WHITE PAPER:
Access to Care Summit

September 10 - 11, 2015
Washington, D.C.
Overview: ASRM Takes Proactive Steps to Address Access to Fertility Care

At its 2014 Annual Meeting, the American Society for Reproductive Medicine introduced its 2014-2019 strategic plan, “Global Impact through Dynamic Engagement.” The plan focuses on how ASRM can have maximum impact on a broad spectrum of reproductive care issues around the globe.

More specifically, ASRM’s strategic plan calls for the need to investigate, address, and act upon specific barriers to reproductive freedom for all individuals. It views the ideal goal of reproductive freedom first and foremost as prevention of infertility. In addition, the plan addresses the greatest barrier for couples with infertility both at home and around the globe: access to care.

It is estimated that only 24 percent of infertile couples in the United States can access all of the care they would need to become pregnant. For the couples who already receive traditional IVF (almost 200,000 treatment cycles in the United States each year), their success rates are as good as any in the world and will only get better and safer as we perfect current technologies.

ASRM believes that the organization’s members should not only continue this traditional IVF care for those who can afford it, but also advocate loudly for insurance coverage for all. Until this ideal and traditional form of IVF is accessible for all, it is important to also advocate for treatments for the majority of infertile couples who cannot afford it.

Our field needs to identify cost-effective treatments, even if their success rate is lower, that couples or individuals shut out by finances can afford. This may well involve identifying minimal-stimulation protocols that are cost-effective, laboratory techniques that use fewer resources perhaps the vaginal incubator, perhaps in vitro maturation, if they could be cost-effective.
ASRM holds the achievement of reproductive freedom through improved access to care as the Society’s true stretch goal for the 2014-2019 Strategic Plan. Working with our partners around the world, ASRM believes its members can have real, meaningful, actionable impact.

When kicking off its strategic plan in 2014, ASRM announced plans for a two-day summit to be held on access to care issues: convening the thought leaders in these fields, hearing about the state of the art practices for each area; discussing barriers and research needed; and then putting into place programs that will move access to care forward and overcome barriers.

ASRM’s Access to Care Summit was held in Washington, D.C. on September 10 - 11, 2015. A full attendee list can be found in the appendix at the end of this document. ASRM’s President, Dr. Rebecca Sokol, welcomed attendees, and the meeting was facilitated and led by ASRM Vice President, Dr. Richard Paulson. ASRM’s Executive Director, Dr. Richard Reindollar, led a brief summary discussion to close the meeting.

In this white paper, we have outlined the major discussion areas; highlighted key findings and educational points from each of our speakers and presenters; shared the summit attendees’ ideas and recommendations in each discussion area; and outlined where ASRM believes it will focus its efforts on access to care issues moving forward. At the conclusion of the meeting, and of this paper, you will find a list of 25 ideas for “actionable items” developed by summit participants. This list will form the basis of ASRM’s future endeavors in this vital area.
Executive Summary

The overarching goal of the American Society for Reproductive Medicine is to have the greatest global impact on reproductive care. Identifying ways to improve access to care isn’t easy. Naming the barriers to care, in addition to finding ways to broaden access, are critical first steps in addressing the global challenge of reproductive care. Once we’ve identified the barriers, we can work together with our partner organizations to begin broadening access to care.

This is not work that will happen overnight. There are cultural, societal, financial, technological, emotional, physical, and other perspectives to consider. Educating patients, practitioners, researchers, and others around the world takes time and effort. It is not something any one organization can do alone. Yes, there are successful models to learn from and that can guide decision making in many different regions and populations around the world, but there is no one-size-fits-all approach to expanding access to care. It takes a coalition effort, global learning and cooperation to make the changes necessary to provide access to care so that individuals and couples can achieve their dream of what a family looks like to them.

We address known and emerging barriers to access: sociocultural, geographic, insurance, financial, economic, outreach to underserved populations and regions, and male infertility education. Whether real or perceived, individuals face a number of challenges when considering reproductive health pathways; and our field needs to explore ways in which we can help patients think through their options with facts from reputable sources, an open mind clear of judgment, and mindful of financial and economic risks with regard to outcomes.

There are ways in which our community can broaden access to care by modifying assisted reproductive technology practices. This might include evaluating and considering natural cycle IVF, lower-stimulation IVF, in vitro maturation, vaginal incubation, and uterine lavage. We also must take into consideration the costs, simplicity, and effectiveness of these modified approaches.
Identifying barriers and finding ways to broaden access does not happen only in labs, clinics, and physicians’ offices. Federal and state governments play a significant role in how we can help steer the conversation around barriers and access. Federal oversight rules and state-mandated insurance exchanges play a significant role in how and where practitioners in our field are able to do its important work. Our own industry-created regulations and guidelines, including SART registry outcomes reporting, make a difference when considering barriers to access. We sometimes face an uphill climb when it comes to public perception of reproductive care and the emotional and political barriers that arise from that.

Our mission is to think big. Think globally. Access to reproductive care -- and overcoming barriers to access -- is a worldwide concern. We must continue to assess and talk openly about global infertility needs. We must continue to share best practices, failures, and ideas in process so that we can continue to learn, adapt, and try new things to ensure we are serving our patients and their families with the utmost care and concern.

We can lead and drive this change. With this paper, we have explored barriers to care. We have made suggestions to broaden access, and we will continue to move this work forward with a series of action steps we can manage from the United States, but collaborate worldwide.

We hope you’ll join us in our mission.
Access to Care Overview:
Dr. Eli Y. Adashi, M.D., M.S., CPE, FACOG

As the first presenter at ASRM’s Access to Care Summit, Dr. Adashi framed the challenges and provided a broad overview on the key issues meeting attendees would be hearing about, discussing, and making recommendations around.

He began his presentation outlining where the United States stands among other nations in the world with regard to procreation rights, protections, and providers. He noted, “The less fortunate among us must negotiate access barriers, which can only be relieved by employers, payers, Congress, and states through the mandate process.”

What is the current state of access to infertility services and ART in the United States? It has decreased by 23 percent since 1995 among women ages 15-44, and is down 16 percent among women ages 25-44.

<table>
<thead>
<tr>
<th>Population</th>
<th>1995 (%)</th>
<th>2006-2010 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women Aged 15-44</td>
<td>15.4 ± 0.5</td>
<td>11.9 ± 0.5 (-23%)</td>
</tr>
<tr>
<td>Women Aged 25-44</td>
<td>20 ± 0.6</td>
<td>16.8 ± 0.8 (-16%)</td>
</tr>
</tbody>
</table>

The United States may be lagging behind other developed nations -- our annual cycle growth rate is 5% (Europe is 7.5%, Australia 9%).
Why are these rates so low, and why is the United States lagging? Barriers to access can be socio-cultural, emotional, infrastructural, geographic, and economic.

The socio-cultural and emotional barriers are discussed later in the meeting. Dr. Adashi went on to address the infrastructural, geographic, and economic barriers.

He does not believe there are great infrastructural barriers to ART treatment. When it comes to geographic distribution, ART barriers reflect those of our larger healthcare system in the United States -- the maldistribution of care availability across the country, with specific medically disenfranchised regions throughout the United States, particularly in the Southwest and Southeast.

What are the specific economic barriers to accessing ART? Dr. Adashi laid out the state of ART underwriting in the United States as having:

- high under- and un-insurance rates;
- high out-of-pocket expenditures;
- constrained public payers;
- reluctant, if evolving, private payers; and
- only six meaningful ART state mandates.

Who in the United States is providing good access to ART care? Surprisingly, Tricare covers 9.5 million active duty beneficiaries, and funded 1,200 ART cycles in 2013 at an out-of-pocket cost of less than $7,000 per cycle. It also fully covers ART for wounded warriors, severely injured service members.

On the flip side, the Veterans Administration cannot and will not provide infertility services to its 10 million beneficiaries, per the Veterans Health Care Act of 1992. ASRM continues to work on getting Congress to repeal this Act.

The news is not encouraging among private-sector employers. Only 27 percent provide ART coverage as part of their plans for employees. Of those considered “mega-employers” (20,000+ employees), just 32 percent cover ART in their insurance packages.

How can we better position our family-building messaging to be more appealing to self-insured employers? We must remind them that fertility benefits:

- attract and retain valuable employees;
- promote a family-friendly environment;
- reduce health-care costs;
- track at <$4 PMPM; and
- constitute <$1.5% of health benefit costs

Dr. Adashi also implored Congress to expand the Tricare ART coverage and repeal the VHA infertility treatment coverage ban.
Barriers to Access

Sociocultural and Geographic Barriers to Access -- Ann V. Bell, Ph.D.
According to Dr. Ann Bell, infertility is a socially constructed phenomenon in the United States. The way we think about infertility is shaped by the social ideologies around us, meaning the perception exists that infertility is a white, high-income, heterosexual, women’s issue.

In reality, she reports this thinking is not entirely correct. Half of all infertility cases can be attributed to men; poor women of color have slightly higher rates of impaired fecundity, and more than seven percent of women in same-sex relationships are receiving fertility treatment.

These numbers, however, are not reflected in who is receiving medical care for infertility. For instance, according to the most recent National Survey of Family Growth, among women experiencing reproductive problems, only five percent with less than a college education received assisted reproductive technologies compared to nearly 20 percent with at least a bachelor’s degree. So those receiving treatment are exactly reflective of our mainstream stereotypes of who is infertile.

The most cited and understood reason for disparities in infertility treatment is financial and insurance accessibility. With the average cost of IVF being $12,400 per cycle, many individuals and couples cannot afford treatment. Insurance is often a barrier because only 14 states have laws covering some form of infertility diagnosis and treatment; and Medicaid doesn’t cover these at all. One could surmise that policies withhold the choice from poor women; and ART is beyond the reach of even some middle-class women.

Bell spoke about the need to go beyond financial and insurance accessibility issues and address larger socioeconomic barriers, including:
- Ensuring physician hours and treatment times are available outside the typical M-F, 9-5 structure, allowing those who work to have greater access;
- Increasing access to telemedicine for those who have limited time and financial resources to handle multiple doctor’s appointments;
- Better education for individuals about the variety of treatments and the safety and security of fertility care;
- Greater discussion and information around the risks of multiple births, and demystifying what patients have learned from TV or social media;
- Addressing racial, class, and sexuality stereotypes in responding to fertility questions and issues.

“To define reproductive choice and rights in terms of democratization of access to treatment would seem to assume that women’s reproductive agency is both without and transcendent of context,” said Dr. Bell, quoting sociologist Deborah Steinberg. “While financial barriers certainly exist, there are deeper social, cultural, and ideological barriers that also prevent individuals from receiving medical care for their infertility.”
Insurance Barriers to Access -- Brian Allen, Principal, Allen Consulting

There are three types of healthcare in the United States, says Mr. Allen:

- Fully funded health insurance companies (individual and small-group policies)
- Self-insured employers
- Government (federal employees, military, Medicare, Medicaid)

Coverage isn’t consistent across these groups, as well as the types of programs within each, and despite state infertility mandates, benefits vary greatly, and this approach to coverage leaves many patients uncovered altogether. One insurance provider with a successful model is Wellmark Blue Cross Blue Shield of Iowa:

Insurance Successes

Wellmark Blue Cross Blue Shield of Iowa

- In 1989, negotiated a $15,000 lifetime infertility benefit
- Coverage given to individuals and small groups
- Offered to self-insured employers at no rate increase
- One million subscribers received coverage
- Unique situation where insurance company partnered with the medical providers to add a new benefit
- Some self-insured employers increased their benefit from $15,000 to $25,000
How can we increase coverage? Allen suggests, after working with Drs. Eli Adashi and Howard Jones, Jr., eliminating expensive iatrogenic multiple pregnancies by performing 21st Century fertility benefits including single embryo transfer. The cost savings fund the infertility benefit. How? By following the Tufts Health Plan in Boston, which now has a mandatory single embryo transfer policy (effective April 1, 2015):

**Insurance Successes**

**Mandated State Insurance Company and Resulting Policy Update**

- Met with Tufts Health Plan in Boston and offered to analyze their multiple pregnancy claims data using a medical billing code algorithm

- Results
  - Mother's delivery and first year of baby/babies life/lives cost equal:
    - Single $15,144
    - Twin $97,987
    - Triplet $91,700
  - Multiple deliveries accounted for 3% of total deliveries but 15.9% of total delivery cost

- Our findings assisted the Medical Director in implementing a Quality Initiative that will improve outcomes, increase patient satisfaction, and decrease cost

- Tufts implemented a mandatory single embryo transfer policy effective April 1, 2015

Allen outlined a series of opportunities for ASRM and those in the field to consider to reduce the insurance barrier to access to fertility care:

- Health plans and self-insured employers are aware of the significant cost associated with multiple pregnancies, but are unaware of technologies (SET) that can reduce them
- Many don’t correlate lack of or inadequate infertility benefits with increased multiple pregnancies
- Employers pay for maternity, NICU and increased multiple birth costs whether they provide fertility benefit coverage or not
- Today there is a compelling argument to reduce iatrogenic multiple pregnancy costs by managing 21st Century fertility benefits
- Educating both health insurance companies and self-insured employers is key to expanding coverage
Eliminating Economic Barriers to Access -- Dominique de Ziegler, M.D.

“If you want to eliminate the economic barriers to access to infertility care, you must make it free,” said Dr. de Ziegler in his opening remarks.

Free access to ART is not all that counts when controlling the number of ART cycles in a given population. It helps, but cultural and religious motives play an important role as well. The country in which fertility treatment is free for all is Israel. Treatment -- including PGD and PGS -- is provided to couples who have no children in their current marriages, and will be provided and funded for up to two healthy children. Single-parent families are also eligible. Many in Israel have taken advantage of this, so that the number of ART cycles per population is significantly higher than in the United States. Other countries -- France, Switzerland, Greece -- also offer free or very low-cost ART coverage, but not as many people take advantage of it for a variety of reasons. Personal beliefs and cultural/religious reasons also impact heavily on ART access.

When it comes to fulfilling current needs, one of Dr. de Ziegler’s associates moved abroad to open a fertility center in Cambodia because there was a need, and no one in country to fill it. It is important to diagnose, reduce and treat infertility in Cambodia and countries like Cambodia because no one has done it before. There is an existing need here, Dr. de Ziegler says, and our field must address it. In the first 10 months of the center opening in Cambodia, the center had done 207 retrievals. The median patient age was 30.5, with an oocytes median of 23.5. The oPR/1st ET was 48.7 percent. We need to address the needs and outcomes more effectively moving forward.

Another step to eliminate economic barriers to access is to create regional education and ART centers, and set standardized international regulations and diverse, region-specific ART offerings.

Dr. de Ziegler looks to the international aviation industry as a model the ART field could follow. Referencing the protocols of the International Civil Aviation Organization (a United Nations Specialized Agency), Dr. de Ziegler believes our field needs a global entity devoted to harmonizing international regulations, adjusting region-specific ART offerings, and organizing training centers, all in conjunction with the IFFS and WHO.

From an economic standpoint, Dr. de Ziegler believes our field is now doing the exact opposite of what we should. In his closing remarks, he called for:

- standardized regulations with diverse offerings
- regional training centers
- medical societies and international organizations lobbying together
Racial and Ethnic Disparities in Assisted Reproductive Technology Access and Outcomes -- Victor Fujimoto, M.D.
The National Survey of Family Growth 2002 study demonstrated that African-American women have a higher rate of infertility than Hispanic or Caucasian women (11.5 percent vs. 7.7 percent and 7 percent respectively). Asian women are twice as likely to wait at least two years to present for infertility treatment compared to Caucasian women (43.9 percent vs. 24.6 percent). Hispanic women are less likely to access infertility care in a cycle cost-controlled system. Cultural beliefs and family values likely contribute to these disparities in access to care.

Summary Points from SART-CDC data include the following:
- Clinical pregnancy and live birth rates are lower in Asian, African-American and Hispanic women from fresh autologous IVF cycles.
- Fetal growth restriction increased in Asian, African-American and Hispanic pregnant women.
- Preterm birth was increased in Hispanic and African-American women.
- Fetal loss rate was higher in African-American women.
Thawed, cryopreserved transfer live birth rates are only slightly reduced between African-American and Caucasian women (Seifer et al).

### Clinic-Specific Live Birth Rate Data by Ethnicity

<table>
<thead>
<tr>
<th>Study</th>
<th>Caucasian</th>
<th>African-American</th>
<th>Asian</th>
<th>Hispanic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fernberg et al</td>
<td>20</td>
<td>15</td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td>Purcell et al</td>
<td>30</td>
<td>25</td>
<td>22</td>
<td>15</td>
</tr>
<tr>
<td>Langen et al</td>
<td>40</td>
<td>35</td>
<td>30</td>
<td>20</td>
</tr>
</tbody>
</table>

Summary points from Clinic-Specific Data are:
- African-American women had lower LBR and higher SAB rates than Caucasian women, explained in part by higher fibroid incidence.
- Asian women had lower clinical pregnancy and LBR rates compared to Caucasian women.
- African-American and Asian women have higher peak estradiol responses during gonadotropin stimulation compared to Caucasian women.
- There is no difference in embryo quality or number transferred among ethnic groups.
- There is no difference in Hispanic and Caucasian LBR.

Racial and ethnic disparities in ART include:
- Increasing evidence has been presented for racial and ethnic disparities in ART.
- In the United States African-American IVF population, controversy remains regarding the presence of disparity in this under-represented subpopulation with fibroids, BMI, duration of infertility, and tubal disease differences presenting as potential confounding variables.
- In the U.S. Asian IVF population, heterogeneity of subpopulations prompt further delineation of at-risk populations for reduced IVF outcomes.
• In the U.S. Asian population, duration of infertility, lower BMI, higher estradiol response to gonadotropin stimulation, and better quality embryos prompt further exploration of biologic origins.
• In the U.S. Hispanic population, further studies are clearly needed to better define the disparity that may exist compared to the non-Hispanic white population and other racial groups.

“We need to understand genomics better, and understand how genomics contributes to the racial disparities we see,” said Dr. Fujimoto. “We also need to understand the environment -- exosinomics -- better, how exposures to chemicals and contaminants are influencing potential reproductive outcomes.”

Dr. Fujimoto added it is important for everyone in the field to find a way to partner with centers and hospitals in underserved areas to offer low-cost IVF to alleviate financial barriers that often go hand-in-hand with racial and ethnic disparities.
Limitations to Access of Care for Male Factor Infertility in the United States --
Ajay K. Nangia, MBBS FACS
Male reproduction and infertility are under-recognized scientifically, medically, professionally, epidemiologically, socially, psychologically, financially, educationally, politically, and societally. Male infertility overall is underrepresented as a disease. What are the barriers to care for men?

Top Barriers to Care and Access for Male Reproductive Health

• **Database Barriers**
  – to define demographics/burden of disease/access to care

• **Financial Barriers**
  – Patient: coverage for care
  – Providers: cost/fee for service charges
  – Government: financial resources
  – Science: funding

• **“Human” Barriers**
  – Patients: gender; cultural; race; education
  – Providers: outcomes, expectations/pressures; biases/education; conflicts of interest; scientific knowledge
  – Government: biases/education; political morals

On the data front, Dr. Nangia reports that the definition of “male factor infertility” is, “abnormal sperm parameters” and the type of sperm retrieval included (ejaculated/TESE/aspiration/retrograde/electroejaculation). Because there is no male age data, no male diagnosis/severity data, and no vasectomy/obstruction/NOA data, there is limited availability to analyze data and severity of the issue. Data also only focuses on those using IVF assisted reproductive techniques, and is the “tip of the iceberg”. We do not know the denominator and the overall incidence or prevalence of male factor infertility. The CDC’s and other databases are small samples, and are also limited by the lack of male data points.
What do we know about men?

**NVSS Census Data (2000) – Men in Repro Years**

- The highest male populations in the reproductive years, 20-49, were seen in:
  - California (7,864,781)
  - Texas (4,774,475)
  - Florida (3,296,219)

- The lowest populations were seen in:
  - Vermont (130,533)
  - Washington, D.C. (136,125)
  - Alaska (153,883)
  - Montana (189,643)

Proximity of services to the potential population in need is important, but is it appropriately distributed? As of 2005, there were 390 ART centers, with 197 designated male infertility specialists. Male specialists and ART centers generally are in the areas of the highest population of men in their reproductive years, but there are gaps.

The National Survey of Family Growth reported that 7.5 percent of men (3.3 - 4.7 million men) reported a visit for help with having a child at some point in their lifetime. Most were ages 35-44 and college educated, with 18.1 percent of them reported as having a male infertility
problem. Most surgeries and care for male infertility were performed in the Northeast. However, a VA Health System study showed that most utilization of services was in the South.

Male infertility only accounts for 17 percent of IVF cycles, and male infertility with or without other diagnoses accounts for another 17 percent of IVF cycles.

So, where are the barriers and how can we address them?

Cost is a significant area, with microTESE costing upwards of $5,000; vasectomy reconstruction or reversal costing up to $10,000; sperm cryopreservation running in the hundreds of dollars; and biopsies costing more than $500. With regard to fee for service, 64% of men spent more than $15,000 out of pocket in the United States, which was 16-20 percent of their annual income, on infertility-related expenses. 47 percent experienced financial strain and the treatment options of 46 percent were limited by cost. State mandates for insurance don’t often help cover expenses. Only six of 16 states with infertility insurance laws explicitly cover male evaluation or treatment.

Another barrier to access is the nature of men themselves. Women are the drivers of health care. Poor men are two times less likely than women to visit a doctor for a medical condition. High-income men are 2.5 times less likely than women to see a doctor for a condition. The culture of being male also has an impact. Men report infertility as a lack of virility or masculinity, or a threat to one’s heterosexuality. There is also a reluctance to consider infertility as something that might affect them -- since infertility is “a woman’s problem.” From adolescence onward, men receive less education about reproduction than women, contributing to the culture of silence, and allowing fallacies regarding the issue to flourish.

There is an assumption that men don’t want to or aren’t willing to be educated, and that’s simply not accurate, says Dr. Nangia. He believes they need to be reached in more creative and comfortable ways that speak to them.

If it’s not the men themselves, then providers can be a barrier to male infertility care. Lack of access to male specialists means more providers jump to female solutions (IUI, IVF) rather than evaluating and treating male reversible conditions. There needs to be increased and better education among community and private providers about male factor infertility, as well as oncofertility for men.

Lastly, government often can be a barrier to access. There is a general lack of knowledge among federal and state policy makers about infertility, let alone male infertility. Federal funding for research has gone down over the past 12 years. Government's assumptions and biases regarding socioeconomic and racial stereotypes can play into “right vs. privilege,” and the insurance debates continue to overlook men in this access to care issue.
What’s working, and what can we do?

Present - Strengths

- CDC National Action Plan – a call to action!
  - Stresses that both partners be evaluated
  - Stresses need for population data
- More national survey male data points added
- More male data points on NASS/SART
- Multi-institutional collaboration:
  - Andrology Research Consortium/EHR
  - Translational research and grants (GEMINI)
- Increased health policy advocacy efforts:
  - Urotrauma Act (2014)
- Some mandated states to be able to study better as a model.

http://www.cdc.gov/reproductivehealth/injuryprevention/PublicHealth.html

Present - Strengths

- Increase in male specialists ongoing to narrow access issues
- Some increase in male education and recognition of the men’s health disease spectrum
- NICHD with CDC: Release of research requests for information (RFI):
  - Most critical gaps to pursue
  - Evidence necessary to move field forward
  - Improvements needed in public health surveillance
  - Key barriers to progress
Future - Opportunities

- Continued joint advocacy effort – always! (one voice)
  - Advocacy groups
  - By media
  - By community/society
  - By specialty societies together through collaboration and joint learning e.g. ASRM PG course – kudos!

- Education

- NICHD with CDC RFI:
  - Continued application for research grants

Group Discussion and Recommendations Regarding Access to Care Barriers
Following the above presentations, small groups of six to eight participants each, answered a series of questions and presented their recommendations to the larger summit audience. The questions and recommendations are as follows:

1. **What is the most important point you took from these discussions?**
   - There is low utilization; and the barriers are not just about cost.
   - Politics -- state and national -- play a role in access to care.
   - Geographical access and reach is a significant challenge.
   - Underserved populations also need access; and we can help propel change.
   - Need a clear message to motivate the change, and a clear definition.
   - How do we talk about the “right to have a child” and the “right to access?”
   - Lower socioeconomic patients have poor facts/access.
   - Middle and lower socioeconomic patients need solutions that are not “ready-made” to work for higher-income women and couples.
   - There is a need to address diversity issues, among them, assuming a person coming in for treatment is heterosexual.
   - We need to make infertility recognized as a disease, not a choice.
   - The magnitude of those underserved is larger than what is widely known in our community.
   - Access is not equal for all.

2. **What do you see as the first priority (i.e., the “low-hanging fruit”) to increase access to care?**
   - Increase education and public awareness and understanding.
   - Prepare and share culturally-specific education to de-stigmatize all fertility treatments.
- Improve our coding, data collection, and analysis.
- Practice greater transparency regarding male and female treatments and costs.
- Educate state and federal governments about fertility costs, care, and practices.
- Reduce the burden on the patient – provide weekend/evening hours, phone consults, less monitoring.
- Ask the CDC to define infertility as a disease.
- Mandate that insurance coverage be tied to single embryo transfer.

3. **What do you believe are the five greatest barriers to access to care, ranked from 1-5, 1 being the greatest? (Consider cultural, medical, technological, educational barriers, etc.) Suggest ASRM solutions for each.**

   - **#1 -- financial**
     - male infertility recognized as a disease (advocacy/education)
     - reduce cost burden
   - **#2 -- education**
     - change perception

4. **Resolve, The National Infertility Association, is planning to gather the chief medical officers of major insurance companies across the country to open a dialogue for understanding how insurance coverage could be enhanced for infertility services. What do you think these insurance executives should be told to help garner their support for infertility coverage? What should be done at this meeting (goals and objectives, strategies to opening the dialogue, etc.) and how would that best be accomplished in a half or full-day meeting?**

   **Topics to cover**
   - Eliminate conflict of interest
   - Third-party evaluation of cost with/without mandated coverage
   - Low percent of usage in those who have coverage
   - Provide model for care with sensitivity to diversity

   **Action items to come from Resolve’s meeting:**
   - Education
   - Data collection
   - White paper
   - Strategies to increase initial access (e.g., telemedicine)

5. **How could ASRM help achieve broader access to infertility services for the underserved and low resource populations?**

   - Provide school-based education.
   - Develop a “creative” legislation strategy and advocacy tool kit.
   - Devise a celebrity media campaign.
   - Engage pro-family faith-based groups.
• Educate OB/GYN community.
• Create satellite centers, or better satellite monitoring centers.
• Educate mid-level providers.

6. **What do you believe are the five greatest barriers to accessing male infertility care, ranked from 1-5, 1 being the greatest?** (Consider cultural, medical, technological, educational barriers, etc.) Suggest ASRM programs that could best address male barriers to access.
   
   #1 -- cost of treatment  
   #2 -- recognition of men’s role in conception  
   #3 -- lack of collaborative care  
   #4 -- geographic access  
   #5 -- lack of data on male barriers that are non-geographic and non-financial

7. **How can community outreach and media campaigns be utilized to raise infertility awareness among underserved populations of men and women in the USA?**
   
   ASRM take leadership role (w/ ACOG, CDC, AFP, etc.) to partner with local community organizations in order to educate underserved populations.
Modifying ART Practice to Broaden Access

Natural Cycle IVF -- Richard Paulson, M.D.
The advantage of natural cycle IVF is that it is less expensive; there are fewer injections; no OHSS, no multiple gestations; its okay to perform back-to-back cycles, and there is better endometrial receptivity. Some drawbacks include fewer eggs, lower per-cycle success rates, no embryo selection, less control, lower margin for error, higher cancellation rates, and no frozen embryos for future transfers.

Modifications to the purely natural cycle include:
- Ovulation triggering
  - HCG
- Prevention of early ovulation
  - GnRH antagonist
- Low-dose HCG for follicular stimulation
- In Vitro Maturation
  - Immature oocytes from natural cycle IVF

As a result of these modifications to the natural cycle, there are similar implantation rates as simulated cycles of IVF; it avoids risks and disadvantages of ovarian stimulation in terms of cost and OHSS; and there is a very low rate of multiple gestations. HCG ovulation triggering allows accurate timing of oocyte retrieval; and GnRH antagonist increases control over ovulation. HCG boost alone can support follicular growth; and the addition of IVM has the potential to enhance the success of natural IVF cycles.

Dr. Paulson concludes that modified natural cycle IVF is a viable first choice for good-prognosis patients and a good second-line option for poor responders. Because of the lower costs and reasonable number of oocytes, modified natural cycle IVF may be a way to remove barriers and increase access to fertility care.

Dr. Paulson recommends addressing the issue of the SART registry and the fact that it penalizes innovative protocols if these are associated with lower success rates (despite the lower costs to those for whom this is a viable option). He suggests separating natural IVF cycles from standard cycles to encourage innovation.
Lower Stimulation IVF -- Bart Fauser, M.D., Ph.D.
Lower stimulation IVF is something clinicians should consider when addressing access to care barriers for patients, says Dr. Fauser.

Ovarian stimulation to achieve multiple follicle development has long been an integral part of IVF treatment. In the context of improved laboratory performance, the need for a large number of oocytes as an integral part of a successful IVF program may be questioned. The aim of the current debate is to summarize the studies performed during the last decade to develop the concept of mild stimulation aiming to obtain fewer than eight oocytes.

It is important to examine the balance between IVF success and patient discomfort, complications and cost, and how these might improve by use of simpler ovarian stimulation protocols aimed at retrieving fewer oocytes.

Lower stimulation IVF uses less gonadotropins by waiting to start them with the objective of avoiding the natural drop in FSH that occurs mid-cycle. This cuts the cost of the cycle and theoretically improves embryo quality by using fewer gonadotropins and being more like a natural cycle.

With this protocol, the patient waits until day five before starting gonadotropins, and then uses an antagonist once the follicle begins to grow to avoid a premature LH surge (which can damage eggs). The pregnancy rate was approximately the same as for a higher-dose regimen, but the cancellation rate was higher than for a higher dose regimen.

Mild stimulation protocols are associated with lower pregnancy rates per cycle although term birth rates after one year were similar. There are clinical barriers to protocols that require more cycles to achieve similar results, even if there are fewer multiple births. There is pressure on clinicians to achieve the highest results in each stimulation cycle without regard to the rewards for the patient and offspring from single fresh and cryopreserved embryo transfer cycles.

The economics of IVF differ among countries and among regions within countries, but in most cases, the focus is on public or private payment per stimulated cycle. The benefit of mild stimulation IVF is a reduced frequency of OHSS, and, with single embryo transfer, a reduced likelihood of multiple births. Since it takes more IVF cycles to achieve an equivalent live birth rate, the downside of this benefit can be avoided only through the provision of additional mild stimulation cycles. Paying a fixed price for a given IVF cycle is a barrier to optimal utilization of the embryos from that cycle because cryopreserved cycles are an additional cost burden.
What is In Vitro Maturation (IVM)?

The advantages of IVM include:
- Safety (eliminate OHSS in PCO/PCOS)
- Low costs due to no stimulation required
- Convenience: lower stress, less medication, and fewer controls

PCO and PCOS patients are the best candidates for IVM, with a pregnancy rate of 32-44 percent and a delivery rate of 22-29 percent (Shalom-Paz et al, 2011, 2012). With normo-ovulatory patients, the clinical pregnancy rate can be as high as 30 percent (Fadini et al, 2009, 2011).
How do the success rates compare between IVM and IVF?

**IVM vs. IVF for PCOS (Walls et al., 2015)**

**Study Design**
- Retrospective case-control study
- 121 participants (56 IVM and 65 IVF) underwent 178 treatment cycles
- Fresh, subsequent FET cycles were included to calculate the cumulative outcomes

**Summary Answer**
- No difference in clinical pregnancy rates in fresh or FET cycles between the two groups, lower cumulative pregnancy rate in IVM
- Significantly fewer live births resulting from IVM treatment for both fresh and cumulative cycle outcomes, however no difference in live birth rates resulting from FETs between IVM and IVF treatment

While this procedure is considered safe and successful for many patients, initial studies show concern regarding the effects of IVM on offspring health. There was a high rate of chromosomal abnormalities in IVM embryos and a higher rate linked to a longer period of IVM. And, IVM may induce permanent changes in the expression of imprinted genes (epigenetic changes). Dr. Vuong cited a 2012 Fadini et al study that showed that the obstetric and perinatal outcomes of births from IVM cycles are comparable with those of ICSI treatments, including the incidence of major and minor abnormalities. IVM does not appear to pose any significantly increased risk of poor obstetric outcomes or congenital abnormalities over those already accepted with IVF or other ARTs.

Dr. Vuong shared the application of IVM in Vietnam (population 96 million), that has an infertility rate of seven percent. Cost for IVF in Vietnam is $3,000 per cycle, where IVM costs just $1,500 per cycle. IVM has been used in Vietnam since 2006, with ≈2,600 cycles performed to date. Seventy-four percent of IVM patients are PCOS, and the mean age is 29.
Dr. Vuong concluded that the barriers to use of IVM for fertility care are as follows:

- Fewer embryos; lower pregnancy rates (especially cumulative pregnancy rate)
- No standard protocol
- Increased lab workload
- Concerns about the health of infants born following IVM

IVM is new, simple, and more convenient for patients, says Dr. Vuong. There is mild or no stimulation, less intensive monitoring, lower cost, and no risk of OHSS. She says there is a good success rate in selected patients, such as those with PCOS, and that our field needs to provide better training for clinicians, conduct more research, and educate more IVF specialists about IVM, as well as collaborate for patient options.
Novel Techniques 1: vaginal incubation and other novel lab techniques -- Kevin Doody, M.D., HCLD

In his remarks, Dr. Doody recognized the work of another Summit attendee, Dr. Claude Ranoux, who published a paper in 1988 titled, *A new in vitro fertilization technique: intravaginal culture*. Since that time, with many technological advances, this procedure has evolved and changed, and is now performed with this device:

Sterility is maintained over five days of intravaginal culture (incubated with sperm only), and osmolarity and pH after five days is no different INVO compared to traditional incubators. There is 100 percent retention and 0 percent dislodging, with 0 percent itching, 11 percent spotting, and 11 percent vaginal discharge.

Human sperm survival is reduced by 64 percent in INVO vs. IVF, which suggests toxicity in the INVOcell system. Mild bio-toxicity was observed not related to vaginal culture directly, off gassing, residue in inner chamber, and is not lot specific. Toxicity was observed in all three components of the inner chamber, and was 100 percent reversed by incubating with 0.3cc Oil for Embryo Culture from Irvine Scientific.

Dr. Doody reported that five-day continuous intra-vaginal culture is possible with INVOcell. There is no contamination observed, it’s generally well tolerated; the pH and osmolality matches IVF control; and sperm survival is normalized by inclusion of oil in inner chamber.

Dr. Doody then reported on a randomized controlled open-label, non-inferiority trial comparing day-five embryos derived from intra-vaginal culture using INVOcell to traditional IVF.

The stimulation/monitoring protocol was as follows:

- Management by sonogram only
- Programmed with oral contraceptives
- Down regulation GnRH agonist
- HP-HMG at a preset dose determined by AMH and body weight

A sonogram was performed after oral contraceptives had been initiated and before the start of leuprolide acetate, and a sonogram after 7-10 days of leuprolide and before initiation of gonadotropins. There was also a sonogram after nine doses of gonadotropins (the 10th day after stimulation) to determine day of trigger.

What were the results?
In terms of birth data, IVC had 11 births; IVF, 12; IVC yielded 16 babies; IVF, 15. Birth weight for IVC babies averaged 5.84 pounds, and 5.94 pounds for IVF babies.
In summary, Dr. Doody reported that IVC is safe and well tolerated. It allows extended culture of embryos without the need for expensive embryology laboratories (clean air, alarm systems, etc.). And, implementation of this or similar simple patient management and culture systems will likely improve affordability and access to ART services.

**Novel Techniques 2: Modifying ART Practice to Broaden Access (uterine lavage) - John E. Buster, M.D.**

E-FSH IUI is an upgraded technology combining traditional FSH IUI with uterine lavage, in vivo fertilization, PGS, vitrification, and SET. It is expected to increase live births, decrease multiples, decrease miscarriages, decrease costs, and increase availability to patients.

Uterine lavage is designed to recover a human blastocyst after in vivo fertilization and embryogenesis. There are two components to the process: catheter custom-fitted to each patient, and programmable fluid delivery and blastocyst recovery system. This empowers access to in vivo blastocysts.

What does the uterine lavage system look like?

![Uterine Lavage Office Setup](image)

Initial study data in the mid-1980s showed a total of 14 intrauterine pregnancies were produced in recipient women with 10 deliveries and four spontaneous abortions.
How does it work?

Advantages of E-FSH IUI are as follows:
1. Uterine lavage: office procedure, no anesthesia, recovers in vivo blasts
2. Superovulation with antagonist FSH Lupron trigger: minimal risk hyperstimulation, uniform oocyte maturation

In vivo blastocyst recovery is the key clinical benefit afforded by lavage:
- fertilization in vivo
- embryogenesis in vivo
- trophectoderm biopsy (many cells, minimal lab equipment, blastocyst, more informative than cleavage)
- Vitrification efficient and safe
- Euploid implantation rates are high
In closing, he enumerated the benefits of this procedure as follows:

**In Conclusion: Traditional FSH IUI vs. E-FSH IUI in a Theoretical Comparison**

<table>
<thead>
<tr>
<th>Traditional</th>
<th>Enhanced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low pregnancy rates</td>
<td>Higher pregnancy rates</td>
</tr>
<tr>
<td>Aneuploid miscarriages</td>
<td>Fewer miscarriages</td>
</tr>
<tr>
<td>Multiples</td>
<td>Singletons</td>
</tr>
<tr>
<td>Subtherapeutic FSH</td>
<td>Therapeutic FSH</td>
</tr>
<tr>
<td>PGS No</td>
<td>PGS Yes</td>
</tr>
</tbody>
</table>

Dr. Buster’s closing remarks suggested the future of uterine lavage is promising, and hoped for clinical validation studies in Europe, the United States, and Panama. In terms of regulatory approval in Europe, the CE Mark was issued for the device in 2015; and approval with the FDA in the U.S. is in process.
Fertility treatment: how simple and cost effective can we make it -- Cynthia Farquhar, CNZM, MBChB, DipObMedGyn, M.D., FRCOG, FRANZCOG, CREI, MPH

When it comes to Assisted Reproductive Technology (ART) costs, Dr. Farquhar says there are never enough resources to meet all potential uses. For many, when you allocate resources for IVF, it means that other health issues may not be diagnosed or treated. A consideration also is weighing costs of IVF vs. costs of live birth:

Cost Studies and Success with IVF

- The cost of a live birth is not the same as the cost of the cycle

- If an IVF cycle costs $10,000
  - Good prognosis: likelihood of a live birth is 33% (fresh); then the cost of one live birth is $30,000
  - Poor prognosis: likelihood of live birth = 10% (fresh); then the cost of live birth is >$100,000

- Success (live birth) and cost are linked...

- And if we lower costs we could increase access

There are myriad challenges to develop cost-effective approaches in ART. One must consider the variation between health systems, and understand what is covered and what is out of pocket. When it comes to drug costs and protocols, prices can be determined by volume and evidence-based practices for success. We must also weigh the variable approaches to ART: how many oocytes, the different approaches to ovum pick up, single embryo transfer, and other methods used in clinical practice. And, we must always have safety in the forefront of our practice and cost decisions, weighing the costs and risks of multiple pregnancies and ovarian hyperstimulation syndrome.

How can we keep costs down in diagnosis?

Keeping Costs Down in Diagnosis

- Tubal patency testing
  - Hysterosalpingogram first (x-ray or ultrasound test of tubal patency)
    - Can delay if no ovulation until 3 cycles of successful ovulation induction completed
  - Laparoscopy – can be avoided if normal history and examination
    - If tubal blockage on HSG then laparoscopy or IVF

- Male – semen analysis, repeated if borderline or abnormal

- Ovulation disorders
  - Simple blood test to confirm, if suspect anovulation—blood tests for androgens and gonadotropins, AMH, ultrasound

- Unnecessary tests unless clinically indicated
  - Post coital tests, hysteroscopy, endometrial biopsy, sperm DNA integrity testing
The “big ticket” cost items in the ART cycle are the combined clinical procedures of oocyte/sperm retrieval, and embryo transfer. Counting obstetric and neonatal costs, single embryo transfer delivers considerable savings. In New Zealand, physicians can maximize success rates and reduce costs by not treating women with high BMIs, who smoke, or are older than age 41. There is a clinical override in five percent of those cases. What were the results?

**What Happened Next?**

- **2000-2004**
  - One IVF cycle included transferring all the frozen embryos which were double embryo transfers (DET) funded for eligible couples
  - Multiple pregnancy rates 30%
- **In 2004** — if all clinics agreed to single embryo transfer for the first two ET then two full cycles were funded (ovum pick up, fresh and frozen transfers)
  - Multiple pregnancy rate 5.2% in 2013

Is this a cost-effective approach for funders? Likely, yes. Why? It allows for patient discussion around success rates, safety, and cost. There is a focus on treatment, not just diagnosis. This approach allows clinicians to select treatments based on cost, effectiveness, safety, and convenience. It allows for lower doses of medication to avoid overstimulation, taking into consideration the long-term outcomes for the baby.

Dr. Farquhar suggests the following for consideration when evaluating cost as a barrier to ART:
- Focus on the treatment because this is where the value lies;
- Promote ART for healthy women with low BMI who are smoke-free;
- Promote safe practices such as mild stimulation and single-embryo transfer;
- Evaluate and consider new procedures; and
- Raise awareness about declining fertility with age among all women.
Group Discussion and Recommendations Around Modifying ART Practice to Broaden Access

Following the above presentations, small groups of six to eight participants at each table answered a series of questions and presented their recommendations to the entire Summit audience. The questions and recommendations are as follows:

1. **Which of the approaches presented do you think is/are most feasible?**
   - We need more research
   - Mild stimulation protocol
   - Setting/context-dependent
   - Vaginal culture, incubation
   - IVM for PCO, ED
   - Minimal monitor-fixed stimulation
   - “After hours” monitoring; very low responder-CC (e.g. AMHLI)
   - Synchronizing cycles and utilizing remote monitoring
   - Programmed cycle and vaginal incubators
   - Increased use of mid-level providers
   - We don’t know: need studies, cost and delivery, not cost/cycle
   - Technology to improve access
     - IUM
     - NIUF for poor responder
     - Natural cycle
   - Modify SART data to reflect different pathways
   - Target specific patient populations
   - Natural cycle - increase efficiency and access
     - Minimal stimulation
     - Known safety margin
   - Measure of success = best outcome = singleton pregnancy/birth
     - Must take patient’s desires into account

2. **What do you believe are the five greatest barriers to access to infertility care that involve protocols for ART treatment?**
   - Lack of research funding
   - Costs to patients and practitioners
   - Time, effort, outcome risks, and success rates
   - Geography, travel
   - Education/misperceptions

3. **If you were planning to set up a program for ASRM to move natural cycle or minimal stimulation more rapidly into practice for the purpose of creating a cost effective approach to IVF, what would be the components of that program (pilot studies, research, treatment, and deployment)?**
   - Research -- RCT, crossover design
4. If you were planning to set up a program for ASRM to move IVM more rapidly into practice for the purpose of creating a cost-effective approach to IVF what would be the components of that program (pilot studies, research, treatment, and deployment)?

- SART reporting
- Free of charge
- Registry for outcomes
- Creation of standardized protocols (lab)
- Hands-on training sessions for IVM retrieval and laboratory maturation
- Worldwide summit, sponsored by ASRM to pool and discuss outcomes; symposium to agree upon definition of IVM and to standardize an approach to IUM
- Increase research with ASRM grant support and/or engage the insurance industry to sponsor RCT
- Support educational seminars/training of surgeons (REI) and embryologists
- Encourage an IVM session at ASRM 2016

5. Come up with new ideas for potential cost-saving treatments for couples needing treatments after clomiphene/IUI. Think outside the box. How could ASRM move them forward?

- Beyond CC/IUI
  - Limit IUI cycles
    - CC/vaginal incubate (depends on DX)
    - Cost effectiveness of PGS (encourage more studies)
    - Financing
  - 1 step: mp drugs/ICSI/transfer national cycle/HCG
  - Website/social media education/prevention and follow-up at encounters

6. If ASRM were to develop a white paper that describes a stripped-down version of IVF, including pre-evaluation, treatments, and evaluations during IVF, what could it suggest to IVF practitioners to consider eliminating in order to offer more affordable treatment.

   We can all agree that too much testing is done prior to IVF, but none of us can agree on which tests to eliminate. We liked Dr. Doody’s approach for good responders involving protocols for minimal stimulation and monitoring; and we’d like to see more studies on that protocol.

7. How could ASRM move vaginal incubation forward for developing cost-saving strategies? How could vaginal incubation be combined with other cost-saving strategies?

   - ASRM & vaginal incubation
     - More research trials/clinical trials in developing countries
8. **What modifications could be made to TESE and other urologic procedures to make them more cost-effective? Present one out of the box idea regarding the topic of modifying ART practice to broaden access for male factor infertility.**

- Better identification of who needs microTESE vs. office-based aspiration for NOA
- Better cryopreservation of single sperm
  - More use of advanced aspiration/cryopreservation to prevent failed fresh cycle
- Expanded use of local anesthesia/office site
- Increased research to reduce incidence of male infertility
- Education re: guidelines (genetic testing, U.S., hormone testing)
- Push mandated coverage - will reduce reimbursement
- OA - no change (aspiration vs. open?)
- NOA - cyro-eliminate fresh sperm
- Technology - incrofludics
  - Others and sperm stain?
- Eliminate pre-hormone Rx?

9. **How would modifying ART practices impact the standard of care and “medically necessary” coverage by insurance companies?**

- Modifying ART may make it more cost effective for insurance companies
- Natural cycle/insurance co/data
- Need to measure real costs of IVF/ART
- Medically necessary definition - stratify risk - age gaps, BMI, legal issues, number of cycles limit
- Bundle services - increased shared risk - frozen transfers free (1)
- Fertility coverage for cancer patients covered same way as associated cancer services - lift experimental level
Governments’ role in health care in the United States -- Susan Wood, Ph.D.

While Congress authorizes and appropriates funds:
- NIH, CDC, HRSA, HIS, SAMHSA, AHRQ, most other parts of HHS, are funded through annual appropriations
- FDA is funded through a combination of user fees (from regulated industry) and annual appropriations
- CMS funded through mandatory spending (if you are eligible for Medicare or Medicaid, the funds are made available, thus the term “Entitlements”)

The federal government does not regulate the practice of medicine:
- It may regulate safety and laboratory quality
- It may regulate medical products and marketing by industry
- It may greatly influence payment policy through Medicare and Medicaid
- It may greatly influence the research priorities through NIH funding
- May influence the training of providers through residency funding

But state governments and professional boards and organizations determine who is a provider and scope of practice, etc.

However, Congress treats women’s health differently than anything else. There are battles of preventive service guidelines on mammography frequency, coverage of contraception, funding bans on abortion and special requirements for abortion covered under private insurance, and fetal tissue research.

The Affordable Care Act is a three-legged stool focused on prevention, with shared responsibility for:
- Insurance Reforms (for all non-grandfathered plans)
- Expansion of Medicaid (in those states that choose to do so, up to 138 percent FPL)
- Establishment of Health Insurance Exchanges (state or federal) for purchasing insurance (with tax subsidies up to 400 percent FPL)
There are two specific protections for women in the ACA:

Section 1302: —in defining the essential health benefits the Secretary must “take into account the healthcare needs of diverse segments of the population, including women, children and persons with disabilities, and other groups.”

Section 1557: —additionally prohibits discrimination on the basis of race, color, national origin, sex, age and disability in health programs or activities that receive federal financial assistance, are administered by an Executive agency, or were established by Title I.

Senator Barbara Mikulski, (D-MD) offered a Women’s Health Amendment which was adopted and includes coverage by group and individual plans for basic women’s preventive care and screenings such as mammograms and Pap smears; services provided by community health centers and women’s clinics; and it directs HRSA and HHS to develop a list of preventive services for women to be included in addition to the USPSTF list.
Abortion care requires segregation of funds for abortion coverage. States can ban abortions in their exchanges, abortion cannot be defined as an essential health benefit, and providers and facilities can refuse to provide, cover, or refer.

When the ACA was announced, some employers expressed opposition to covering contraception as a preventive service. The Obama administration crafted a narrow exemption that allows churches and houses of worship to be exempt from the ACA on contraception and not require them to offer coverage to employees. Religious-affiliated organizations such as schools or hospitals use an additional transition period. The U.S. Supreme Court ruled in the “Hobby Lobby” case that closely held for-profit companies do have religious freedom rights and should have relief from coverage. Similar cases for nonprofit religiously-affiliated organizations that don’t want to use the accommodation are pending before the Supreme Court now.

Dr. Wood says women’s reproductive health remains and will continue to remain controversial inside and outside Washington, D.C. She believes it’s key to educate Members of Congress, the media, and the public to share data and clinical knowledge, but that we must understand it’s not going to drive policy debates. Wood believes advances are far more likely at the local, state, and regional levels.
Public Policy and Infertility -- Sean Tipton, M.S.

When it comes to oversight issues, ART care has the same basic structure as other fields of medicine -- a combination of state, federal, and professional self-regulation. States regulate both family law and the licensure of professionals. Professional self-regulation is critically important to what we do through large boards and SART. The federal government’s FDA, CLIA, and others play a role, as well.

There’s one very important difference in the United States when it comes to oversight, Tipton notes. The Fertility Clinic Success Rate and Certification Act (FCSRCA) -- also known as the “Wyden Law” -- says that any physician who does IVF must report that he/she did it, and what the outcome was, to the federal government. We have the most onerous reporting of any medical field in the U.S., which shows how reproductive health is thought of here.

Another role the government plays in ART and infertility is as the payer. Medicare and Medicaid have very strict restrictions on reproductive care and essentially no infertility care. Active duty military can receive some infertility care, but it’s incredibly restrictive and only under very limited conditions. Tricare has covered 18 wounded active duty members with IVF.

When it comes to the veterans community, by statute, veterans cannot receive IVF and the rest of their reproductive care offerings are extremely limited, despite more men needing it post-battle and the number of women veterans on the rise.

ASRM has been working on the veterans issue. Last spring, in both the House and Senate, Congress was close to reversing the IVF ban. Between cost offsets, embryo control issues, and the fetal tissue footage making Members of Congress want to attach terrible, counterproductive amendments to our bill, we asked Senator Murray to pull it until we could take a clean approach to it later.

ASRM will continue to move this forward when the time is right. It’s an issue very important to our field, and ASRM will keep fighting this fight.

Government plays a significant role in insurance. State governments are the insurance regulators, and this is why states have been the focus of insurance mandates. Only six states have recognized mandates to cover infertility treatment.
When it comes to the Affordable Care Act, the value, importance, and even legitimacy of infertility care was the leading example of struggles of determining what should be an “essential” health benefit. Ultimately, it was left out. Current ACA mandates and interpretations of those mandates may or may not change -- it’s complicated, says Tipton. The current mandates will stay in place for 2016, and no changes are expected beyond the new mandates being released by HHS. At every turn, in every comment period, ASRM pushes for infertility to be covered, but it’s not realistic to expect it will ever happen.

Social issues dominate some state regulations, placing limitations or prohibitions on donor gametes and gestational carriers, and instituting intrusive, burdensome reporting requirements such as number of eggs retrieved and what happened with each one. Because states control family law, this is where those battles happen with results. The “big kahuna” of these pushes has been personhood, with movement to codify into state and federal law the idea that legal status as a person occurs at conception.

ASRM has been behind the fight to defeat these ballot initiatives in many states, and will continue to be. Why? Personhood raises many issues for our field:

- Would it make ART illegal?
- Would cryopreservation of embryos be legal?
- Could patients choose not to transfer all their embryos?
- Could patients choose to discard their embryos?
The area of fetal tissue research — though not necessarily our issue — continues to have fallout that affects us. Will there be efforts to go after fetal tissue research at both the state and federal level? And will these efforts spill into questions of infertility care and status of an embryo?

These are the kinds of issues we handle in public affairs and advocacy; and with ASRM’s 2014-2019 strategic plan in place to focus on many of these and other issues, it’s an exciting and rewarding time to be a part of ASRM.

**Addressing the emotional barriers to access — Alice Domar, Ph.D.**

Emotional barriers to care come into play most often when there is a delay or lack of visits to a healthcare professional when conception doesn’t occur; a failure to return for treatment after a first consult or diagnostic workup; or treatment termination when the prognosis is still optimistic.

Dr. Domar says the tricky issue is that, by definition, we don’t attend to patients who don’t come into our centers. Women and couples who never see an infertility specialist are completely off our radar. Women and couples who come in for a consult and/or a diagnostic workup, but do not come back for treatment tend to be unaccounted for. And, patients who drop out of ART treatment are also often unaccounted for, or at least not likely to be noticed.

What are the barriers to the first visit for ART care? In one study:

- 75% were not concerned about being able to conceive
- The majority overestimated the odds of conceiving per cycle
- 85% stated a willingness to pursue infertility treatment, if necessary

There also are several factors which impact pretreatment decisions. Some feel ART is unnatural and goes against God’s will. There is a deficit in people’s level of fertility knowledge and awareness. And, there is a lack of knowledge about how, exactly, to seek help.

After the first visit, individuals and couples have concerns prior to treatment, and often put off beginning their IVF cycles:

- They’d be upset if the treatments didn’t work
- The costs are too high
- They’re concerned about safety
- They’re concerned about side effects
- They have anxiety about giving self-injections
- They have anxiety about actually undergoing the treatment

Some women considering ART were diagnosed or self-reported with anxiety or depression. This spanned all ages, education levels, incomes, and years of infertility.
Some women going through ART were able to cite infertility treatment as the cause of their depression symptoms:

- 80% of women taking leuprolide acetate scored higher than 20 on the Hamilton Rating Scale
- 75% of women using GnRH agonist medication reported depressive symptoms

The psychological impact isn’t just a U.S. phenomenon:

In a European survey of 445 women from France, Germany, Italy and Spain*, of whom 160 were currently receiving treatment:

- 32% had been concerned about the possibility of infertility
- 55% reported feeling “inadequate as a woman”
- 58% stated that they had waited too long to try to conceive
- 24% felt that infertility had made them closer to their partner
- 74% felt resentment when others easily conceived
- 67% were tired of suggestions on how to conceive
- 64% felt uncomfortable around pregnant women or babies


Dr. Domar reports that the field has spent more focus on increasing pregnancy rates and not on patient well-being. Addressing treatment burden is critical to individuals and couples preparing for and staying with ART.

For non-insured patients, cost is usually the number one reason why patients drop out of treatment. For insured patients, it is stress/psychological burden. Even for insured patients, dropout rates tend to be high, ranging from 46-58 percent. In the Netherlands, 32 percent dropped out before completing three cycles in Germany, 39 percent dropped out after the first cycle, and in France more than a third dropped out after only one cycle.
Treatment Termination

- The main reasons cited by patients include:
  - Fear and negative treatment attitudes
    - Unfavorable attitude about treatment
    - Ethical and moral values
  - Psychological and emotional factors
    - Pre-existing psychological issues
    - Hard time coping with negative emotions brought on by unsuccessful treatment
    - Uncertainty
    - Strain of repeated cycles
  - Relational strain
    - Impact of ART on relationship
    - Asymmetry in treatment between partners

How can we address the patient burden? Dr. Domar recommends the following:
- Tailored educational information materials
- Checklists to make sure all treatment worries are addressed
- Screen high-risk patients for psychological issues
- Implement coping interventions for patients
- Refer high-risk patients for emotional support
- Ensure partner is involved
- Improve staff performance in areas known to impact discontinuation decisions
- Address workload issues
- Teach staff stress management skills
- Simplify treatment protocols
- Use persuasive communication about lifestyle change
Improving public perception of infertility through media -- Jennifer Corbett,
Group Director, Twist Marketing

Where are we now with perception? Myths and misperceptions run rampant:

Myths and Misperceptions Run Rampant...

- It must be something wrong with ME, not him; infertility is a female problem...
- Infertility treatment is too expensive; I’ll just keep trying the “natural way”.
- I know it’s all in my head: As soon as I stop stressing about it, it will happen!
- With all these new treatment options, I can wait till I’m 45 to have a baby!
- I don’t want to talk to a doctor. I don’t have the time or the money for IVF.
- I am TOO YOUNG to start thinking about babies!

In addition to the misperception, there is still stigma around infertility; and many people don’t want to talk about it. Anecdotal evidence shows middle- and upper-class white women feel less stigma, as more and more are waiting to have children, so more are experiencing infertility and talking about it in their circles, says Corbett.

But certainly among men, there is a huge stigma, adds Corbett. “It’s a kind of macho thing, and no one wants to talk about male infertility, especially the men it’s happening to.”

When it comes to the media, Corbett says they don’t always get it right. The seemingly obsessive coverage of celebrities having children well into their forties has led to the myth that women can get pregnant at any age – they often don’t discuss that many of these women used donor eggs. And certainly celebrity media do not attempt to explain how egg donation works. And coverage of stories about Octomom and families with dozens of kids doesn’t help dispel the myth that IVF will always lead to multiple births.

Add to all of this differences in cultural values, religious views, politics, and societal shifts, and you have a lot of factors shaping public perception about infertility.
All of these barriers in the media have just one solution: education. But how do we successfully educate our audiences through the media? None of what we would need to educate them on is breaking news, so we have to find a way to make our story attractive to patients. ASRM and its partners could educate patients through patient stories, data and numbers, local angles, timely news hooks, and promoting innovative new tools:

### Patient Stories
- Any story is better when you put a face on it
- People want to hear what others have gone through
- When others are open about experiences, stigma is reduced
- A patient’s voice is stronger than any reporter’s words
- And if that patient happens to be a well-known celebrity, media will clamor to tell their real story

### Data and Numbers
- The media likes STATS
- Studies and surveys attract attention
  - Fertility awareness surveys
  - Prevalence data
  - Head-to-head clinical studies or Phase III data
- Large educational campaigns can be built around one or two stats

### The Local Media Likes a Local Angle
- Local stats, local patients and local stories are compelling to local media
- National educational campaigns can have a local angle with the use of existing data
- The more grassroots the media, the more trusted by community members

### A Timely Hook
- Observance weeks such as NIAW provide a hook that the media can leverage
- Mother’s Day, Father’s Day, Back to School, and New Year’s can all be a viable hook for a fertility story
- Medical society annual meetings can be a timely, if crowded, time to roll out news/announce a campaign

### Innovative New Tools
- Building new educational tools to address the issue of infertility can attract reporters looking for a “shiny new toy”
- In the process of covering a new tool, they will end up educating their audience with facts
How do we get there? Corbett advises ASRM to take a leadership position among its colleague organizations in the field and coordinate a centralized campaign. Important to that campaign is educating patients and the media; and it will be successful when bringing in advocacy groups like Resolve and P2P to motivate patient advocates around the messages. National and local media, together, will drive awareness, but it’s important not to overlook social media. Social media allows you to go directly to patients and potential patients and speak to them about your issues and materials.

**Changing reporting outcomes to the SART registry -- Kevin Doody, M.D. HCLD**

What is the role of SART? The SART registry function is the oldest U.S. medical registry of any type. It offers data collection and reports (CSR and national), provides data for QA committee, conducts research, and identifies outliers for the Validation Committee. All Registry Committee members are elected by SART membership. SART works with the CDC to coordinate data collection and reporting; and their work is also with QA, Validation, and Research committees to plan collection of additional “meaningful” data fields not yet collected by NASS.

There are recent changes to SART data collection and reporting that the field should pay attention to:
- Embryo banking / fertility preservation
- Other “freeze all” cycles
- New CSR report labels for success metrics
- Cycle types
- Conventional stimulation
- Natural cycles
- Minimal stimulation
- IVM
- Research cycles
- New CSR design

Dr. Doody believes the public and insurers must be educated regarding the limitations of the SART public report. He says ART outcomes (successes) can vary, and that data is best interpreted by the patient and physician together.

SART’s goals are and will continue to be to level the playing field, provide transparency, and provide improved data to facilitate the ability of physicians to help patients predict their chances of success with different ART treatments.

**Group Discussion and Recommendations Around the Patient, the Public, and Government**

Following the above presentations, small groups of 6-8 participants at each table answered a series of questions and presented their recommendations to the entire summit audience. The questions and recommendations are as follows:
1. **What resonated most with you from this session that you believe ASRM should aggressively approach?**
   - Burden of disease (stress/anxiety)
   - Great need for more support - of patients/staff/psych guidelines
   - Research into strategies for reduction (female and male)
   - Access - how to implement reproductive rights language from WHO/international court
   - Destigmatization is important to use the media and social media
   - Advocate to minimize
     - Adverse pregnancy complications
     - Disparities in access to care
   - Advocate for inclusion of standard family building health questionnaire in EMR
   - Educate policy makers that a large segment (male to female) of the population is affected by impairment of reproductive function
   - CDC should declare infertility a disease
   - Address patient dropouts
     - Reduce burden
     - Staffing, shorter, simpler cycles
     - Training/research
   - ASRM to pursue
     - SART reporting alters treatment and patient base/selection
     - May result in denial of care or treatment of inappropriate patient
   - Change SART reporting to region/state
     - Remove individual clinic statistics
   - Development of standards for reporting
     - i.e., OHSS, cycle cancellation, to level to allow accurate comparisons between clinics
   - VA bills

2. **How does ASRM move forward the concept that infertility is a disease as defined by WHO? How does ASRM garner governmental support of this concept in the United States? What strategy can ASRM take to influence governmental support of infertility research?**
   - Using SART more for more research
   - Fertility rate by state
     - Mandated states - are they any better?
     - Motivator - lower FR - growing taxpayers
   - VA try again to change legislation
     - “Has symbolic value”
   - Preventative care - information need/preconception advice
   - Raise awareness of fertility problems with older age
   - Move forward: infertility as a disease
     - Consistent definition
     - Engage CDC to endorse the definition
• ASRM needs to increase lobby efforts
• Train MDs on political advocacy
• Engage MDs in the field with history of infertility to share their stories
  ○ Create a PAC
  ○ Coordinate efforts with other fertility-focused advocacy groups, including industry
• Research:
  ○ White paper identifying next research goals/focus
  ○ “Low hanging fruit”
    ■ i.e. medical disease research assoc. with infertility obesity
  ○ Advocate the repeal of Dickey-Wicker

3. **List strategies for ASRM to further reduce the stigma of infertility and overcome the emotional impact of infertility.**
• Organize a march on Washington to increase awareness
• Increase or assist with organizing philanthropic efforts
• TED Talk
• Religious leaders/communities
• Contraceptive counselling
• Infertility is a disease

4. **Suggest changes to the registry that would be most helpful in getting IVF centers to perform lower cost treatments that may be perceived as less successful? What is the best strategy for incorporating male reproductive data into registries?**
• Filter out procedures such as: shared donor egg cycles and other lower-cost treatments
• Male - a lot already added

5. **What steps can ASRM take to stimulate the public’s support of infertility care?**
• Sell “family building” (treatment tax credit)
• IVF (low risk, change perception, multiples)
• Fertility treatments are not just IVF
• Partner with patient advocates
• Lower-cost treatments/simpler
• Lobby locally - educational materials for local advocates to use
• Terminology to describe/reposition fertility language

6. **What other governmental or non-governmental entities should ASRM work with to further public awareness and education about infertility?**
• WHO - March of Dimes
• IFFS
• CDC/NIH
Global Infertility Care

What are global infertility needs? -- Sheryl Vanderpoel, WHO/RHR/HRP

The field of fertility care which can address, on a global level, those with fertility problems such as infertility or onco-fertility interventions, requires the use of a common global nomenclature to ensure that the terms used are consistent. For example, the most commonly accepted definition of infertility published by the World Health Organization (WHO) in collaboration with ICMART, an NGO in official relations with WHO, in 2009 is “a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.” While not perfect, it helps to recognize infertility as a disease. This is further emphasized by the World Bank and WHO, both who define infertility as a disease that can render a status of disability.

There are a number of misconceptions around global infertility issues:

Misconception 1: Low and middle-income countries have a problem of fertility, not infertility.
In reality, a diagnosis of infertility is not dependent on social status or economic status. Infertility has many causes: reproductive, lifestyle and genetic.

Misconception 2: Women’s empowerment and economic success will ONLY assist in decreasing birth rates.

Women’s empowerment and economic success do initially better ensure that women have choices, and often do choose to have fewer children that are closer to fertility replacement levels. However, a new trend is emerging as evidenced from recent OECD data (UN World Statistics Pocketbook, 2010). As countries transition and become highly developed, often more educated women and those with stable employment, are having more children than are those who are less educated and who lack economic stability.

Misconception 3: Infertility is majorly a problem of high-income countries, due to the advanced age of women with a first birth, and due to lifestyle factors. It is a reproductive “choice” that can be resolved by those economically advantaged.

An infertility diagnosis or childlessness can be blind to socio-economic status. The contrary can be true and indeed, infertility can have an effect of generating poverty. Infertility, due to high cost of out-of-pocket treatments, can become a diagnosis that has been defined by researchers as a medical and social poverty trap.

Misconception 4: If the global public health community provides STI management, then through “prevention,” we eliminate most causes of infertility.

These pie charts represent data from studies completed in the early-to-mid 1980s. It can appear that tubal factors, assumed at the time to be caused by STIs, are the main cause of infertility. However, if an individual suffers from fertility problems with no access to appropriate medical care, many years will pass before that individual attempts to actively seek or can even avail herself of appropriate and quality diagnosis and care. By then, identification of tubal factor infertility is often inevitable (STIs/RTIs, genital TB, or in the case of secondary
infertility, complications from previous maternal deliveries, surgery and unsafe abortion practices) and therefore, often the true underlying cause of either primary or secondary infertility has been lost due to the much-delayed diagnosis.

**Misconception 5:** If the global public health community prioritizes the following: Contraceptive use (decrease), unintended pregnancies and increased child spacing; provision and access to care for STI management; innovations/interventions that decreases maternal and child mortality and morbidity ... then prioritization is not needed for access to quality fertility care for the infertile.

The assumption can be that infertility is only caused due to the inadequacy of other forms of reproductive or maternal health care, (thus preventable) rather than recognizing the fact that infertility or fertility problems do have causes of their own that cannot be prevented – and, that indeed, many fertility problems require their own interventions.

**Misconception 6:** WHO cannot get a prevalence number – as it has multiple values representing global prevalence of infertility.

There are multiple values for many reasons. WHO and other researchers use different definitions for infertility and different modeling algorithms to define different types of fertility problems within different population groups.

![Burden of Disease; Burden of Disability](image)
Misconception 7: Despite evidence-based guidelines and terms/definitions, it is impossible to ensure access to care through national policies, systems and programs on a global scale.

This is not true. Fertility interventions can include provision of cost-effective pre-pregnancy care that also can have an added benefit of preventing any future fertility problems; and, as the field moves forward, access to infertility technologies are becoming more possible due to new innovative technologies.

Conclusion

Provision of quality care for individuals and couples who desire a child requires responsive national health policies, systems and services. However, it is paramount that misconceptions about the disease of infertility - as well as the disability that it can render - are recognized along with recognition that cost-effective interventions exist that will increase access to fertility care for the populations in need.

What can we learn from countries with better access to care and more cost-effective care? -- David Adamson, M.D.

“If we look at global ART data, you can see, despite our wealth, that we’re well down in the pack,” said Dr. Adamson. The role of public funding for ART plays a significant role in our global ranking, to be sure.
What role does effectiveness play in access to ART? ART is not a panacea for every patient in every country. We all wish it was, but on a global basis, it’s not. We have to remember that, says Dr. Adamson.
What about the safety of ART? The United States has a much higher multiples rate than other countries around the world. Why is this? There’s a relationship between access to ART and the number of embryos transferred.

When you concentrate on single embryo transfer, as in the following example in Sweden, the pregnancy rate did not change. These data have been replicated in multiple countries, and is the only way to get the twin rate down and increase safety.
Dr. Adamson covered the cost implications around the globe when it comes to ART. Costs overall are 30-50 percent less in other countries vs. the United States. And the average cost of a standard fresh IVF cycle as it relates to a percentage of GNI per capita shows the U.S. with the tightest squeeze.

**Average Cost of a Standard Fresh IVF Cycle, and as a Percentage of GNI Per Capita (USD 2006)**
Cost-effectiveness of ART is a concern for patients. Looking at the cost per live birth for autologous ART treatment cycles, the United States isn’t doing too badly; we compare very favorably to other countries.

Cost Per Live Birth in 2003 for Autologous ART Treatment Cycles

How do we help shape the economic implications of public or insurance coverage for IVF? The affordability of ART treatment is related to:

- Cost of treatment
- Socioeconomic status
- Disposable income
- Government coverage
- Insurance coverage
- Access to financing/loan programs

Net costs to patients can be significantly reduced by subsidies. When analyzing out-of-pocket costs for IVF as a percent of annual disposable income, the U.S. is the least affordable in the world.
It’s important to have government funding because affordability predicts utilization:

- Irrefutable evidence on the economics
  - Countries with better coverage
  - States with mandated coverage
  - Countries that have introduced coverage
  - Countries that have reduced coverage
  - Provinces that have reduced coverage
- Regulations and guidelines (when followed) have had similar results
- USA: issue of publication of clinic-specific pregnancy rates

What are the effects of insurance mandates on choices and outcomes in infertility treatment markets? Broad insurance mandates for IVF result in large increases in treatment access and significantly less aggressive treatment. More limited insurance mandates, which may apply to a subset of insurers or provide weaker guidelines for insurer behavior, generally have little effect on IVF markets.

Dr. Adamson said in summary, “Access is affected by many factors, but only countries with funding arrangements that minimize out-of-pocket expenses meet expected demand. ART is expensive from a patient perspective, but not from a societal perspective.”

Adamson believes we must:

- Change societal attitudes towards infertility
- Change payer attitudes towards reproductive care
- Convince payers of cost-effectiveness
• Develop effective payment plans and programs
• Improve protocols (e.g., eSET)
• Educate patients and professionals
• Use technology appropriately
• Standardize treatments through research
• Innovate new technologies to reduce costs; and
• Develop patient criteria for inclusion in subsidization

**Group Discussion and Recommendations Around Global Infertility Care**

Following the above presentations, small groups of 6-8 participants at each table answered a series of questions and presented their recommendations to the entire Summit audience. The questions and recommendations are as follows:

1. **What strategies have other countries used that ASRM could implement/promote to increase access to care?**
   - Use example of Costa Rica = to implement WHO definition of infertility and improve access to care
   - ASRM should use new WHO definition AWSAP
   - Leverage disability case law (to try to bypass issues that are so politically charged)
   - Engage legal consultation to approach from legal point of view
   - Mandate covering the use of pre-established guidelines
   - Very limited choices

2. **Suggest strategies to increase availability of infertility care for women and men in low-resource countries.**
   - Access to education materials
   - Offer full range of treatments options
     - Vaginal capsule - IVF
     - Oral stim - GND
   - Build needs assessment with international associations
   - Simplify ART
     - FSH-IUI
     - PG course
   - Provide mobile and online education tools
   - Train people to use toolbox; develop learning module
   - Support NGOs; health ministries developing registries
   - Identify infertility needs by country
   - Needs assessment
     - Identify physicians/embryologists
     - How to identify patients
     - Define care currently available
     - Identify international partners
     - Establish registry
3. What educational role should ASRM play in increasing global infertility care?
- Establish international registry of outcomes - SART, CDC, etc.
- Develop and disseminate materials to dispel myths, stereotypes, etc.
- Translate educational materials into other languages
- Learn from other countries what has worked to increase access
- Partner with local organizations/governments to provide training/education to help establish local care
- Distribute/market ASRM practice guidelines internationally
- NGO status: spread awareness through health ministers
- Encourage and highlight members’ efforts in outreach (“profiles in fertility caring”)
- Globalize e-learning modules with translation (Spanish, Chinese, Arabic)
- Make PG course materials available to emerging countries
- Improved cooperation among industry partners globally to achieve our common goals

4. How should ASRM leverage its NGO status to help improve global access?
- Training modules for public - culturally sensitive
- Standardization - consent forms, practice guidelines
- Collaborate with WHO in developing guidelines, policies, etc., and in promoting initiatives in reproductive health
- Ongoing programming on global access to care at Annual Meetings
- Sponsor research to study access to care
- As an NGO:
  - Sponsor regional meetings
  - Offer training programs
  - Online journal clubs and other
- Identify global needs and communicate with ASRM members
- Encourage the development of an international registry
- Have the ASRM send representatives to international societies to present evidence-based medicine
- Interact with the U.S. State Department to influence international trade societies
- Interact with not-for-profit organizations with fertility focus
- Support WHO to establish fertility consulting
- Work with partnerships for financial support
- Funded fellowship in global health with focus on fertility
Summit Conclusion:
Summary and Recommendations for Next Steps

Following the Access to Care Summit, ASRM leadership met to discuss the summit, the presentations and discussions that followed, and evaluated the recommendations each member put forth.

That conversation resulted in the following Access to Care Actionable Strategies the organization will focus on in the coming years:

Addressing Barriers to Access
- Make Access to Care Track in Annual Meeting with keynote lecture, abstract session (with prize for best), interactive session, and symposium.
- Have session at Annual Meeting for individual practices to present their strategy used to improve some aspect of access for their patients. These would have to be pre-submitted and selected. Give prizes for most innovative and most impactful.
- Develop an Access to Care SIG.
- Develop an ASRM foundation or promote the development of private foundations to which practitioners or grateful patients could donate for low-resource individuals.
- Develop a council whose members have each developed or belong to a foundation to develop the methodologies, etc. for encouraging the formation of other similar foundations for funding care throughout the country.
- ASRM to support RESOLVE’s meeting with Insurance companies as needed by RESOLVE. For meeting, consider sending a third party in our (ASRM’s) place because of possible perceived conflict.
- Encourage the provision of unreimbursed care (some percentage of total cases or a total number of cases annually).
- Encourage providers to donate their time to underserved, uninsured clinics.
- Encourage provision of evening hours.

Modifying ART to Increase Access
- Sponsor research that tests new treatments/protocols, paradigms, or strategies that are hypothesized to reduce cost and or improve access to care.
- Host an In Vitro Maturation Summit.
- Develop a document that encourages reduced testing before and monitoring during ART cycles.
- Develop guidelines for providing care that will decrease cost (what steps can be eliminated?).
- Develop a document of “Best Practices” from infertility clinics on “how to ....”
- Develop guidelines for innovations.
• Develop a “How To” book for new technologies with best practices (e.g., IVM, vaginal incubation, etc.).
• Encourage appropriate access to primary care providers and GYN generalists for baseline information and referral to specialists.
• Develop Reproductive Vital Signs partnering with CDC.
• Work with CDC to label infertility as a disease.

Addressing Patient, Public and Policy Barriers
• ASRM to fund studies about infertile individuals who never get to our offices.
• Standardize care (to improve quality, success, patient expectations, etc.).
• Develop a fertility App for the general public. Answer general questions about becoming pregnant; provide sources of information; provide information about how to find providers, etc.
• Develop a fertility score card.

Global Infertility Care
• Develop telemedicine for underserved areas.
• Develop a document that encourages reduced testing before and monitoring during ART cycles.
• Develop guidelines for providing care that will decrease cost (what steps can be eliminated?).
• Develop an ASRM foundation or promote the development of private foundations to which practitioners or grateful patients could donate for low resource individuals.
• Develop a council whose members have each developed or belong to a foundation to develop the methodologies, etc. for encouraging the formation of other similar foundations for funding care throughout the world.
• Develop a “How To” book for new technologies with best practices (e.g., IVM, vaginal incubation, etc.).
Appendix 1: Meeting Attendees
Those in attendance at the Access to Care Summit were:
David Adamson, M.D.
Eli Adashi, M.D.
Taiwo Ganiyat Alausa, M.B.B.Ch.
Brian Allen
Paula Amato, M.D.
Andrew La Barbera, Ph.D.
Melissa Brisman, J.D.
Christine Briton-Jones, Ph.D., H.C.L.D.
John Buster, M.D.
Maria Bustillo, M.D.
Samantha Butts, M.D.
Douglas Carrell, Ph.D., H.C.L.D.
Ryszard Chetkowski, M.D.
Lee Collins, J.D.
Barb Collura, M.A.
Susan Crockin, J.D.
Ann Bell, Ph.D.
Kris Bevilacqua, Ph.D.
Catherine Racowsky, Ph.D.
Tongtis Tongyai, M.D., Ph.D.
Moneim Younis, Ph.D., H.C.L.D.
Barb Stegmann, M.D., Ph.D., M.P.H.
Ali Dabaja, M.D.
Haim Dahan, M.D.
Marian Damewood, M.D.
Owen Davis, M.D.
Debbie Davies, R.N.
Ali Domar, Ph.D.
Kevin Doody, M.D., H.C.L.D.
Jim Dupree, M.D., M.P.H.
Cynthia Farquhar, M.D.
Bart Fauser, M.D., Ph.D.
Eve Feinberg, M.D.
Victor Fujimoto, M.D.
Sue Gitlin, Ph.D.
James Goldfarb, M.D.
Violanda Grigorescu, M.D., M.S.P.H.
Nancy Harrington, R.N.
Christopher Herndon, M.D.
Avner Hershlag, M.D.
Joanne Frankel Kelvin, R.N., C.N.
Amy Kern, J.D.
Appendix 2:
Following the Summit, attendee, Mary Wingfield, M.D., consultant obstetrician/gynecologist at Holles Street and director of the Merrion Fertility Clinic, wrote and had published, this op-ed in the Irish Times about her experience at the Summit and her recommendations for how Ireland needs to adapt its practices.
Why fertility treatment deserves State funding

Mary Wingfield

Last Updated: Friday, September 18, 2015, 02:00

Recently I attended a “summit meeting” in Washington to discuss means of improving access to fertility treatment globally for those who need it.

Delegates had to apply to attend this conference and my raison d’etre was that I work in Ireland, one of only three countries in the EU where fertility treatments such as IUI or IVF are not funded by the State.

In comparison to the US (which hosted this meeting), Ireland has a socialised model of health care. All Irish citizens are entitled to State-funded medical treatment. Surgery (whether emergency or elective) is covered for all, as is in-patient care for any medical condition.

Pregnancy care is available to all in the public system, as is gynaecological care. For men, surgery for testicular problems, ejaculation problems and testosterone treatments are all available publicly as is Viagra for medical cardholders.

Plastic surgery is covered by the public system as are treatments for obesity, smoking and other lifestyle-related health problems.

Drug-related and alcohol-related illnesses are covered.

Mental health problems are treated in the public health system. And all that is as it should be in a country where we believe in social justice and universal health care. But how has it happened that fertility treatment is not provided by our State health system?

Infertility is defined as a disease by the World Health Organisation. Like many other medical conditions, infertility can be caused by infection, surgery, hormone disturbances, drug treatments, cancer or birth defects. Some cases are unexplained and lifestyle can also be contributory.

There is undisputed evidence showing the inability to conceive has a devastating effect on physical and mental health. It is a significant cause of depression, marriage breakdown and general unhappiness.

Clinical depression

Some 30-40 per cent of those with fertility problems suffer clinical depression and anxiety because of their inability to have children. Other studies show fertility patients have similar stress levels to those with cancer. Infertility is a “disease” and those affected need treatment. So what is our problem? At the summit in Washington, many delegates assumed Ireland did not fund fertility treatment such as IVF because we are a Catholic country. I argued that we have an increasingly pluralist and tolerant society.

With 20 years experience of working in infertility in Ireland, I know the vast majority of Irish people with fertility problems do not have ethical objections to assisted reproduction treatments.

Fertility clinics

At my public fertility clinics in Holles Street I meet couples every week who walk away, unable to afford their treatment. The refusal by successive ministers for health to refuse to consider funding fertility treatment is not just unfair—it is also shortsighted.

As the results of IVF treatment improve (and Ireland has excellent success rates), it is becoming obvious that it is the optimal treatment for many of those with fertility problems.

By failing to fund treatment, patients and their doctors are forced to waste precious resources on excessive investigation and inadequate, ineffective treatments.

We know female fertility declines with age and, all too often, if patients can eventually afford treatment it is too late and their chance of success is at least half what it would have been if they had received assistance five years earlier. This breaks my heart.

Another wasteful and medically indefensible consequence of the lack of funding is that more and more Irish patients are being forced to access fertility treatment in other countries. A worrying number of these patients return to Ireland with twin and triplet pregnancies.

It has been shown conclusively that multiple pregnancies are high risk, for the mother and especially for the babies. Our larger maternity hospitals with neonatal intensive care units are struggling to cope with these high-risk pregnancies, so many of them a consequence of multiple embryo transfer abroad.

Multiple pregnancies are also extremely costly pregnancies. A twin pregnancy costs at least six times more than a singleton and a triplet 18 times more for the delivery and first year of life. Countries such as Belgium have successfully funded IVF treatment by insisting on single embryo transfer. The money saved by avoiding multiple pregnancy helps fund the cost of the IVF treatment. Unfortunately, successive Irish ministers for health have refused to acknowledge this.

Ireland’s fertility rate is declining. In time we may well have no choice but to actively promote fertility treatments such as IVF as a means of survival. However, that is cold comfort for our sons, daughters, brothers, sisters and friends who currently need fertility treatment but who can’t afford it. As another election looms, can any health minister “do the right thing”? Mary Wingfield is consultant obstetrician gynaecologist at Holles Street and director of Merring Fertility Clinic, a not-for-profit fertility/IVF clinic

© 2015 irishtimes.com