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## Predictive value of fluorometric method and tandem mass spectrometry for hyperphenylalaninemia and its subtypes in China: A Systematic review and Meta-analysis

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Leng, QH<sup>8</sup>; Liu, SY<sup>9</sup>; He, CC<sup>10</sup>.**ADMINISTRATIVE INFORMATION****Support** - This study was supported by 2020 research topic of Sichuan Provincial Health Commission (No. 20PJ270) and 2019 Sichuan Medical Research project (No. S19027).**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202430036**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 March 2024 and was last updated on 11 March 2024.**INTRODUCTION**

**Review question / Objective** The present study aims to conduct a comprehensive meta-analysis to assess the predictive value of the fluorometric assay and tandem mass spectrometry (MS/MS) in the diagnosis of hyperphenylalaninemia (HPA) and its subtypes.

**Rationale** The present study aims to conduct a comprehensive meta-analysis to assess the predictive value of the fluorometric assay and tandem mass spectrometry (MS/MS) in the diagnosis of hyperphenylalaninemia (HPA) and its subtypes.

**Condition being studied** Patients with HPA.

**METHODS**

**Search strategy** “(((genetic[Title/Abstract] OR (screening[Title/Abstract])) AND ((hyperphenylalaninemia[Title/Abstract] OR (HPA[Title/Abstract]))) AND ((China[Title/Abstract] OR (Chinese[Title/Abstract]))” for Pubmed, “screening:ab,ti AND genetic:ab,ti AND (hyperphenylalaninemia:ab,ti OR hpa:ab,ti) AND (china:ab,ti OR chinese:ab,ti)” for Embase and “((genetic):ti,ab,kw OR (screening):ti,ab,kw) AND ((hyperphenylalaninemia):ti,ab,kw OR (HPA):ti,ab,kw) AND ((China):ti,ab,kw OR (Chinese):ti,ab,kw)” for Cochrane Library.

**Participant or population** patients with HPA“(((genetic[Title/Abstract] OR (screening[Title/Abstract])) AND ((hyperphenylalaninemia[Title/

Abstract]) OR (HPA[Title/Abstract])) AND ((China[Title/Abstract] OR (Chinese[Title/Abstract]))” for Pubmed, “screening:ab,ti AND genetic:ab,ti AND (hyperphenylalaninemia:ab,ti OR hpa:ab,ti) AND (china:ab,ti OR chinese:ab,ti)” for Embase and “((genetic):ti,ab,kw OR (screening):ti,ab,kw) AND ((hyperphenylalaninemia):ti,ab,kw OR (HPA):ti,ab,kw) AND ((China):ti,ab,kw OR (Chinese):ti,ab,kw)” for Cochrane Library.

**Intervention** Not applicable patients with HPA.

**Comparator** Not applicable.

**Study designs to be included** cross-sectional.

**Eligibility criteria** Inclusion criteria: the study type is cross-sectional; studies that reports the newborn screening and genetic features of patients with HPA; the language is limited to English. Exclusion criteria: repeated publication; studies without full text, incomplete information or inability to conduct data extraction; animal experiments; reviews and systematic reviews. the study type is cross-sectional; studies that reports the newborn screening and genetic features of patients with HPA; the language is limited to English.

**Information sources** We searched Pubmed, Embase, Cochrane Library from establishment of the database to Oct, 2023.

**Main outcome(s)** Screening positive rate, PPV, Incidence of HPA patients with BH4D, Incidence of HPA patients with PAHD.

**Quality assessment / Risk of bias analysis** The quality of evidence for each study was assessed by two independent researchers using Methodological index for non-randomized studies (MINORS) scale [12]. There are a total of 12 items, each with a score of 0-2 and a total score of 24. Studies were classified as moderate quality from 9 to 16 and high quality from 17 to 24.

**Strategy of data synthesis** All data analyzed by STATA (15.1, StataCorp LP, College Station, TX, USA) [13]. I<sup>2</sup> and Q test were used to evaluate heterogeneity. If the heterogeneity test is  $P \geq 0.1$  and  $I^2 \leq 50\%$ , it indicates that there is homogeneity between studies, and the fixed effects model is used for combined analysis; if  $P > 0.1$  and  $I^2 > 50\%$ , it indicates that there is heterogeneity and sensitivity analysis (A sensitivity analysis was conducted by eliminating each included study individually and performing a summary analysis of the remaining

studies) was used to find the source of heterogeneity. If the heterogeneity is still large, use the random effects model or give up the combination of results and use descriptive analysis. Funnel plot and Egger's test was used to assess the publication bias.

**Subgroup analysis** We performed a subgroup analysis of PPV based on different screening methods.

**Sensitivity analysis** A sensitivity analysis was conducted by eliminating each included study individually and performing a summary analysis of the remaining studies.

**Language restriction** English.

**Country(ies) involved** China.

**Keywords** Predictive value; Fluorometric method; Tandem mass spectrometry; Hyperphenylalaninemia; Systematic review and Meta-analysis.

#### Contributions of each author

Author 1 - Zhirong Shang - Author 1 drafted the manuscript.

Author 2 - Pan Xie - Author 2 drafted the manuscript.

Author 3 - Ke Pan - Author 3 drafted the manuscript.

Author 4 - Jialin Liu - The author provided statistical expertise.

Author 5 - Wei Xu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 6 - Yue Hu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 7 - Li Tang - Literature screening and data extraction.

Author 8 - Qinghua Leng - Literature screening and data extraction.

Author 9 - Shuyu Liu - Literature quality assessment.

Author 10 - Chengchuan He - The author read, provided feedback and approved the final manuscript.