SOUTH AFRICAN SOCIETY
OF ANAESTHESIOLOGISTS (SASA)

POSITION STATEMENT:

Intravenous Paracetamol Usage in Patients <33kg

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SASA notes with concern the reports of children receiving overdoses of intravenous paracetamol with subsequent liver compromise.

Intravenous paracetamol has been used extensively as part of perioperative analgesia in children, infants and neonates. Its use is recommended in national and international guidelines, and it has a long, well-established, and extensively documented safety record.

The package insert for the 100 ml vial of intravenous paracetamol, in all brands currently available in South Africa, states that the 100 ml vial should not be used in children <33kg, making the use of the 100 ml vial in these children, by definition, off label.

The concentration of the drug (10mg/ml) and the constitution thereof are identical in the 100ml and 50ml formulations. Due to regulatory and cost issues there are no 50ml bottles currently available in South Africa.

The use of intravenous paracetamol is considered an acceptable standard of care, and the benefits of its use outweigh the risks (with correct dosage and dose scheduling). Additionally, when used in the perioperative setting, it is not being used in an experimental capacity. As such, there should be no burden on the anaesthetist to seek additional consent for the prescription and administration of iv paracetamol. SASA therefore recommends that, as per our SASA Practice Guidelines 2022 edition (click here), it is expected practice for the anaesthetist to assume responsibility for the safe use of anaesthetic drugs. In this case, this then refers to the specific dosage calculation, appropriate prescription, and /administration of intravenous paracetamol to children <33kg in weight.

SASA will continue to engage with our members, the healthcare industry, our regulators, pharmacies, and hospital facility groups in order to improve the safety of intravenous paracetamol use perioperatively.

As an additional safety measure, we suggest that ward prescriptions are clearly written as both dosage (mg) and volume (ml) - e.g., 180mg (18ml) 6 hourly ivi - and that intravenous administration is changed to the oral route as soon as is feasible.

The above position statement is issued by the Regulation Business Unit, on behalf of the South African Society of Anaesthesiologists.