

# **Regulation: International & USA Comparative ART Practice**

**AALS/ASRM  
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# Disclosures

- **Advanced Reproductive Care (ARC)**
  - Founder and CEO
- **Professional Organizations**
  - ASRM: President-elect
  - IFFS: Executive Committee
  - ICMART: Int'l Committee Monitoring ART
- **Funded Research Studies**
  - Serono
  - IBSA



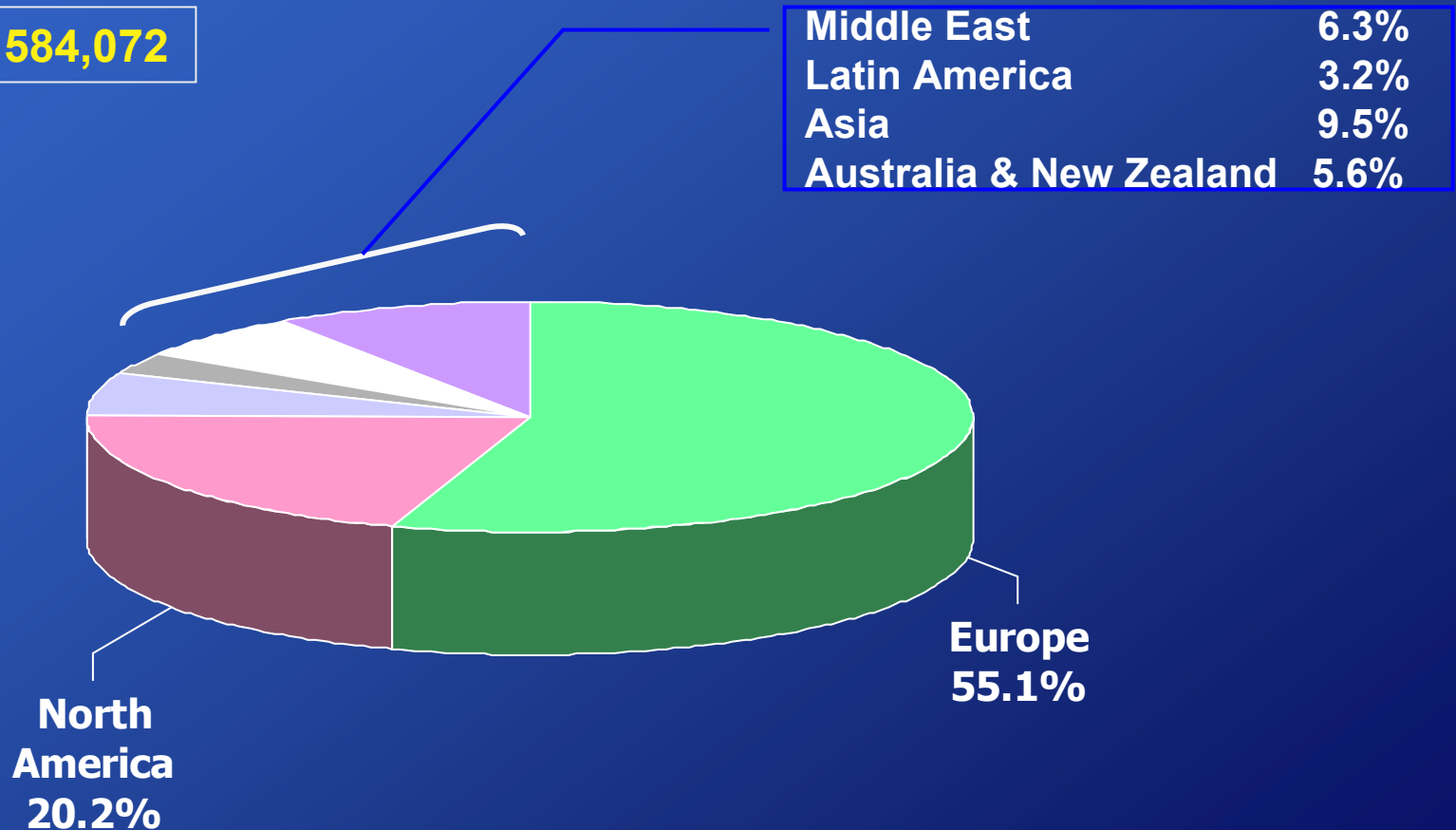
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**ART Results**

**Around the World**

# Regional Contribution of ART Cycles to the World Report (2002)

**N = 584,072**



\* Corresponds to: aspiration cycles in IVF, ICSI & GIFT; transfer cycles in FET & OD.

# Availability By Country: Cycles / Million Inhabitants (1)

Israel	3263	Cyprus	1290	UK	609
Belgium	2192	Iceland	1255	South Korea	584
Greece	2173	Sweden	1225	Croatia	582
Denmark	2054	Germany	1109	Italy	582
Spain	1870	France	1085	Tunisia	572
Lebanon	1618	Netherlands	986	Japan	562
Australia	1525	Norway	909	Ireland	466
Jordan	1500	Switzerland	719	Bahrain	424
Finland	1454	New Zealand	681	USA	413
Slovenia	1295	Hungary	681	Portugal	398

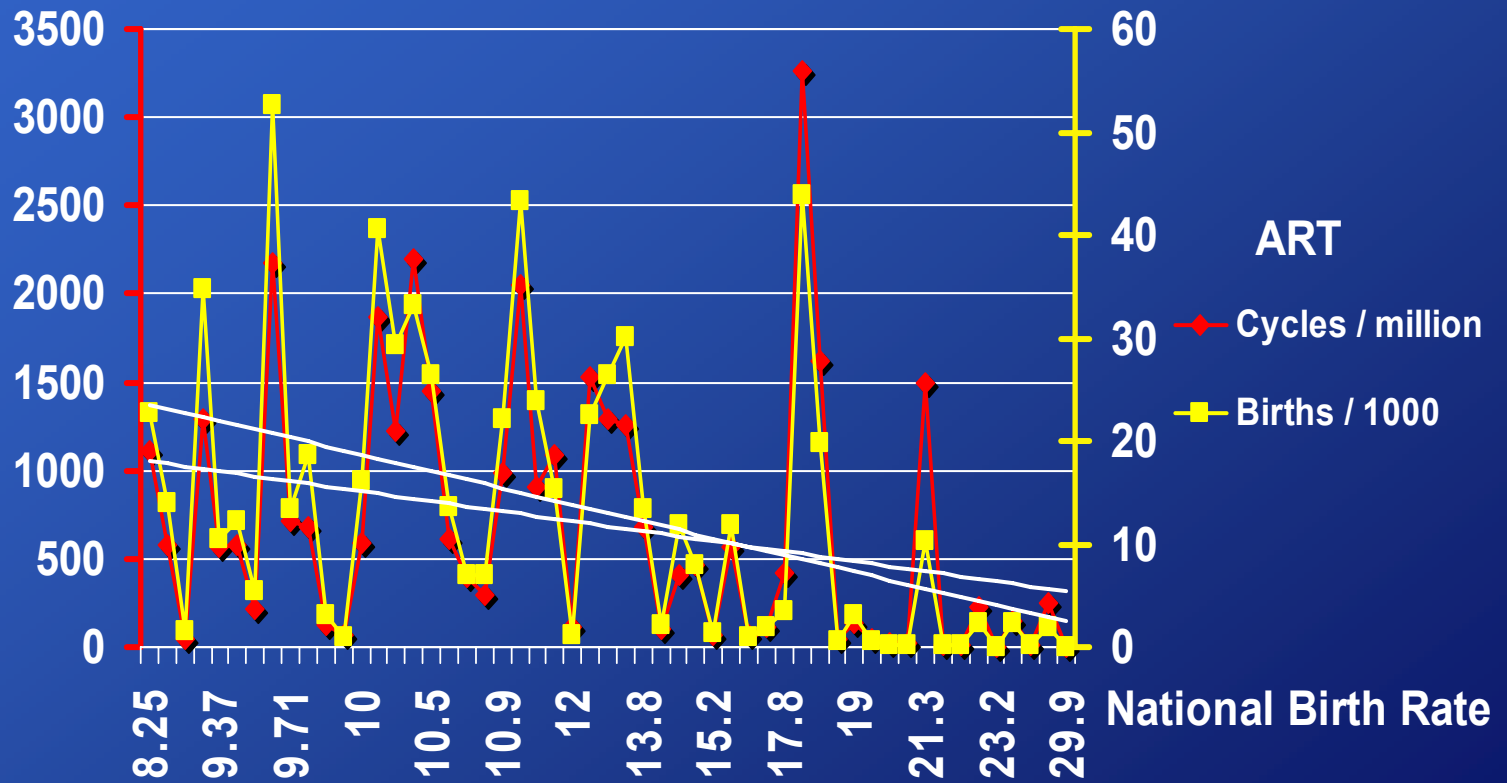
(1) Based on estimated number of cycles per participating country

# Availability By Country: Cycles / Million Inhabitants (2)

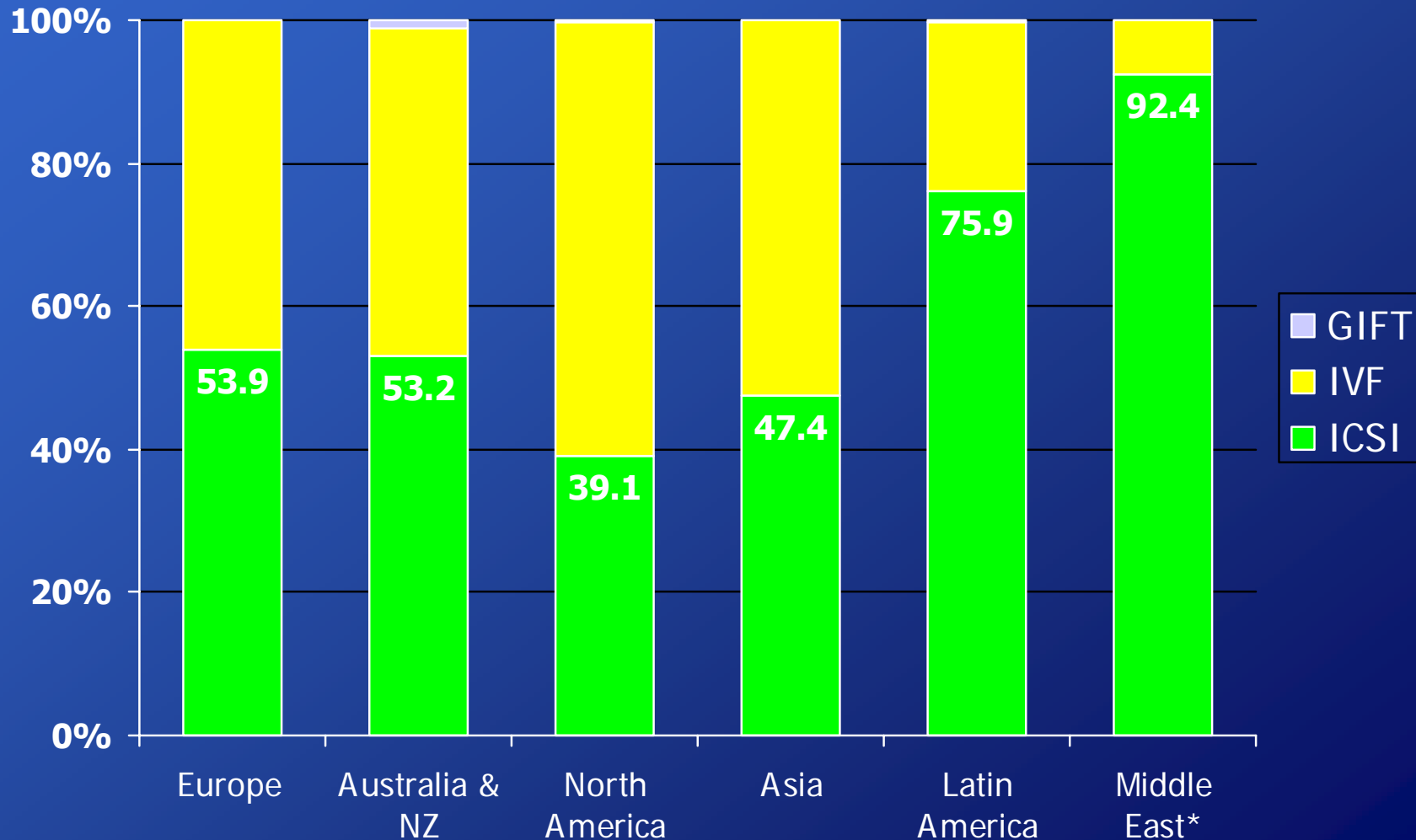
<b>Saudi Arabia</b>	<b>248</b>	<b>Uruguay</b>	<b>101</b>	<b>Ecuador</b>	<b>9</b>
<b>Egypt</b>	<b>221</b>	<b>Russia</b>	<b>69</b>	<b>India</b>	<b>9</b>
<b>Bulgaria</b>	<b>219</b>	<b>Brasil</b>	<b>65</b>	<b>Dominican Rep</b>	<b>2</b>
<b>Libya</b>	<b>150</b>	<b>Chile</b>	<b>64</b>	<b>Guatemala</b>	<b>2</b>
<b>U.A.E.</b>	<b>131</b>	<b>Ukraine</b>	<b>50</b>		
<b>Poland</b>	<b>127</b>	<b>Peru</b>	<b>23</b>		
<b>Argentina</b>	<b>118</b>	<b>Mexico</b>	<b>17</b>		

(2) Based on estimated number of cycles per participating country

# Availability According To National Birth Rate

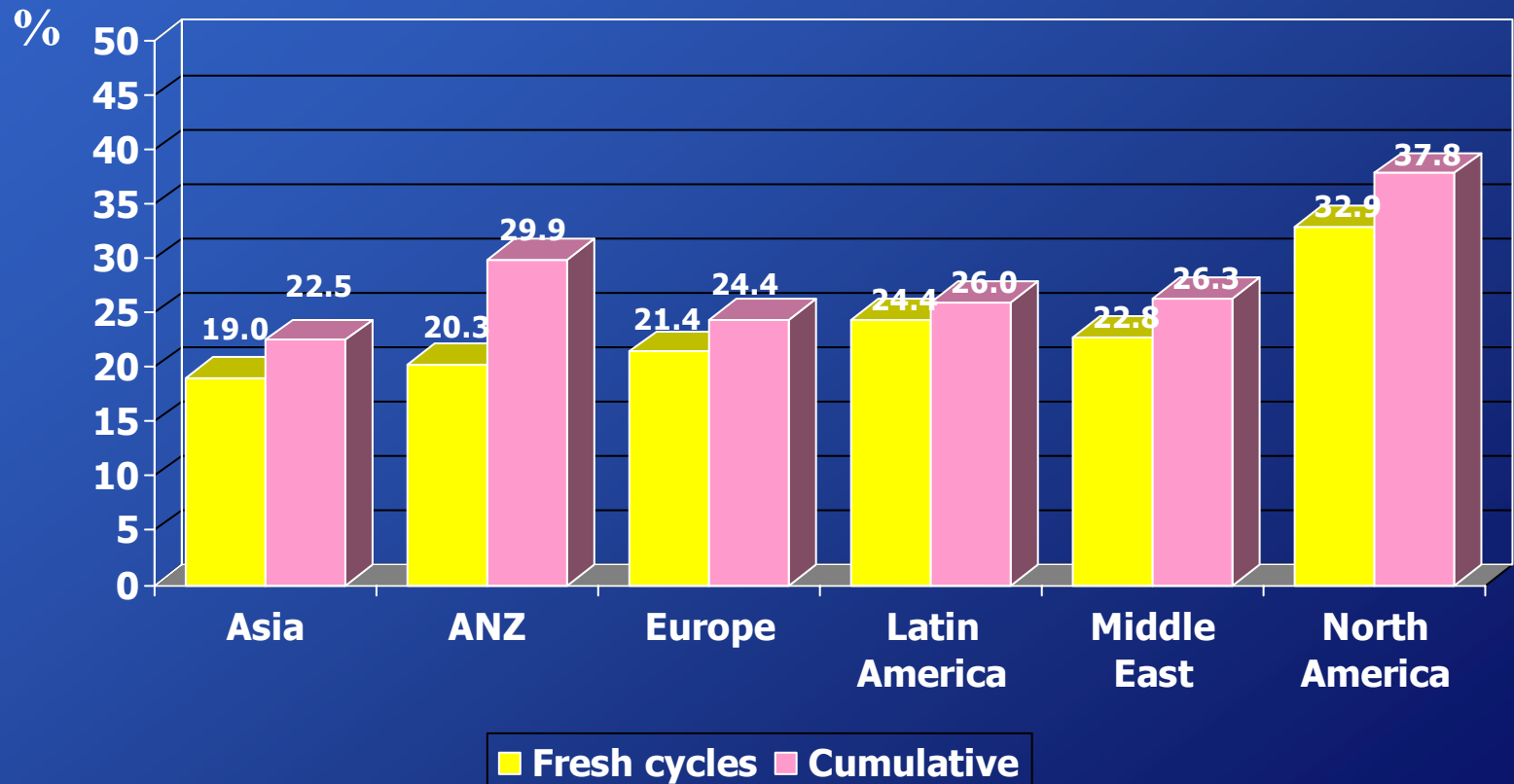


# Procedures Distribution According to Region (2002)

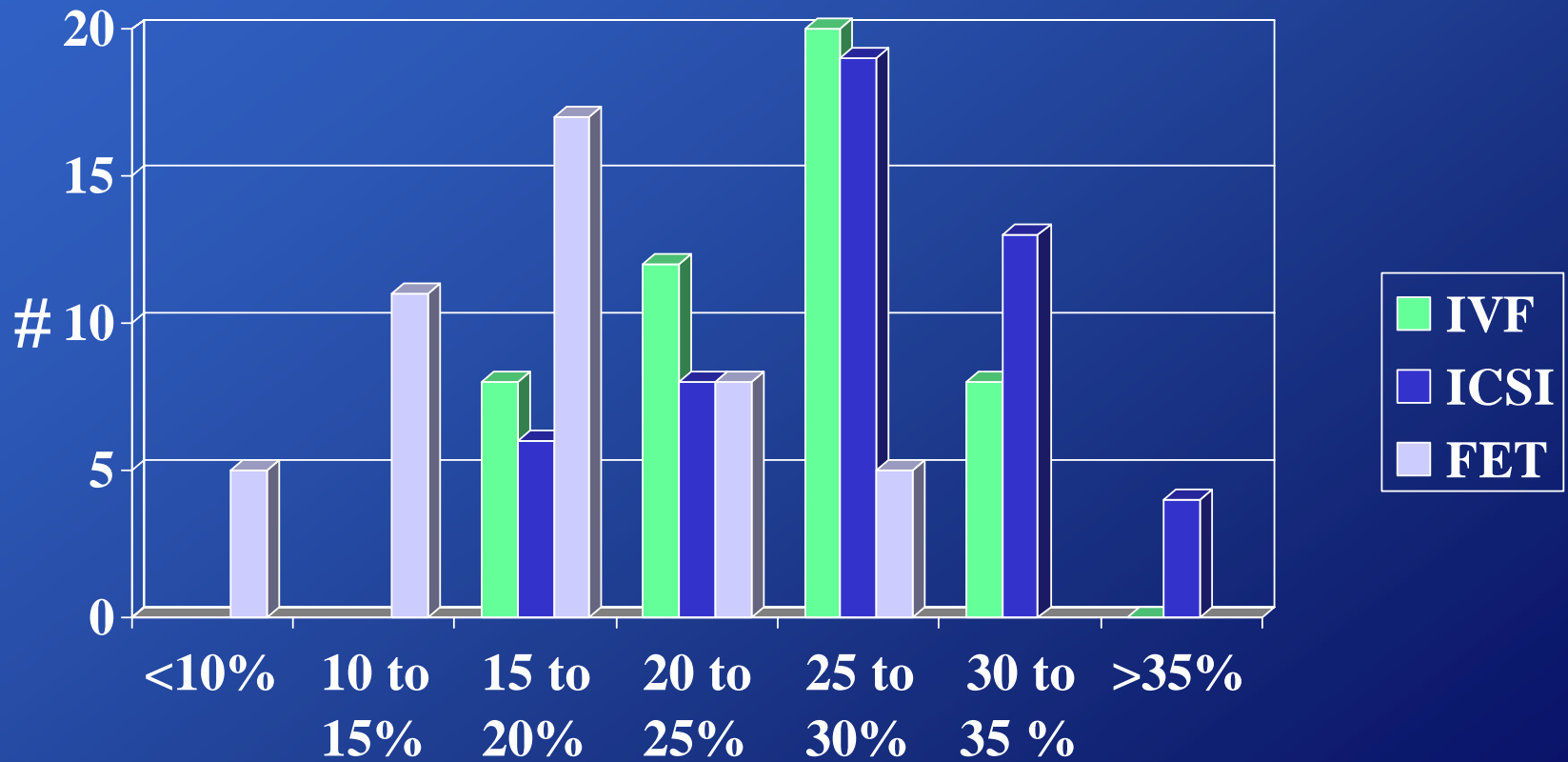


\*excludes Israel

# Delivery Rate (IVF & ICSI) Per Retrieval By Region 2002

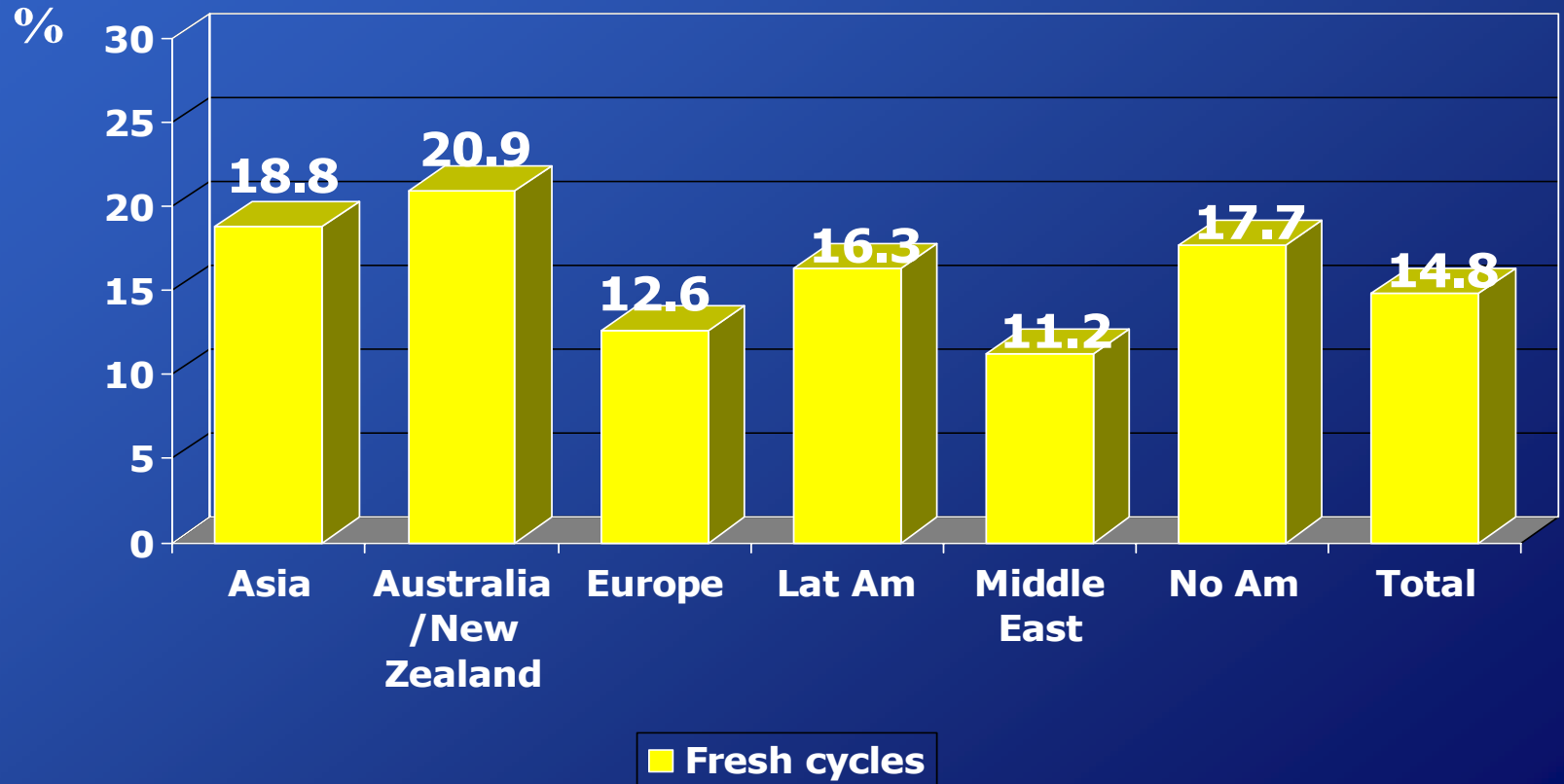


# Heterogeneity Among Countries: (# Countries vs. PR/Transfer)

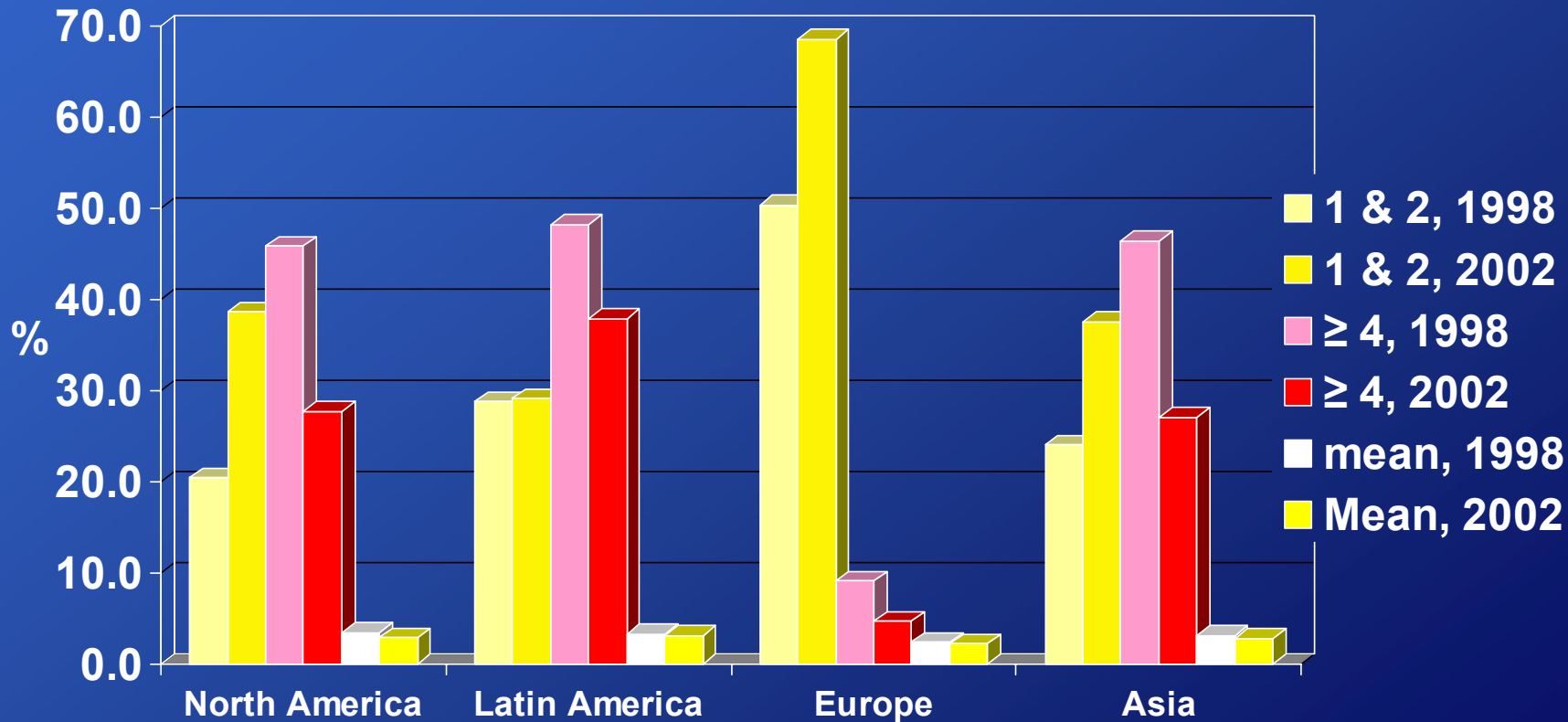


# Women Age $\geq 40$ By Region

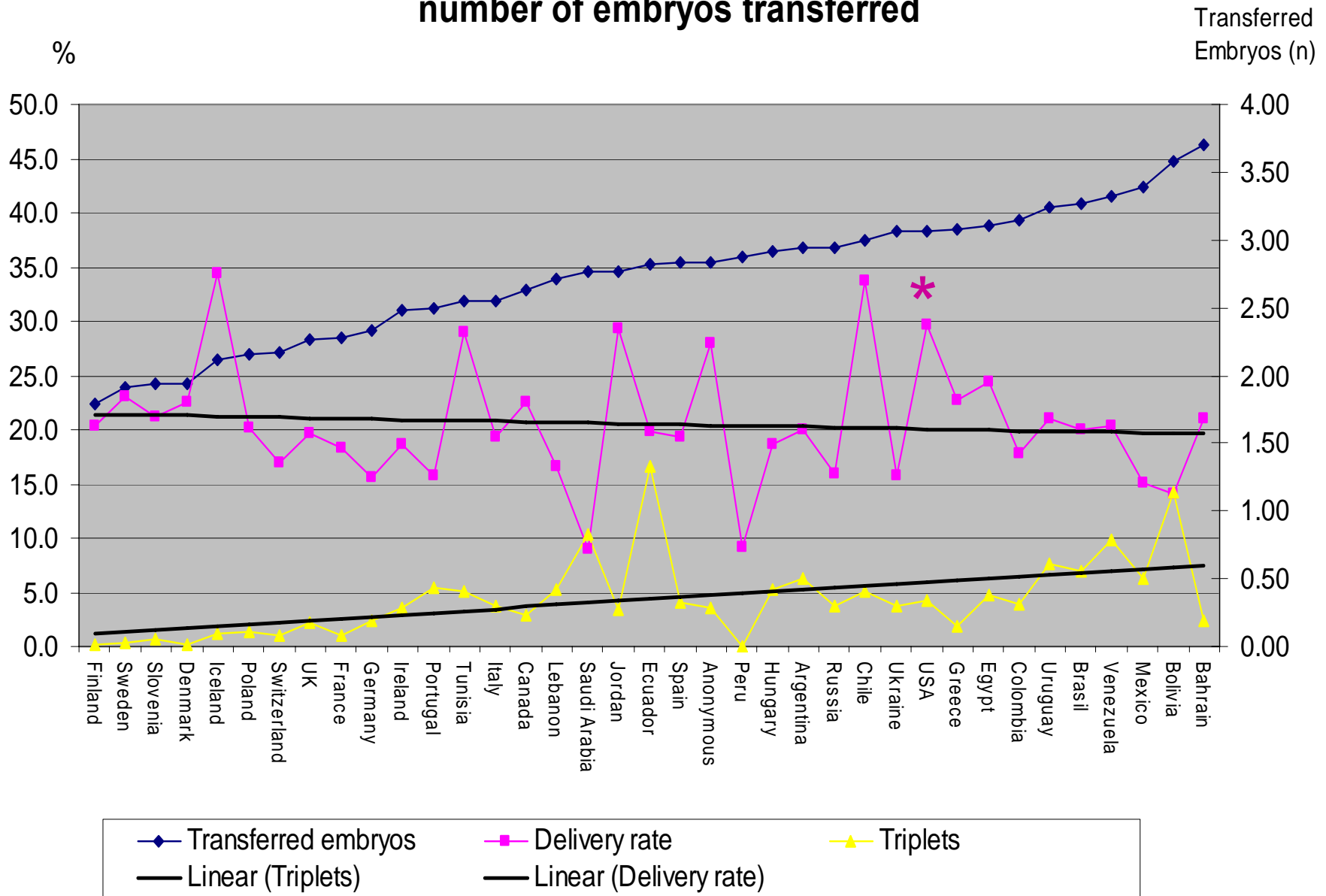
## (IVF & ICSI, 2002)



# Number of Embryos Transferred By Region 2002



# Delivery rate per aspiration cycle and triplet rate according to number of embryos transferred



# Conclusions

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- **Similarities and differences reflect complex characteristics:**
  - Population demography
  - Culture
  - Science/practice of medicine
  - Economics
  - Ascertainment and other biases
  - Etc.

# ART in the USA: Current Regulatory Status

Adamson GD.

Regulation of Assisted Reproductive Technologies in the United States.

*American Bar Association Family Law Quarterly* Fall 2005; 39(3); 727-44.

# Perception of Current Regulatory Status in the USA

- **ART UNREGULATED**
  - Absence of socialized healthcare system
  - No single, national regulatory body
  - Illegal, immoral, irresponsible, and unethical behavior
  - Rapid scientific advances
  - Minimal federal involvement in research
  - Publicity focused on harms
  - Ethical disagreements in society

# **General Mandatory Federal Regulation of ART in the USA**

- **Clinical Laboratory Act of 1998 (CLIA88)**
  - **Andrology Laboratories**
  - **Endocrinology Laboratories**
- **NIH & Federal Research Regulations cover all human research**
- **FDA (Somatic cell nuclear transfer—SCNT)**
- **Federal Law (e.g. embryo, SCNT & stem cell research)**
- **Federal Trade Commission (FTC)**
  - **Marketing of ART programs**
- **Centers for Medicare and Medicaid Services (CMS)**
- **DHHS**
  - **Genetic testing and genetic policy**
  - **Health Care Portability Accountability Act limits gene test data use**
  - **Equal Opportunity Commission prohibits genetic test discrimination**
  - **Public Health Service Act prohibits human embryo research**
  - **Embryo classified as “human subject” in 2002**

# *Mandatory State and Institutional Regulation of ART in the USA*

- STATE
  - License to practice medicine
  - Hospital, operating and procedure room licenses
  - Embryology laboratory license (e.g. CA, NY)
  - Regulations regarding embryo use and research
  - Informed consent regulations (e.g. CA)
  - Multiple miscellaneous regulations affecting reproductive medicine
- UNIVERSITY
  - Clinical regulations
  - Ethical regulations
  - Research regulations (e.g. IRB)
  - Funding regulations

# The Fertility Clinics Success Rate and Certification Act of 1992 (WYDEN LAW)

- FCSRCA; PL 102-493
- Passed with support of SART and ASRM
- Required:
  - Annual reporting of clinic-specific success rates
  - Listing of clinics that do not report
  - Development of model program for certification of embryo laboratories
  - Promulgation of criteria and procedures for approval of accreditation programs to inspect and certify labs

# Professional Accomplishments Overseeing ART in the USA

- American Society for Reproductive Medicine (ASRM) - (1944)
- Society for Assisted Reproductive Technology (SART) - (1987)
- SART publication of clinic-specific success rates on a voluntary basis (1989)
- Assistance developing and passing the Wyden Law (1992)
- American Association of Bioanalysts (AAB)  
Proficiency Testing
- College of American Pathologists (CAP)/SART/ASRM  
Reproductive Laboratory Accreditation Program
  - Guidelines for embryo laboratories (1992)
  - On-site accreditation of embryo laboratories
    - 2/3 of programs through CAP/SART/ASRM
    - 1/3 through JCAHO or NY state)
- ASRM/SART Practice and Ethical Guidelines

# **Current Oversight of ART in the USA**

## **Professional Society Guidelines and Practice Standards**

### **ASRM/SART**

- Minimum Standards for IVF (1984), GIFT (1988)**
- Minimum Standards for Practices Offering Assisted Reproductive Technologies (1990, 1998, 2003)**
- Guidelines Human Embryology and Andrology Laboratories (1992, 2004)**
- Guidelines for Practice including Gamete Donation (1993)**
- Guidelines for the Provision of Infertility Services (1996)**
- Nurses Performing Ultrasound (1997)**
- Induction of Ovarian Follicles with Gonadotropins (1998)**
- Guidelines Gamete and Embryo Donation (1998,1999,2002)**

# **Current Oversight of ART in the USA**

## **Professional Society Guidelines and Practice Standards**

### **ASRM/SART**

- Intravenous Immunoglobulin (IVIG) and Recurrent Spontaneous Pregnancy Loss (1998)**
- Guidelines on Number of Embryos to Transfer (1998, 1999, 2004)**
- Guidelines for Advertising (1998, 1999, 2004)**
- Elements to Consider in Informed Consent (1998)**
- Antiphospholipid Antibodies (1999)**
- Who is to Report ART Cycles (1999)**
- Assisted Hatching (2000, 2003)**

# **Current Oversight of ART in the USA**

## **Professional Society Guidelines and Practice Standards**

### **ASRM/SART**

- Multiple Pregnancy Associated with Infertility Therapy (2000, 2003)**
- Evaluation of the Infertile Female (2000)**
- Repetitive Oocyte Donation (2000, 2003)**
- Compensation of Oocyte Donors (2000)**
- Does ICSI Carry Inherent Genetic Risks? (2000, 2003)**
- Blastocyst Production and Transfer (2001, 2003)**
- Salpingectomy for Hydrosalpinx Before IVF (2001,2003)**
- Preimplantation Genetic Diagnosis (2001)**

# Current Oversight of ART in the USA

## Professional Society Guidelines and Practice Standards

- Aging and Infertility in Women (2002)
- Information/Questions about Genetic Evaluation (2002)
- Round Spermhead Nucleus Injection (RSNI) (2003)
- Ovarian Tissue and Oocyte Cryopreservation (2004)
- Donor suitability of recipients of smallpox vaccine (2004)
- Correct coding for laboratory procedures during assisted reproductive technology cycles (2004)
- [www.asrm.org](http://www.asrm.org)

# Multiple Birth: ASRM/SART Guidelines Number of Embryos to Transfer (2006)

Day 3	<35	35-37	38-40	>40
Favorable*	1-2	2	3	5
All Others	2	3	4	5
Day 5				
Favorable*	1	2	2	3
All Others	2	2	3	3

\* 1st cycle, good embryos, # to cryopreserve, or prior IVF success

# **Current Oversight of ART in the USA**

**Professional Society Guidelines and Practice Standards**

## **American College of Obstetricians and Gynecologists (ACOG)**

- Technical Bulletin on Infertility (1989)**
- Technical Bulletin on New Reproductive Technologies (1990)**
- Technical Bulletin Male Infertility (1990)**
- Technical Bulletin Male Infertility (1994)**
- Practice Opinion on ZIFT (1993)**
- Practice Opinion on Use of Frozen Semen (1994)**

# Current Oversight of ART in the USA

## Professional Society Ethical Guidelines

- ASRM and SART: Ethical considerations of the Assisted Reproductive Technologies (1986, 1988, 1990, 1994, 1997)
  - Disposition of abandoned oocytes
  - Oocyte donation to postmenopausal women
  - Embryo splitting for infertility treatment
  - The use of fetal oocytes in assisted reproduction
  - Posthumous reproduction
- ASRM and SART: Ethical issues with respect to specific ART practices including IVF, GIFT, ZIFT, gamete donation, surrogacy, cryopreservation of embryos, and research
- ASRM and SART: Guidelines addressing quality assurance and formation of public policy
- ACOG Committee on Ethics: Opinions on IVF (1986), surrogacy (1990), and research on preimplantation embryos (1993)
- NABER (1991-1998)

# Current Oversight of ART in the USA

## Professional Society Ethical Guidelines

- Definition of “Experimental” (1993)
- Definition of “Infertility” (1993)
- Informed Consent and Use of Gametes and Embryos for Research (1997)
- Outcome Based Fee Schedule for ART (1998)
- ASRM/SART Guidelines for Advertising (1998,1999)
- Sex Selection and PGD (2000)
- Financial Incentives for Oocyte Donors (2000)
- Human Somatic Cell Nuclear Transfer—Cloning (2000)
- Preconception Gender Selection (2001)

# Current Oversight of ART in the USA

## Professional Society Ethical Guidelines

- HIV and infertility treatment (2002)
- Donating spare embryos for embryonic stem-cell research (2002)
- Family members as gamete donors and surrogates (2003)
- Informing offspring of their conception by gamete donation (2004)
- Child-rearing ability and the provision of fertility services (2004)
- Fertility treatment when the prognosis is very poor or futile (2004)

# Current Mandatory Regulation of ART Mandatory for SART Programs

- **SART**
  - Personnel requirements: Program, Medical and Lab Directors
  - On-site accreditation of laboratory by CAP/ASRM, JCAHO or NY state
  - Reporting of results to SART/CDC
  - On-site validation of reported results by SART/CDC
  - On-site review of adherence to SART Practice, Laboratory, Advertising and Ethics Guidelines
  - Mandatory participation in SART quality assurance program
- **CDC (“Mandatory”, but not enforceable, for all ART programs)**
  - Reporting of results to SART/CDC
  - On-site validation of reported results by SART/CDC
  - Listing of non-responder clinics by CDC
- **FEDERAL TRADE COMMISSION (FTC)**
  - Truth-in-advertising

# **ASRM/SART Practice Committees Guidelines Updates**

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**Essentially all practice and ethics  
guidelines updated November, 2006.**

**Fertility and Sterility 2006;86(5)(Suppl1):S1-277.**

# Mandatory FDA Regulations

- **FDA Beginning 2002**
  - NDA for cytoplasmic transfer
  - NDA for co-culture
  - NDA for paternal leukocyte immunization
- **FDA (As of May 25, 2005)**
  - Registration of laboratory (January 21, 2004)
    - Listing of products used in laboratory
  - Requirements for Donor Suitability Screening
    - Laboratory and Clinical
  - Requirements for Good Tissue Practices (Deferred)
  - On-site inspection by FDA inspectors
  - Compliance with all FDA requirements

# Mandatory FDA Regulations

- **1. Establishment Registration and Listing for Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps):**
- **Registration is required within five days of beginning operation and annually in December.**
- **<http://www.fda.gov/cber/tissue/tisreg.htm>**

# Mandatory FDA Regulations

- 2. Eligibility Determination for Donors of Human Cells, Tissue and Tissue-Based Products (HCT/Ps): This rule becomes effective May 25, 2005.
- <http://www.fda.gov/OHRMS/DOCKETS/98fr/97N-484S-nfr0001.pdf>
- The guidance document may be accessed at <http://www.fda.gov/cber/gdlns/tisssdonor.pdf>

# Mandatory FDA Regulations

- 3. **Current Good Tissue Practice for Human Cell, Tissue and Cellular and Tissue-based Product Establishments: Inspection and Enforcement.**

- **This was published November 18 and became effective May 25, 2005.**

- **However, reproductive tissue is temporarily exempt. It is not known when they will become subject to the GTP regulations.**

- **Although compliance with the Good Tissue Practices is not mandatory, the FDA is urging “voluntary compliance” for reproductive tissue facilities.**

- **Therefore SART recommends that SART programs become familiar with this document and begin to formulate plans on how to implement it in their labs when reproductive tissues become subject to these regulations.**

- **<http://www.fda.gov/cber/rules/gtp.pdf>**

# Ongoing Professional Initiatives to Increase Oversight of ART in the USA

- Cooperation with government in developing reproductive oversight
  - CDC, FDA, NIH, FTC
  - Congress
- Cooperation with Other Interested Parties
  - RESOLVE, American Fertility Association (AFA)
  - New York State Task Force on Life and the Law
  - American Medical Association (AMA)
  - Health Care Financing Administration (HCFA)
  - American Bar Association (ABA)
  - American College of Obstetricians and Gynecologists (ACOG)
- Advocacy for insurance coverage of ART

# NCOART

## National Coalition for Oversight of the Assisted Reproductive Technologies

- SART (Co-Chair)
- RESOLVE (Co-chair)
- ASRM
- CDC
- FDA
- FTC
- Invited Guests: NIH, ABA, AFA, AATB

# Current Oversight Status of ART in the USA

- Significant regulation and oversight currently in place
- Much ongoing progress in improving oversight through cooperative efforts
- Multiple diverse overseeing authorities and organizations
- Inconsistencies, duplication and potentially inappropriate regulations a current and future issue

# IFFS Surveillance 07

Jones HW, Cohen J, Cooke I, Kempers R.  
Fertil Steril 2007;87(Suppl 1):S1-67.

# General Purpose

- Internationally wide divergence
- 1998 survey:  
“...hope...discrepancies...resolved.”
  - Attempt at consensus
  - Not repeated since
- Attempt to “record the situation”
- Purpose: to document the current status of the various issues in hopes of further steps along the road to a scientifically based consensus.
- Moral status of embryo causes divergence

# Number of Centers

- **Same IFFS correspondents: different answers**
- **Comparison with ICMART number**
- **No exact numbers**
  - **Absence of national registry**
  - **Centers opening and closing**
  - **What is the definition of a “center”**
- **All international data collection efforts suffer similar and significant problems**

# Legislation and Guidelines

- Information on 2/3 of world population
- 57/198 countries
- Classification arbitrary because of complexity (e.g. USA, India)
- Changes in regulations
  - Comprehensive: Belgium, Greece
  - ? Retrogressive: Australia, Italy, Norway, UK
  - Italy: Maximum 3 eggs fertilized, all replaced
  - Many with improved legislation/guidelines
- Regulations: availability, research, etc.

# Insurance Coverage

- **Great variation**
- **~ 50% no 3<sup>rd</sup> party reimbursement**
  - either government or private insurance
  - Many in countries with strong religious culture
- **6 countries complete coverage:**
  - Belgium, France, Greece, Israel, Slovenia, Sweden
- **Belgian plan ~ # embryos transferred**
- **USA: Centers of Excellence ~ P4P**

# Marital Status

- In most countries ART is supposed to be only for heterosexual couples, married or in a relationship
- Single and homosexuals have gained access in many countries around the world
- Reproductive tourism has resulted from restrictive laws
- Preliminary studies are encouraging regarding health of children conceived in such relationships

# Number of Embryos To Transfer

- Surveillance 04: 3-4 → 2-3
- Surveillance 07: 2-3 → 1-2
- 26 countries with legislation or guidelines re # embryos to transfer
- Maximum # to transfer: >3, 3, 2
- SET proposed in some Nordic countries, imposed in Belgium
- DET reduces triplets, not twins
- SET reduces twins & pregnancy rate

# Cryopreservation of Sperm, Eggs, Embryos and Reproductive Tissue

- **Regulations in 25 countries**
- **Guidelines in 17 more**
  - **May restrict to married couples**
  - **Often limits duration of egg cryopreservation**
  - **Often prevents deliberate destruction of embryos**
  - **Recently, more donation to research**
- **Less sperm cryopreservation because of ICSI**

# Posthumous Insemination

- **Highly controversial**
- **Both permissive and restrictive regulations**
  - Allowed in 11 countries
  - Not permitted in 19 countries
  - Variable requirements where it is used
  - Some time limits
  - Extensive legal & counseling mandated
- **If no statutes or guidelines, it is rarely performed**

# Donation of Sperm, Eggs, Embryos and Reproductive Tissue (1)

- Donor sperm
  - Allowed in 23 countries
  - Not allowed in 5 countries
  - Often must use registered banks
  - Some countries allow for IVF (12), others NOT for IVF (4)
  - Some must use known donors, some must use anonymous donors
  - Some countries payment, some not
  - Some countries married, some not
  - Informed consent requirements

# Donation of Sperm, Eggs, Embryos and Reproductive Tissue (2)

- **Donor Sperm**
  - Screening requirements
  - Limits on number of offspring
  - Some countries have central registries
  - 6 months testing & quarantine in USA
  - Some must be related, others cannot be
  - Donor age stipulated
- **Ovarian or testicular donation**
  - Possible in 3 countries by regulation, not in 5, not mentioned in statute in 5

# Donation of Sperm, Eggs, Embryos and Reproductive Tissue (3)

- **Donor Embryos**
  - Not permitted in 13 countries, is in 12
  - Controlled in 3
  - Genetic screening, specific consent
  - Anonymity required in 4 countries
  - No payment in Greece and Vietnam
  - # children limited, sometimes 6
  - May have access to non-identifying info
  - Performed in 6 with no regulations
  - Reproductive tourism occurs

# Anonymity of Gamete Donation

- **Traditionally anonymous**
  - 18/54 countries now require some information if requested (3 non-identifying)
  - USA legal cases settled out of court
  - Anonymity protected in France
- **Lack of anonymity a major problem for recruitment in some countries**
- **Lack of compensation severely limits availability of donors (e.g. Canada)**
- **Many guidelines changing**
- **Self regulation a challenge**

# Micromanipulation

- **ICSI**
  - Performed ~ 50% of cases
  - Performed in all countries
  - Genetic evaluation recommended
- **Assisted hatching**
  - Controversial/experimental
  - Performed in all countries
- **Cytoplasmic transfer**
  - Done in 5 countries where permitted
  - Not allowed in 13 countries

# Oocyte Maturation

- **Experimental because of poor results**
  - PCOS, risk of OHSS
  - Severe male infertility
  - Poor responders
  - Poor embryo quality
  - Fertility preservation
- **Restrictive legislation on freezing embryos (e.g. Italy) is promoting research on this technique**

# Welfare of the Child

- UK, Greece, New Zealand have laws
  - No official action ever taken under this statute in UK
- Many countries have laws regarding right to information about donor if necessary for health of child
- Important for physician to consider welfare of child
- Counselors can be helpful

# Fetal Reduction

- **Effective, safe to reduce risk of adverse complications of multiples**
- **Potential significant emotional issues**
- **Of 56 countries surveyed**
  - Not allowed in 8 (1 statute, 7 guidelines)
  - Performed in 20
  - Not performed where abortion illegal
- **Lack of long-term data on outcomes**
- **Widely accepted and practiced**
  - France 1.78% of IVF LB, 1.42% ICSI LB

# Preimplantation Genetic Diagnosis (1)

- One of fastest growing techniques
- Effective for ~ 1,000 single genes
- Allowed in 20/29 regulated countries
  - Not in Germany, Italy, Switzerland
  - Actually used in 18
  - Some: number of centers limited
  - Some: only for research
- Allowed 12/17 w guidelines, 0 prohibit
- Only performed in 34/54 countries

# Preimplantation Genetic Diagnosis (2)

- **PGD for aneuploidy**
  - Used in 23/54 surveyed countries
  - In 29 with statutes
    - Not allowed in 6 (Fr, Germ, Greece, Italy, Norway, Switz)
    - Not mentioned in 10
    - Allowed in 13
  - In 16 with guidelines
    - Not allowed in 3 (Chile, Japan, Singapore)
    - Not mentioned in 7
    - Done in only 5
  - In 23 countries where allowed or not mentioned, is done in only 12
- **Not widely used, and is controlled**

# Preimplantation Genetic Diagnosis (3)

- **Indications in USA**
  - Aneuploidy 66%
  - Autosomal disorders 12%
  - Chromosome rearrangements 9%
  - X-linked diseases 3%
  - Nonmedical sex selection 9%
  - HLA typing 1%
- **Technical, social, ethical, legal issues**
- **Self-regulation remains a challenge**

# IVF Surrogacy

- < 50% of countries perform
- Frequency low, difficult to determine
- Many limitations
  - Panel/court to approve
  - Altruistic only
  - Marital status of surrogate/others
- Still much legal uncertainty
- No follow-up studies of outcomes
- Only indicated for medical reasons

# Experimentation on the Preembryo

- Difficult to define research
- Very limited availability of embryos
- Related to moral status of embryo
- Many countries prohibit creation of embryos for research
- Moral issue of using reproductive embryos for research
- 50% of countries said not acceptable
  - Half on laws, half on social basis
- No international consensus

# Cloning = Somatic Cell Nuclear Transfer (SCNT)

- **Creation of a developing entity by the transfer of a whole exogenous genome (46 chromosomes) into an enucleated oocyte**
  - **Reproductive (create another person)**
    - No countries have approved
    - Many have legislation opposing
    - Not done publicly
  - **Therapeutic (cells/tissue for treatment)**
    - Not done or used in over half of all countries
    - Over half the remaining it is not mentioned
    - < 20 countries actually doing therapeutic cloning
  - **Research**
    - No unanimity
- **SCNT is inefficient and associated with abnormal offspring**
- **Carryover of opposition to therapeutic SCNT from reproductive**

# Gamete Intrafallopian Transfer

- Statutes/guidelines don't differentiate from IVF
- In some countries, GIFT is not covered under the umbrella of IVF
- Some limit number of eggs transferred
- Rarely done
- Italy: GIFT plus 3 oocytes for IVF

# Status of the Conceptus

- Moral and legal status of the embryo is often the key to the acceptability of many procedures that are made available by IVF technology.
- Differences among/within countries
- Legal difficulty of dealing with an entity that is neither a thing nor a person.
- Great diversity of opinion
- Personhood
  - Entity that deserves protection by society
  - ~ 50% of countries starts at fertilization
  - Costa Rica constitution bans IVF
  - Germany starts at pronuclear stage
  - Many countries personhood starts at 14 days wrt research
  - Influenced greatly by religious tradition
  - No international consensus
  - Personhood a controlling issue with respect to research

# IFFS Conclusion (1)

- ~ 50% of countries surveyed regulate and control ART
- Laws & guidelines highly divergent
- # of countries satisfied = 3
  - Belgium, Latvia, UK
- # of countries feel “disastrous” for patients, physicians, biologists = 3
  - Germany, Italy, Switzerland

# IFFS Conclusion (2)

- # countries that want laws/guidelines = 3
  - Bulgaria, Brazil, Chile
- Other countries
  - Want to modify regulations for specific items
    - Preimplantation genetic diagnosis
    - Gamete donation
    - Anonymity of gamete donors
    - Gamete research
- Reproductive tourism

# IFFS Conclusion (3)

- **No consensus because of diversity**
  - Religion
  - Traditions
  - Political situations
  - Medical practices
- **International consensus would be “the lowest common denominator”**
- **“Actual situation is illogical, unfair to couples and difficult for doctors and scientists”**
- **Still allows solutions for patients**
- **Future: slow harmonization of legislation/guidelines/oversight**

# Advantages of Oversight (1)

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- Establishes national standards
- Recognizes uniqueness of ART
- Promotes high quality patient care
- Ensures minimum standards of care
- Improves research
- Protects patients' interests

# Advantages of Oversight (2)

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- **Provides forum for national debate and participation**
- **Ethics statements can be mandated by law**
- **Precedents in other fields can be utilized**
- **Increases society's confidence in and acceptance of ART**
- **Increases insurance funding (?)**

# Disadvantages of Oversight (1)

- Requires funding
- Requires mechanisms of enforcement
- Requires support of overseers, clinics, and patients
- May fail to solve problems
- Does not prevent psychopathic, sociopathic or illegal behavior
- Complicates legal issues of intent and due process vis-à-vis criminal vs. inadvertent error in the practice of medicine

# Disadvantages of Oversight (2)

- Interferes in the practice of medicine
  - Intended (e.g. embryo research)
  - Unintended (e.g. Wyden Law and clinic-specific success rates)
- Interferes in patients' rights
- Leads to reproductive tourism
- Discriminates against some patients
- Increases cost to patients
- Politicizes medical and personal issues

# Characteristics of an Oversight Authority

- Partnership of patients, providers, public
- Independence from any one interested party
- Authority for mandatory enforcement
- Flexible mandate
- Standards of care
- Specific regulations (few)
- Financed by all three groups
- Avoidance of political/moral agendas

# Current Proposed Mandates for an Oversight Authority

- **Mandatory compliance**
- **Meaningful sanctions**
- **Uniformity in reporting**
- **On-site inspection and validation**
- **Practice standards**
- **Research standards**
- **Education standards**
- **Counselling standards**
- **Insurance coverage**
- **Research funding**
- **Limitation of regulation**

# Oversight Authority Needs to Establish Priorities

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- **Meet consumer needs**
- **Allay public fears**
- **Protect embryos/future children**
- **Control physicians**
- **Control research**

# Different Parties Interested in Oversight of ART

- RESOLVE
- AFA
- Payers

**Patients**

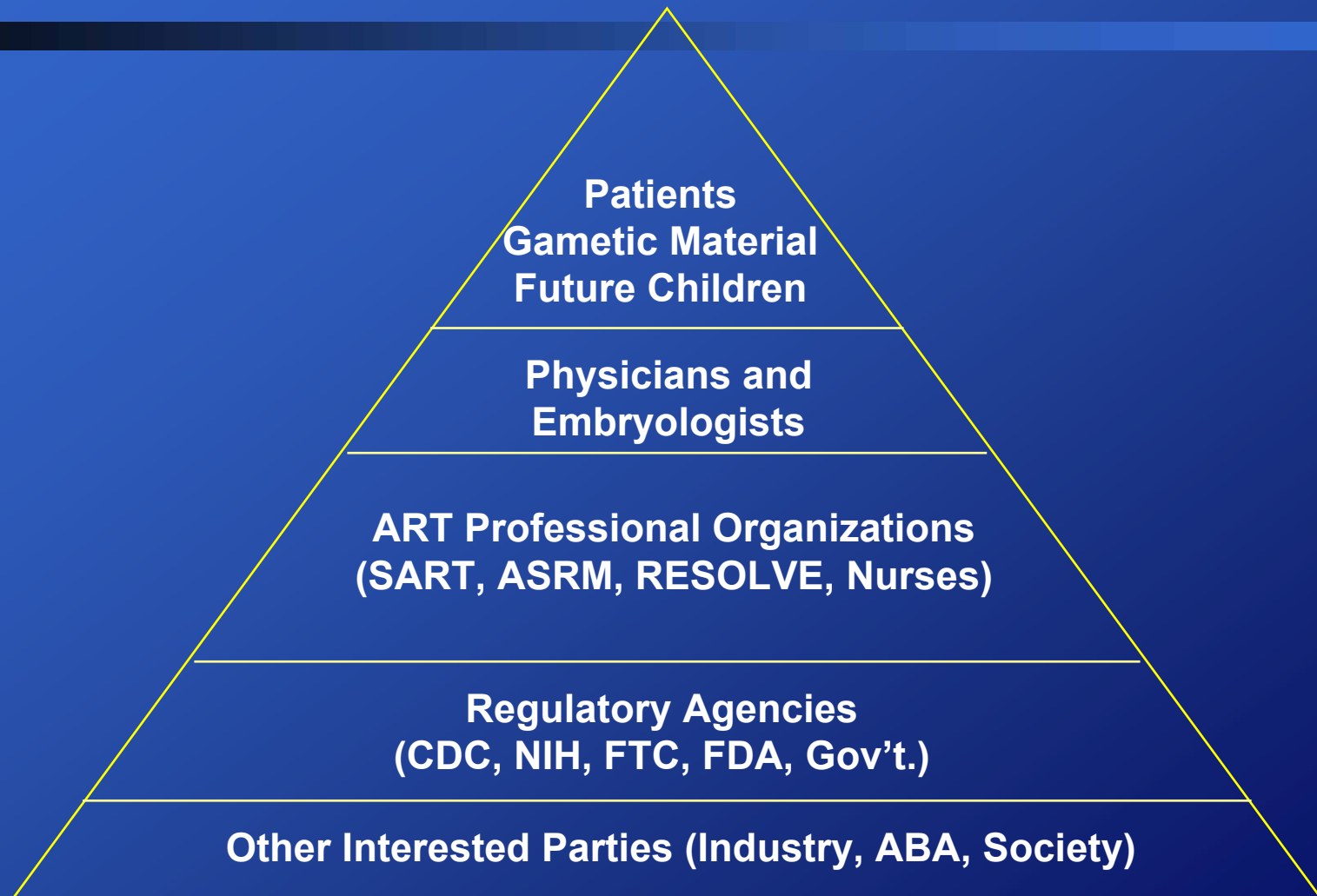
**Providers**

- Government
- CDC
- FDA
- FTC
- ABA
- IRB
- NIH

**Public**

- SART
- ASRM
- SRE
- RBPG
- MHPG
- AATB
- NPC
- ACOG
- AMA
- CAP
- Hospital
- University
- ART Industry (BIO)
- Reproductive Laboratory Technology (RLTPG)
- Others

# The Hierarchy of Interest



# Conclusion

- **Significant progress in developing oversight**
  - Significant Professional involvement and oversight
  - ART very regulated: federal, state, institution
  - FDA regulation now “closes the loop” with sanctions
- **Complex and rapidly changing clinical, scientific, and ethical field of human endeavor**
- **Highly visible and emotional issues**
- **Heterogeneous society(ies)**
- **Hierarchy of interest**
  - Patient choice
  - Practice of medicine
  - Social good
  - Human good

**Thank**

**You!**