

Response to Moldenhauer, Johnson & Van Mieghem ISPD 2022 DEBATE: There should be formal accreditation and ongoing quality assurance/review for units offering fetal therapy that includes public reporting of outcomes.

MFAET, an international standardised medical terminology to support quality assurance/review for units offering fetal therapy.

Dear Editor

In their debate on formal accreditation and ongoing quality assurance/review for units offering fetal therapy, authors Johnson, Moldenhauer and Van Mieghem highlight the importance of communicating outcomes and results to be able to compare centre performance <sup>1</sup>. They point out that formal audit programs face considerable challenges not least that core outcome sets are only just becoming available for a few fetal conditions <sup>2-4</sup>. Without objective measures of performance, however it is difficult for fetal therapy programs to assess their quality despite strong recommendations from international societies to do so voluntarily.

In 2021, Prenatal Diagnosis journal published MFAET, the first terminology to define maternal and fetal adverse events, and capture information on complications which can occur during fetal interventions <sup>5</sup>. This system provides objective grading of a variety of fetal surgical complications including for example, fetal operative injury, procedural and post-procedural haemorrhage, fetal bradycardia/tachycardia and fetal fluid collection. The terms have been mapped to MedDRA, the Medical Dictionary of Regulatory Activities <sup>6</sup>, an international standardised medical terminology which facilitates sharing of information between regulators, healthcare professionals, patients and research organisations.

Although designed as a tool for clinical trials, MFAET provides a standardised comprehensive assessment of medical occurrences in observational studies. Complications are graded 1-5 from mild

with limited effect on the mother/fetus, to grade 4 life-threatening and grade 5 indicating death.

The system allows for the fact that some complications will have the potential to differentially affect the pregnant woman and the fetus, as some adverse events for example haemorrhage in pregnancy, preterm prelabour rupture of membranes and chorioamnionitis can be graded independently for the mother and fetus. Finally, the international consensus process that developed MFAET included patient input to ensure that it was relevant to all stakeholders of fetal therapy.

The MFAET adverse event terms have already been used to systematically classify maternal and fetal intervention-related complications following open fetal myelomeningocele repair in a large Swiss prospective cohort <sup>7</sup>. This allowed the team to assess their learning curve according to the complication rate and to observe for any correlation between life-threatening maternal and fetal complications.

While work is still ongoing to generate the necessary core outcome sets, we recommend MFAET to fetal therapy programs to quality assess and benchmark their practice. Resources to support its use are available here with options to recommend ways to improve the MFAET terminology system <sup>8</sup>.

Yours sincerely

Anna L David, Rebecca N Spencer on behalf of the MFAET Steering Committee

## References

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