



Quality in ART

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Meeting between Comission, T&C CAs and Stakeholders
Brussels, 16th November 2017

Quality in ART

Main issues

- How to define quality in ART?
- Keeping pace with scientific and technological changes
- Registries

Quality in ART

- **How to define quality in ART?**

Procedures:



Improvement of standards (at least in some countries)
Reduction of risk of misidentification
Increased awareness of traceability issues
Harmonisation of inspections (ongoing work)



Increase in financial costs
Increase in bureaucratic workload
“Misunderstanding” of ART specificities

Quality in ART

- **How to define quality in ART?**

Efficacy:

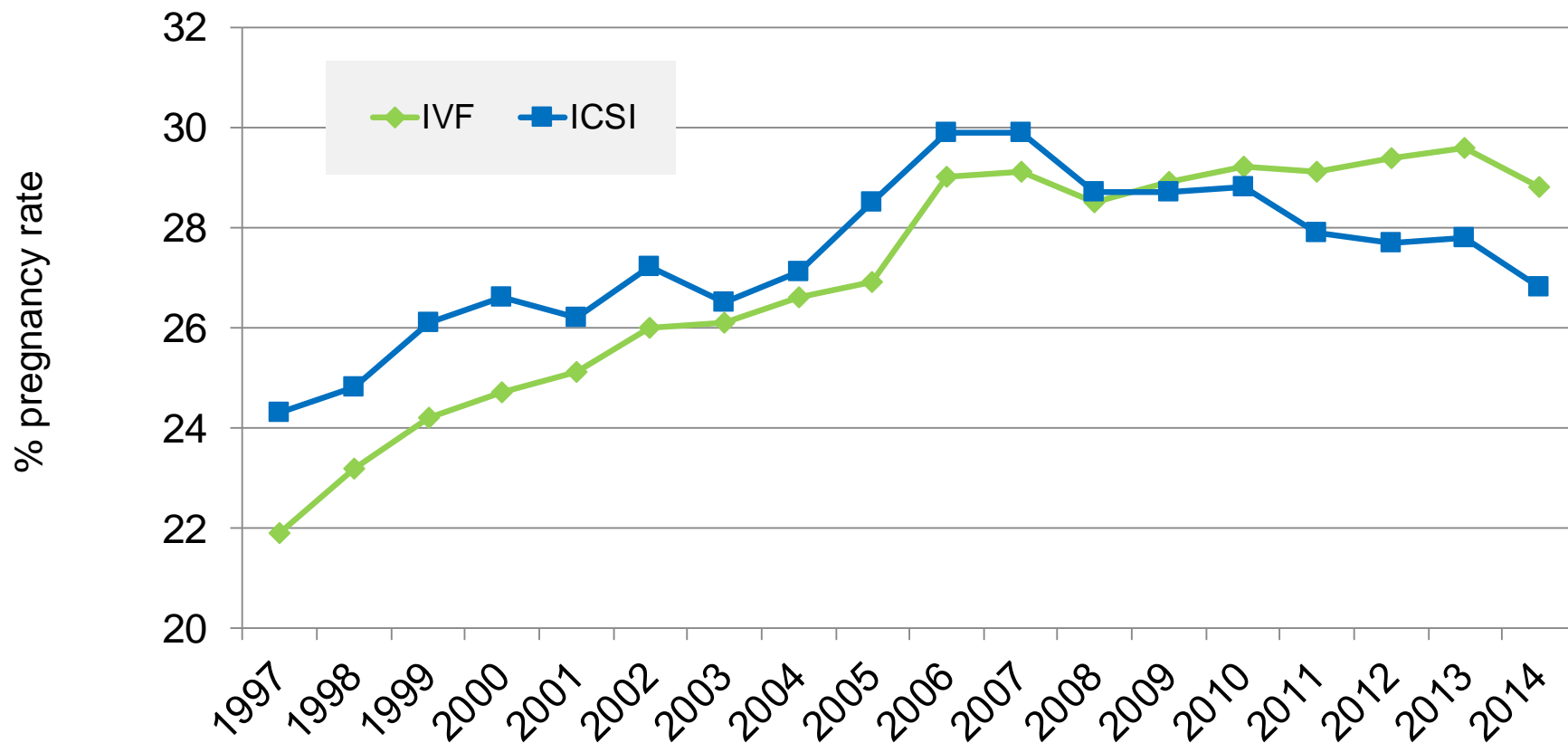
- **Live birth rate per treatment initiated**
(*but* multiples, cumulative rate, ...)



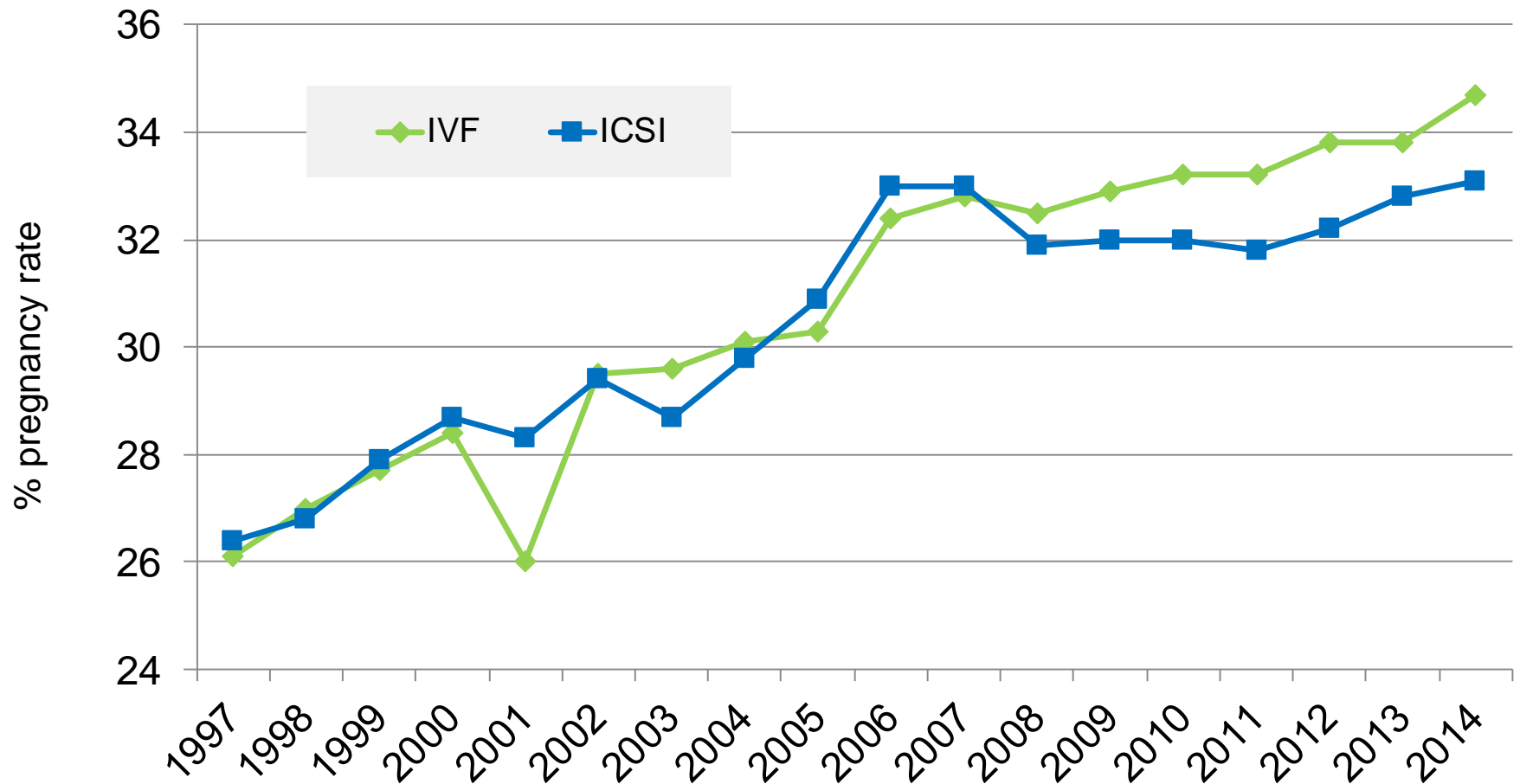
Intermediate outcomes:

- **Clinical pregnancy per initiated cycle, per ovarian aspiration, per embryo transfer**
- **Clinical - % of cancelled cycles**
 - no. of oocytes retrieved
 - % of matured oocytes retrieved
 - ...
- **Laboratorial - fertilization rate**
 - % of embryos of good quality
 - ...

EIM 1997-2014 Pregnancy rates per aspiration



EIM 1997-2014 Pregnancy rates per transfer



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Specificities of ART

- **Partner donation and Non-partner donation**
- **(Desired) outcome is the birth of a (healthy) baby** (not life- or function-saving)
- **Clinical application depends of MS legislation** (diverse social and cultural implications)
- **Treatments are usually repeated *but* the same treatment can provide multiple opportunities for getting pregnant throughout a long time span**
- **Fertility preservation** (medical and nonmedical reasons)
- **Surrogacy**

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Keeping pace with scientific and technological changes

- Legitimate concern for all
- but*
- Beyond the scope of Directives

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Experimental, Innovative and Established treatments

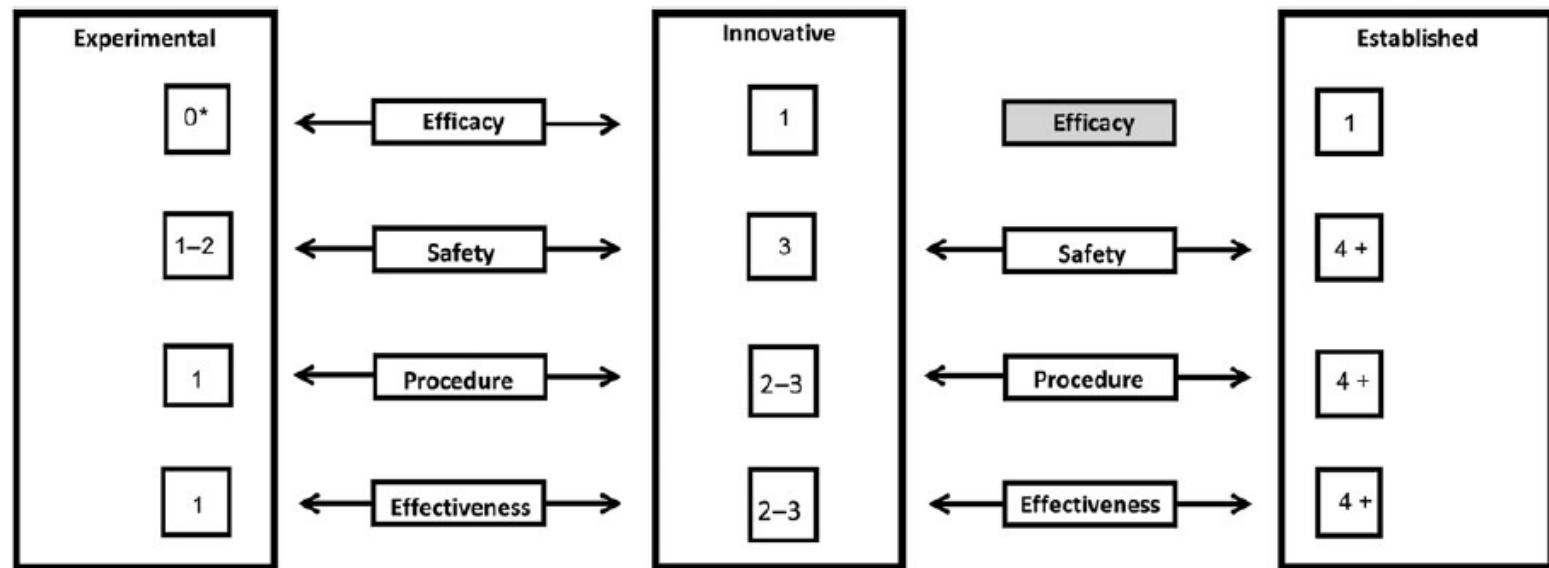


Figure 1 Sequential four-criterion assessment tool to consider the transition of a treatment from experimental through innovative to established. *Numbers represent the scores at either end of the threshold for each of the four criteria for the first transition (from experimental to innovative) and for each of the three last criteria for the second transition (from innovative to established).

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Registries of ART activity (ideal characteristics)

- Compulsory and complete
- Cycle-by-cycle (not only global aggregation of data)
- Coherent in the different MS (core data)
- Covering long-term offspring characteristics

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EIM data

year	countries	clinics	cycles	cycle-increase (%)	ART infants
1997	18	482	203,225		35,314 *
1998	18	521	232,225	+ 14.3	21,433 *
1999	21	537	249,624	+ 7.5	28,212 *
2000	22	569	275,187	+ 10.2	17,887 *
2001					24,063 *
2002					24,283*
2003					68,931
2004					67,973
2005					72,184
2006					87,705
2007					96,690
2008					107,383
2009	34	1005	537,463	+ 1.0	109,239
2010	31	991	550,298	+ 2.4	120,876
2011	33	1,314	609,873	+ 11.3	134,108
2012	34	1,354	640,144	+ 4.9	143,844
2013	38	1,169	686,271	+ 7.2	149,468
total			7 233,971		1 308,289

- No. of EU countries with 100% coverage – 14
- No. of EU countries with compulsory registry – 17 (3 incomplete information)
- No. of EU countries with cycle-by-cycle registry - 12

* Data only from countries reporting 100% coverage of ART activity

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ESHRE supports and values all principles in Directives regarding quality and safety of procedures that contribute to

- **an increase in the efficacy of treatments**
- **the protection of patients**
- **the protection of the future generations of children born from ART**
- **ensure practitioners qualification**

but

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We think there is a strong need to consider ART specificities in a future legislation and to:

- **clarify the scope of EU legislation in the ART field**
- **implement/improve systematic registries in ART**
- **be realistic in requirements such as the quality of air**
- **reduce regulatory burden in partner donation**

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Thank you