Statutory Approvals Committee - minutes

Centre 0102 (Guys Hospital)

Preimplantation Genetic Testing for Monogenic Disorders (PGT-M) - application for Developmental and Epileptic Encephalopathy, type 63 (DEE63); OMIM #617976

Date:	26 August 2021
Venue:	HFEA, 2nd Floor, 2 Redman Place, London E20 1JQ via Microsoft Teams
Committee Members:	Margaret Gilmore (Chair) Emma Cave Anne Lampe Ruth Wilde Tim Child
Specialist Adviser:	Alan Fryer
Legal Adviser:	Tom Rider - FieldFisher LLP
Members of the Executive:	Moya Berry - Committee Officer Catherine Burwood - Licensing Manager
Apologies:	No apologies were received for the meeting
Declarations of Interest:	Members of the committee declared that they had no conflicts of interest in relation to this item

The Committee had before it:

- HFEA Code of Practice 9th edition
- Standard Licensing and Approvals Pack

The following papers were considered by the committee:

- Executive Summary
- PGT-M Application Form
- Redacted Peer Review
- Genetic Alliance (UK) Statement
- Letter of Support from the Genetics Department
- 2018-07-26 Statutory Approvals Committee Minutes for EIEE7, OMIM #613720
- 2017-06-29 Statutory Approvals Committee Minutes for EIEE48, OMIM #617276
- 2017-03-30 Statutory Approvals Committee Minutes for EIEE multiple Autosomal Recessive types
- 2012-07-19 Licence Committee Minutes – PGD for Dravet Syndrome, OMIM #607208

1. Consideration of application

1.1. The committee welcomed the advice of its specialist adviser, Dr Alan Fryer, who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the PGT-M application for Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976, is consistent with the peer review.

1.3. The committee noted that the condition being applied for is not on the list of approved PGT-M conditions.

1.4. The committee noted that the Genetic Alliance (UK) statement provided a perspective on the impact of the condition and similar conditions on patients, their families, and carers.

1.5. The committee had regard to its decision tree. The committee noted that the centre is licensed to carry out PGT-M. The committee was also satisfied that the centre has experience of carrying out PGT-M and that generic patient information about its PGT-M programme and associated consent forms had previously been received by the HFEA.

1.6. The committee noted that the proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of Schedule 2 of the Act, i.e., 'where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality'.

1.7. The committee noted that Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976, is inherited in an autosomal recessive manner, which means there is a 25% chance of an embryo being affected by the condition in each pregnancy if each parent has a relevant mutation.

1.8. The committee noted that the penetrance of the condition is 100%.

1.9. The condition Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976, is characterised by infantile spasms and migrating/progressive myoclonic seizures (including tonic and generalised seizures) which commence in the first months to years of life. Seizures often do not respond to medication and can occur up to 100 times per day. Affected individuals have severe to profound developmental delay, often with hypotonia and an inability to sit or

speak, as well as significant intellectual and physical disability. Seizures can potentially lead to status epilepticus and death.

1.10. There is no cure for this condition and the seizures can be resistant to medication. Treatment focuses on the treatment of symptoms.

1.11. The committee noted the executive's request to consider Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976, for inclusion on the list of conditions approved for PGT-M. The committee agreed to consider the application on this basis.

1.12. The committee also noted that the peer reviewer had considered seventy-one additional conditions associated with Developmental and Epileptic Encephalopathy and made recommendations for inclusion on the list for which PGT-M can be applied and agreed to consider the application on this basis.

1.13. Firstly, the committee considered twenty autosomal recessive condition types. The penetrance of these conditions is 100%. Symptoms of all these condition types are comparable to DEE63, OMIM #617976, in that there is a significant risk of infantile onset refractory seizures and severe developmental delay that can lead to status epilepticus and death. In many, early death in childhood is possible. The conditions are: DEE44, OMIM #617132; DEE49, OMIM #617281; DEE50, OMIM #616457; DEE51, OMIM #617339; DEE52, OMIM #617350; DEE53, OMIM #617389; DEE55, OMIM #617599; DEE60, OMIM #617929; DEE61, OMIM #617933; DEE68, OMIM #618201; DEE71, OMIM #618328; DEE75, OMIM #618437; DEE76, OMIM #618468; DEE77, OMIM #618548; DEE80, OMIM #618580; DEE81, OMIM #618663; DEE82, OMIM#618721; DEE83, OMIM #618744; DEE84, OMIM #618792; DEE89, OMIM #619124.

1.14. Secondly the committee considered seven DEE conditions that are inherited in an X-linked dominant and recessive manner.

1.15. The committee noted that of the conditions inherited in an X-linked dominant manner, for most affected individuals their condition has been due to a gene change that is present for the first time in them as a result of a genetic alteration in a germ cell (egg or sperm) of one of the parents or a variant that arose in the fertilised egg itself during early embryo development; recurrence risk is thus very low. Hence, such families who have an affected child would be unlikely to present for PGT-M. Nevertheless, there have been a very few familial cases reported where a clinically mildly affected or unaffected mother carries a relevant mutation on an X chromosome in a mosaic form or where she has been protected from the phenotypic effect of the mutation by a skewed X-inactivation pattern. In such cases up to 50% of male children will be affected (and may present as a prenatally lethal disorder given that males would be more severely affected than females) as will up to 50% of female children. One exception is found in DEE9, OMIM #300088, where females are affected, and males are clinically unaffected. In this situation, if the father carries a relevant mutation on his X chromosome, all male children will be unaffected, but all female children will inherit the mutation and will be at very high risk of exhibiting the symptoms of the condition.

1.16. If the condition is inherited in an X-linked recessive manner and the mother carries a relevant mutation on an X chromosome, 50% of male children will be affected and 50% of female children will be carriers, inheriting the abnormality but usually being unaffected or only mildly affected by it.

1.17. Symptoms of the X chromosome linked DEE condition types in affected individuals are comparable to DEE63, OMIM #617976, in that there is a significant risk of infantile onset refractory seizures and severe developmental delay, which can lead to status epilepticus and death. The conditions are DEE1, OMIM #308350; DEE2, OMIM #300672; DEE8, OMIM #300607; DEE9, OMIM #300088; DEE36, OMIM #300884; DEE85, OMIM #301044; DEE90, OMIM #301058.

1.18. Finally, the peer reviewer recommended that the committee consider forty-four autosomal dominant types of the Developmental and Epileptic Encephalopathies (DEE). The penetrance of the condition types is high, and symptoms are again severe and comparable to DEE63, OMIM #617976. As with most of the X-linked dominant conditions, for most affected individuals their condition has been due to a gene change that is present for the first time in them as a result of a genetic alteration in a germ cell (egg or sperm) of one of the parents or a variant that arose in the fertilised egg itself during early embryo development. Hence such families who have an affected child would be very unlikely to present for PGT-M. Nevertheless, there have been a very few familial cases reported where a clinically mildly affected or unaffected parent carries a relevant mutation in a mosaic form or where the condition can be highly variable in its severity within families. The condition types are: DEE4, OMIM #612164; DEE5, OMIM #613477; DEE6B Non Dravet, OMIM #619317; DEE11, OMIM #613721; DEE13, OMIM #614558; DEE14, OMIM #614959; DEE17, OMIM #615473; DEE19, OMIM #615744; DEE24, OMIM #615871; DEE26, OMIM #616056; DEE27, OMIM #616139; DEE30, OMIM #616341; DEE31, OMIM #616346; DEE32, OMIM #616366; DEE33, OMIM #616409; DEE41, OMIM #617105; DEE42, OMIM #617106; DEE43, OMIM #617113; DEE45, OMIM #617153; DEE46, OMIM #617162; DEE47, OMIM #617166; DEE54, OMIM #617391; DEE56, OMIM #617665; DEE57, OMIM #617771; DEE58, OMIM #617830; DEE59, OMIM #617904; DEE62, OMIM #617938; DEE64, OMIM #618004; DEE65, OMIM #618008; DEE66, OMIM #618067; DEE67, OMIM #618141; DEE69, OMIM #618285; DEE70, OMIM #618298; DEE72, OMIM #618374; DEE73, OMIM #618379; DEE74, OMIM #618396; DEE78, OMIM #618557; DEE79, OMIM #618559; DEE87, OMIM #618916; DEE91, OMIM #617711; DEE92, OMIM #617829; DEE93, OMIM #618012; DEE94, OMIM #615369; DEE96, OMIM #619340.

1.19. The committee also noted the recommendation of the executive to update the names of a number of Developmental and Epileptic Encephalopathy (DEE) condition types, with phenotypic OMIM numbers, which are already approved for PGT-M and are listed using the outdated nomenclature Early Infantile Epileptic Encephalopathy (EIEE).

1.20. The suggested new names for the conditions to be used on the PGT-M approved condition list are: EIEE3 to DEE3, OMIM # 609304; Dravet syndrome to Dravet syndrome (DEE6A), OMIM #607208; EIEE7 to DEE7, OMIM #613720; EIEE10- MCSZ to Microcephaly, seizures, and developmental delay (MCSZ), OMIM #613402; EIEE12 to DEE12, OMIM #613722; EIEE15 to DEE15, OMIM #615006; EIEE16 to DEE16, OMIM #615338, EIEE18 to DEE18 OMIM # 615476; EIEE21 to DEE21, OMIM #615833; EIEE23 to DEE23, OMIM #615859; EIEE25 to DEE25, OMIM #615905; EIEE28 to DEE28, OMIM #616211; EIEE29 to DEE29, OMIM #616339; EIEE34 to DEE34, OMIM #616645; EIEE35 to DEE35, OMIM #616647; EIEE37 to DEE37, OMIM #616981; EIEE38 to DEE38 OMIM #617020; EIEE39 to DEE39 OMIM #612949; EIEE40 to DEE40, OMIM #617065 and EIEE48 to DEE48, OMIM #617276.

2. Decision

2.1. The committee considered that, in the worst-case scenario, Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976, is a severe and incurable condition that presents in early childhood. The committee noted that those affected are likely to have drug resistant epilepsy making this condition very difficult to control. Affected individuals may also have severe to profound developmental delay. Seizures may lead to death in infancy. The committee considered the potential significant, emotional, and physical implications, on the quality of life of those affected by the condition.

2.2. The committee also considered the autosomal recessive forms, the autosomal dominant forms, and the X-linked forms of the condition. These conditions can all present in early infancy and have symptoms that are very similar to Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976, in that there is, in all, a significant risk of infantile seizures and severe developmental delay which in the worst-case scenario can have a devastating effect on the quality of life of those affected. In many, early death in childhood is possible. The conditions are:

Autosomal Recessive

- Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976
- Developmental and Epileptic Encephalopathy, type 44 (DEE44), OMIM #617132
- Developmental and Epileptic Encephalopathy, type 49 (DEE49), OMIM #617281
- Developmental and Epileptic Encephalopathy, type 50 (DEE50), OMIM #616457
- Developmental and Epileptic Encephalopathy, type 51 (DEE51), OMIM #617339
- Developmental and Epileptic Encephalopathy, type 52 (DEE52), OMIM #617350
- Developmental and Epileptic Encephalopathy, type 53 (DEE53), OMIM #617389
- Developmental and Epileptic Encephalopathy, type 55 (DEE55), OMIM #617599
- Developmental and Epileptic Encephalopathy, type 60 (DEE60), OMIM #617929
- Developmental and Epileptic Encephalopathy, type 61 (DEE61), OMIM #617933
- Developmental and Epileptic Encephalopathy, type 68 (DEE68), OMIM #618201
- Developmental and Epileptic Encephalopathy, type 71 (DEE71), OMIM #618328
- Developmental and Epileptic Encephalopathy, type 75 (DEE75), OMIM #618437
- Developmental and Epileptic Encephalopathy, type 76 (DEE76), OMIM #618468
- Developmental and Epileptic Encephalopathy, type 77 (DEE77), OMIM #618548
- Developmental and Epileptic Encephalopathy, type 80 (DEE80), OMIM #618580
- Developmental and Epileptic Encephalopathy, type 81 (DEE81), OMIM #618663
- Developmental and Epileptic Encephalopathy, type 82 (DEE82), OMIM #618721
- Developmental and Epileptic Encephalopathy, type 83 (DEE83), OMIM #618744
- Developmental and Epileptic Encephalopathy, type 84 (DEE84), OMIM #618792
- Developmental and Epileptic Encephalopathy, type 89 (DEE89), OMIM #619124

X - Linked

- Developmental and Epileptic Encephalopathy, type 1 (DEE1), OMIM #308350
- Developmental and Epileptic Encephalopathy, type 2 (DEE2), OMIM #300672
- Developmental and Epileptic Encephalopathy, type 8 (DEE8), OMIM #300607
- Developmental and Epileptic Encephalopathy, type 9 (DEE9), OMIM #300088
- Developmental and Epileptic Encephalopathy, type 36 (DEE36), OMIM #300884
- Developmental and Epileptic Encephalopathy, type 85 (DEE85), OMIM #301044

- Developmental and Epileptic Encephalopathy, type 90 (DEE90), OMIM #301058

Autosomal Dominant

- Developmental and Epileptic Encephalopathy, type 4 (DEE4), OMIM #612164
- Developmental and Epileptic Encephalopathy, type 5 (DEE5), OMIM #613477
- Developmental and Epileptic Encephalopathy, type 6B (DEE6B) Non Dravet, OMIM #619317
- Developmental and Epileptic Encephalopathy, type 11 (DEE11), OMIM #613721
- Developmental and Epileptic Encephalopathy, type 13 (DEE13), OMIM #614558
- Developmental and Epileptic Encephalopathy, type 14 (DEE14), OMIM #614959
- Developmental and Epileptic Encephalopathy, type 17 (DEE17), OMIM #615473
- Developmental and Epileptic Encephalopathy, type 19 (DEE19), OMIM #615744
- Developmental and Epileptic Encephalopathy, type 24 (DEE24), OMIM #615871
- Developmental and Epileptic Encephalopathy, type 26 (DEE26), OMIM #616056
- Developmental and Epileptic Encephalopathy, type 27 (DEE27), OMIM #616139
- Developmental and Epileptic Encephalopathy, type 30 (DEE30), OMIM #616341
- Developmental and Epileptic Encephalopathy, type 31 (DEE31), OMIM #616346
- Developmental and Epileptic Encephalopathy, type 32 (DEE32), OMIM #616366
- Developmental and Epileptic Encephalopathy, type 33 (DEE33), OMIM #616409
- Developmental and Epileptic Encephalopathy, type 41 (DEE41), OMIM #617105
- Developmental and Epileptic Encephalopathy, type 42 (DEE42), OMIM #617106
- Developmental and Epileptic Encephalopathy, type 43 (DEE43), OMIM #617113
- Developmental and Epileptic Encephalopathy, type 45 (DEE45), OMIM #617153
- Developmental and Epileptic Encephalopathy, type 46 (DEE46), OMIM #617162
- Developmental and Epileptic Encephalopathy, type 47 (DEE47), OMIM #617166
- Developmental and Epileptic Encephalopathy, type 54 (DEE54), OMIM #617391
- Developmental and Epileptic Encephalopathy, type 56 (DEE56), OMIM #617665
- Developmental and Epileptic Encephalopathy, type 57 (DEE57), OMIM #617771
- Developmental and Epileptic Encephalopathy, type 58 (DEE58), OMIM #617830
- Developmental and Epileptic Encephalopathy, type 59 (DEE59), OMIM #617904
- Developmental and Epileptic Encephalopathy, type 62 (DEE62), OMIM #617938
- Developmental and Epileptic Encephalopathy, type 64 (DEE64), OMIM #618004
- Developmental and Epileptic Encephalopathy, type 65 (DEE65), OMIM #618008
- Developmental and Epileptic Encephalopathy, type 66 (DEE66), OMIM #618067
- Developmental and Epileptic Encephalopathy, type 67 (DEE67), OMIM #618141
- Developmental and Epileptic Encephalopathy, type 69 (DEE69), OMIM #618285
- Developmental and Epileptic Encephalopathy, type 70 (DEE70), OMIM #618298
- Developmental and Epileptic Encephalopathy, type 72 (DEE72), OMIM #618374
- Developmental and Epileptic Encephalopathy, type 73 (DEE73), OMIM #618379
- Developmental and Epileptic Encephalopathy, type 74 (DEE74), OMIM #618396
- Developmental and Epileptic Encephalopathy, type 78 (DEE78), OMIM #618557
- Developmental and Epileptic Encephalopathy, type 79 (DEE79), OMIM #618559
- Developmental and Epileptic Encephalopathy, type 87 (DEE87), OMIM #618916
- Developmental and Epileptic Encephalopathy, type 91 (DEE91), OMIM #617711
- Developmental and Epileptic Encephalopathy, type 92 (DEE92), OMIM #617829
- Developmental and Epileptic Encephalopathy, type 93 (DEE93), OMIM #618012
- Developmental and Epileptic Encephalopathy, type 94 (DEE94), OMIM #615369
- Developmental and Epileptic Encephalopathy, type 96 (DEE96), OMIM #619340

2.3. The committee also agreed that the following conditions should be updated on the HFEA website to be referred to by the suggested new names. These are:

- Early Infantile Epileptic Encephalopathy 3 (EIEE3) to Developmental and Epileptic Encephalopathy 3 (DEE3), OMIM # 609304
- Dravet syndrome to Dravet syndrome (DEE6A), OMIM #607208
- Early Infantile Epileptic Encephalopathy 7 (EIEE7) to Developmental and Epileptic Encephalopathy 7 (DEE7), OMIM #613720
- Early Infantile Epileptic Encephalopathy -EIEE10- MCSZ to Microcephaly, seizures, and developmental delay (MCSZ), OMIM #613402
- Early Infantile Epileptic Encephalopathy 12 (EIEE12) to Developmental and Epileptic Encephalopathy 12 (DEE12), OMIM #613722
- Early Infantile Epileptic Encephalopathy 15 (EIEE15) to Developmental and Epileptic Encephalopathy 15 (DEE15), OMIM #615006
- Early Infantile Epileptic Encephalopathy 16 (EIEE16) to Developmental and Epileptic Encephalopathy 16 (DEE16), OMIM #615338
- Early Infantile Epileptic Encephalopathy 18 (EIEE18) to Developmental and Epileptic Encephalopathy 18 (DEE18), OMIM #615476
- Early Infantile Epileptic Encephalopathy 21 (EIEE21) to Developmental and Epileptic Encephalopathy 21 (DEE21), OMIM #615833
- Early Infantile Epileptic Encephalopathy 23 (EIEE23) to Developmental and Epileptic Encephalopathy 23 (DEE23), OMIM #615859
- Early Infantile Epileptic Encephalopathy 25 (EIEE25) to Developmental and Epileptic Encephalopathy 25 (DEE25), OMIM #615905
- Early Infantile Epileptic Encephalopathy 28 (EIEE28) to Developmental and Epileptic Encephalopathy 28 (DEE28), OMIM #616211
- Early Infantile Epileptic Encephalopathy 29 (EIEE29) to Developmental and Epileptic Encephalopathy 29 (DEE29), OMIM #616339
- Early Infantile Epileptic Encephalopathy 34 (EIEE34) to Developmental and Epileptic Encephalopathy 34 (DEE34), OMIM #616645
- Early Infantile Epileptic Encephalopathy 35 (EIEE35) to Developmental and Epileptic Encephalopathy 35 (DEE35), OMIM #616647
- Early Infantile Epileptic Encephalopathy 37 (EIEE37) to Developmental and Epileptic Encephalopathy 37 (DEE37), OMIM #616981
- Early Infantile Epileptic Encephalopathy 38 (EIEE38) to Developmental and Epileptic Encephalopathy 38 (DEE38), OMIM #617020
- Early Infantile Epileptic Encephalopathy 39 (EIEE39) to Developmental and Epileptic Encephalopathy 39 (DEE39), OMIM #612949
- Early Infantile Epileptic Encephalopathy 40 (EIEE40) to Developmental and Epileptic Encephalopathy 40 (DEE40), OMIM #617065
- Early Infantile Epileptic Encephalopathy 48 (EIEE48) to Developmental and Epileptic Encephalopathy 48 (DEE48), OMIM #617276

2.4. The committee had regard to its explanatory note and confirmed that, on the basis of the information presented, it was satisfied that there is a particular risk that an embryo may have the abnormalities in question and that there is a significant risk that a person with such abnormalities will, given the conditions' worst symptoms, have or develop a serious physical disability, a serious illness, or any other serious medical condition.

2.5. The committee was therefore satisfied that the following conditions meet the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act. The committee agreed to authorise testing for:

- Developmental and Epileptic Encephalopathy, type 63 (DEE63), OMIM #617976
- Developmental and Epileptic Encephalopathy, type 44 (DEE44), OMIM #617132
- Developmental and Epileptic Encephalopathy, type 49 (DEE49), OMIM #617281
- Developmental and Epileptic Encephalopathy, type 50 (DEE50), OMIM #616457
- Developmental and Epileptic Encephalopathy, type 51 (DEE51), OMIM #617339
- Developmental and Epileptic Encephalopathy, type 52 (DEE52), OMIM #617350
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- Developmental and Epileptic Encephalopathy, type 1 (DEE1), OMIM #308350
- Developmental and Epileptic Encephalopathy, type 2 (DEE2), OMIM #300672
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- Developmental and Epileptic Encephalopathy, type 9 (DEE9), OMIM #300088
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- Developmental and Epileptic Encephalopathy, type 41 (DEE41), OMIM #617105
- Developmental and Epileptic Encephalopathy, type 42 (DEE42), OMIM #617106

- Developmental and Epileptic Encephalopathy, type 43 (DEE43), OMIM #617113
- Developmental and Epileptic Encephalopathy, type 45 (DEE45), OMIM #617153
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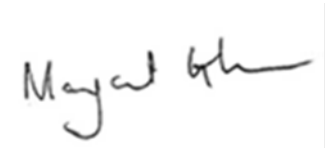
- Developmental and Epileptic Encephalopathy, type 94 (DEE94), OMIM #615369
- Developmental and Epileptic Encephalopathy, type 96 (DEE96), OMIM #619340

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Margaret Gilmore

Date

21 September 2021