



Implementation Steering Group for Organ Utilisation (ISOU) UK Xenotransplantation sub-group - Terms of Reference

Purpose of the Sub-Group

1. The purpose of the Xenotransplantation sub-group is to provide independent advice to DHSC Ministers and the Secretary of State for Health and Social Care to support the UK policy response to the emerging technology of Xenotransplantation (XT).
2. The sub-group will be tasked with producing a discussion paper on XT, including a review of the technology, key policy, regulatory, ethics and research gaps, animal welfare, evaluation of commercial, clinical delivery, regulatory options, and patient benefit (and risks including any unintended impact on human organ donation) from this activity in the future.

Scope

3. It is acknowledged XT is a reserved matter for UK parliament however organ transplantation is organised across the UK and there is significant interest in developments in this area from the Devolved Governments. Therefore, the sub-group outputs will be developed with relevance to the whole UK and representatives from the Devolved Governments will be invited to observe all subgroup meetings.

Membership

4. The Co-Chairs of the sub-group will be nominated by DHSC ISOU Co-Chairs. The sub-group membership will include (a) patient/lay representation (b) senior representatives of key organisations relevant to XT and (c) subject matter experts across the disciplines relevant to discharging the duties of the sub-group.
5. Representatives of Government and/or health commissioners from all four UK nations will be invited as observers. Policy leads from all four UK nations will also receive updates from the subgroup at the main ISOU meetings as well as from sub-group members that are based in their respective nations.
6. At the discretion of the Co-Chairs and ISOU Co-Chairs additional members may be co-opted for specific input as needed.
7. At the discretion of the sub-group Co-Chairs and ISOU Co-Chairs representatives from the commercial sector may be invited to speak to specific points related to their products/innovations. In this scenario, all possible providers of the product/innovation will be invited to prevent any undue commercial advantage to a specific provider. DHSC will provide any commercial advice required prior to inviting commercial representatives to XT sub-group meetings.
8. Members will not be remunerated for their time, but reasonable travel and subsistence costs will be re-imbursed in line with DHSC expenses policy.
9. In addition to patient-public engagement by the sub-group, independent patient-public engagement on XT will be pursued in parallel.

Meetings

10. The sub-group will conduct in-person and/or hybrid and/or virtual meetings at the discretion of the Co-Chairs. In-person or hybrid meetings where possible will be conducted at DHSC (or NHSBT) premises.
11. The sub-group will meet bi-monthly over approximately 12 months. Additional meetings may be called at the discretion of the Co-Chairs. The sub-group will be disbanded on the completion of its task.
12. The meeting will be considered quorate if attended by at least one representative of key organisations plus one patient/lay representative and one subject matter expert from each of the five key themes of regulation, ethics, clinical, research, safety (including animal welfare).
13. Members will have signed a declaration form to alert the secretariat to potential conflicts of interest or concerns and to agree to honour confidentiality in terms of information shared or the purposes of sub-group discussions.

Secretariat

14. DHSC will provide the Secretariat and administrative support for the sub-group, including the following activities:

Secretariat:

- Working with the Co-Chairs, collate the agenda and papers
- Draft papers, to be cleared by Members and Co-Chairs as appropriate
- Drafting and or compiling reports to Ministers and others, but the responsibility for the content lies with the members and ultimately the Co-Chairs of the sub-group.
- Working under the instruction of the Co-Chairs, drive activity and progress between meetings

Administration:

- Setting dates and issuing invites
- Hosting virtual meetings
- Organising venues for in-person/hybrid meetings
- Taking notes, clearing notes with the Co-Chairs, circulating notes to delegates

Governance

15. The sub-group will report to ISOU. The discussion paper (as detailed in point 2 above) produced by the sub-group will be submitted to the DHSC ISOU Co-Chairs.
16. At the request of the DHSC ISOU Co-Chairs, the sub-group may be invited to consider additional aspects related to XT, that have not already been identified or considered by the sub-group.
17. The Co-Chair or identified member of this sub-group who is also a member of ISOU will escalate to the DHSC ISOU Co-Chairs any requests for help or intervention that may be necessary to successfully discharge the duties of the sub-group.
18. The Co-Chair or identified member of this sub-group who is also a member of ISOU will provide regular updates at ISOU meetings.

Appendix:

Membership list:

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| 1. Prof John Iredale | Co-chair |
| 2. Anthony Clarkson | Co-chair (ISOU member) |
| 3. Prof Derek Manas | NHSBT rep (ISOU member) / Clinical (Liver) |
| 4. Dr Rommel Ramanan | NHSBT rep (ISOU member) / Research SME /Clinical (Kidney) |
| 5. Prof Lorna Marson | Research SME / Scotland rep / Clinical (Kidney) |
| 6. Prof Sara Fovargue | Legal SME |
| 7. Prof Anthony Wrigley | Ethics SME / lay rep |
| 8. Marius Berman | BTS rep / Clinical (Heart) |
| 9. Matthew Wellberry-Smith | BTS rep / Ethics SME |
| 10. Prof AW (Dan) Tucker | Veterinary / Zoonoses SME |
| 11. Prof Linda Scobie | Veterinary / Zoonoses SME |
| 12. Nicola Rose | MHRA rep / Regulation SME |
| 13. Louise Dineley | HTA rep / Regulation SME |
| 14. Margaret Harrison | Lay rep |
| 15. Fez Awan | Patient rep (Kidney) |
| 16. Nigel Dickinson | Patient rep (Heart) |

Observers

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| 1. Prof Anthony Dorling | Xenotransplantation SME |
| 2. Kevin Francis | Wales rep / Policy SME |
| 3. Joan Hardy | NI rep / Policy SME |
| 4. Vicky Gauden | Quality SME / NHSBT |
| 5. John Forsythe | ISOU Clinical Co-Chair |
| 6. Nick Mays | Policy Innovation Research Unit (PIRU) |
| 7. Mustafa Al-Haboubi | Policy Innovation Research Unit (PIRU) |
| 8. Dr Natasha Rogers | International observer (Australia) |
| 9. Dr Paul Manley | International observer (New Zealand) |
| 10. Prof Emanuele Cozzi | International observer (Italy) |
| 11. Prof Ralf Reinhard Tönjes | International observer (Germany) |
| 12. Prof Jean Christian Roussel | International observer (France) |
| 13. Dr Beatriz Dominguez-Gil | International observer (Spain) |
| 14. Dr Alicia Pérez Blanco | International observer (Spain) |