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ORIGINAL ARTICLE

Analysis of Imprecision for Internal Quality Control of Newborn Screening by Tandem Mass Spectrometry in China, 2015 - 2021

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SUMMARY

Background: **This study aimed to assess the performance of the newborn screening laboratories in China through retrospective analysis of the coefficient of variation (CV) of the internal quality control (IQC) data in the national tandem mass spectrometry screening for inherited metabolic disorders in newborns.**
Methods: **From 2015 to 2021, the IQC data of amino acid and acylcarnitine test were collected twice each year. $CV_{monthly\ in\text{-}control}$ was calculated by excluding outliers for the current month and its discrete distribution and changes in trend were comprehensively evaluated for both normal and high concentration levels. The proportion of laboratories meeting both 1/3 and 1/4 quality criteria of the total error allowable (TEa), based on the $CV_{monthly\ in\text{-}control}$ for each testing item, was calculated.**
Results: **The analysis of $CV_{monthly\ in\text{-}control}$ for the two concentration levels for the amino acids and acylcarnitine parameters showed that $CV_{monthly\ in\text{-}control}$ for the normal concentration levels were more discrete before 2018, while $CV_{monthly\ in\text{-}control}$ for the high concentration levels were less discrete than the normal concentration levels, but there were relatively more outliers. More than 80% of laboratories were able to meet the 1/3 TEa standard for each test at the high concentration level, while the pass rate for the 1/4 TEa standard was significantly lower than 80% (except for C2).**
Conclusions: **According to the current status of testing in China, it is recommended to use 1/3TEa as the imprecision level standard; for laboratories with relatively high precision, the 1/4TEa standard can be used.**
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Supplementary Data

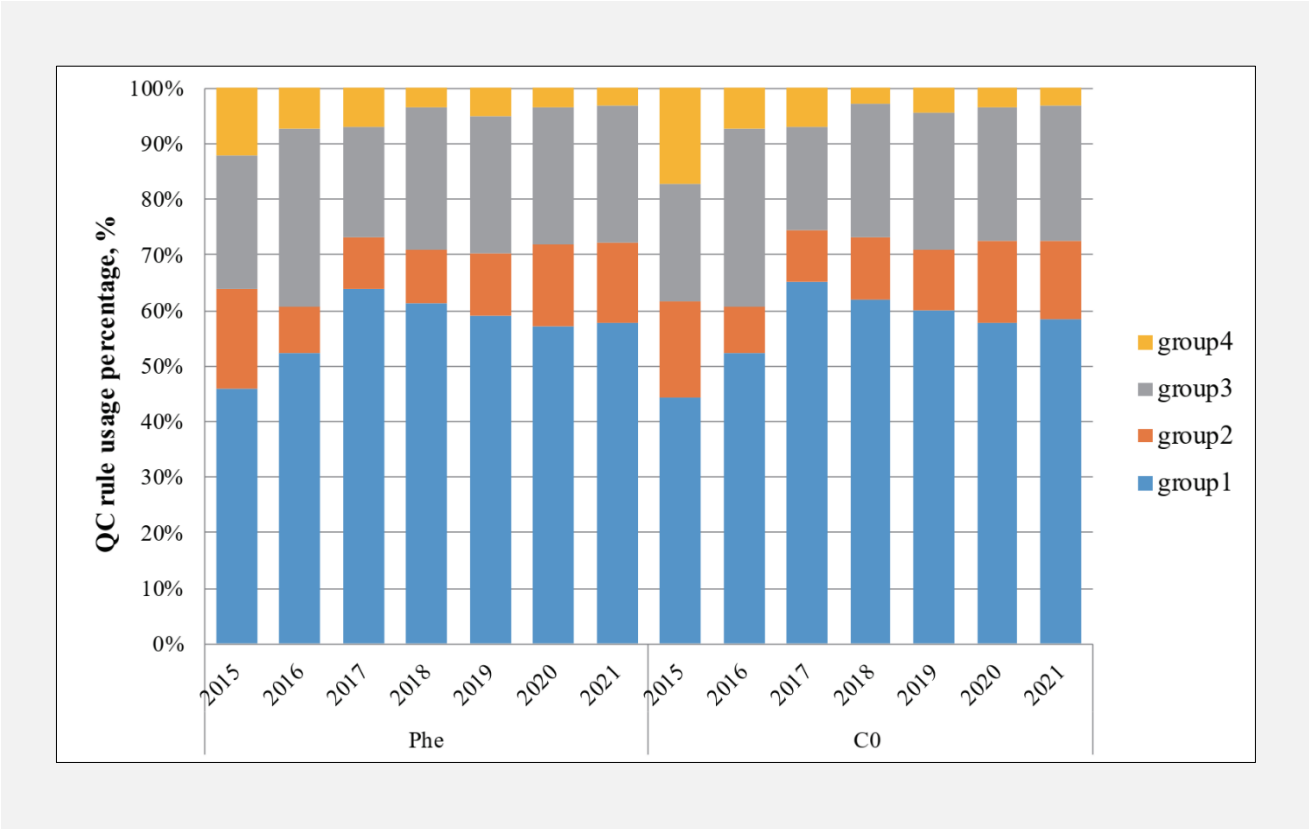

Figure 1. 2015 - 2021 phenylalanine (Phe) and free carnitine (C0) IQC quality control rule usage percentage (%).