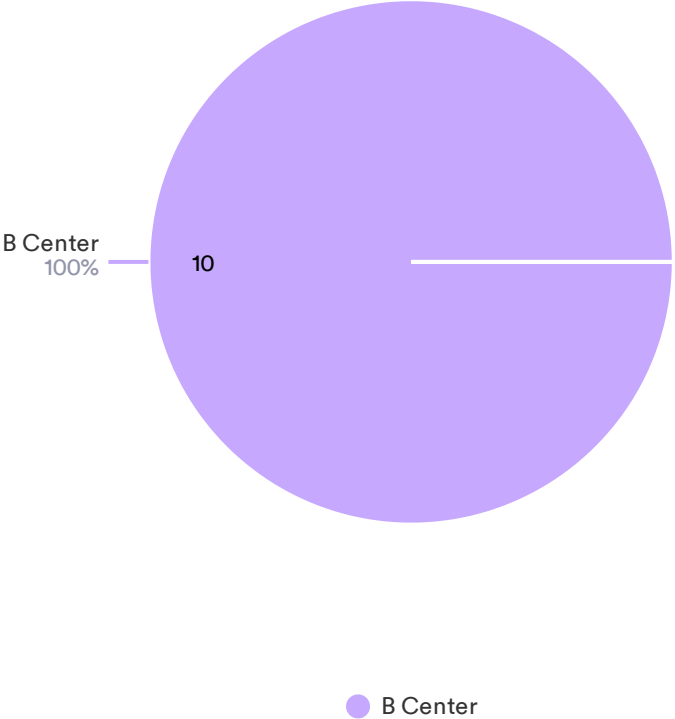


Fertility Centers Survey

To which center do you belong?

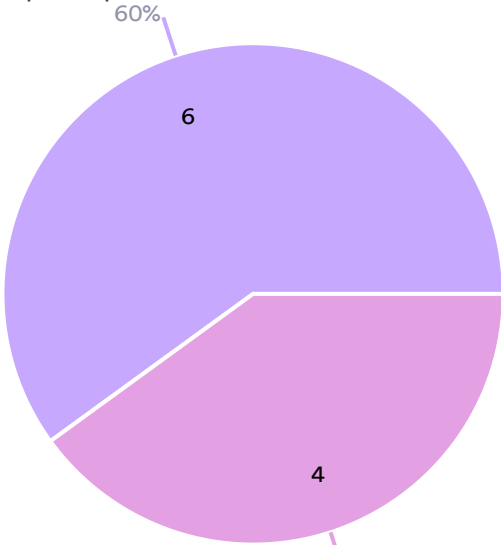
10 Responses



Inspections: How to deal with conflicting remarks made by successive inspectors?

10 Responses

and eventually go backward if inspectors have not the same opinion on a specific point

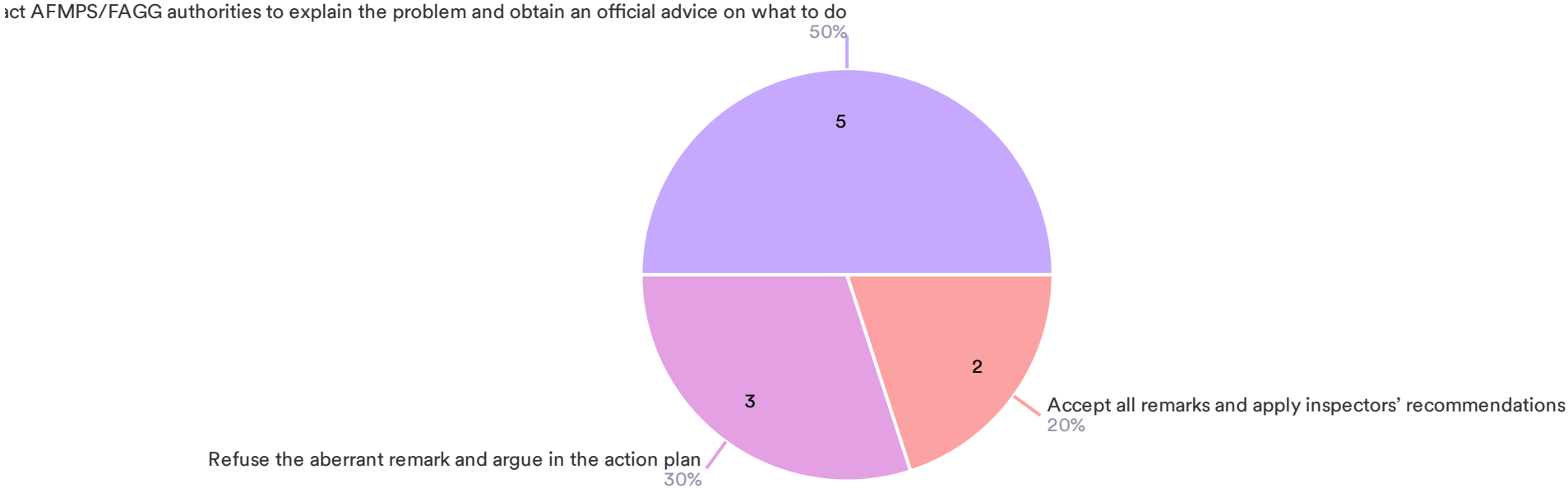


Refuse to go backward and contact AFMPS/FAGG authorities to obtain an official notice

- Always accept all remarks and eventually go backward if inspectors have not the same opinion on a specific point
- Refuse to go backward and contact AFMPS/FAGG authorities to obtain an official notice on what to do

How to deal with aberrant remarks made by inspectors?

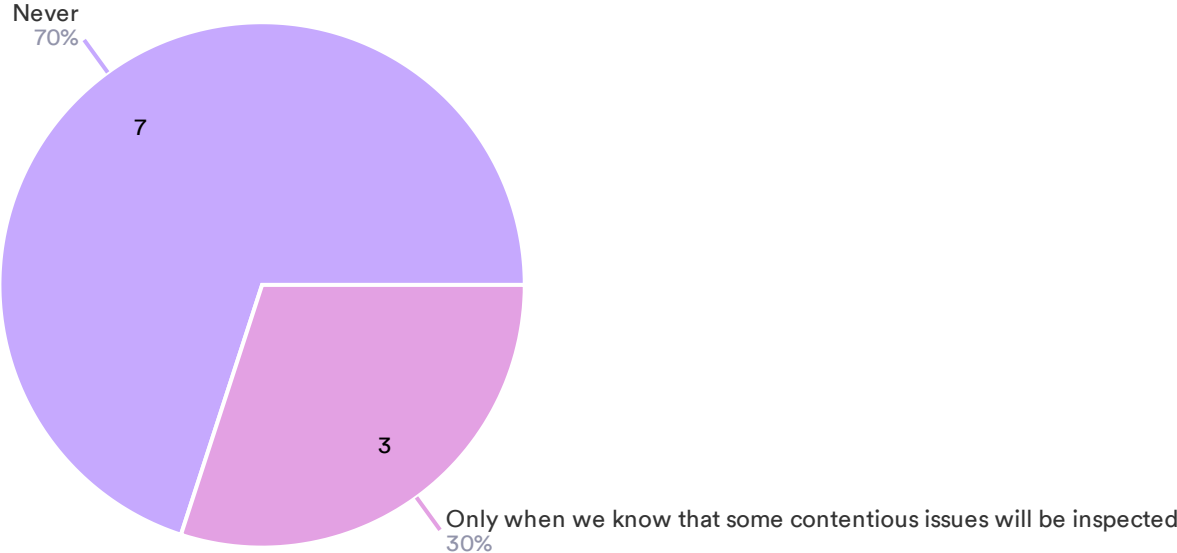
10 Responses



- Eventually contact AFMPS/FAGG authorities to explain the problem and obtain an official advice on what to do
- Refuse the aberrant remark and argue in the action plan
- Accept all remarks and apply inspectors' recommendations

Do you invite a jurist/lawyer during AMPF/FAGG inspections?

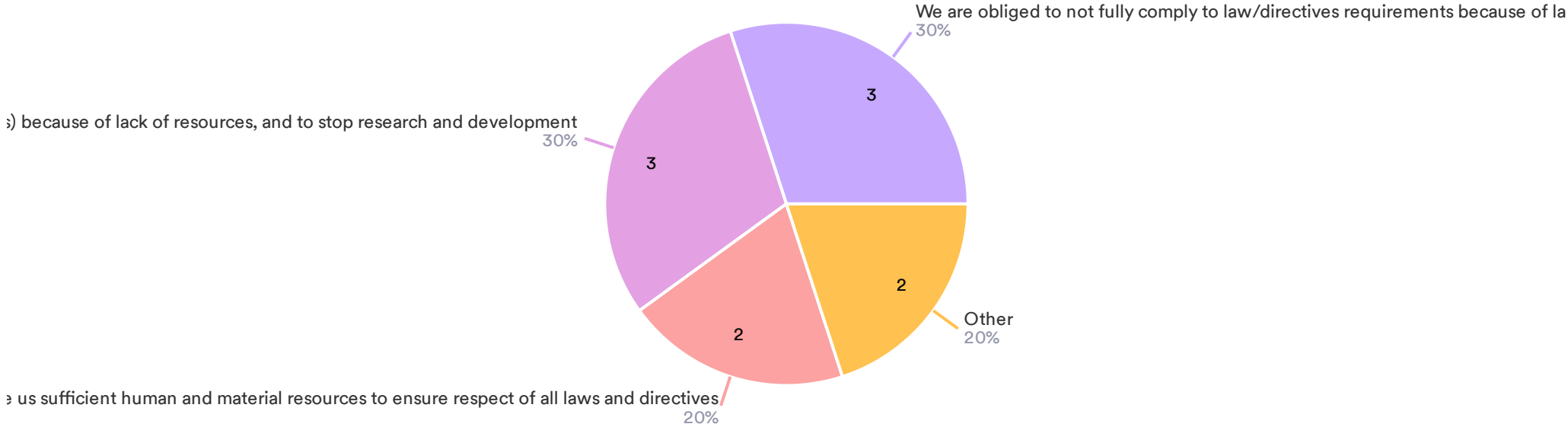
10 Responses



● Never ● Only when we know that some contentious issues will be inspected

How to manage increasing requirements of AFMPS/FAGG inspectors and centers 'human resources?

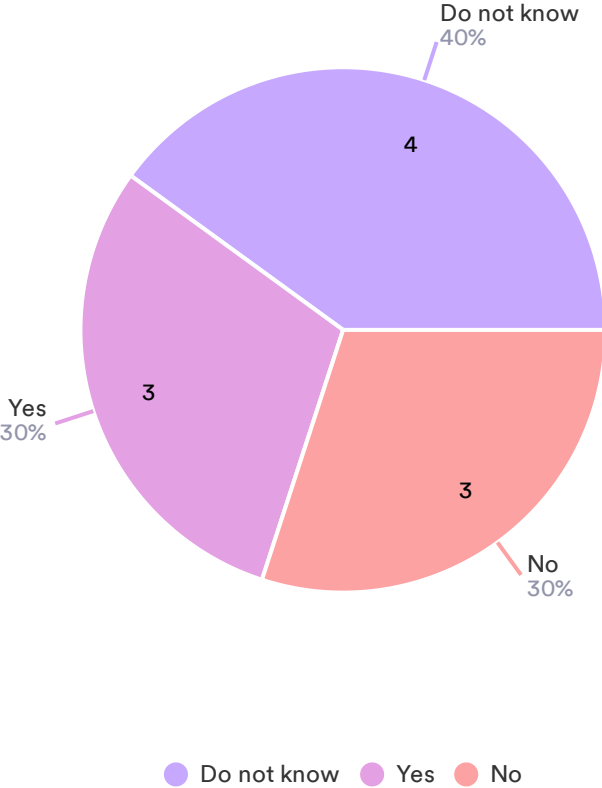
10 Responses



- We are obliged to not fully comply to law/directives requirements because of lack of resources
- We can only perform basic ART activities (i.e., basic ART treatments) because of lack of resources, and to stop research and development
- Our hospital authorities provide us sufficient human and material resources to ensure respect of all laws and directives
- Other

Do you think that one of the final goals of all that requirements will be the reduction of the number of ART centers in Belgium?

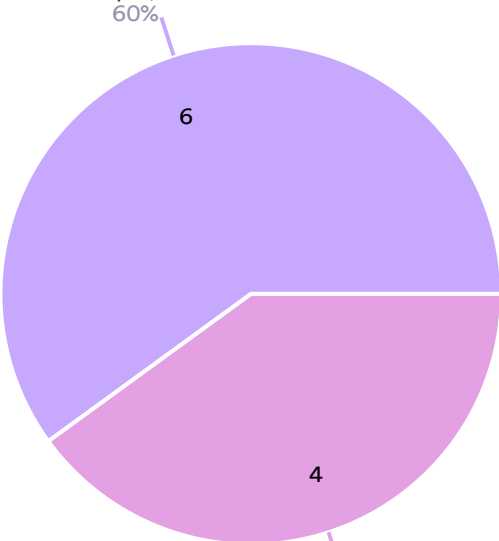
10 Responses



AFMPS/FAGG notifications: non-conformities encountered in the lab: when to declare?

10 Responses

with a direct proven impact on patient (loss of a significant amount of HBM for example)

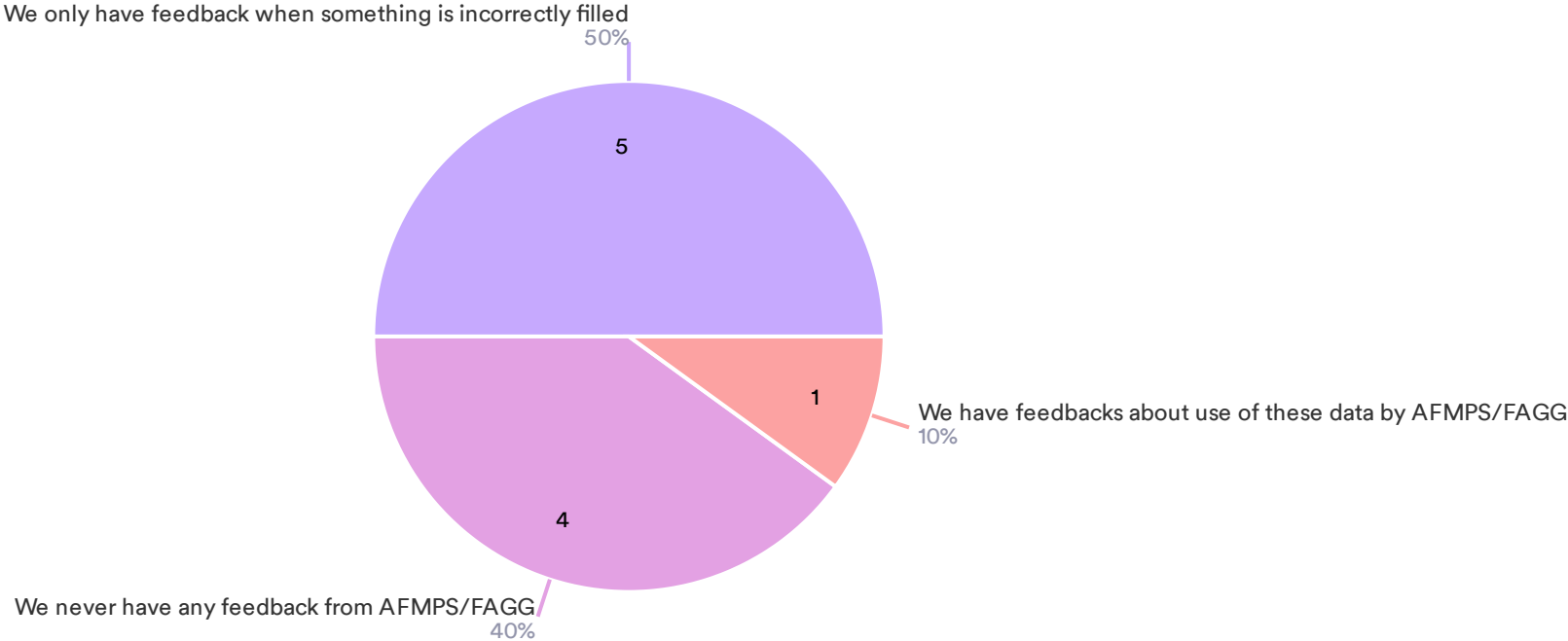


Response 1 + Problems with a potential impact on patients, but which is not proven (for example, at random: media used after expiration date, HVAC failure during some HBM manipula...)

- Only NC with a direct proven impact on patient (loss of a significant amount of HBM for example)
- Response 1 + Problems with a potential impact on patients, but which is not proven (for example, at random: media used after expiration date, HVAC failure during some HBM manipula...)

Activity reports for FAGG/AFMPS

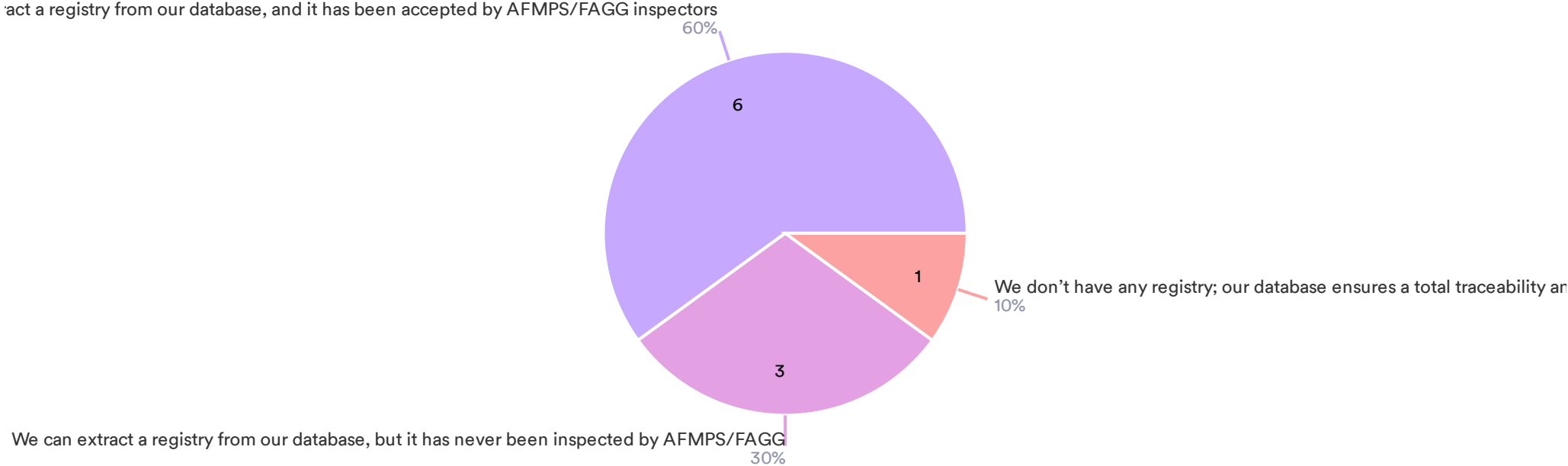
10 Responses



- We only have feedback when something is incorrectly filled
- We never have any feedback from AFMPS/FAGG
- We have feedbacks about use of these data by AFMPS/FAGG

Registries: How are they managed in your center?

10 Responses



- We can extract a registry from our database, and it has been accepted by AFMPS/FAGG inspectors
- We can extract a registry from our database, but it has never been inspected by AFMPS/FAGG
- We don't have any registry; our database ensures a total traceability and has been judged sufficient by AFMPS/FAGG inspectors

Quality system and your institution

10 Responses

We are alone to face this challenge

50%

5

5

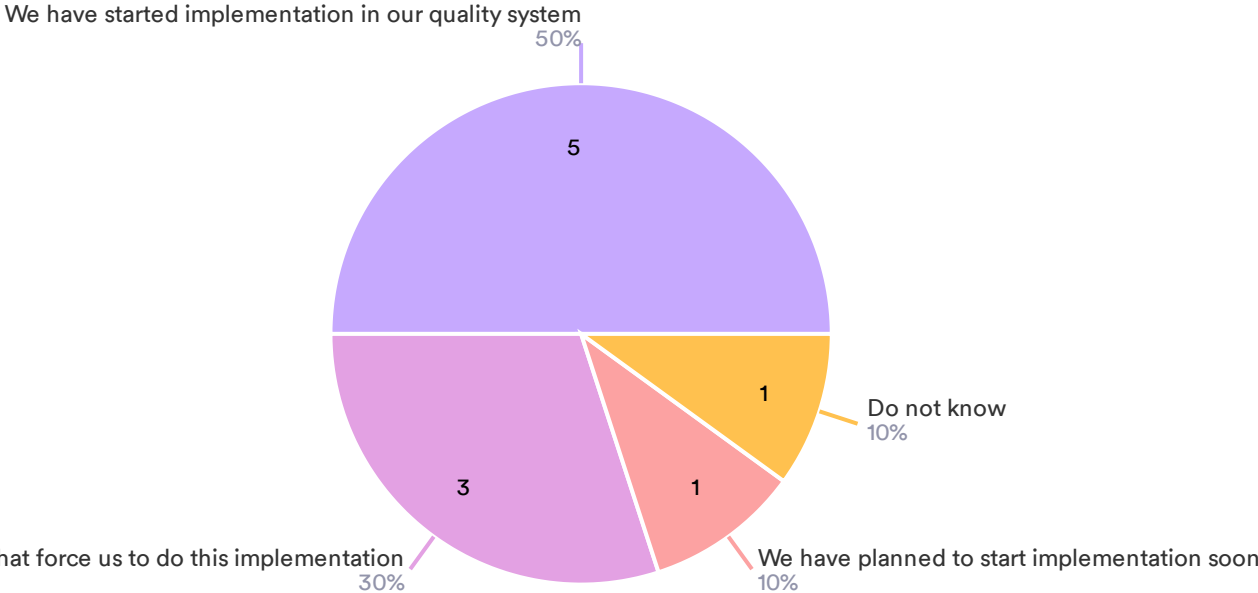
Several services in our institution to be obliged to have a quality system, and there is a good mutual support

50%

- We are alone to face this challenge
- We are several services in our institution to be obliged to have a quality system, and there is a good mutual support

Discussion about the new European directive on in vitro diagnostic devices

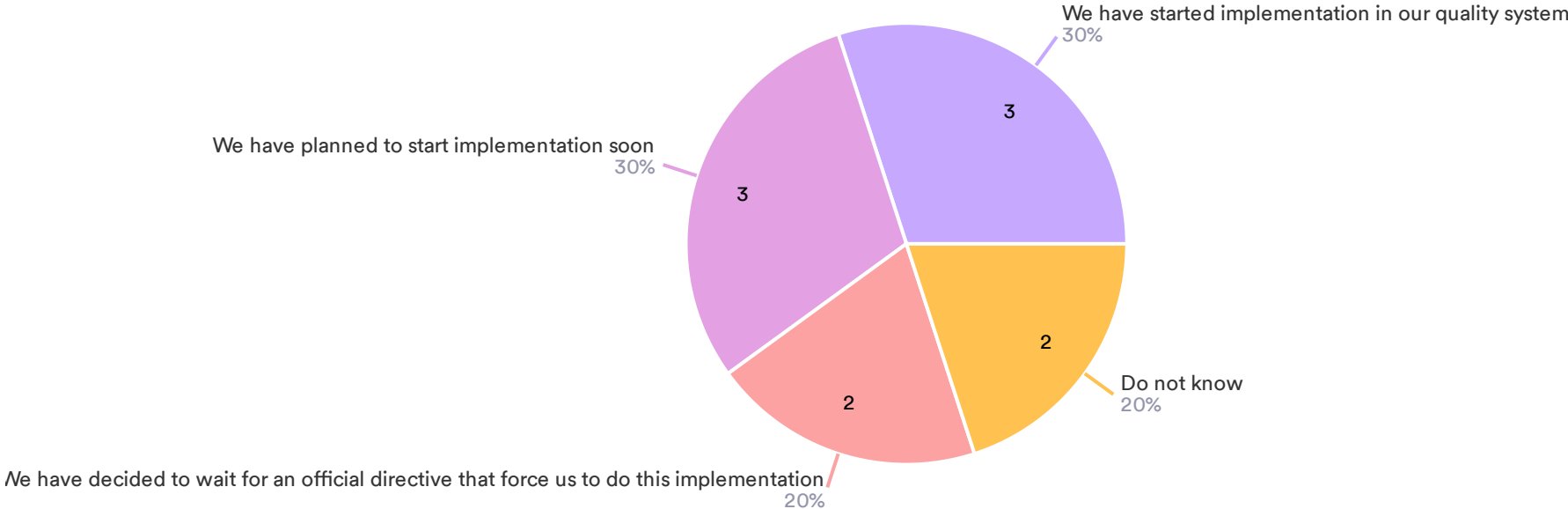
10 Responses



- We have started implementation in our quality system
- We have decided to wait for an official directive (or for the next inspection) that force us to do this implementation
- We have planned to start implementation soon
- Do not know

Discussion about the EDQM (European Directorate for the Quality of Medicines & HealthCare)

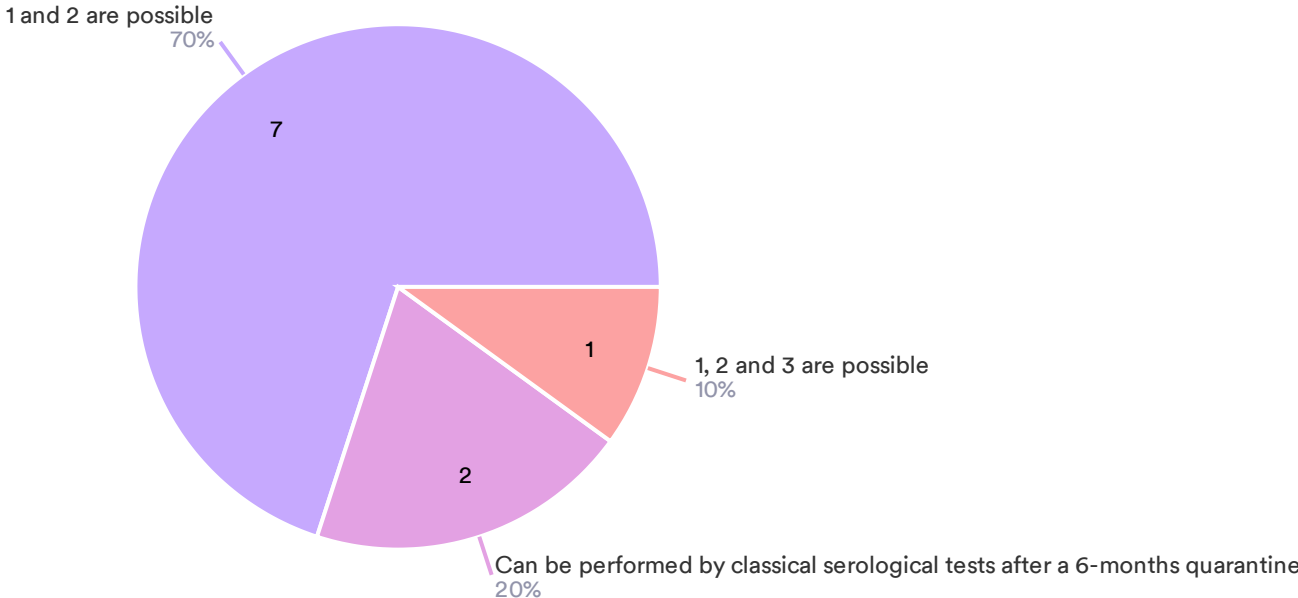
10 Responses



- We have started implementation in our quality system
- We have planned to start implementation soon
- We have decided to wait for an official directive that force us to do this implementation
- Do not know

Sperm donation, own donors: serological tests in the Belgian law?

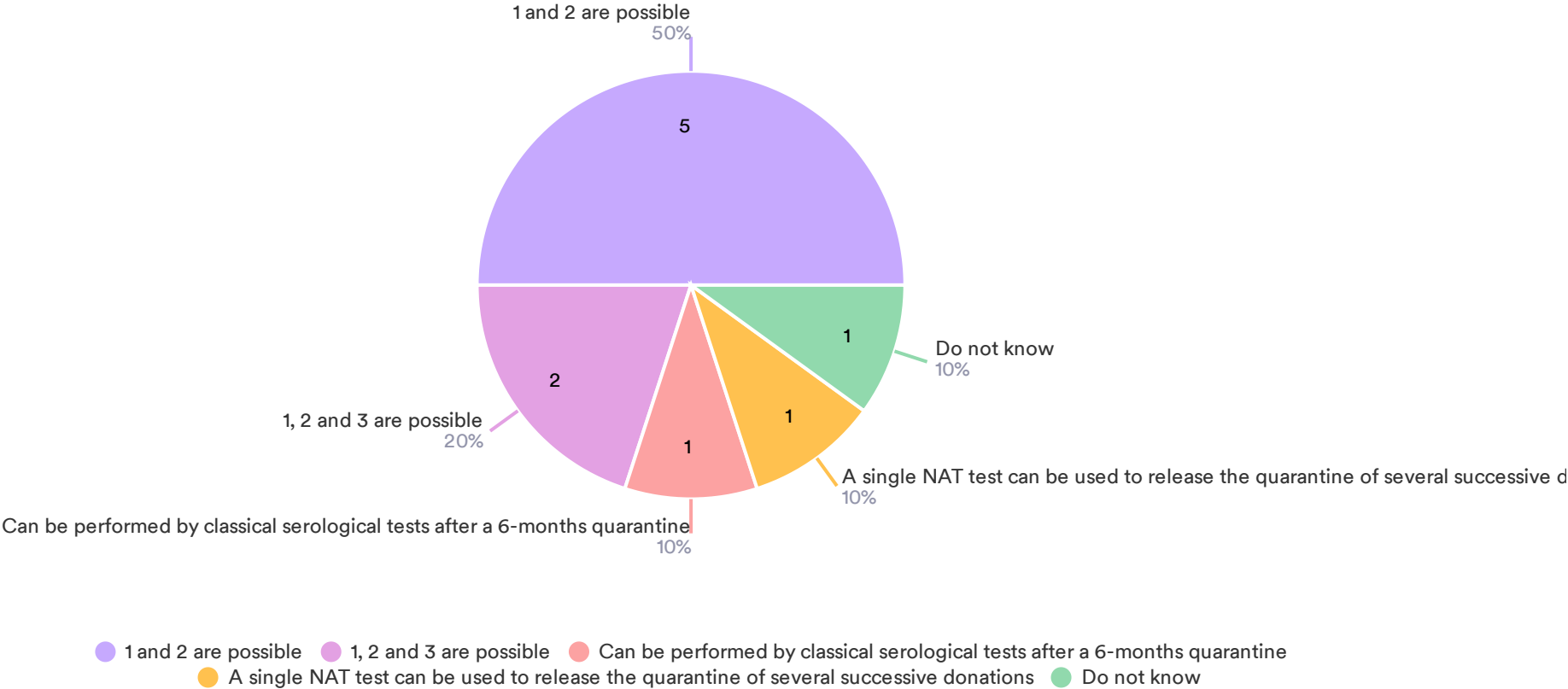
10 Responses



● 1 and 2 are possible ● Can be performed by classical serological tests after a 6-months quarantine ● 1, 2 and 3 are possible

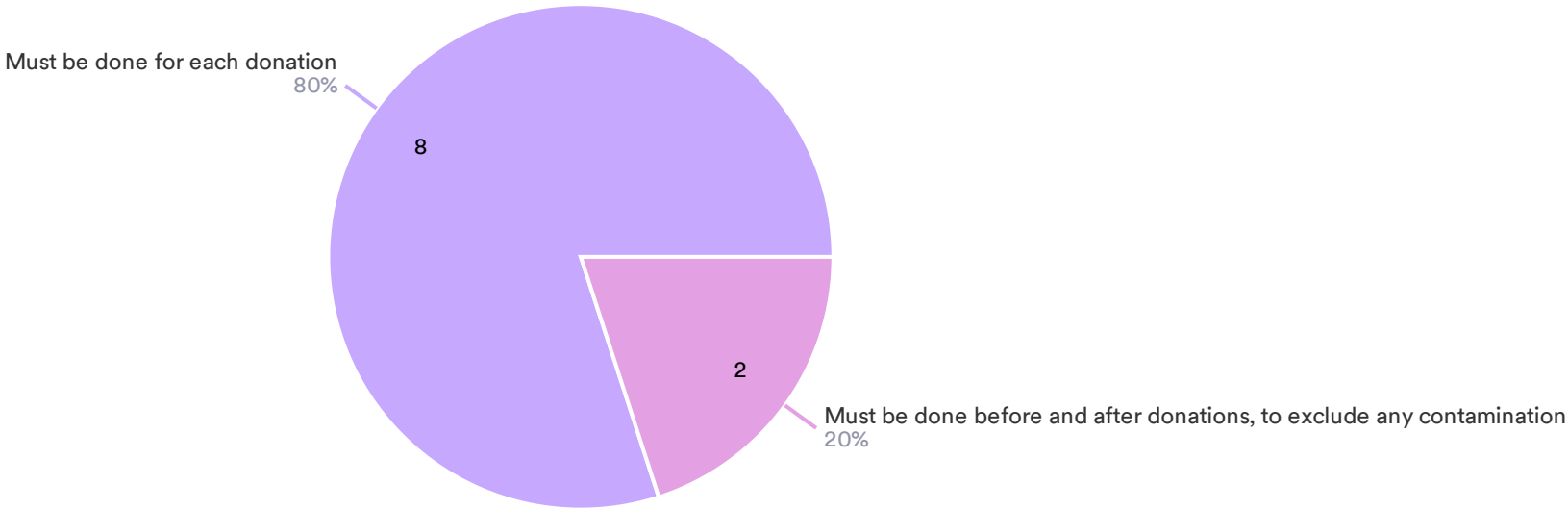
Sperm donation, purchased donors: serological tests as for the center's own donors?

10 Responses



Sperm donation: urinary tests (Chlamydia trachomatis, Neisseria gonorrhoeae)?

10 Responses

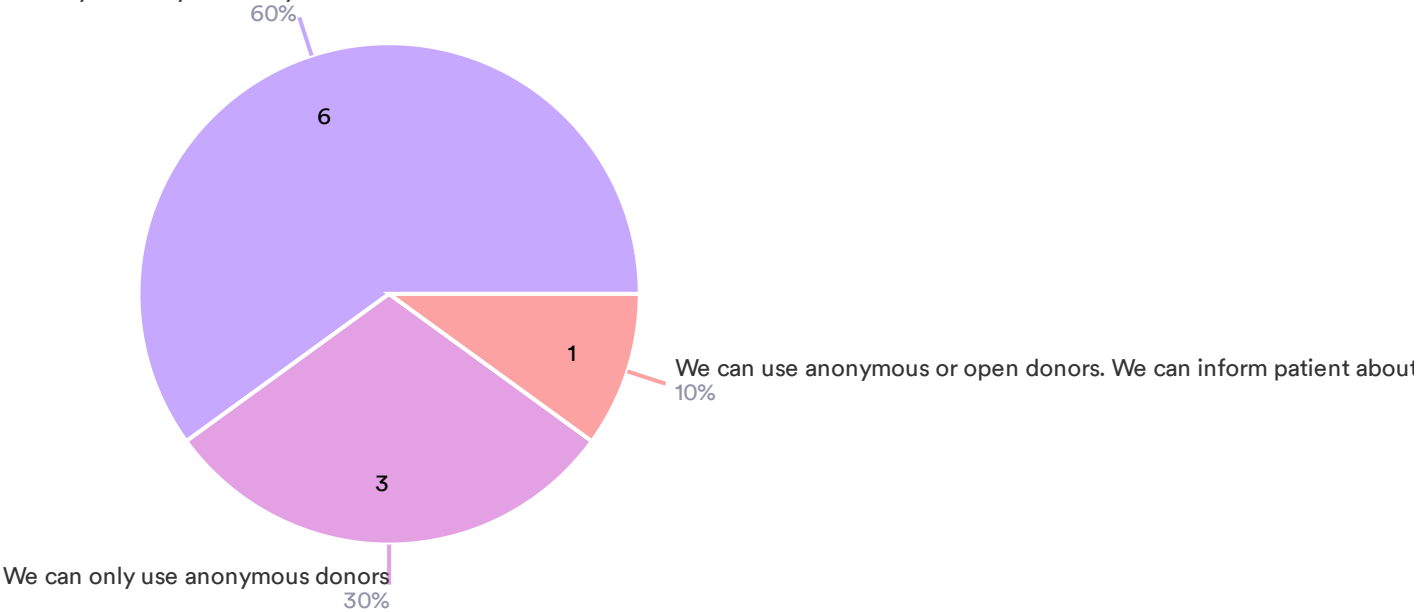


● Must be done for each donation ● Must be done before and after donations, to exclude any contamination during donations

Sperm donation: donor anonymity

10 Responses

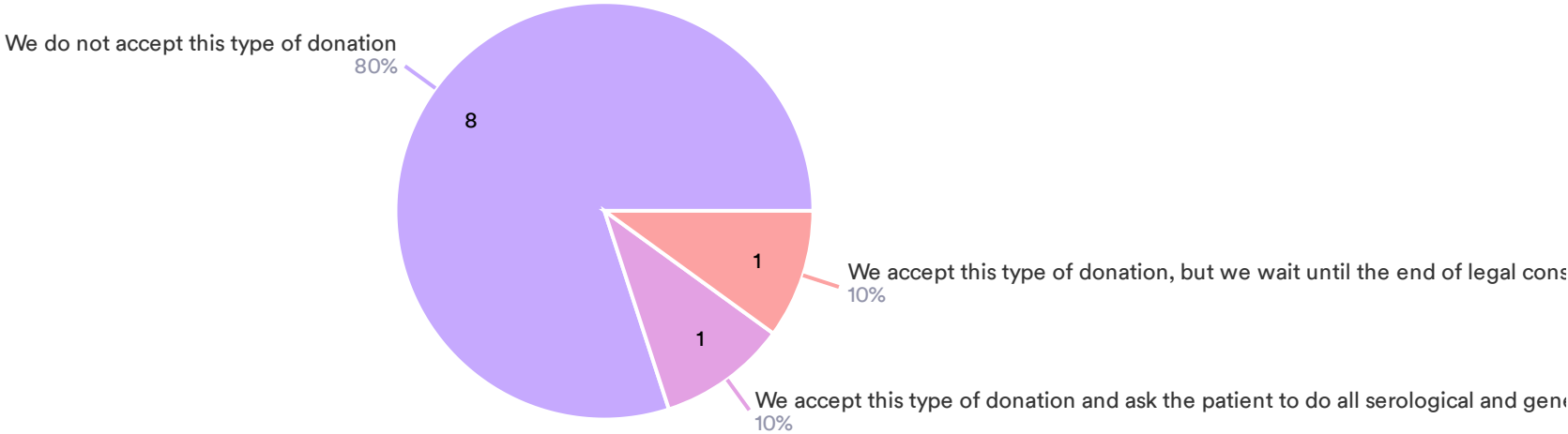
n use anonymous or open donors from international banks, but only in anonymous way



- We can use anonymous or open donors from international banks, but only in anonymous way
- We can only use anonymous donors
- We can use anonymous or open donors. We can inform patient about the « open » status of their donor

Sperm donation: how to manage with patients who freeze sperm for their own purpose, but accept to give their gametes for donation at the end of legal conservation delay

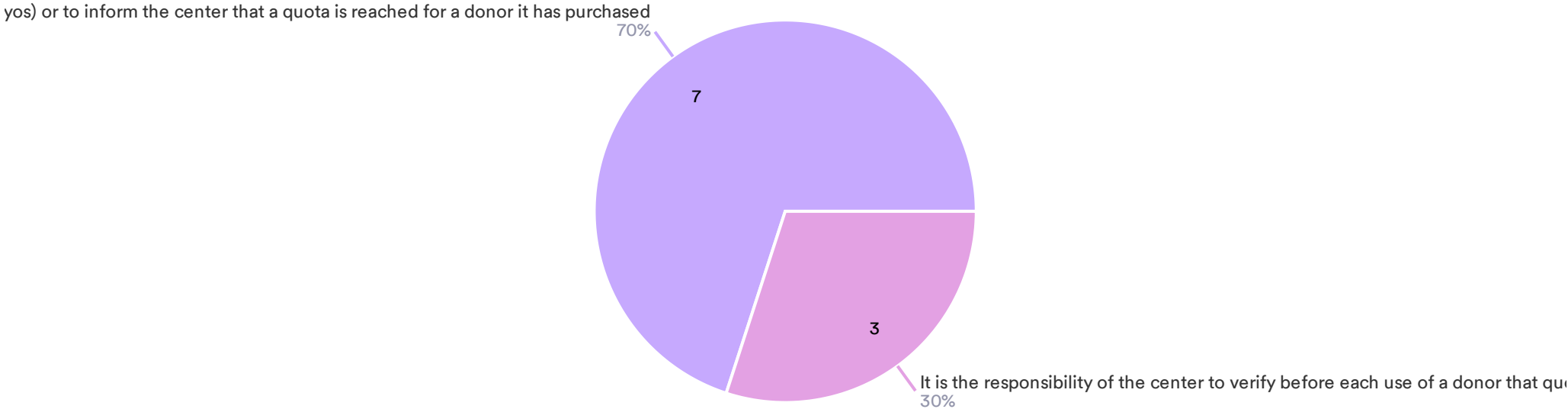
10 Responses



- We do not accept this type of donation
- We accept this type of donation and ask the patient to do all serological and genetic tests at time of freezing to be sure that we can use these samples later (as long as the rules remained...)
- We accept this type of donation, but we wait until the end of legal conservation delay to recontact patient, make all tests to be sure that the samples comply with the current rules

Sperm donation: how to manage pregnancy quota for purchased donors

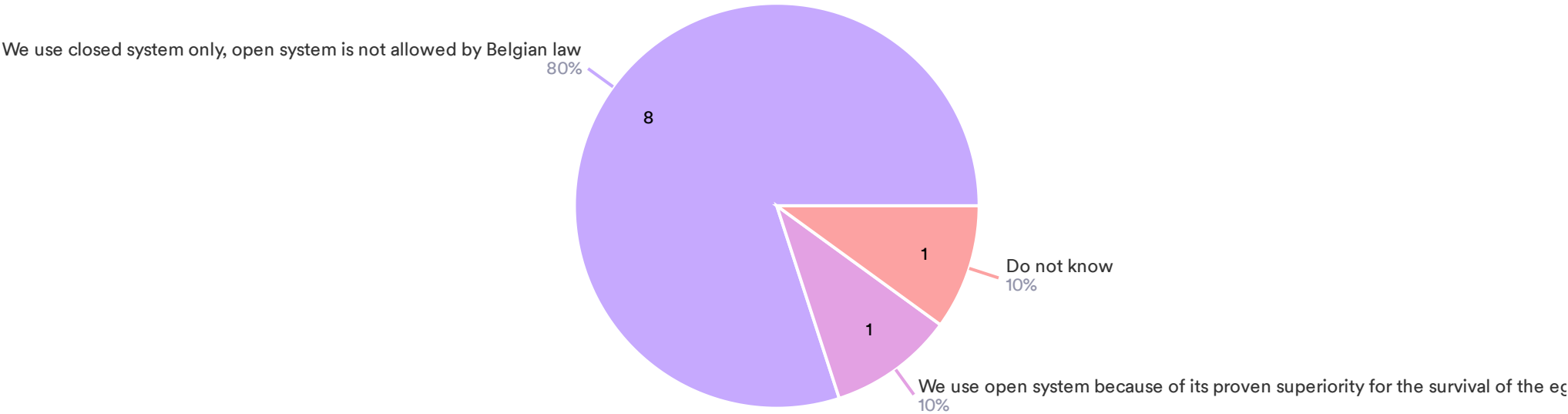
10 Responses



- It is the responsibility of the bank to organize the pregnancy quotas (like Cryos) or to inform the center that a quota is reached for a donor it has purchased
- It is the responsibility of the center to verify before each use of a donor that quota is not reached

Egg donation, own donors: open or closed system?

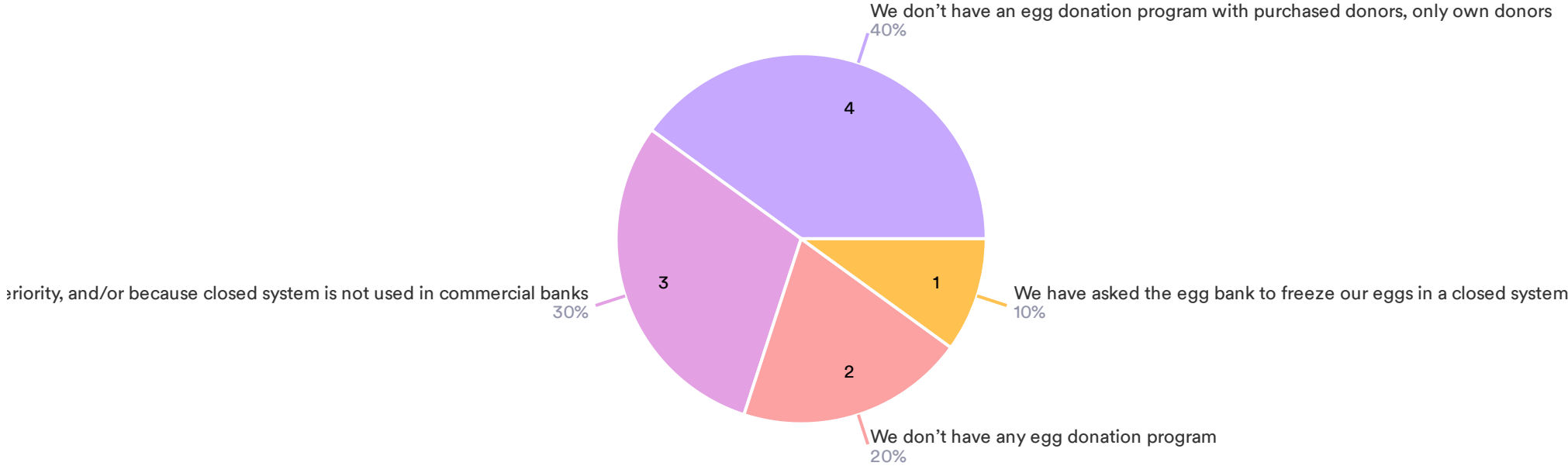
10 Responses



● We use closed system only, open system is not allowed by Belgian law ● We use open system because of its proven superiority for the survival of the egg ● Do not know

Egg donation, purchased donors: open or closed system?

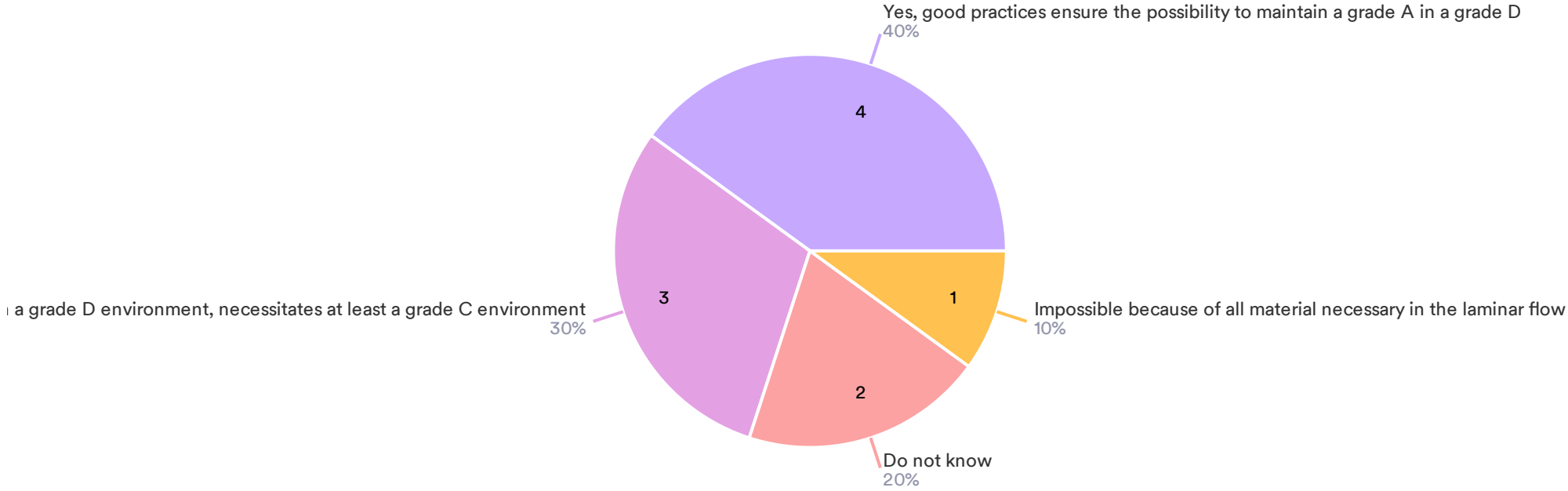
10 Responses



- We don't have an egg donation program with purchased donors, only own donors
- We use open system because of its proven superiority, and/or because closed system is not used in commercial banks
- We don't have any egg donation program
- We have asked the egg bank to freeze our eggs in a closed system

Is it possible to maintain a grade A in IVF labs?

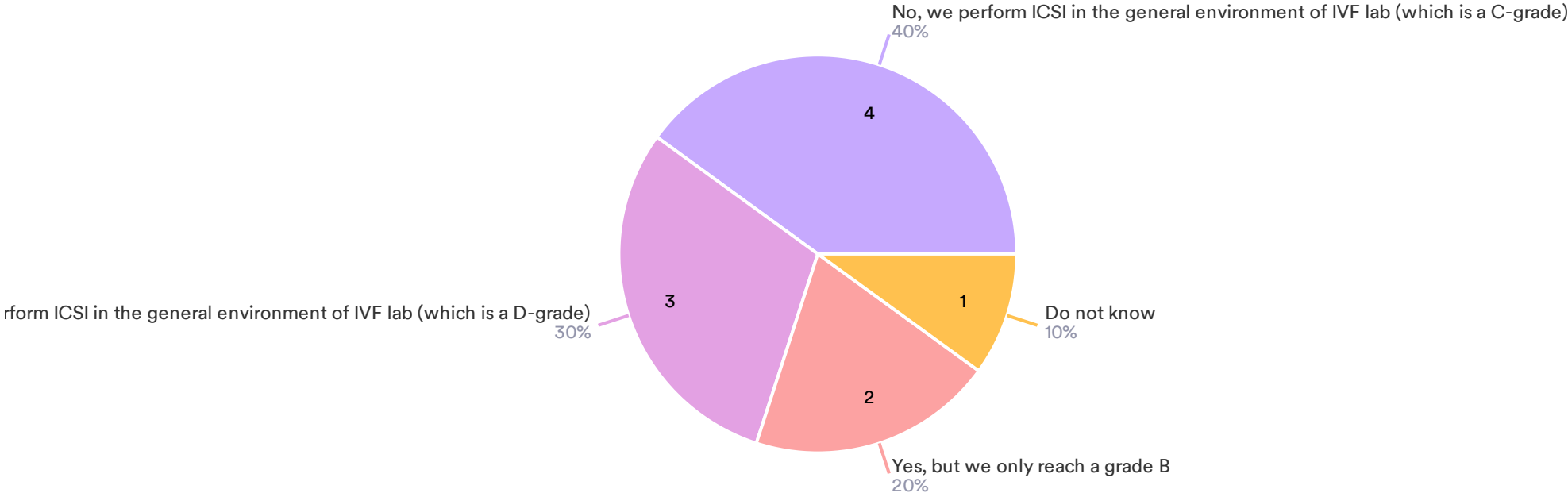
10 Responses



- Yes, good practices ensure the possibility to maintain a grade A in a grade D
- Impossible in a grade D environment, necessitates at least a grade C environment
- Do not know
- Impossible because of all material necessary in the laminar flow

Do you perform ICSI in laminar flows?

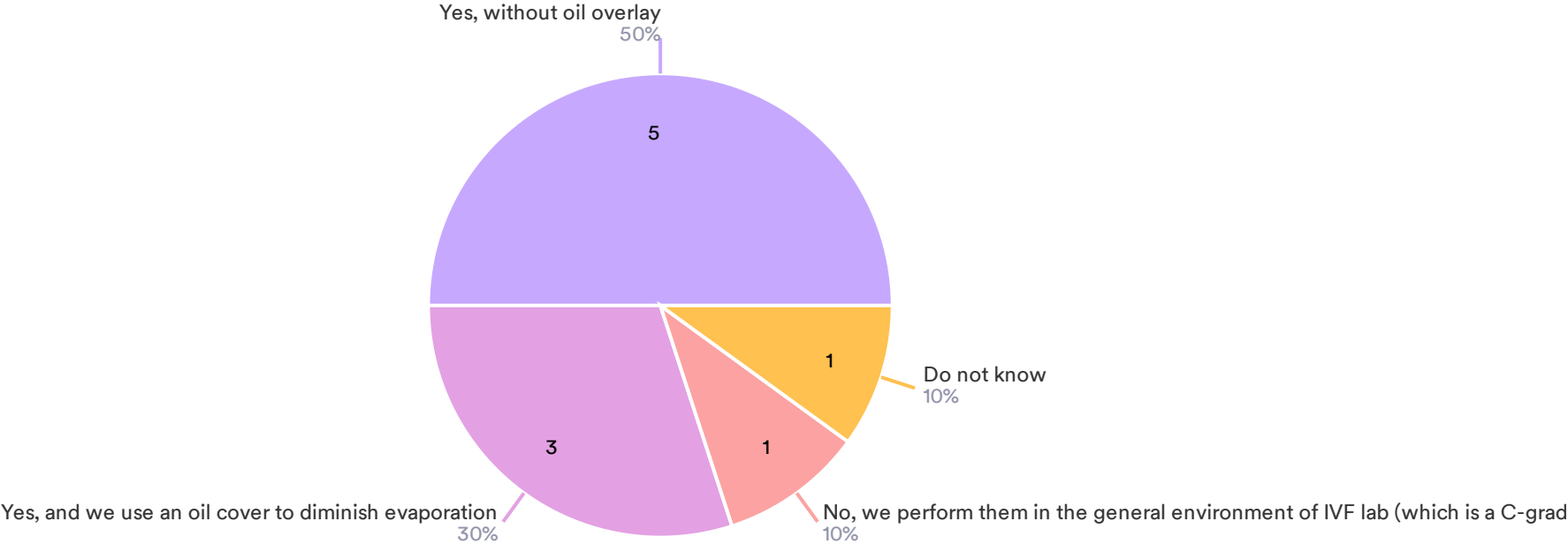
10 Responses



- No, we perform ICSI in the general environment of IVF lab (which is a C-grade)
- No, we perform ICSI in the general environment of IVF lab (which is a D-grade)
- Yes, but we only reach a grade B
- Do not know

Do you perform vitrification in laminar flows?

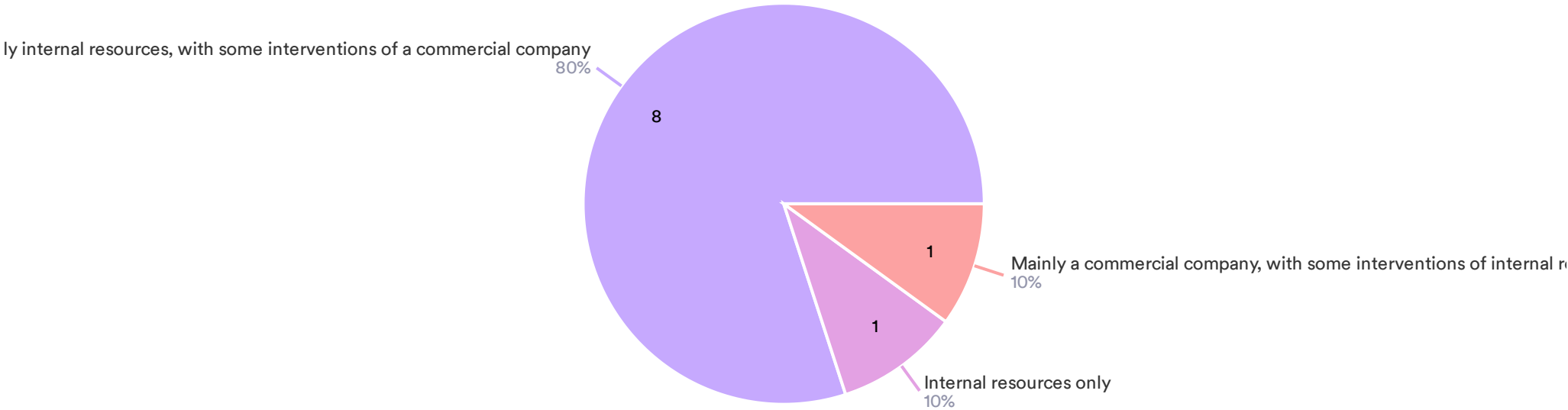
10 Responses



● Yes, without oil overlay ● Yes, and we use an oil cover to diminish evaporation ● No, we perform them in the general environment of IVF lab (which is a C-grade) ● Do not know

Who is performing your environment monitoring?

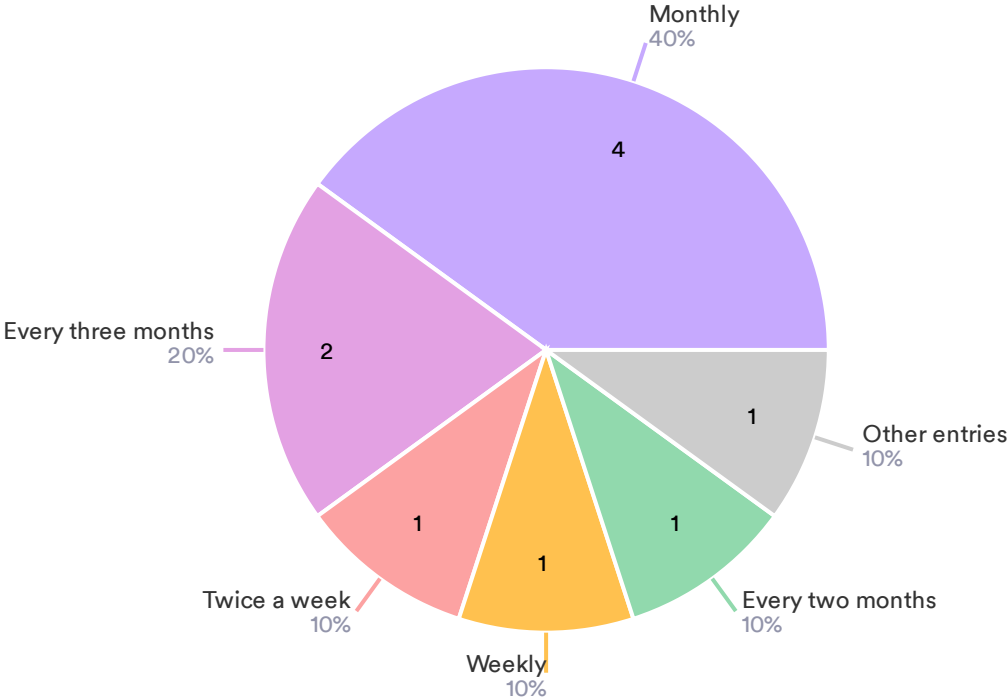
10 Responses



● Mainly internal resources, with some interventions of a commercial company ● Internal resources only ● Mainly a commercial company, with some interventions of internal resources

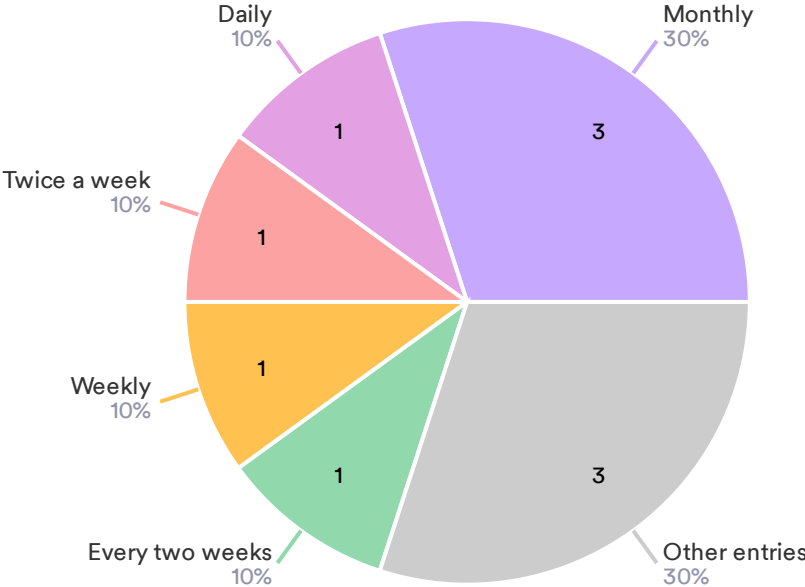
What is the frequency of sampling for your general environmental monitoring?

10 Responses



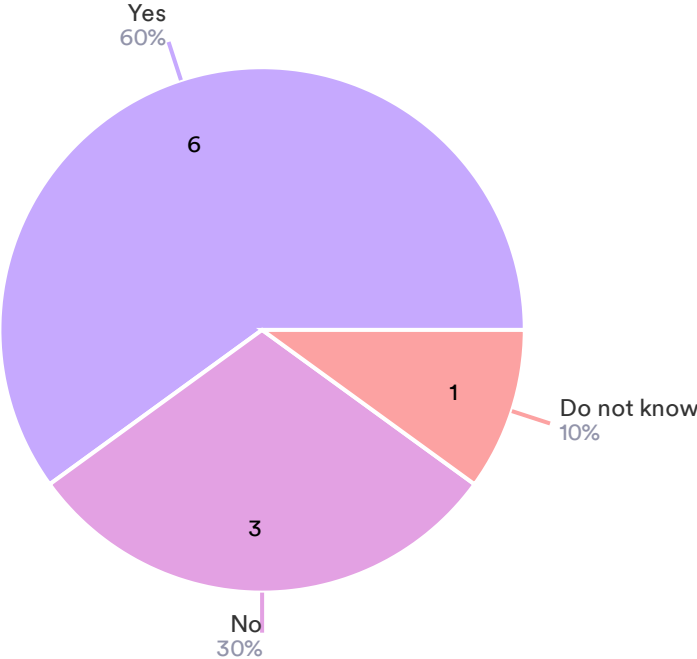
What is the frequency of sampling for your grade A environmental monitoring?

10 Responses



Is it allowed to wear jewelry (earrings) in the cleanroom?

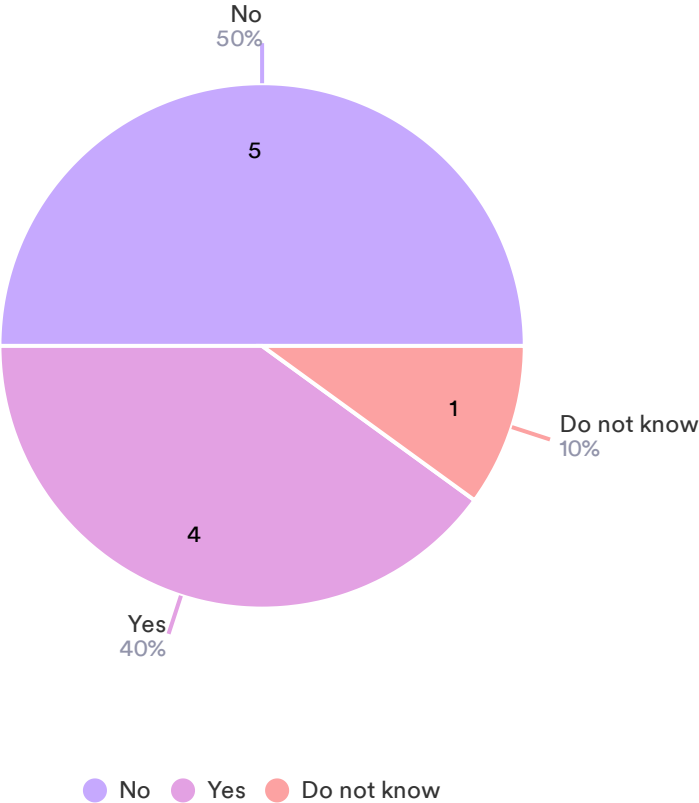
10 Responses



● Yes ● No ● Do not know

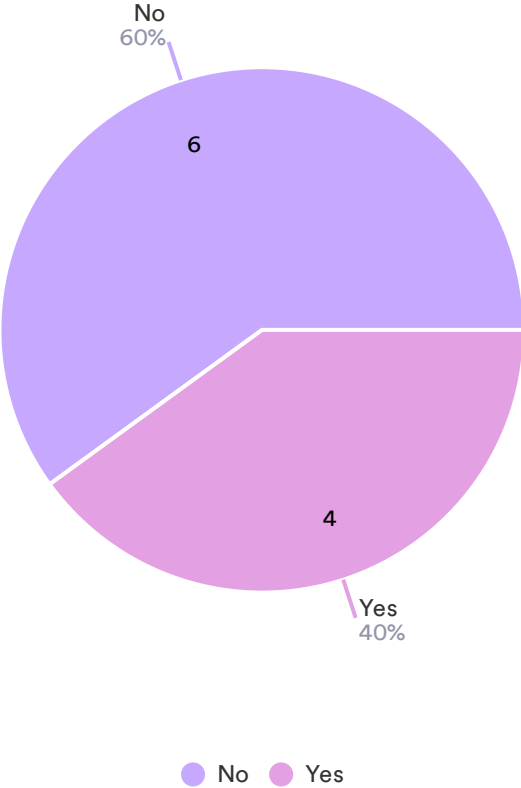
Is wearing of makeup allowed in the cleanroom?

10 Responses



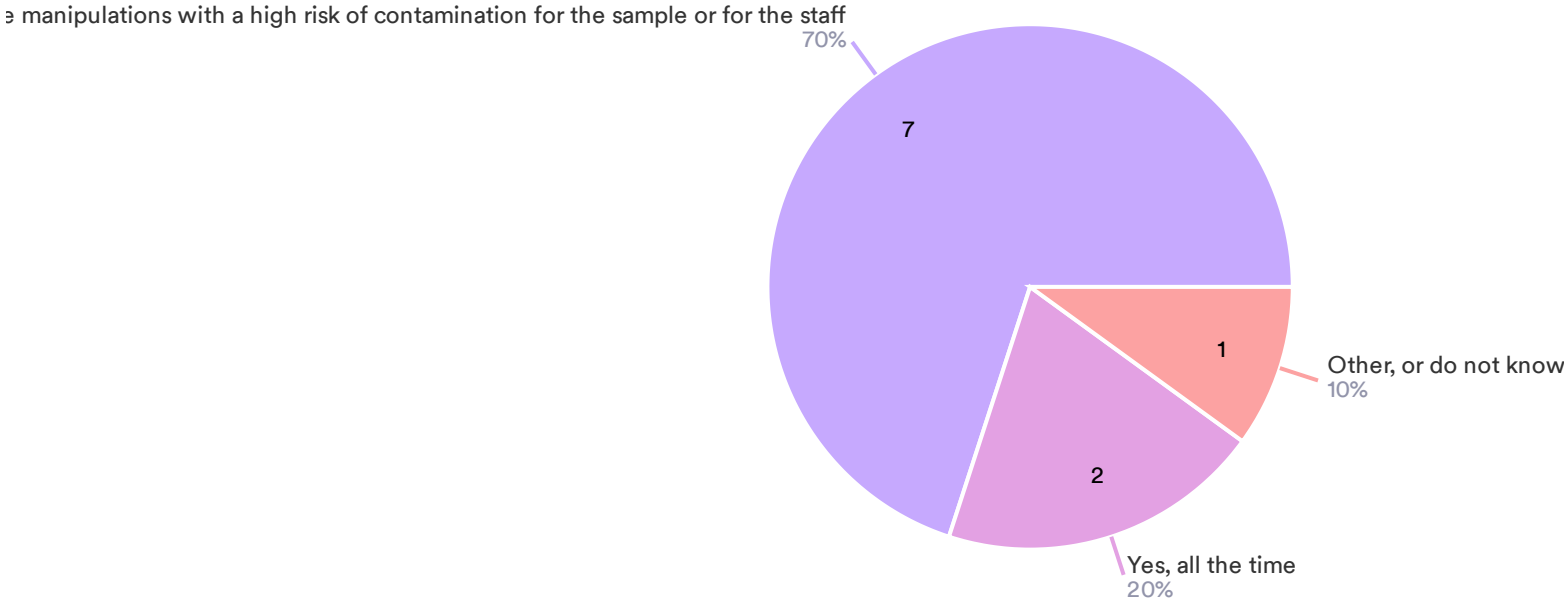
Do you wear long sleeves in the cleanroom?

10 Responses



Do you use gloves during manipulations?

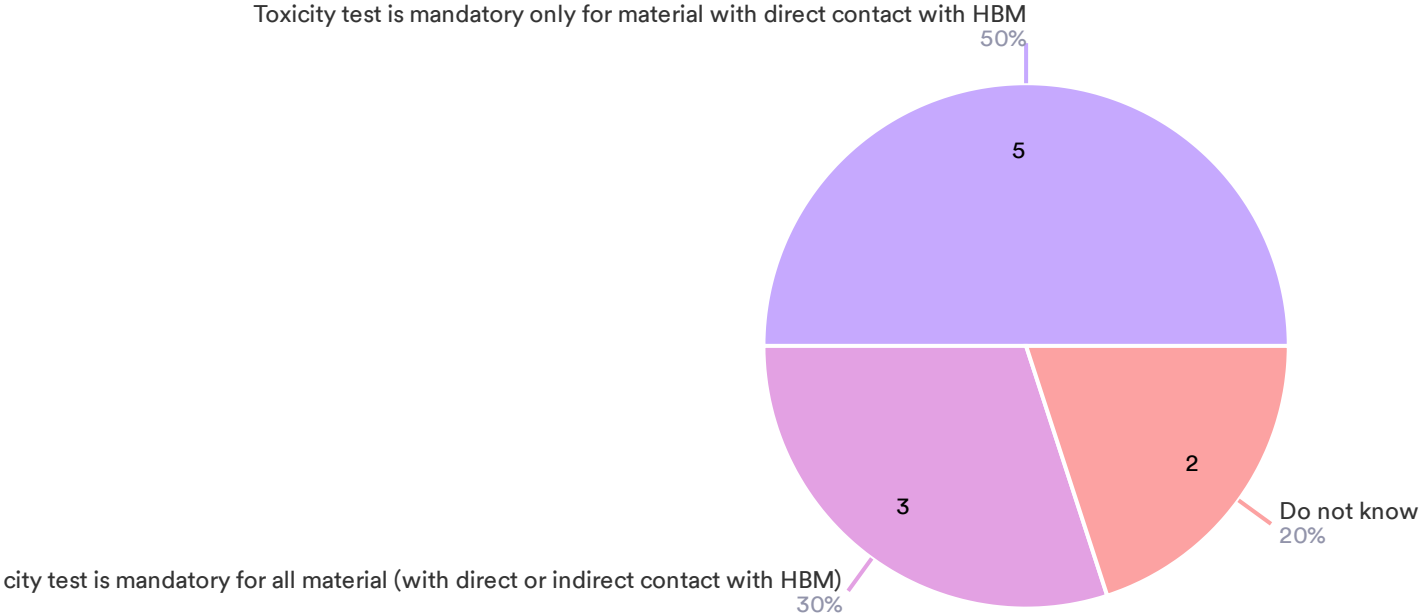
10 Responses



● Only for some manipulations with a high risk of contamination for the sample or for the staff ● Yes, all the time ● Other, or do not know

Toxicity tests for disposable material (plastics and media):

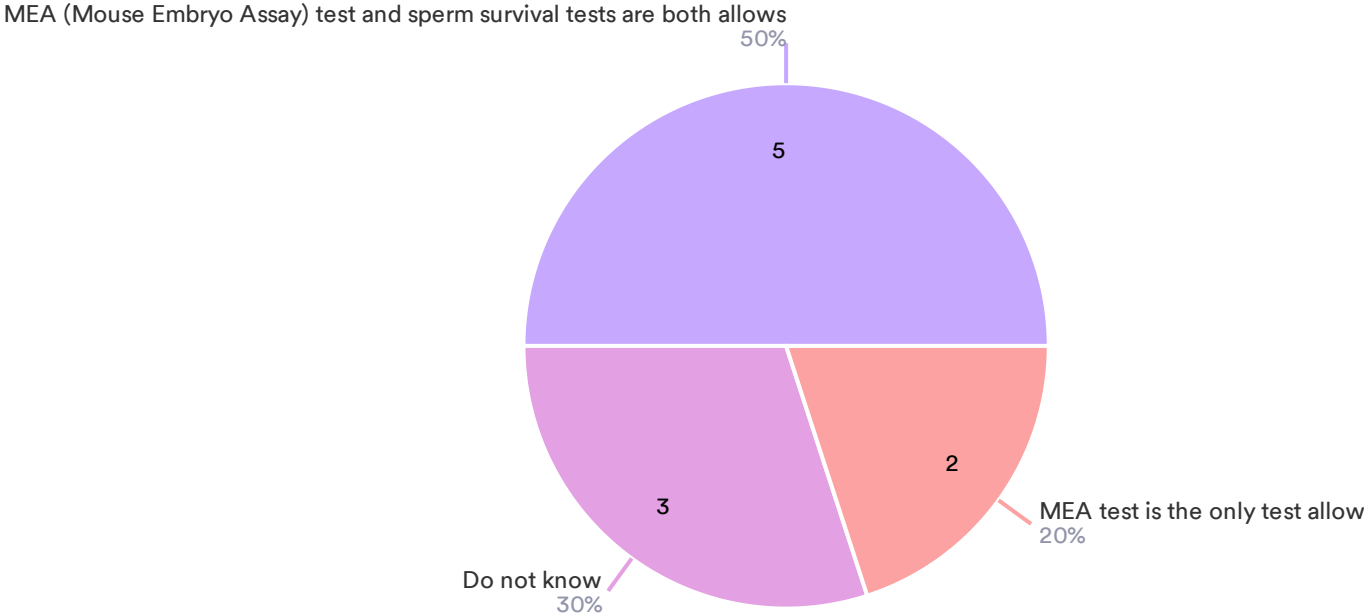
10 Responses



● Toxicity test is mandatory only for material with direct contact with HBM ● Toxicity test is mandatory for all material (with direct or indirect contact with HBM) ● Do not know

Toxicity tests for disposable material (plastics and media):

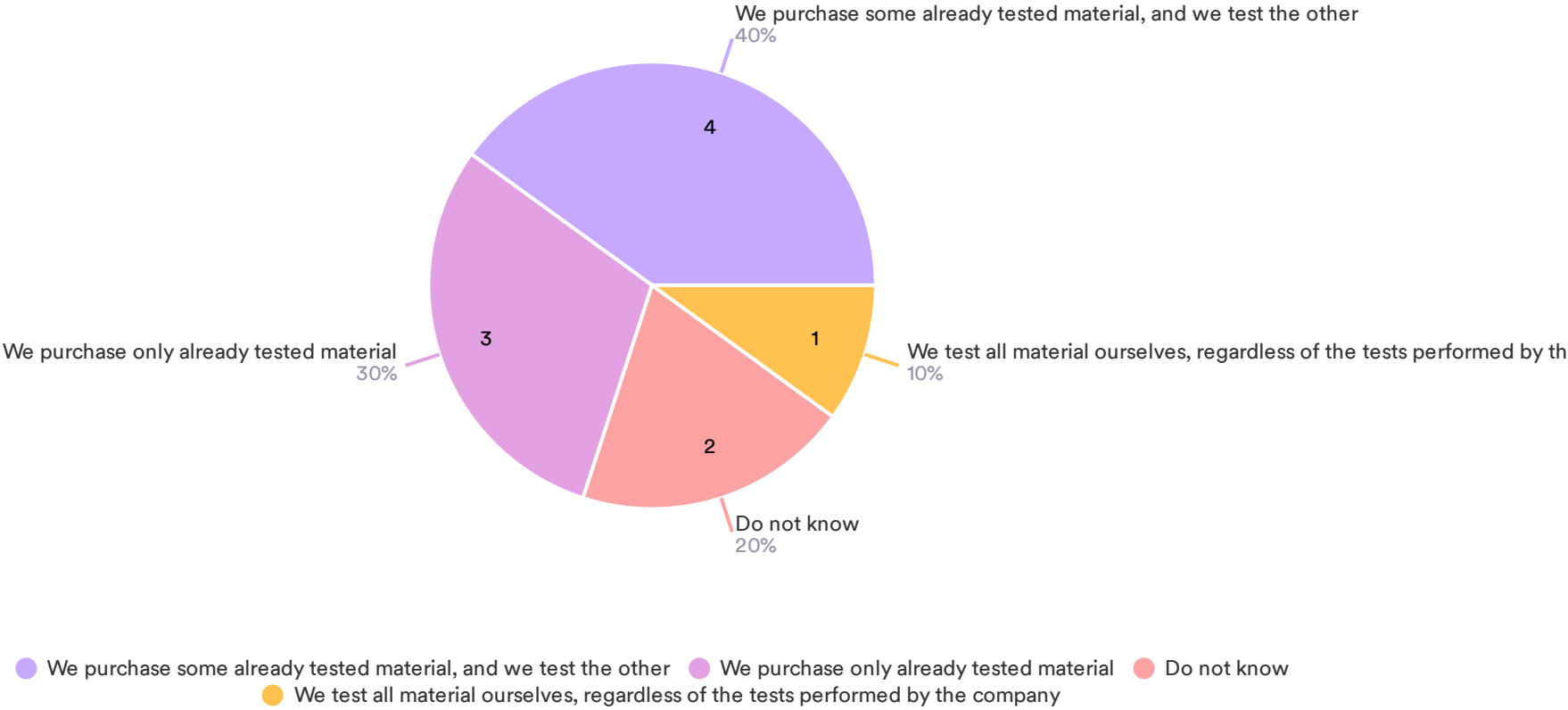
10 Responses



● MEA (Mouse Embryo Assay) test and sperm survival tests are both allows ● Do not know ● MEA test is the only test allow

Toxicity tests for disposable material (plastics and media):

10 Responses



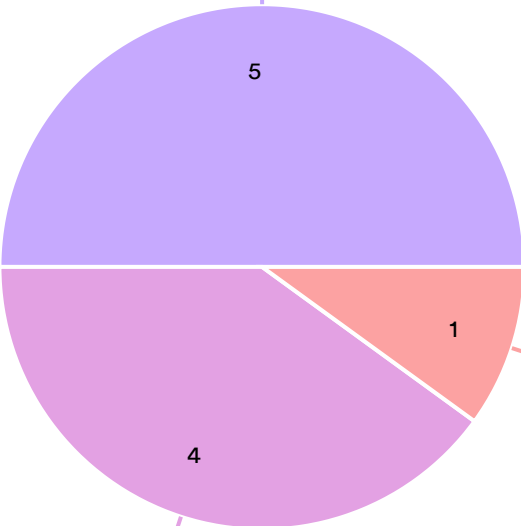
Traceability of material:

10 Responses

Traceability is managed in a separate database (included Excel files) from that of patients

50%

5



1

Do not know
10%

4

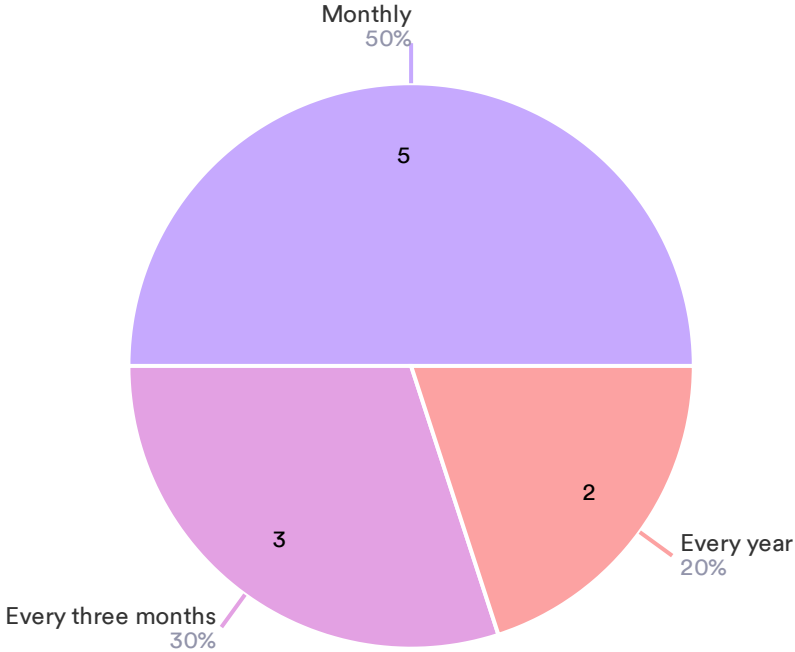
Traceability is managed in the same database as for patient treatments

40%

- Traceability is managed in a separate database (included Excel files) from that of patients
- Traceability is managed in the same database as for patient treatments
- Do not know

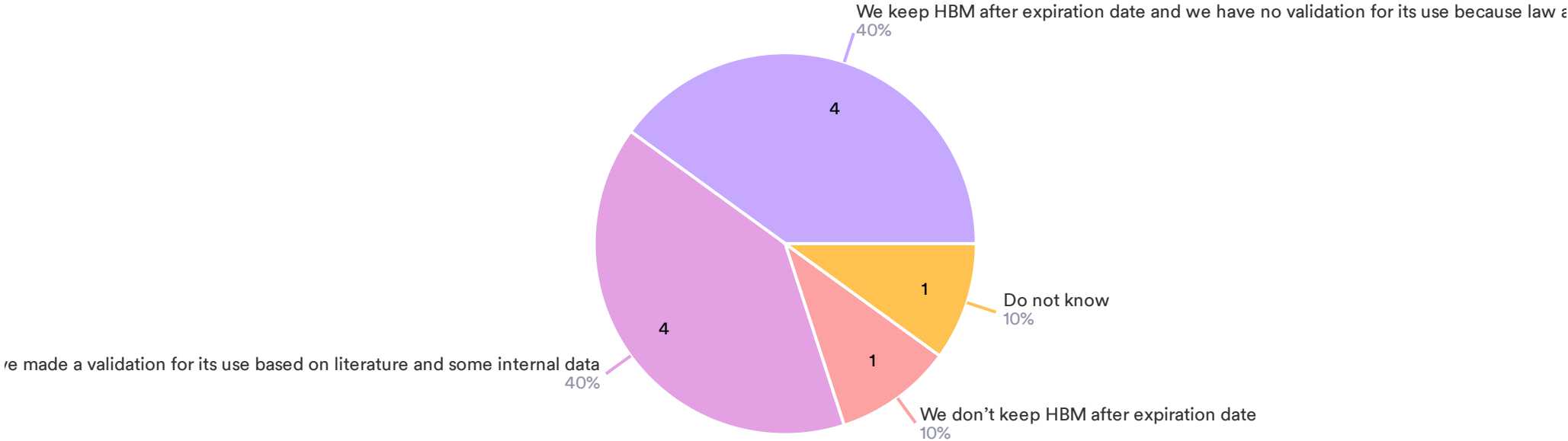
KPI (Key Performance Indicator): frequency of evaluation

10 Responses



« Expiration date » of HBM:

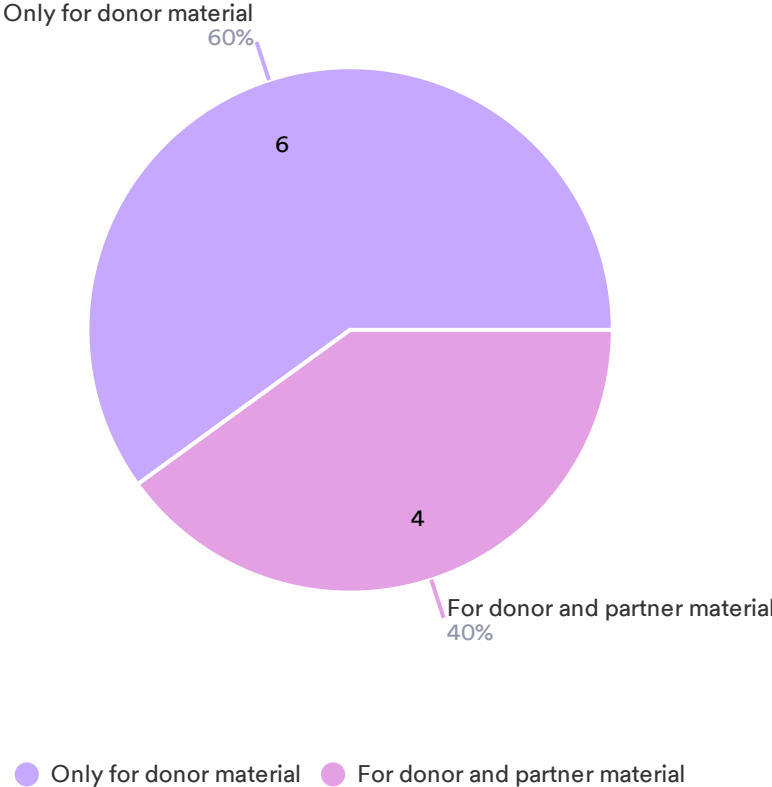
10 Responses



- We keep HBM after expiration date and we have no validation for its use because law allow us to prolong the conservation by signing a new agreement with the patient
- We keep HBM after expiration date and we have made a validation for its use based on literature and some internal data
- We don't keep HBM after expiration date
- Do not know

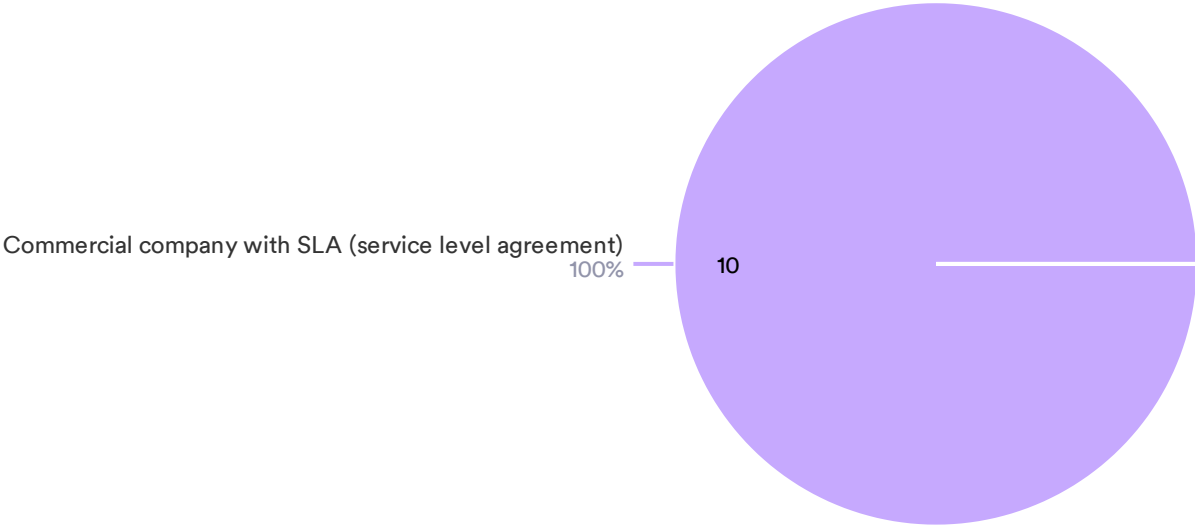
SEC code, for which HBM do you use this?

10 Responses



Transport of human material between centers?

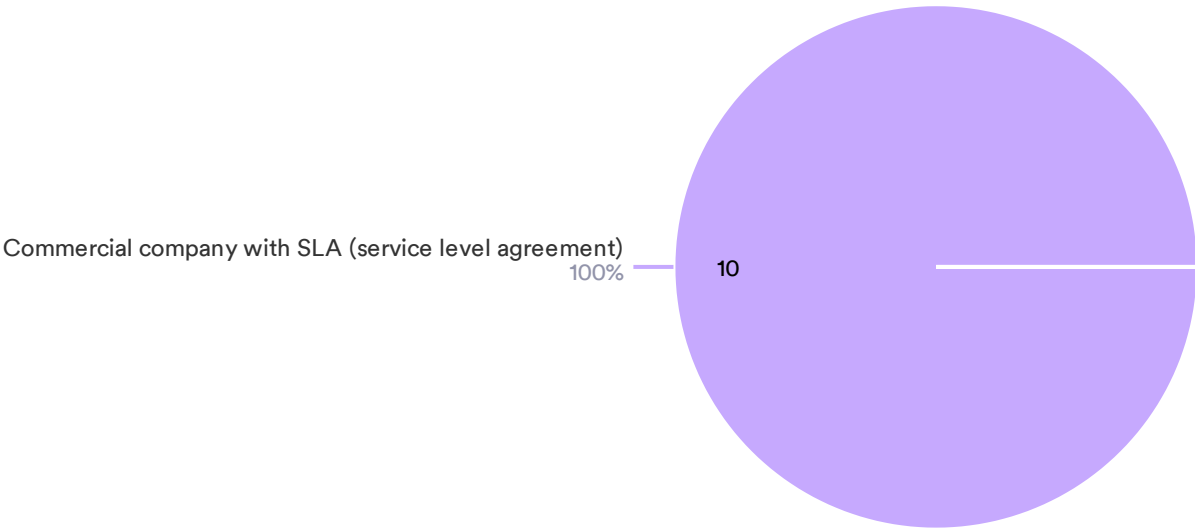
10 Responses



● Commercial company with SLA (service level agreement)

Transport IN/OUT international or national: with whom?

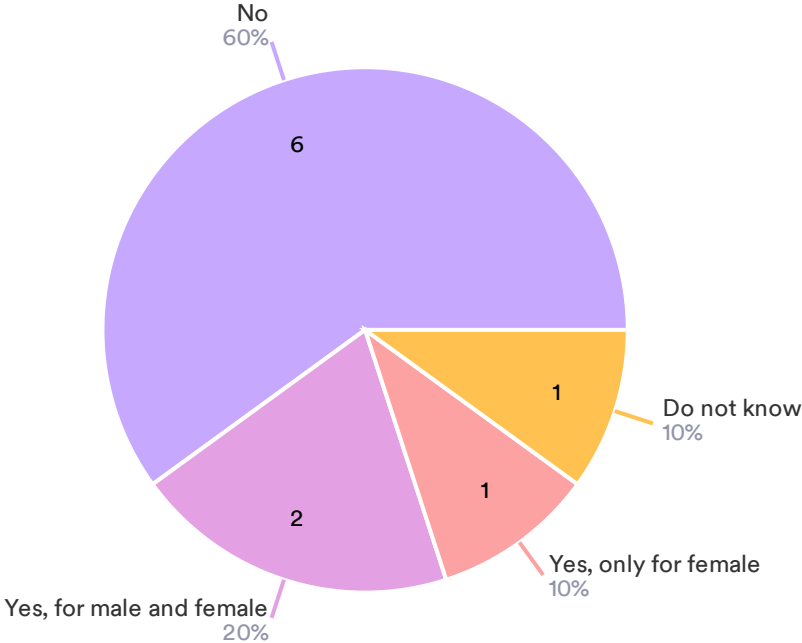
10 Responses



● Commercial company with SLA (service level agreement)

Serology in frozen embryo transfers: should it be repeated?

10 Responses



● No ● Yes, for male and female ● Yes, only for female ● Do not know

Any remarks?

1 Response- 9 Empty

Data	Responses
Dubbelzinnige vragen, niet altijd duidelijk. Soms zit juiste antwoord er ook niet tussen.	1

Thank You!

Fertility Centers Survey