EUROPEAN
SPERM·BANK

Response from ESB to the submission from DR and associated news outlets from the EBU

This is an attachment to the email answer send to DR on 04.12.2025 related to the TP53 case. This attachment should be read in connection to the email.

In this document you will find

- Our statements for quotation regarding both TP53 and family limits. We expect the statements to be presented faithfully, in their entirety, and in a relevant context across all news formats in which you choose to publish. This applies to both DR and your partners. We also ask that you share the English versions of the statements, which are included immediately after the Danish versions.

- In addition, you will find supplementary information on:
  a) legal limitations on sharing information about the donor and donor-conceived children, b) a family limit of 75, c) screening for rare genetic variants, d) rapid alert reports, and e) information for clinics regarding TP53.

ESB assumes that this supplementary information will be reflected in your coverage, regardless of format, to ensure accurate reporting, cf. A1 of the Guidelines for Good Press Conduct. The information may be used editorially but may not be reproduced as a quotation.

Below is written in both Danish and English versions

1. **Udtalelser fra ESB til citat // Statement from ESB for quotation**

Vi forventer, at nedenstående udtalelser bringes loyalt og i deres helhed og bringes i relevant sammenhæng på tværs af og i alle de nyhedsformater, som I vælger at udkomme i. Det gælder både for DR og jeres samarbejdspartnere
We expect the following statements to be published loyally and in their entirety and to be brought into relevant context across and in all the news formats in which you choose to be published. This applies to both DR and your partners

ESBs udtalelser i relation til TP53-sagen, dens konsekvenser og håndtering

"Vi er meget berørte af sagen og den betydning, som den sjældne TP53- mutation har for en række familier, børn og donor, og de har vores dybeste sympati."

"ESB tester og udfører en individuel lægefaglig vurdering af alle donorer i fuld overensstemmelse med anerkendt og videnskabelig praksis og lovgivning."

"I den konkrete sag er der tale om en nyopstået tidligere ubeskrevet TP53-mutation. Den forekommer som en gonademosaik, altså kun i en lille del af donorens sædceller og ikke i resten kroppen. I disse tilfælde er donoren og dennes familie ikke selv syge, og mutationer af denne type opdages ikke præventivt ved genetisk screening. Da vi i 2023 fik mistanke om, og sidenhen bekræftet, en gonademosaik, blev donor straks blokeret, og vi underrettede

myndigheder og klinikker i henhold til lovgivningen. Klinikkerne har ansvaret for at informere patienterne, blandt andet fordi vi som sædbank ikke nødvendigvis kender patienterne, og fordi patienternes egen behandlende læger er bedst klædt på til at rådgive dem i den konkrete situation".

ESB's statements regarding the TP53 issue and its consequences and handling

UK

"We are deeply affected by the case and the impact that the rare TP53 mutation has on a number of families, children and the donor. They have our deepest sympathy."

"ESB tests and performs an individual medical assessment of all donors in full compliance with recognized and scientific practice and legislation."

"In this specific case, it is a new, previously undescribed TP53 mutation. It occurs as a gonadal mosaicism, i.e. only in a small part of the donor's sperm cells and not in the rest of the body. In such cases the donor himself and his family members are not ill, and a mutation of this type is not detected preventively by genetic screening. When we suspected and later confirmed a gonadal mosaicism in 2023, the donor was immediately blocked and we notified authorities and clinics in accordance with the law. The clinics are responsible for informing the patients, partly because we as a sperm bank do not necessarily know the patients, and because the patients' own treating physician are best equipped to advise them in the specific situation."

ESB's udtalelser i relation til spørgsmålet om familiegrænser

"Vi har desværre konstateret, at grænserne for, hvor mange familier en donor må bruges til, er blevet overskredet i enkelte lande både i den konkrete sag vedr. TP53 og i andre tilfælde. Dette blandt andet på grund af mangelfuld indrapportering fra klinikkerne, ikke-robuste systemer og fertilitetsturisme. Det er vi i dialog med myndighederne i Danmark og Belgien om."

"ESB har gennem de seneste år løbende forbedret sine kontrolmekanismer for at understøtte de eksisterende online-rapporteringsværktøjer, der har været tilgængelige for klinikkerne. Det gælder blandt andet introduktionen af kvotereservationer på donorsæd - også kaldet pregnancy slots. Et system ESB udviklede og introducerede, som den første sædbank. Pregnancy slots reducerer muligheden for, at brugen af den enkelte donor overstiger grænsen. Der har været en markant forbedring af systemet siden introduktionen, og ESB har siden udviklet og implementeret pregnancy slots i flere lande."

"Der er forskellige årsager til overskridelserne, dog primært af teknisk og administrativ art. Det er vigtigt at understrege, at både klinikker og donorbanker arbejder ud fra et fælles formål: at hjælpe kvinder og par med at opnå en ønsket graviditet. Valget af donor træffes i sidste ende af den enkelte familie, og der er et bredt udvalg af donorer at vælge imellem. Set i bakspejlet vil vi ønske at der havde været bedre koordinering og systemer mellem donorbanker, klinikker og sundhedsmyndigheder for at mindske risikoen for at overskride de nationale grænser. Fremadrettet vil bedre koordinering og systemer mellem donorbanker,

klinikker og sundhedsmyndigheder i endnu højere grad understøtte overholdelsen af de nationale grænser."

ESB's statements regarding family limits

UK

"Unfortunately, we have identified that the limits for how many families a donor can be used for have been exceeded in some countries both in the specific case regarding TP53 and in other cases. This is partly due to inadequate reporting from the clinics, non-robust systems and fertility tourism. We are in dialogue with the authorities in Denmark and Belgium about this."

"ESB has continuously improved its control mechanisms to support the existing online reporting tools that have been available to clinics. This applies, among other things, to the introduction of quota reservations for donor sperm - also called pregnancy slots. A system ESB developed and introduced, as the first sperm bank. Pregnancy slots reduce the possibility of the use of the individual donor exceeding the limit. There has been a significant improvement since the system's introduction and ESB has since developed and implemented pregnancy slots in a number of countries."

"There are various reasons for the exceedances, but primarily of a technical and administrative nature. However, it is important to emphasize that both clinics and donor banks work from a common purpose: to help women and couples achieve a desired pregnancy. The choice of donor is ultimately made by the individual family, and there is a wide selection of donors to choose from. In hindsight, we wish there had been better coordination and systems between donor banks, clinics, and authorities to minimize the risk exceeding national limits. Looking ahead, improving coordination and systems between donor banks, clinics and health authorities will further support compliance with national limits."

ESB overordnede udtalelser til citat om sikkerhed ved brug af donorsæd og behovet for en fælles EU familiegrænse

"Det er vigtigt, særligt i lyset af denne sag, at huske på, at tusindvis af kvinder og par ikke har mulighed for at få et barn uden hjælp af donorsæd. Potentielle donorer screenes intensivt, og kun ca. 5 procent af de mænd, der ønsker at blive donorer, bliver godkendt af ESB. Det er således generelt mere sikkert at få et barn ved hjælp af donorsæd, hvis sæddonorerne screenes efter medicinske retningslinjer og gældende lovgivning end at få et barn med en mand, der ikke er screenet."

"Lovgivningen på dette område er kompleks, med mange og ofte modsatrettede hensyn, og implementeringen af reglerne er meget forskellige fra land til land. Derfor er der et stort behov for at få skabt fælles og transparente europæiske standarder. ESB har i en årrække arbejdet aktivt for fælles standarder og et donorregister på EU-niveau samt en international familiegrænse på 75 familier for at skabe bedre fælles rammer og regulering af hele området."

ESB statements for quotation about the safety of donor use and the introduction of an EU family limit

UK

"It is important, especially in light of this case, to remember that thousands of women and couples do not have the opportunity to have a child without the help of donor sperm. Potential donors are screened intensively, and only about 5 percent of the men who want to be donors are approved by ESB. Thus, it is generally safer to have a child with the help of donor sperm if the sperm donors are screened according to medical guidelines and current legislation than to have a child with a man who has not been screened."

"The legislation on this areas is complex, with many and often conflicting considerations, and the implementation of the regulation differs greatly from country to country. Hence, there is need for common and transparent European standards. ESB has for several years been actively working for common standards and a donor registry at EU level as well as an international family limit of 75 families to create a better common framework and regulation of the entire area."

2. **Forklarende oplysninger til de hovedspørgsmåI I rejser // Explanatory information regarding key questions you raise**

I forlængelse af jeres forelæggelse og spørgsmål har vi behov at bibringe en række forklarende oplysninger for undgå misforståelser og sikrer en korrekt repræsentation af vores position og grundlaget for denne.

Vi forudsætter, at den uddybende information er afspejlet i jeres dækning uanset format med henblik på korrekte meddelelser, jf. A1 i Retningslinjer for god presseskik. De pågældende informationer kan bruges redaktionelt, men ikke viderebringes som citat.

Det skal understreges, at nedenstående ikke er til citat, men til baggrund og information.

UK

In continuation of your presentation and questions, we need to provide a number of explanatory information to avoid misunderstandings and ensure a correct representation of our position and its basis.

ESB assumes that this supplementary information will be reflected in your coverage, regardless of format, to ensure accurate reporting, cf. A1 of the Guidelines for Good Press Conduct. The information may be used editorially but may not be reproduced as a quotation.

It should be emphasized that the following is not for quotation, but for background and information.

A) Spørgsmål der vedr. information om donor og helbredsoplysninger om donorbørn

I relation til spørgsmål vedr. antal donorbørn fra den konkrete donor og spørgsmål vedr. donorbørnenes helbredssituation, samt spørgsmål om deling af sundhedsinformationer med genetikere og andre tredjeparter, gør ESB opmærksom på nedenstående.
ESB's forpligtelse til at beskytte donorer i henhold til den nedenfor nævnte lovgivning betyder, at ESB ikke har et juridisk grundlag for lovligt at kunne udlevere de efterspurgte oplysninger til medier eller andre tredjeparter.

Donor er allerede dybt påvirket af denne ulykkelige situation, for hvilken han på ingen måde kan drages til ansvar. Vi henstiller derfor kraftigst muligt til at vigtigheden af donorens ret til et privatliv respekteres ved at undlade at offentliggøre donornummeret.
På samme måde kan ESB heller ikke dele sundhedsinformation om donorbørnene, da disse informationer omhandler det individuelle donorbarn.

ESB er forpligtet til at beskytte donorers anonymitet, hvilket omfatter såvel beskyttelse af donorers identitet som beskyttelse af oplysninger om brugen af det donerede vævsmateriale. Oplysninger om antallet af børn, som en specifik donor er biologisk ophav til, udgør juridisk set en personoplysning om donoren. De efterspurgte oplysninger om antallet af børn, som den konkrete donor er ophav til, er således beskyttet i henhold til vævsbekendtgørelsen og databeskyttelsesforordningen. Sundhedsoplysninger er en særlig kategori i GDPR -reglerne, der specifikt beskytter personlige helbredsoplysninger. Det er særlig relevant i denne sag, da donor-identifikationsnummeret kan linkes direkte til donors helbredsoplysninger.

A) Questions regarding information about the donor and health information about donor-conceived children

UK

In relation to questions regarding the number of donor-conceived children from the specific donor and questions regarding the donor children's health situation, as well as questions about the sharing of health information with geneticists and other third parties, ESB draws attention to the following.

ESB's obligation to protect donors under the legislation mentioned below means that ESB does not have a legal basis to legally disclose the requested information to media or other third parties. The donor is already deeply affected by this unfortunate situation, for which he can in no way be held responsible. We therefore strongly advice that the importance of the donor's right to privacy is respected by refraining from publishing the donor number.
In the same way, ESB cannot share health information about the donor-conceived children, as this information concerns the individual donor-conceived child.

ESB is committed to protecting the anonymity of donors, which includes both the protection of donors' identities and the protection of information about the use of the donated tissue material. Information about the number of children of which a specific donor is the biological origin constitutes legal personal data about the donor.

The requested information about the number of children of which the specific donor is the origin is thus protected under the Executive Order on Tissue and the General Data Protection

Regulation. Health information is a special category in the GDPR regulations that specifically protects personal health information. This is particularly relevant in this case, as the donor identification number can be linked directly to the donor's health information.

B) Grundlaget og rationale for ESB's forslag om en familiegrænse på 75 familier

I relation til spørgsmål vedr. en international familiegrænse på 75 kan ESB oplyse følgende: ESB's familiegrænse på 75, som ESB har implementeret og advokeret for siden 2022, er blandt andet baseret på nogle af de mest omfattende studier på området (bl.a. de Boer et al 1995, Sawyer & MacDonald 2008 og Janssens, Thorn et al, 2015). Studier, der i årenes løb har været udgangspunkt for bl.a. anbefalingerne fra ASRM, den amerikanske pendant til ESHRE. Studierne vurderer en række centrale faktorer, man bør tage i betragtning, når man fastsætter en overordnet grænse for, hvor mange familier en donor kan hjælpe. Forskerne bag artiklerne er enige om, at hvis man udelukkende ser på den genetiske risiko ved donorbrug, kan én donor bruges af mere end 75 familier (fx ASRM sætter standarden ved 25 per 800,000 indbyggere). ESB har dog valgt at lægge sig væsentligt under anbefalingerne ved at benytte og advokere for en grænse på 75 familier for også at tage højde for andre faktorer som psychosociale.

ESB følger den videnskabelige udvikling på området tæt og er dybt engageret i dialog med både donor-undfangede og deres familier og er naturligvis opmærksomme på, at ESHRE i forrige uge har udsendt et debatoplæg, der diskuterer familiegrænser specifikt i EU, og her bl.a. diskuterer en mulig EU-grænse på 50 familier. Vi vil naturligvis bidrage i den officielle høringsproces, da vi arbejder for en fælles EU familiegrænse.

B) The basis and rationale of the ECB's proposal for a family limit of 75 families

UK

ESB's family limit of 75, which ESB has implemented and advocated for since late 2022, is based in part on some of the most comprehensive studies in the field, for example de Boer et al 1995, Sawyer and MacDonald 2008, and Janssens, Thorn et al 2015. Over the years, these studies have formed part of the basis for recommendations from ASRM, the American counterpart to ESHRE. The studies assess a range of key factors that should be considered when setting an overall limit for how many families a donor can help. The authors of these articles agree that if one looks only at the genetic risk associated with donor use, a single donor could be used by far more than 75 families, for example ASRM sets a standard of 25 per 800,000 inhabitants. ESB has nevertheless chosen to set its limit significantly below those recommendations by using and advocating for a limit of 75 families, in order to also include other factors such as psychosocial considerations.

ESB closely follows the scientific developments in this area and is deeply engaged in the dialogue among donor conceived people and their families, and we are of course aware that ESHRE last week issued a position paper discussing family limits specifically in the EU, including a possible EU wide limit of 50 families. We will naturally contribute to the official consultation process, as we are working towards a common EU family limit.

C) Det er standard videnskabelig praksis ikke at teste for sjældne genetiske mutationer, når donorer screenes

I det omfang screening og test af sæd, herunder test for gonademosaik, indgår I jeres nyhedsdækning skal vi bede om at DR og jeres samarbejdspartnere gør seere, lyttere og læsere opmærksomme på følgende.

TP53-mutationer og andre tilsvarende genetiske varianter indgår ikke i den lovpligtige rekrutteringsscreening af sæddonorer. Den danske screening bygger på en lægefaglig helhedsvurdering af donorens helbred og familiehistorik kombineret med de obligatoriske genetiske og smittemarkørundersøgelser (https://www.retsinformation.dk/eli/retsinfo/2015/9356).

Der stilles ikke krav om præventiv genetisk screening af raske donorer for sjældne og/eller nyopståede mutationer.

Ved første indberetning i 2020 blev sagen håndteret korrekt efter gældende regler og standard medicinsk praksis. Donor havde ingen kliniske symptomer, og sædtesten for den konkrete mutation var negativ. Som de danske regler fastslår entydigt, "en karantæne ophæves hvis mutationen og eller kliniske symptomer hos donor ikke forefindes, da gentagelsesrisikoen i denne situation er defineret som meget lav (< 1 %)". Se også https://www.retsinformation.dk/eli/retsinfo/2015/9351

Der var derfor ingen klinisk indikation for yderligere specialundersøgelser i 2020.
Da der i 2023 blev indrapporteret endnu et barn med samme mutation, ændrede risikobilledet sig og gav en begrundet klinisk mistanke.

På den baggrund blev der lavet en specialiseret analyse, hvor en lavgrads gonademosaik blev påvist, en sjælden biologisk tilstand som kun undersøges målrettet, når der er klinisk indikation.

C) It is standard scientific practice not to test for gonadal mosaicism when the donor is screened

UK

To the extent that screening and testing of sperm, including testing for gonadal mosaicism, is part of your news coverage, we would ask DR and your partners to make viewers, listeners and readers aware of the following.

TP53 mutations and other similar genetic variants are not part of the legally required recruitment screening of sperm donors. The Danish screening is based on an overall medical assessment of the donor's health and family history combined with the mandatory genetic and infectious disease marker tests.
(https://www.retsinformation.dk/eli/retsinfo/2015/9356).

There is no requirement for preventive genetic screening of healthy donors for rare and or newly arising mutations.

At the first report in 2020, the case was handled correctly in accordance with applicable rules and standard medical practice. The donor had no clinical symptoms, and the sperm test for the specific mutation was negative. As the Danish rules state clearly, “a quarantine is lifted if the mutation and or clinical symptoms in the donor are not present, as the recurrence risk in this situation is defined as very low (< 1 %).” See also https://www.retsinformation.dk/eli/retsinfo/2015/9351

There was therefore no clinical indication for further specialised investigations in 2020. When another child with the same mutation was reported in 2023, the risk picture changed and gave rise to a well founded clinical suspicion.

On that basis, a specialised analysis was carried out in which a low level gonadal mosaicism was identified, a rare biological condition that is only investigated in a targeted way when there is a clinical indication.

D) Tidligere indberetninger via rapid alert

Vi skal i relation til DR og jeres samarbejdspartneres spørgsmål, relateret til tidligere indberetninger gennem Rapid Alert systemet, gøre opmærksom på følgende:
Som beskrevet ovenfor må vi ikke dele sundhedsinformation om donorbørnene.
Vi kan dog generelt oplyse, at reglerne for Rapid Alerts betyder, at en indberetning om en sygdom/tilstand hos en person undfanget med donorsæd, der giver anledning til yderligere undersøgelser, fører til en midlertidig blokering af donor. Herefter undersøges det, om årsagen kan tilskrives donor eller andre faktorer, som fx moderen, eller at sygdommen/tilstanden er opstået af sig selv i barnet. Alt efter indberetningens karakter vil der både kunne ske test af donors blod og sæd, samt undersøgelser af donors families sygdomshistorik. Hvis undersøgelserne konkluderer, at der ikke er væsentligt øget risiko for, at donor er årsag til hændelsen, frigives donorens sæd til brug igen. Derved vil det være naturligt at mange donorer har indrapporterede adverse reactions, uden at de bliver permanent blokerede.

ESB anser i øvrigt indberetninger, der udløser Rapid Alerts og efterfølgende midlertidig eller permanent blokering af en donor, som et tegn på, at systemet fungerer, og at den feedback der modtages om sygdomme eller tilstande hos personer undfanget med donorsæd, håndteres korrekt. Af den grund gennemfører ESB en stærk og ensartet anvendelse af Rapid Alert reguleringen på tværs af alle lande og arbejder for, at alle EU-medlemsstater og markedsdeltagere gør det samme. Undlades dette, indebærer det en risiko for, at donorrelaterede sygdomme forbliver uopdagede og eller ikke bliver kommunikeret.

D) Previous reports via rapid alert

UK

In relation to the questions from DR and your partners concerning previous reports through the Rapid Alert system, we would like to draw attention to the following.

As described above, we are not permitted to share health information about donor conceived children.
However, we can state in general terms that the Rapid Alert rules mean that a report of a disease or condition in a person conceived with donor sperm, which gives rise to further investigations, leads to a temporary block of the donor. We then investigate whether the cause can be attributed to the donor or to other factors, such as the mother, or whether the disease or condition has arisen spontaneously in the child. Depending on the nature of the report, this may involve testing of the donor's blood and sperm, as well as a review of the donor's family medical history. If the investigations conclude that there is no significantly increased risk that the donor is the cause of the event, the donor's sperm is released for use again. It is therefore natural that many donors have reported adverse reactions without being permanently blocked.

ESB also considers reports that trigger Rapid Alerts and subsequent temporary or permanent blocking of a donor to be a sign that the system is working and that the feedback received about diseases or conditions in people conceived with donor sperm is being handled correctly. For that reason, ESB implements a strong and consistent application of Rapid Alert regulation across all countries and advocates that all EU member states and market participants do the same. Not to do this risks donor related diseases remaining undiscovered and or not being communicated.

E) Klinikker, der blev informeret om TP53 i 2023 og kliniklister

I forbindelse med den opdaterede liste over klinikker, der blev orienteret om TP53 i 2023, kan vi oplyse til DR og jeres samarbejdspartnere:
For at sikre, at alle klinikker blev underrettet hurtigst muligt om karantæne og blokering af den pågældende donor, og de dermed kunne informere patienter berørt af sagen, fik vi orienteret enkelte klinikker i 2023, som ikke havde benyttet donor. Derfor tilrettede vi listen over relevante klinikker i vores senere dialog med de danske myndigheder. Det vigtigste for os i denne sag er dog, at alle klinikker, der faktisk havde benyttet donoren, blev underrettet i 2023, straks efter vi havde opdaget mutationen i TP53.

Specifikt vedr. de lister over donorer, som I har delt fra 2013:
Den danske lovgivning blev i 2012 ændret fra en tilstræbelse på 25 børn til en lovgivningsmæssig grænse på 12 familier. I forbindelse med overgangen til den nye lovgivning var det imidlertid uklart, om for eksempel udenlandske patienter, der modtog behandling i Danmark, skulle tælles med i grænsen på de 12 familier.
For at sikre overholdelse af reglerne valgte ESB således at blokere flere donorer, end det senere viste sig nødvendigt. Efterfølgende blev det præciseret, at personer bosat i udlandet, men behandlet i Danmark, ikke skal medregnes i de 12 familier. På den baggrund blev flere af de donorer, der stod som blokerede i januar 2013, senere genåbnet til anvendelse.

E) Clinics informed about TP53 in 2023

UK

Regarding the updated list of clinics that were informed about TP53 in 2023, we can state to DR and your partners:
To ensure that all clinics were notified as quickly as possible about the quarantine and blocking of the donor in question, so that they could inform patients affected by the case, we informed a few clinics in 2023 that had not used the donor. We therefore adjusted the list of relevant clinics in our subsequent dialogue with the Danish authorities. What matters most to us in this case is that all clinics that had actually used the donor were notified in 2023, immediately after we discovered the TP53 mutation.

Specifically regarding the lists of donors you have shared from 2013:
Danish legislation was changed ultimo 2012 from an aim of 25 children to a limit of 12 families. During the transition to the new legislation, however, it was unclear whether, for example, foreign patients who received treatment in Denmark should be counted within the limit of 12 families.
To ensure compliance with the rules, ESB therefore chose to block more donors why later turned out to be necessary. It was subsequently clarified that people living abroad but treated in Denmark should not be included in the 12-family limit. On that basis, several of the donors who appeared as blocked in January 2013 were later reopened for use.