K2 Medical System / Athena Maternity System 'Customised Charts'

Review by GAP and Statistical Teams;
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K2 Medical Systems claim to have produced 'customised charts' which are equivalent to the Perinatal Institute's customised GROW charts referenced in the RCOG's SGA guidelines and in use in the majority of Trusts in the UK. We undertook a review of K2's supporting documents sent to us by users, and this revealed the following points of concern:

1. **Database:** K2 charts are based on less than 40,000 births while coefficients in GROW are derived from a database of over one million deliveries from 2015 – 2019 from over 120 NHS Trusts and Health Boards in the UK GAP programme.

2. **Ethnic groups:** K2 uses broad, non-specific ethnic categories such as White, Asian and Black, which are imprecise and misleading. For example, for a standard mother, the effect of South Asian ethnicity (e.g. Indian, Pakistani) on birthweight is the opposite to South East Asian, but both are listed under the category 'Asian'. GROW has >10 detailed, specific ethnic categories representing the main groups in the UK, as defined in the national maternity notes (www.preg.info).

3. **Maternal size:** No adjustments are made by K2 for maternal height and weight even though they are each strongly associated with birthweight, as repeatedly demonstrated in analyses of databases from many different countries. Adjustment for maternal size, controlled for BMI, has been shown to significantly improve the association between SGA and perinatal mortality, while lack of adjustment overestimates significant SGA in small mothers and underestimates it in large mothers: https://www.gestation.net/Value_of_cust_centiles-parity_and_maternal_size_BJOG_2009.pdf

4. A **'Target Weight'** is calculated by K2 on the basis of an unspecified formula which is not based on a multivariable analysis to adjust for confounding, as tried and tested for the last 25 years and validated repeatedly in international publications. We are in fact not aware of any publication that would validate the K2's idiosyncratic approach.

5. **SGA Limit**: Based on the data provided in K2's tables, we estimate that the target weight of a standard, 'white' mother in her first pregnancy is approximately 100g higher than that calculated by GROW. A 100g discrepancy is amplified to an approx. 40% variation at the 10th centile SGA limit (see http://onlinelibrary.wiley.com/doi/10.1046/j.1469-0705.1995.06030168.x/epdf ; Figure 2). This would mean that 40% of babies considered SGA according to K2 would not be SGA according to GROW, and their mothers will be subject to unnecessary anxiety, investigations and interventions.

In summary, K2's charts are not 'customised' along standard, peer reviewed and published methods; they are furthermore untested, unvalidated, and likely to produce the wrong SGA cut-offs for the assessment of babies at risk, with potentially serious clinical consequences.

Quality Assurance: Each application of the GROW software, as a stand-alone app or linked with local Maternity Information Systems, is comprehensively tested before release. Furthermore, supply of GROW is accompanied by training (Growth Assessment Protocol, GAP) to help ensure competency.

Evidence: We acknowledge a potential conflict of interest in this review; however there have also been many independent studies recommending our customised GROW charts, before and since the RCOG guidelines, while we are not aware of *any* published evidence in favour of K2 charts. For a recent review of GROW and GAP, see: http://perinatal.org.uk/pdfs/Cust_growth_charts_AJOG_2018.pdf .

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