(c)(3) nonprofit foundation that awards donated IVF cycles and grants to those with demonstrated financial need. In contrast to lottery-based or subjective allocation systems, applications are scored according to medical prognostic criteria in addition to personal characteristics.
Patients: Grant recipients from 2015 to 2019.
Interventions: None.
Main outcome measures: Live birth rate (LBR) and cumulative LBR (CLBR) among grant recipients were compared with 2019 Society for Assisted Reproductive Technology (SART) national averages.
Results: A total of 435 applications were reviewed, with 59 grants awarded for 51 autologous IVF cycles, 6 donor oocyte cycles, and 2 gestational carrier cycles, resulting in 39 live births after initial embryo transfer (LBR 61.9%) and 43 CLBRs (CLBR 72.9%). Among autologous cycles, the mean (±SD=3.9 years) age was 31.8 years, and LBR and CLBR were 62.8% and 68.6% vs. 28.2% and 37.1% among all autologous SART cycles, respectively. A subanalysis of grant recipients aged <35 years (n=39) revealed LBR and CLBR of 66.7% and 74.4% vs. 40.7% and 47.8% among autologous SART cycles aged <35 years, respectively.
Conclusions: A scoring system incorporating medical criteria identified IVF grant applicants with a high likelihood of achieving a LB. Although most IVF grant programs select recipients through a lottery or personal characteristics, a prognosis-based scoring system should be considered to maximize LBR in a limited resource setting. (Fertil Steril Rep® 2023;4:286–91. ©2023 by American Society for Reproductive Medicine.)
Key Words: In vitro fertilization, grant, scoring system, allocation

Infertility affects >6.7 million women in the United States, impacting approximately one in eight couples (1). However, access to fertility treatment remains limited (2). Of those requiring assisted reproductive technology (ART) to conceive, only approximately one in four are able to access these services (3). This disparity is largely driven by the prohibitively high cost of ART, compounded by inadequate insurance coverage, contributing to an overwhelming economic burden for patients.

Although 19 states have enacted some form of infertility coverage mandate, there are numerous restrictions and gaps in coverage, leaving patients uninsured or underinsured (4). Benefits differ from state to state considerably, as do inclusion criteria (4, 5). Even in mandated states, coverage is not universal (4). In response to this disparity, the American Society for Reproductive Medicine developed a strategic plan to improve access to infertility care (6). Although this has triggered numerous initiatives to recognize infertility as a medical disease and thus expand insurance coverage accordingly, in vitro fertilization (IVF) remains largely inaccessible for most Americans.

Several nonprofit organizations have arisen with the mission of reducing barriers to fertility treatment through donated services and financial assistance grants. As of 2019, 37 such nonprofit organizations had been identified, providing almost 1,740 grants per year and over 10,000 to date (7). Most of these grants are awarded using a lottery system or on the basis of individual factors, such as a personal statement, with little consideration of medical prognosis. In a landscape in

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which demand is high and resources are sparse, a framework to predict IVF success would optimize these limited resources by triaging grant allocation to those with the highest chance of achieving live birth (LB).

The Chicago Coalition for Family Building (CCFB) is a 501(c) (3) organization that provides both donated IVF cycles and financial grants of up to $15,000 to individuals and couples with demonstrated financial need requiring fertility treatment (8). In contrast to other organizations' random or subjective selection of grant beneficiaries, the CCFB has formulated a novel prognosis-based numeric scoring system to identify applicants with the highest likelihood of treatment success (8). This study aimed to validate the CCFB prognosis-based scoring system for IVF grant allocation to maximize LB rate (LBR) in a limited resource setting.

MATERIALS AND METHODS

This study was evaluated and approved by the Northwestern University Institutional Review Board. The CCFB awards donated IVF cycles and financial grants of up to $10,000 toward the cost of fertility treatment. Individuals and couples with an annual income of <$200,000 and a need for intrauterine insemination or IVF are eligible to apply. Applicants are asked to provide demographic information and past obstetric, gynecologic, medical, surgical, and social histories. Applicants are asked also to provide a copy of their driver's license and the prior year's Wage and Tax Statement and to write a personal statement describing their story and why they are applying for a grant. A separate medical form is sent to the applicant's physician or treating provider. This form collects data on laboratory test results, semen analysis where applicable (volume, count, motility, and morphology), and results of the uterine cavity and fallopian tube evaluation, including specific questions on whether tubal obstruction or hydrosalpinx are visualized and whether adhesions, polyps, or fibroids are present. For patients with fibroids, information on fibroid size and location is gathered. Additionally, each medical professional is asked an overall assessment of whether they would "highly recommend," "recommend without reservation," "recommend," or "do not recommend" the applicant, with space for free text to add commentary. There is one grant cycle annually in which applications open and are reviewed. Each application is scored by two board certified reproductive endocrinologists independently on both medical criteria (up to 55 points, Table 1) and personal characteristics (up to 45 points) for a maximum possible total score of 100 points. All applications are also reviewed by three Executive Board members (E.C.F., J.H.C., and J.S.) to ensure accuracy in scoring.

Thirty-five of the 55 possible medical points are awarded on the basis of ovarian reserve parameters, and the other 20 points are from the combination of uterine, tubal, and male factors. When ovarian reserve is scored, applicants can receive up to 15 points on the basis of age, up to 15 points on the basis of antimüllerian hormone (AMH) levels, and up to 5 points on the basis of follicle-stimulating hormone (FSH) levels, with

TABLE 1

Medical criteria for prognosis-based scoring of in vitro fertilization (IVF) grant applicants.

Ovarian reserve[a,b] (35 points)				BMI[c] (5 points)	Uterine factor[d,e] (5 points)	Male factor[f] (5 points)	Children (5 points)
Points	Age (y)	AMH (ng/dL)	FSH (mIU/mL)	Points	BMI (kg/m^2)		
1	>40	0.5	15	1	40 or ≤18.5	1–5 points on the basis of medical history	5 points to applicants without living children
3	38–39	0.5–1.0	10–15	2	35–39		
5	35–37	1.0–1.5	<10	3	30–34		
10	31–34	1.5–2.0		4	25–29		
15	≤30	>2.0		5	18.5–24		

AMH = antimüllerian hormone; BMI = body mass index; FSH = follicle-stimulating hormone.
[a] Donor egg: 35 points.
[b] Autologous cycle applicants excluded for aged ≥42 years, AMH < 0.5 ng/dL, FSH > 15 mIU/mL, or ≥3 prior failed fresh IVF cycles.
[c] Applicants excluded for BMI > 40 kg/m^2.
[d] Applicants are excluded for ≥20-week-size uterus, submucosal fibroids, intramural fibroids ≥ 5 cm, or severe Asherman syndrome.
[e] Gestational carrier: 5 points.
[f] Donor sperm: 5 points.

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TABLE 2

Demographic characteristics and cycle outcomes among 2015–2019 in vitro fertilization grant recipients.

Age (y)	**32.70 ± 0.64**
AMH (ng/mL) [a]	2.95 (2.04–5.48)
Cycle type	
Autologous	51 (86.4%)
Donor oocyte	6 (10.2%)
Gestational carrier	2 (3.4%)
Live birth rate after first ET	39 (66.1%)
Cumulative live birth rate	43 (72.9%)

Note: All values are reported as mean ± SD, median (interquartile range), or n (%) as appropriate.
AMH = antimüllerian hormone; ET = embryo transfer.
[a] Calculated among cycles for whom an AMH level was available (n=42).

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more favorable values receiving more points. Applicants are awarded up to 5 points on the basis of body mass index (BMI), with the maximum point allocation in the normal weight category. A healthy uterus and uterine cavity with the absence of pathology receive the full 5 points, and points are deducted on the basis of the severity of adhesions and fibroid burden. Semen analysis is scored on the basis of volume, concentration, motility, and morphology. Scores for sperm and uterine factors are determined on the basis of the clinical judgment of the scoring physician. Of note, applicants planning to use an oocyte donor are allocated the full 35 points in the ovarian reserve category; those planning to use a gestational carrier (GC) are awarded an automatic 5 points in the uterine scoring category; and those planning to use donor sperm receive an automatic 5 points in that category, provided that indications are appropriate and a recommended psychoeducational consultation has been offered per the American Society for Reproductive Medicine guidelines (9, 10). Of note, in Illinois, patients planning to use a GC must have a medical indication for a GC with a physician affidavit, and the intended parent(s) must undergo a mental health evaluation (11). Five points are added for applicants who have zero living children, and applicants with two or more living children are not eligible to apply for a grant. The personal statement accounts for the remaining 45 points and is scored by each of the physician reviewers subjectively. The applicant's scores from the two medical reviewers are averaged, and grants are awarded to applicants with the highest scores in each application cycle.

Cycle outcomes for 2015–2019 grant recipients were reviewed. Cycles from 2020 and 2021 grant recipients were not included because many cycles were delayed because of the coronavirus disease 2019 pandemic and outcomes were not yet available for all cycles. Live birth rate after the first fresh or frozen embryo transfer and cumulative LBR (CLBR) after all embryos transferred from a single stimulation cycle were analyzed and compared with 2019 national averages according to the 2019 Society for Assisted Reproductive Technology (SART) National Summary Report using a one-sample test of proportions (12). A P value of $<.05$ was considered statistically significant.

RESULTS

A total of 435 applications were reviewed during the study period. Grants were awarded to 59 recipients, including 51 pursuing autologous IVF, 6 pursuing donor oocyte cycles, and 2 pursuing GC cycles. Demographic characteristics and cycle outcomes among all grant recipients are summarized in Table 2.

Among autologous cycles only, the mean (±SD=3.9 years) age was 31.8 years, and LBR and CLBR were 62.8% and 68.6% vs. 28.2% and 37.1% among all autologous cycles reported nationally in the 2019 SART National Summary Report ($P<.0001$ and $P<.0001$, respectively) (Fig. 1).

Given the relatively young age of grant recipients pursuing autologous cycles, a subanalysis was conducted among patients aged <35 years. The LBR and CLBR among grant recipients (n=39) were 66.7% and 74.4%, compared with just 40.7% and 47.8% among autologous SART cycles from the same age group ($P<.001$ and $P<.001$, respectively) (Fig. 2).

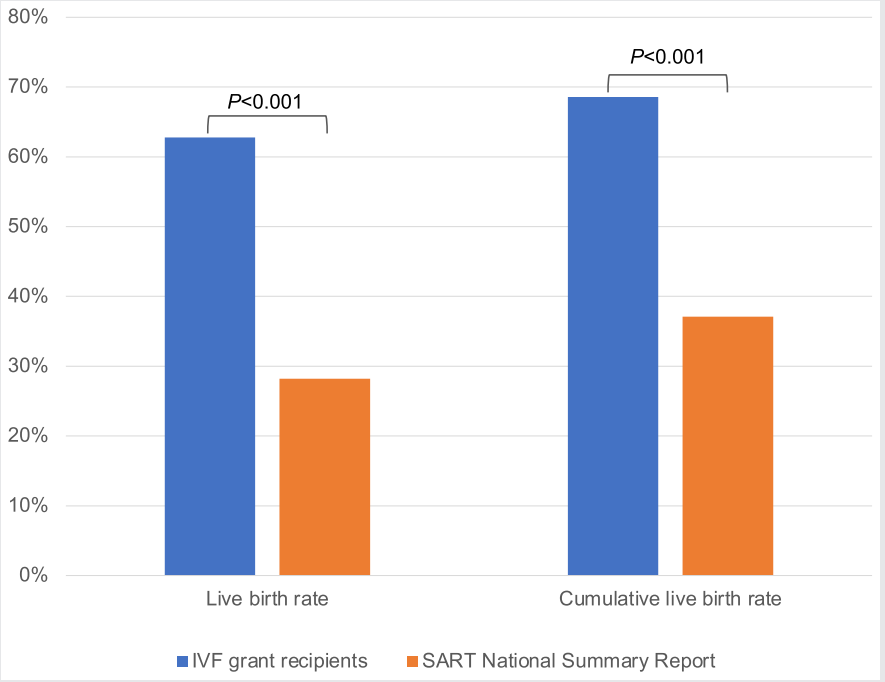
DISCUSSION

The use of a prognosis-based scoring system by the CCFB, a nonprofit organization, to select grant recipients resulted in a high likelihood of achieving a LB. The LBR and CLBR were markedly higher among grant recipients when compared with national averages. These findings held true when limiting the analysis to patients aged <35 years old, highlighting the prognostic value of factors beyond age alone in evaluating grant applications.

Although the systematic incorporation of medical criteria into IVF grant funding decisions may seem intuitive, a web-based search of private fertility foundations suggests that most do not prioritize prognosis. Although selection processes lack transparency, applications typically consist of personal statements or essays, financial disclosures, and medical information provided by a physician. Several programs advertise that selections are made by committees comprised of a board of directors, reproductive specialists, financial advisors, clinical psychologists, volunteers, and/or members of the community. Some programs select recipients using a lottery system, whereas others consider personal statements and individual factors (13–18). Although few consider medical prognosis, some provide set criteria that must be met to be considered for a grant (14). Although the CCFB similarly applies absolute cut-offs surrounding key medical criteria such as age, ovarian reserve, and BMI, the unique point-based system and composite score allow for a more nuanced evaluation of medical prognosis.

Although potentially novel in reproductive medicine, the use of prognostic models to maximize patient outcomes in limited resource settings has been effective in other fields of medicine. In transplant surgery, the model for end-stage liver disease score is a prospectively developed and validated chronic liver disease severity scoring system that uses a patient's laboratory values for serum bilirubin, serum creatinine, and the international normalized ratio for prothrombin time

FIGURE 1



Live birth rate and cumulative live birth rate after autologous in vitro fertilization (IVF) among grant recipients (n=51) compared with national averages from the 2019 Society for Assisted Reproductive Technology (SART) National Summary Report.

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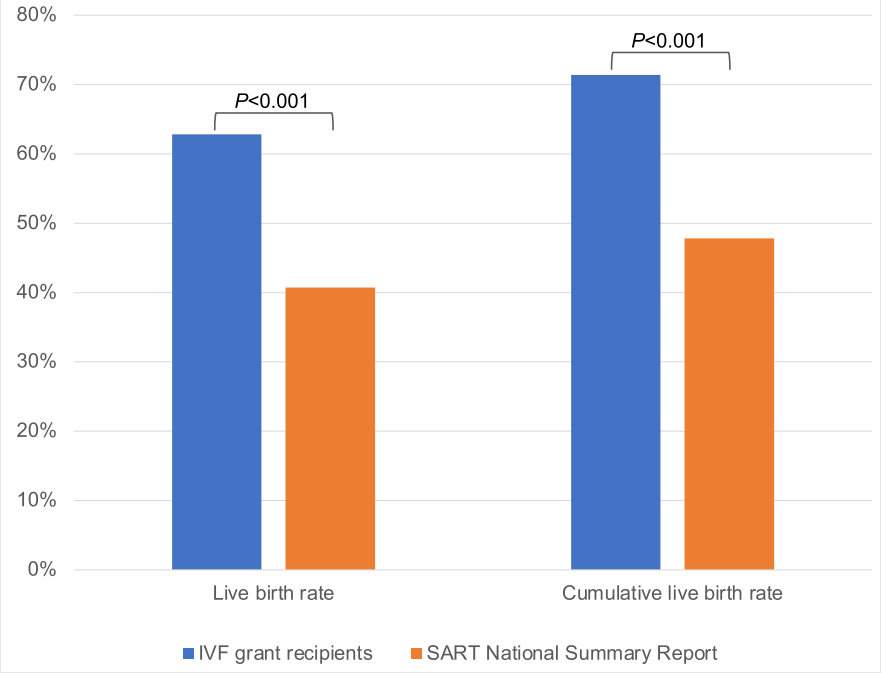
to predict three-month survival (19). Given its accuracy in predicting short-term survival among patients with cirrhosis, the model for end-stage liver disease score was initially adopted by the United Network for Organ Sharing in 2002 to prioritize patients awaiting liver transplantation in the United States. Just as the number of patients awaiting transplantation exceeds available organs vastly, the number of patients requiring but unable to afford fertility treatment exceeds available funding. Although all patients are deserving of care, in settings with limited resources, there is an even greater need to maximize outcomes and minimize waste. Prognostic scoring systems allow for a more objective and equitable allocation of resources although balancing the ethical principles of justice and beneficence

The criteria incorporated in the current model include age, measures of ovarian reserve, including AMH and FSH, BMI, uterine factors, tubal factors, and male factors. Maternal age has been found routinely to be the most predictive factor in determining the likelihood of success with IVF (20–22), with markedly diminished success rates with increasing age of women (23). This pattern reflects a progressive decline in response to ovarian stimulation, resulting in fewer oocytes and embryos and a decreased embryo implantation rate because of declining oocyte quality and increasing embryo aneuploidy (24–26). An absolute cut-off for autologous cycles was incorporated on the basis of the markedly low success rates typically demonstrated beyond age 42: approximately 3% for women ages 43–44 years and just 1% for those over 44 years (23). Markers of ovarian reserve, including AMH and FSH levels, have shown utility also in predicting success with IVF because of the strong association between the number of oocytes retrieved and LBR (27–33). Body mass index has been associated with increased risk of pregnancy loss and decreased risk of LB after IVF for both autologous and donor-recipient cycles, and whereas the mechanisms behind this association are less clear, it remains an important prognostic factor (34–37). Uterine pathologies, including but not limited to fibroids, endometrial polyps, congenital anomalies, and intrauterine adhesions, have been shown also to impact embryo implantation negatively because of distortion of the uterine cavity and/or disruption of the endometrium and its receptivity (38). Finally, the male factor is implicated in approximately 35% of all ART cycles and is one of multiple infertility factors in another 18% of cycles (23). Although abnormal semen parameters may be overcome with intracytoplasmic sperm injection, marked semen abnormalities such as nonobstructive azoospermia may require more extensive treatment, including testicular sperm extraction, and may represent a significant barrier for couples pursuing ART (23, 39, 40). The results of this preliminary study represent the first step in validating a scoring system incorporating these known prognostic factors capable of identifying applicants with a high likelihood of success with IVF.

FIGURE 2



Subanalysis of live birth rate and cumulative live birth rate after autologous in vitro fertilization (IVF) among grant recipients aged <35 years (n=39) compared with national averages from the 2019 Society for Assisted Reproductive Technology (SART) National Summary Report.

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Limitations of this study include its lack of randomization and retrospective design. Patient outcomes were compared with publicly available national averages available through the SART Clinic Outcome Reporting System National Summary Report; however, these averages may not reflect outcomes specifically among unselected grant applicants. Furthermore, only medical information tracked in the Coalition database, such as age and AMH levels, was available for retrospective analysis, whereas precise information, including gravidity, parity, and fertility diagnosis, was not available. It is important, however, to note that applicants were only eligible to apply when they had zero or one living child, and those with two or more LBs were excluded from the grant selection process. Finally, although the results of this study show that this scoring system is effective in identifying good-prognosis patients within a large urban and suburban setting, it may not be generalizable to all populations. We acknowledge that our results represent the first step in the validation of these selection criteria, and anticipate that publication will prompt further research and continued optimization of the scoring system. It is our hope to inspire collaboration and share best practices between organizations to improve grant selection processes more broadly. To this end, we have developed a publicly available online calculator accessible to peer organizations for use in their own grant selection processes, which can be found at https://pbs-five.vercel.app/. The results of this study should encourage organizations to adopt this tool or employ a similar prognosis-based system to identify IVF grant applicants with a high likelihood of achieving a LB.

CONCLUSIONS

This study is the first of its kind to validate a prognosis-based scoring system used to guide the distribution of grant funds for fertility treatment. Although most IVF grant programs select recipients through a lottery system or on the basis of personal characteristics alone, a prognostic scoring system incorporating medical criteria should be considered to maximize LBR in a limited resource setting.

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