

Met de wind in de zeilen: Biovigilantie bij reproductieve weefsels en cellen

**Kelly Tillemans
TRIP 16/11/2022**



Biovigilantie MAR ~ zeilen



Erwin Van Iseghem

MAR kliniek ~ zeilboot

verschillende disciplines

verschillende expertise

verschillende opleidingsniveaus

verschillende ervaring

verschillende teamleiders

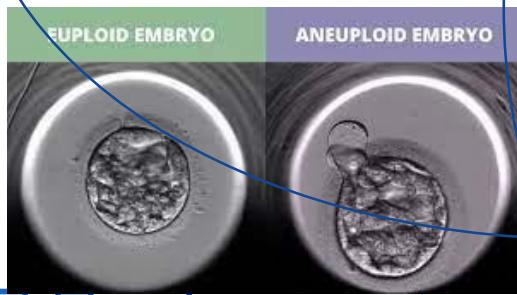
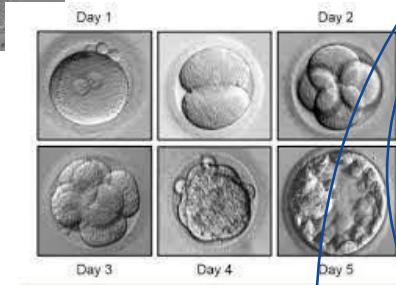
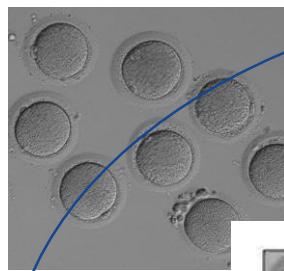
2 kapiteins?

Responsible Person vs afdelingshoofd

Juridische vs medische verantwoordelijkheden



MAR kliniek ~1 richting



UZ
GENT

UNIVERSITEIT
GENT



Biovigilantie MAR ~ risico's zeilen



Risico's in MAR

IVF klinieken =

busy units

hoge graad van complexe processen en procedures

hoog technologisch material

hoog aantal cellen aanwezig van ≠ donoren/patiënten

hoge turnover van material

meerdere taken gebeuren simultaan

verschillende collega's bewerken materiaal

Biovigilantie MAR ~ boot kapseist

'I GAVE BIRTH TO THE WRONG BABY'

Couples had to swap their daughters after IVF mix-up

CONFUSION: The Cardinales' older daughter with a child who belonged to another family



LAWSUIT: Daphne and Alexander Cardinale are suing the IVF clinic in LA

A MUM has told of the horror of finding out she and another woman had given birth to each other's babies after an IVF error. After the two women gave birth to each other's babies, they spent four months raising the wrong child before swapping the infants, according to a US lawsuit. Daphne Cardinale and husband Alexander, from LA, allegedly used the LA that allegedly mixed up the embryos.

The couple and another couple spent two months raising the wrong babies before a DNA test revealed the mistake, a US lawsuit states.

When they got the results – when the baby was two months old – they were shocked. Neither was related to the child.

Numb

The couple had immediate concerns in the delivery room when they said their daughter was not right.

"The room shrank, I got really dizzy... everything was numb," Alexander said. "For a moment he couldn't even see his baby's appearance. And then, in an attempt to answer her husband's fears, Daphne ordered a DNA test."

Daphne said the couple's "heartbreak and confusion can't be understated."

She said: "Our memories of childbirth will be tainted by the sick reality that

our biological child was given to someone else, and the baby I fought to bring into this world was not mine to keep."

She added: "We were in a separate room when the baby awoke looking nothing like them. They expected a 'fair child,' like their firstborn, but the baby was with much darker skin," says the lawsuit.

After Daphne ordered a DNA test, which revealed neither of them were the biological parents, the fertility clinic helped them find the woman who had their real daughter.

Struggled

The couples met when the babies were four months old and went through the legal process of exchanging the children in 2010.

Daphne said the incident had been "most difficult for their seven-year-old daughter, who has struggled to understand the swap."

The Cardinales are suing the LA-based fertility clinic, the California Center for Reproductive Health (CCRH), and in VitroTech Labs, an embryology lab.

The lawsuit alleges medical malpractice, negligence and breach of contract.

The other couple are also considering legal action.

Neither company have yet to respond.

Biovigilantie MAR ~ de theorie

Melden van SAR aan de overheid: ernstige bijwerkingen

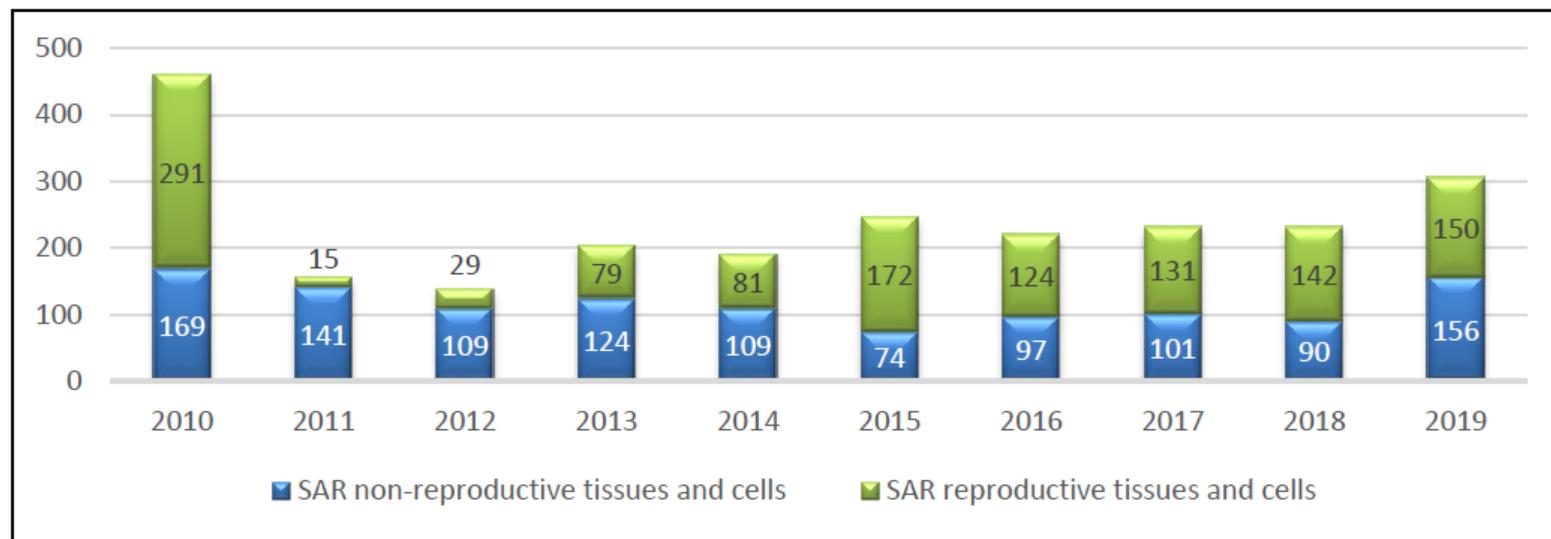


Figure 14. Total number of serious adverse reactions: 2010-2019 comparative data.⁸

SAR: 0.0003-0.025% SAR/# reprod. tissues and cells distributed

Bron: EU commissie data 2019 (17 landen)

Biovigilantie MAR ~ de theorie

Melden van SAE aan de overheid: ernstige voorvallen (incidenten)

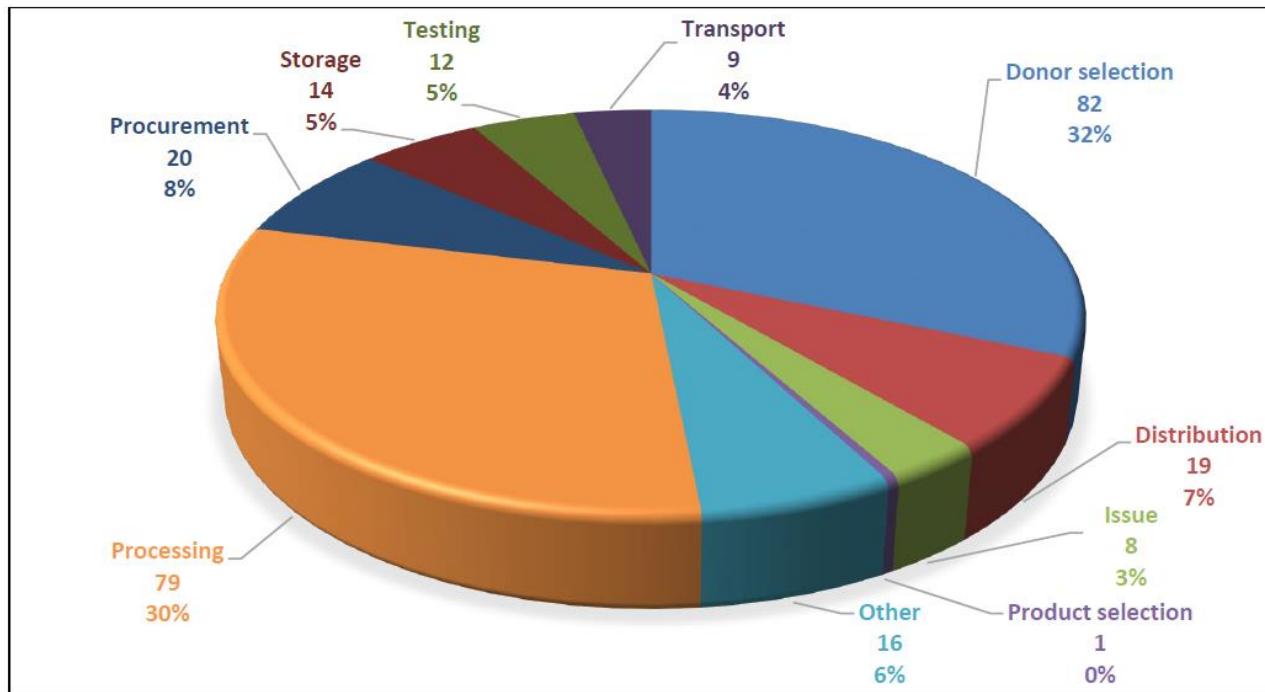


Figure 30. Number of SAE and percentage of total SAE reported for reproductive tissues and cells by type of activity (absolute values and percentages of total); data 2019.

260 SAE MAR -> 1 SAE occurred every 903 286 units processed

Bron: EU commissie data 2019 (17 landen)

Biovigilantie MAR ~ de theorie

Niet alle landen staan in EU rapport, wat leren we?

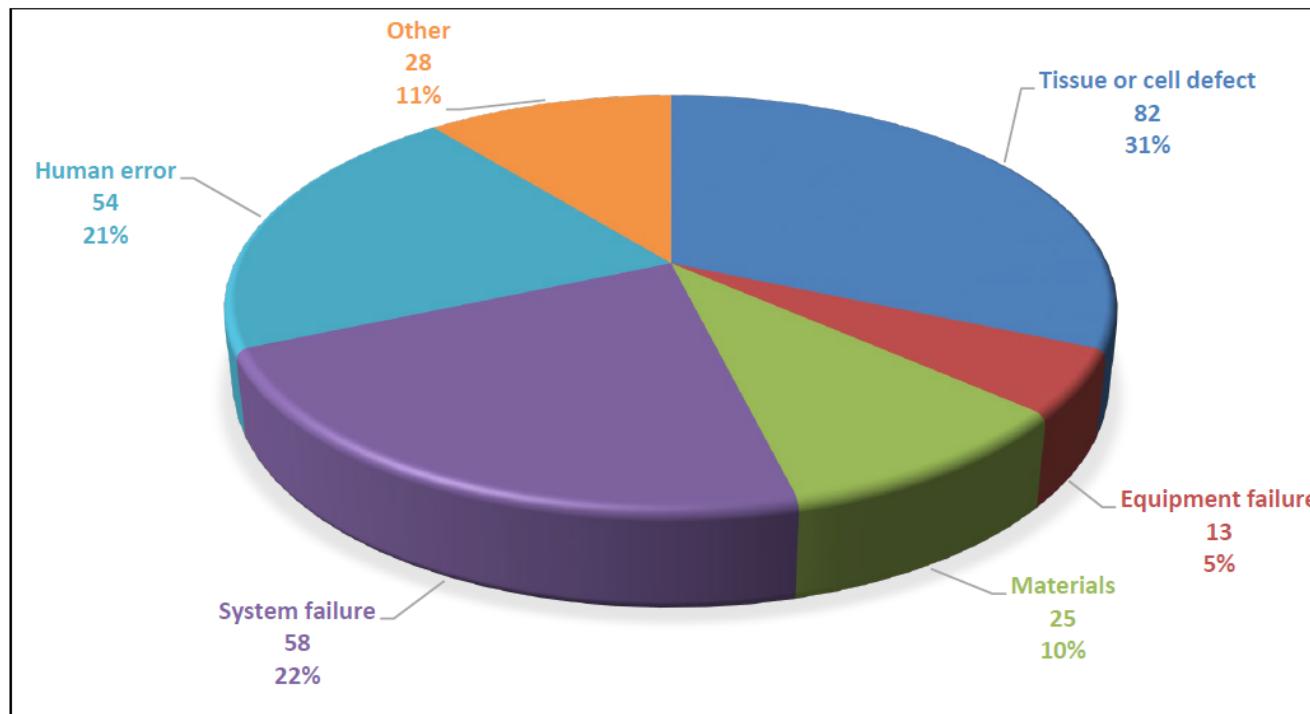


Figure 32. SAE types for reproductive tissues and cells (absolute values and percentages of total); 2019 data.

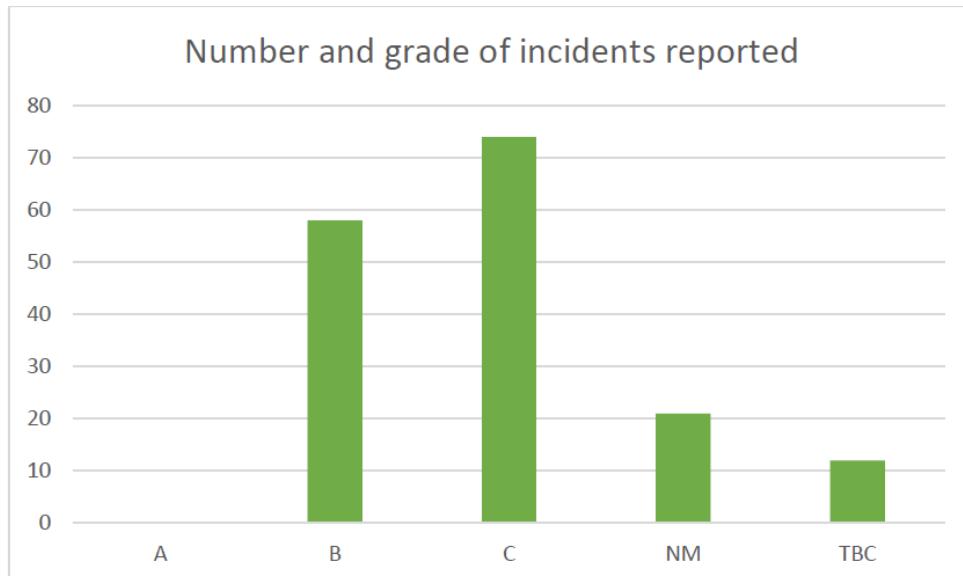
260 SAE MAR -> 1 SAE occurred every 903 286 units processed
Bron: EU commissie data 2019 (17 landen)



Biovigilantie MAR ~ de theorie

HFEA: alles wordt gerapporteerd ~quaterly update

Graph 2 shows the number and grades of incidents reported



Grade A: the most serious type of incident. They happen infrequently and examples may include a patient being implanted with an embryo that is intended for someone else, the death of a patient or an incident which affects a number of patients, for example, when a storage unit malfunctions.

Grade B: serious adverse events or reactions such as the loss of embryos for one patient, breaches of confidentiality where sensitive personal data or data relating to more than one patient is sent to the wrong recipient, or when a piece of equipment malfunctions affecting the quality of a patient's embryos.

Grade C: adverse events or reactions such as one of many eggs rendered unusable during processing (for example the moving of an egg between dishes).

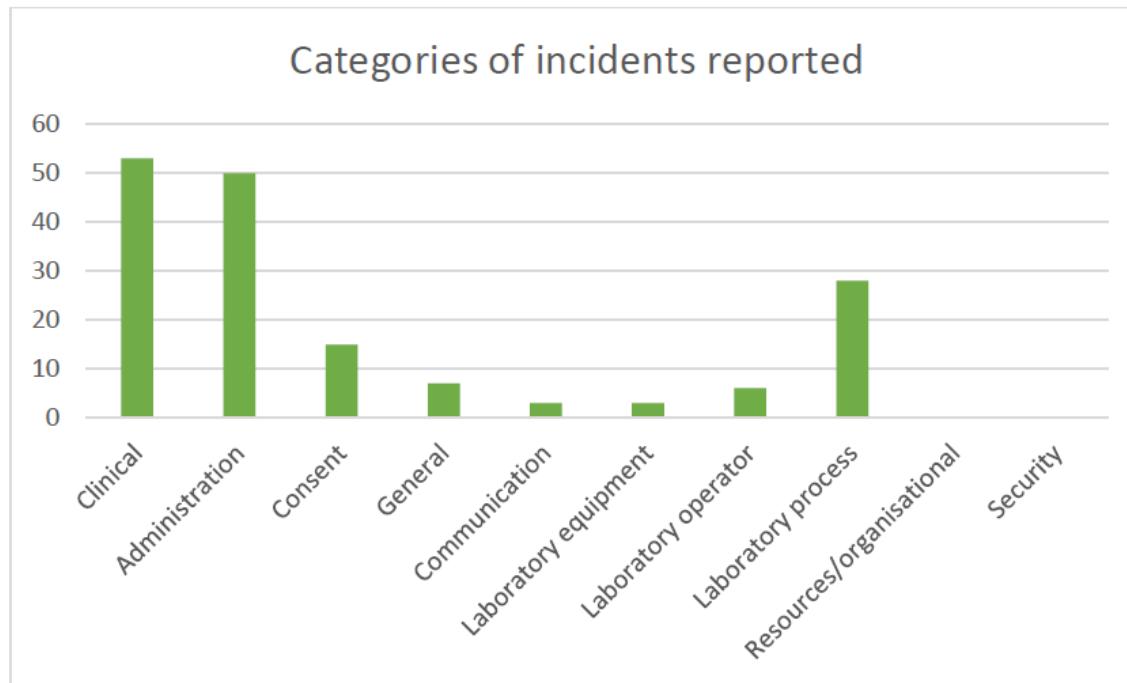
Near Miss: is an event that might have resulted in harm, but the problem did not reach the patient because of timely intervention by clinic staff or the patient, or due to good fortune. Near misses may also be referred to as "close calls" or "good catches."

Bron: HFEA April – June 2022

Biovigilantie MAR ~ de theorie

Categorie van incidenten:

Graph 3 shows the breakdown of the categories of incidents reported. Incidents classed as 'not an incident' (n=33) have not been included.



Bron: HFEA April – June 2022

Biovigilantie MAR ~ de theorie

Categorie van incidenten: uitleg

Appendix 3: Incident categories

The table below shows incident categories

Category	Example
Resources/organisational	Theatre list cancelled or rearranged, impacting on patients.
Communication	Incorrect information given to patient regarding medication, resulting in an abandoned cycle.
Security	Break ins and/or theft of equipment from clinics.
Clinical equipment	Clinical equipment malfunctioning.
General	Adverse weather conditions causing flooding in a laboratory or clinical area.
Consent	Embryos removed from storage without the patient's consent.
Laboratory equipment	Most commonly equipment faults and failures eg, dewar failure.
Laboratory operator	Dishes containing eggs or embryos knocked or dropped and failure to inject or inseminate eggs.
Laboratory process	Failure to follow laboratory protocols.
Administration	Breach of patient confidentiality.
Clinical	Hospital admissions due to ovarian hyperstimulation syndrome (OHSS) or a failure to follow clinical protocols eg, incomplete screening prior to treatment.

Bron: HFEA April – June 2022



Biovigilantie MAR ~ de theorie

Voorbeelden:

Examples of incidents reported

Clinical:

- Cases of severe OHSS.
- Bladder injury from the egg collection needle.
- Hospital admission for hematoma in the pelvis.
- Egg donor found to be pregnant during an egg collection.
- Requirements for screening not followed.

Administration:

- Breaches of patient confidentiality: partner informed clinic he had separated from patient but had received an email regarding offer of donor sperm; patient was able to access two unrelated patient invoices via his own portal; the wrong patient blood results were attached to an email and sent to another patient; patient requested a form for a copy of their notes via email. The centre inadvertently attached a list of all patients who had requested copies of their notes.
- A member of staff breached patient confidentiality by informing a friend that a patient was attending the clinic and having tests completed.

Consent:

- Storage of gametes or embryos without effective consent.
- PBR consent form not completed prior to frozen embryo transfer treatment.

Laboratory equipment:

- Malfunction with the holding needle during an ICSI.
- Power failure to Embryoscope incubator and alarm.

Laboratory processes:

- Discarded sperm centrifuge tube used for treatment in error instead of the centrifuge tube containing the sperm pellet. Patient was converted to ICSI on the day due to low sperm numbers.
- Loss of eggs or embryos during manipulation.

Biovigilantie MAR ~ de praktijk UZ

Work in progress:

Gradaties volgens HFEA

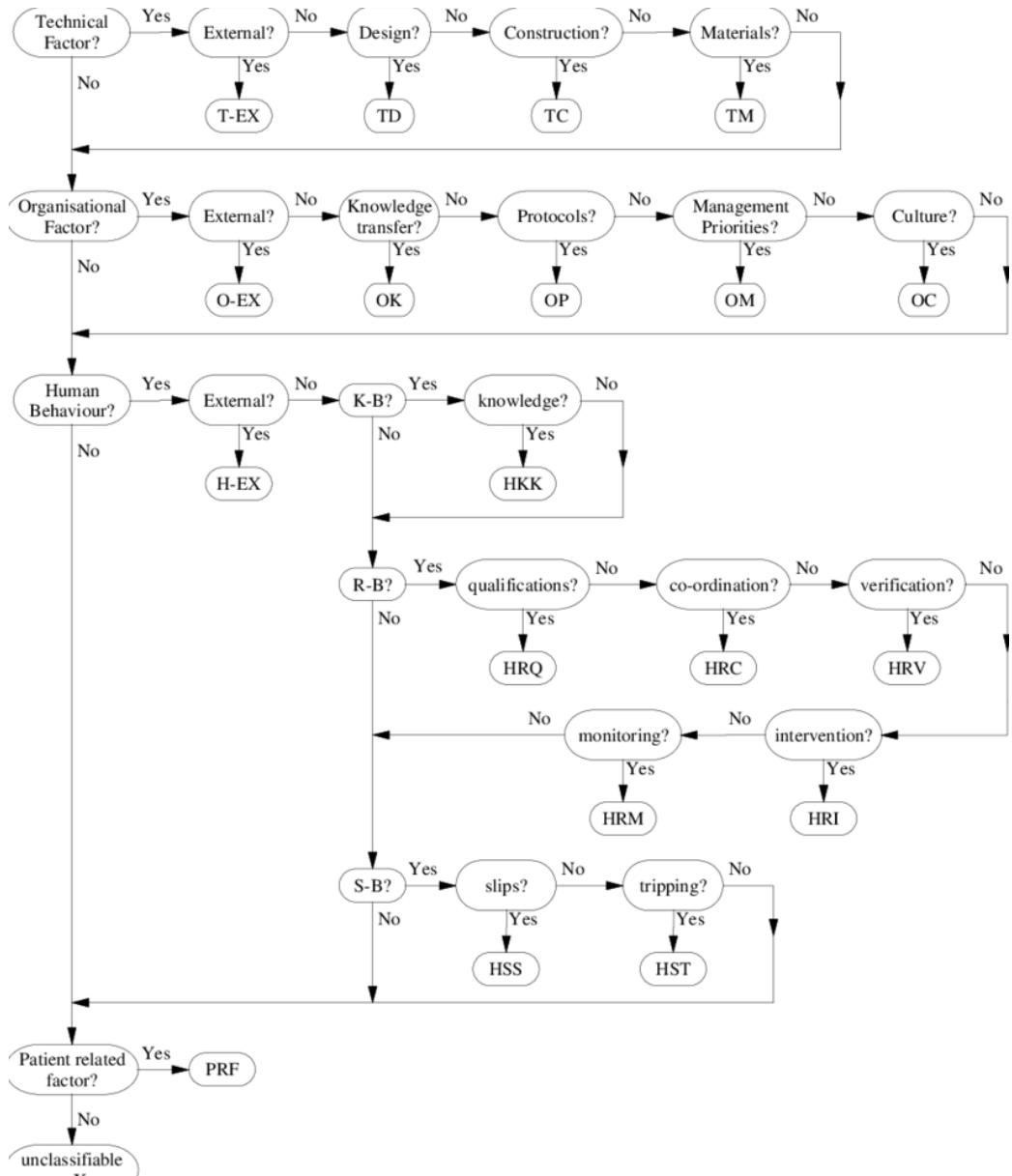
Human factor??

Eindhoven classificatie model

Informatie naar team

risico preventie

vs error management



Biovigilantie MAR ~ de praktijk UZ

Meldingen FAGG:

2020:

17: *blocked sperm donors*

2: SAE

2021:

19: *blocked sperm donors*

1: SAE

Biovigilantie MAR ~ de praktijk

Questionnaire ESHRE 2022 (unpublished)

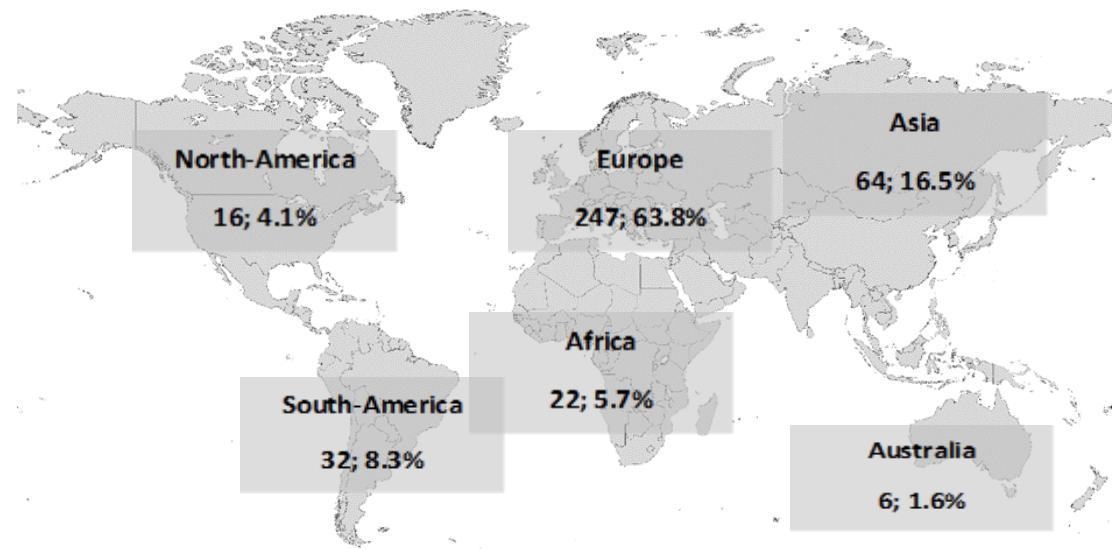
464 replies

Respondents disagreed with
ESHRE processing their
personal data (n=12)¹

Empty replies (n=57)²

Only demographic
information (n=8)³

Dataset of 387 replies



Biovigilantie MAR ~ de praktijk

What types of errors do you record in your centre? (Tick all that apply)

More than half of the centers record all errors including near-misses.

Over 30% reports major errors to health authority.

~15% does not report to health authority or does not have an authority to report to

Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~optimalisaties in het labo: embryo cultuur



Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~ optimalisaties in het labo: witnessing



Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~optimalisaties in het labo: automatisatie & AI



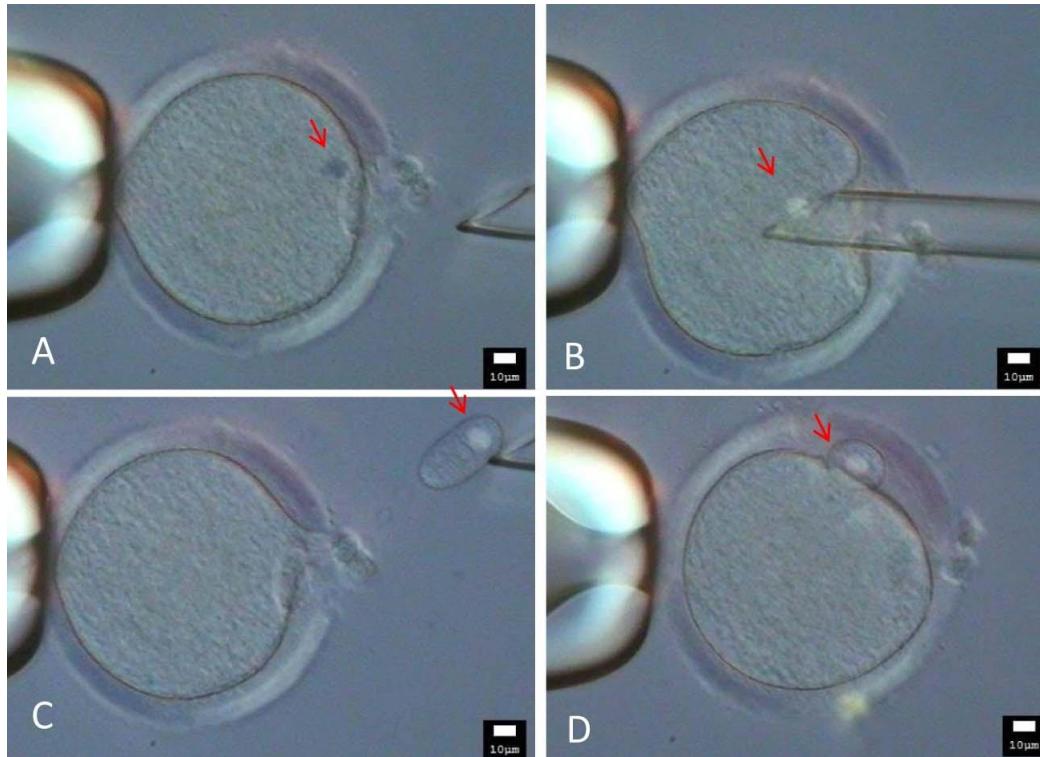
Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~optimalisaties in het labo: opleiding



Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~ geavanceerde micromanipulatie
nuclear transfer



Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~ extended carrier screening: donor selectie



Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~ extended carrier screening (unpublished)

Title

Incidence of and indications for sperm donor restriction, characteristic of women continuing treatment and drivers for this decision: a retrospective single centre study.

Authors

Eva Vanbelleghem¹; PhD, MD, Vanessa Muyshond²; BSc, Roos Colman³; PhD, MSc, Frauke Vanden Meerschaut²; PhD, MD, Dominic Stoop²; PhD, MD, Sandra Janssens¹; PhD, MD, Kelly Tillemans²; PhD, MSc

Biovigilantie MAR ~ toekomst

Nieuwe soorten risico's ~ extended carrier screening (unpublished)

Results. Of 1,124 sperm donors identified, 200 (17.8%) had been restricted.

Multifactorial (27.5%) and autosomal recessive (17.5%) disorders were the most common reasons. The sperm had been used in 798 recipients, of which 172, who received sperm from 100 donors, constituted the ‘decision cohort’. The odds for accepting the restricted sperm or decreased with increasing age (OR 0.857 [95% CI 0.800-0.918]; P <0.001) and the time between MAR treatment and the restriction date (OR 0.806 [95% CI 0.713-0.911]; P <0.001).

Biovigilantie MAR ~ bouwt vertrouwen



TRIP RAPPORT 2020
BIOVIGILANTIE
UITGEBREIDE VERSIE

Biovigilantie MAR ~ beter leren zeilen

Leren van incidenten

Informatie leidt tot betere inschatting van risico's

Team opleiden

Om beter te doen
voor onze patiënten en ons team



Biovigilantie MAR ~ tevreden matrozen



Erwin Van Iseghem

Biovigilantie MAR ~ tevreden team



Biovigilantie MAR ~ tevreden patiënten



45j successen
en technologische vooruitgang

Biovigilantie MAR ~ opportuniteiten

Om echt te kunnen leren van elkaar =

méér melden

duidelijke definities

categorisatie

voorbeelden

informatievere rapportering

gebruiksvriendelijke registratie

mogelijkheid tot benchmarking

communicatie tss centra en overheden

Biovigilantie MAR ~ zorgt voor transparantie

Course description

This course will discuss errors in ART from a multidisciplinary perspective and will focus both on the lab and the clinic. The course will examine:

- What can go wrong in the hands of the embryologist?
- What can go wrong in the hands of the clinician?
- How can mistakes and errors be prevented?
- How open should we communicate about errors?
- What are the legal ramifications of errors in ART?

This course hopes to break the taboo on errors and enable a more transparent communication in the interest of better patient care.



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Hybrid - Athens, Greece



Hartelijk dank



KELLY TILLEMAN
Director IVF lab
Dept. Reproductive Medicine
Kelly.Tilleman@UZGent.be
09/332 04 38

Universitair Ziekenhuis Gent
C. Heymanslaan 10 | B 9000 Gent
T +32 (0)9 332 21 11
E info@uzgent.be

www.uzgent.be

Volg ons op

