**Supplementary Table 3: The working tools of the QMIP-NBS for NBS agencies.**

| **Indicators** | **Questionnaires** | **Investigation methods** | **Scoring criteria** | **Scores** |
| --- | --- | --- | --- | --- |
| **I. Organizational Management** |  |  |  |  |
| (I) Institutional settings and management requirements |  |  |  |  |
| 1. Does the institutional setting meet the requirements? | (1) Did your organization obtain the health administrative approval from the health administration of the provinces, autonomous regions, and municipalities directly under the central government: A. YES B. NO | Check relevant documents on site and the annual screening test volume in the last 3 years. | Question (1) chooses to get 5 points, if chooses B, all the following indicators are not scored. |  |
| (2) The average annual screening amount of your institution in the past 3 years is >30,000: A. YES B. NO | Question (2) chooses A to get 5 points, and choose B to get no points. |  |
| 2. Does the management of the cooperating blood collection agencies meet the requirements? | (1) Evaluate the blood collection quality of the cooperating blood collection institutions at least once a year: A. YES B. NO | View blood collection quality assessment records and training records on site. | Question (1) chooses A to get 5 points, and choose B to get no points. |  |
| (2) Regularly conduct (at least once a year) NBS related knowledge training for blood collection agencies: A. YES B. NO | Question (2) chooses A to get 5 points, and choose B to get no points. |  |
| 3. Is there a specialist clinic for NBS? | (1) Is there specialist outpatient clinics or designated specialists to diagnose and treat neonatal screening diseases: A. YES B. NO | Ask and view the clinics or specialists on site. | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (II) Personnel requirements |  |  |  |  |
| 4. Do the qualifications of the director of the NBS center meet the requirements? | The qualifications of the person in charge of the newborn screening laboratory should meet the following requirements of the “Technical Specifications for Newborn Disease Screening”: | On-site inquiries and check the training qualification certificate, education, or professional title of the person in charge. |  |  |
| (1) Medical-related bachelor’s degree or above: A. YES B. NO | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) Senior professional title: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| (3) Experience in pediatrics or clinical laboratory work: A. YES B. NO | Question (3) Choose A to get 4 points, and choose B to get no points. |  |
| (4) Have engaged in NBS work for >5 years: A. YES B. NO | Question (4) Choose A to get 5 points, and choose B to get no points. |  |
| (5) Master the operation and management of the NBS service: A. YES B. NO | Question (5) Choose A to get 5 points, and choose B to get no points. |  |
| 5. Do the laboratory technicians meet the requirements/qualifications? | (1) Number of laboratory technicians: ; The number of personnel whose qualifications meet the requirements: . | Check the number of laboratory technicians, training qualification certificates, academic qualifications, or professional titles on site, and examine their basic professional knowledge and skills. | At least one laboratory technician meets the requirements to get 2 points. |  |
| 6. Whether the diagnosing and treating clinicians meet the requirements/qualifications? | The qualifications of the personnel should meet the qualification requirements： | Check the number of diagnosing and treating clinicians and their qualification certificates and relevant materials on site. |  |  |
| (1) Must meet the qualifications of practicing physicians: A. YES B. NO | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) Have intermediate or above pediatric clinical professional titles: A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| (3) Have knowledge of inherited metabolic diseases, endocrinology and other relevant knowledge and have passed NBS skills trainings: A. YES B. NO | Question (3) Choose A to get 2 points, and choose B to get no points. |  |
| 7. Do personnel engaged in NBS receive continuing education? | (1) Number of personnel engaged in NBS: ; Number of NBS personnel who have received at least one training: . | View training qualification certificates or credits on site. | All personnel engaged in the NBS must have received at least one training to get 2 points. |  |
| (III) Laboratory construction requirements |  |  |  |  |
| 8. Does the laboratory instruction meet the requirements? | The laboratory site for NBS should meet the following requirements: | View the laboratory room, comprehensive room, DBS storage room or cold storage on site, and view the laboratory’s work zone, space layout, various signs, temperature records, and humidity records. |  |  |
| (1) There’re 2 laboratory rooms with a usable area of at least 40 square meters: A. YES B. NO | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) There’re 2 comprehensive rooms with at least 20 square meters for DBS check and acceptance, computer entry, and data registration and preservation: A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| (3) There’s 1 DBS storage room or cold storage room for long-term storage of DBS: A. YES B. NO | Question (3) Choose A to get 2 points, and choose B to get no points. |  |
| (4) The house area can be appropriately increased according to the amount of and the types of diseases to be screened: A. YES B. NO | Question (4) Choose A to get 2 points, and choose B to get no points. |  |
| (5) The laboratory’s working partitions are reasonably set up: A. YES B. NO | Question (5) Choose A to get 2 points, and choose B to get no points. |  |
| (6) The space layout is convenient for the experiment process: A. YES B. NO | Question (6) Choose A to get 2 points, and choose B to get no points. |  |
| (7) The identification in the laboratory is clear: A. YES B. NO | Question (7) Choose A to get 2 points, and choose B to get no points. |  |
| (8) Temperature and humidity records are available: A. YES B. NO | Question (8) Choose A to get 2 points, and choose B to get no points. |  |
| 9. Does the equipment configuration meet the requirements? | The configuration of the experimental equipment should comply with the following requirements: | View laboratory equipment configuration on site. |  |  |
| (1) At least 1 microplate reader or fluorescence analyzer for experimental testing: A. YES B. NO | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) At least one plate washing instrument for washing the experimental plate: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| (3) At least one oscillator for mixing experimental reagents: A. YES B. NO | Question (3) Choose A to get 1 points, and choose B to get no points. |  |
| (4) At least one computer (including printers) for data processing: A. YES B. NO | Question (4) Choose A to get 1 points, and choose B to get no points. |  |
| (5) At least 1 thermostat or water bath for experimental thermostatic treatment: A. YES B. NO | Question (5) Choose A to get 1 points, and choose B to get no points. |  |
| (6) At least one 2 – 8 °C refrigerator for reagent storage: A. YES B. NO | Question (6) Choose A to get 1 points, and choose B to get no points. |  |
| (7) At least 2 multichannel samplers for experimental sampling: A. YES B. NO | Question (7) Choose A to get 1 points, and choose B to get no points. |  |
| (8) At least 2 singlechannel sampler for experimental sampling: A. YES B. NO | Question (8) Choose A to get 1 points, and choose B to get no points. |  |
| (9) Have Puncher for punching DBS: A. YES B. NO | Question (9) Choose A to get 1 points, and choose B to get no points. |  |
| (10) At least one ultraclean worktable for experimental operation of bacterial inhibition methods: A. YES B. NO | Question (10) Choose A to get 1 points, and choose B to get no points. |  |
| (11) Have general low-value laboratory supplies: A. YES B. NO | Question (11) Choose A to get 1 points, and choose B to get no points. |  |
| (IV) Rules construction |  |  |  |  |
| 10. Are there ideal and constantly updated personnel rules? | (1) There is a personnel position responsibility rule and it is constantly updated: A. YES B. NO | View materials on personnel management related rules on site. | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) There is personnel conduct code and it is constantly updated: A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| 11. Are there ideal and constantly updated rules for the diagnosis and treatment of IEMs? | (1) The diagnosis and treatment rules for inherited metabolic diseases complies with the “Technical Standards for Screening Neonatal Diseases” and is continuously updated: A. YES B. NO | View rules related to the diagnosis and treatment of inherited metabolic diseases on site. | Question (1) Choose A to get 4 points, and choose B to get no points. |  |
| 12. Are there ideal and constantly updated rules for case management? | (1) There is a referral rule and it is constantly updated: A. YES B. NO | View rules related to the case management on site. | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) There is a recall and follow-up rule and it is constantly updated: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| (3) There is a statistical summary and reporting rule and it is constantly updated: A. YES B. NO | Question (3) Choose A to get 1 points, and choose B to get no points. |  |
| 13. Are there ideal and constantly updated rules for archives management? | (1) There is a file management rule for confirmed patients and it is constantly updated: A. YES B. NO | View rules related to archives management on site. | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) There is an information management and security rule for confirmed patients and it is constantly updated: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| 14. Are there ideal and constantly updated rules for laboratory equipment and specimen management? | (1) There is a rule for equipment management: A. YES B. NO | View rules related to laboratory equipment and specimen management on site. | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) There is a rule for reagents and materials management: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| (3) There is a rule for specimen registration and preservation: A. YES B. NO | Question (3) Choose A to get 1 points, and choose B to get no points. |  |
| (V) Information system construction |  |  |  |  |
| 15. Is there a well-established information system for screening data management? | (1) There is a neonatal screening information system: A. YES B. NO | View the neonatal screening information system on site. | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) The whole process, from blood collection to reporting, is computerizedt: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| (3) There is an information module for preliminary screening: A. YES B. NO | Question (3) Choose A to get 1 points, and choose B to get no points. |  |
| (4) There is an information module for preliminary diagnosis: A. YES B. NO | Question (4) Choose A to get 1 points, and choose B to get no points. |  |
| 16. Is there a well-established information system for case records, diagnosis and treatment, and follow-up management? | (1) There is an information system for the diagnosis and treatment of inherited metabolic diseases: A. YES B. NO | View the information system for the diagnosis and treatment on site. | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) The entire process, from rescreening (confirmation) and diagnosis to follow-up, is computerized: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| (3) There is a complete information module for recall : A. YES B. NO | Question (3) Choose A to get 2 points, and choose B to get no points. |  |
| **II. Screening Management** |  |  |  |  |
| (VI) Prescreening health education and publicity |  |  |  |  |
| 17. Does the informed consent meet the requirements? | Informed consent should meet the requirements, and the following contents should be included: | View the informed consent on site. |  |  |
| (1) There are name of the mother, neonatal sex, date of birth and medical record number of hospitalization in the informed consent: A. YES B. NO | Question (1) Choose A to get 0.5 points, and choose B to get no points. |  |
| (2) There are sections for popularizing newborn screening health education publicity and related policies: A. YES B. NO | Question (2) Choose A to get 0.5 points, and choose B to get no points. |  |
| (3) There is a section for informed choice of the family member of the child, including the signature and date of the signature by the guardian: A. YES B. NO | Question (3) Choose A to get 0.5 points, and choose B to get no points. |  |
| (4) If the newborn’s guardians do not agree to the screening after the neonatal screening health education, the guardians are informed of the possible adverse consequences of disease: A. YES B. NO | Question (4) Choose A to get 0.5 points, and choose B to get no points. |  |
| (5) If the newborn’s guardians do not agree to accept the neonatal screening, the guardian’s signature, signature date, current address and contact information are recorded: A. YES B. NO | Question (5) Choose A to get 0.5 points, and choose B to get no points. |  |
| (6) There is a medical (caregiver) statement section (example statement: I have informed the caregiver of the nature, purpose, risk, necessity and cost of genetic metabolic disease screening, and have answered any questions related to this examination), medical (caregiver) signature, and date of the signature: A. YES B. NO | Question (6) Choose A to get 0.5 points, and choose B to get no points. |  |
| (VII) Pretesting quality control |  |  |  |  |
| 18. Do the consumable materials for blood collection meet the requirements? | (1) The filter paper for the DBS sample making has been approved by the Food and Drug Administration department for registration or filing: A. YES B. NO | Check the Food and Drug Administration department approval registration or filing documents of the filter paper on site. | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| 19. Do the equipment and reagents meet the requirements? | (1) Equipment and reagents for NBS have approval registration or filing: A. YES B. NO | View the approval or registration documents of instruments and equipment and reagents, records of the use, maintenance and calibration of instruments and equipment, and the inbound and outbound records of reagents. | Question (1) Choose A to get 1 points, and choose B to get no points. |  |
| (2) There are records for equipment maintaining: A. YES B. NO | Question (2) Choose A to get 1 points, and choose B to get no points. |  |
| (3) There are inbound and outbound records for all reagents: A. YES B. NO | Question (3) Choose A to get 1 points, and choose B to get no points. |  |
| (4) Is the instrument calibrated annually: A. YES B. NO | Question (4) Choose A to get 1 points, and choose B to get no points. |  |
| 20. Completeness of specimen information. | (1) There are records for specimens acceptance, and the records record the time of receipt of the specimens, the number of specimens, and the state of the specimens: A. YES B. NO | Randomly check specimens acceptance records and five specimens and their information cards on site. | Question (1) Choose A to get 4 points, and choose B to get no points. |  |
| (2) Check 5 specimens and their order information cards on site, the number of specimens with complete information cards: . (a complete application form must include the following: date of birth of the child, mother’s name, gender, weight, and gestational age of the child, date of blood collection, and blood collector) | In question (2), 10 points can only be scored if the contents of the 5 information cards are completed; otherwise, 2 points are deducted for each missing item in each information card, until 10 points are deducted. |  |
| 21. Unqualified specimen rate. | (1) The number of the quarterly □ or yearly □ specimens: , in which the number of unqualified specimens: , and the unqualified specimen rate: . | Check the information system; quarterly or yearly as the statistical cycle (in the statistical cycle, the number of accepted specimens must be >1000), count the number of unqualified specimens and the total number of samples, calculated the rate according to the calculation formula: the unqualified specimen rate = number of nonconforming specimens/total number of specimens in the same period × 100%. | If the unqualified specimen rate＜0.5%, 10 points are scored. If 0.5%≤ the unqualified specimen rate <1%, 5 points are scored. If the unqualified specimen rate ≥1%, no point is scored. |  |
| 22. Recollection rate of unqualified specimens. | (1) The number of the quarterly □ or yearly □ unqualified specimens: , in which the number of the specimens recollected within 42 days: , the recollection rate of unqualified specimens: . | Check the information system; quarterly or yearly as the statistical cycle, count the number of unqualified specimens and the number of specimens recollected within 42 days, calculated the rate according to the calculation formula: the number of recollected specimens within 42 days/the number of unqualified specimens×100%. | If the recollection rate of unqualified specimens >90%, 10 points are scored. If 80%≤ the recollection rate of unqualified specimens ≤90%, 5 points are scored. If the recollection rate of unqualified specimens＜80%, no points are scored. |  |
| 23. Specimen turnaround time before testing. | (1) The median of the time from the collection of the DBS sample to the receipt of the DBS sample in the laboratory (annual statistics) ≤5 work days: A. YES B. NO | Check the relevant statistical reports or other materials of the institution; quarterly or yearly as the statistical cycle, count the time taken from the delivery of the specimen to the laboratory to receive the specimen (the most recent year) for every specimens in the statistical cycle, take the median. | If YES, 10 points are scored. Otherwise, no point is scored. |  |
| 24. Intime-delivery rate of specimens. | (1) The total number of specimens collected during the annual screening: , the number of specimens transported within 5 working days: , and the timely rate of blood film turnover before testing: . | Check the relevant statistical reports or survey reports of the institution; yearly as the statistical cycle, count the time taken from the delivery of the specimen to the laboratory to receive the specimen (the most recent year) for every specimens in the statistical cycle, and then calculate the total number of annual specimens and the number of specimens transported within 5 days, the intime-delivery rate of specimens = the number of specimens delivered within 5 working days/total number of specimens × 100% (annual statistics). | If the rate is > 90%, 16 points are scored. If 80%≤ the rate ≤90%, 8 points are scored. If the rate＜80%, no points are scored. |  |
| (VIII) Testing quality control |  |  |  |  |
| 25. Completeness of the laboratory testing SOP. | (1) There are SOPs for the collection, storage and processing of DBS: A. YES B. NO | Check the relevant SOP files on site and randomly observe the operation of a laboratory technician to check whether each operation stage is consistent with the actual SOPs. | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) Does DBS processing meet the SOP: A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| (3) There is an SOP for the use of testing technology and/or testing equipment: A. YES B. NO | Question (3) Choose A to get 2 points, and choose B to get no points. |  |
| (4) Does the uso of testing technology and/or testing equipment meet the SOP: A. YES B. NO | Question (4) Choose A to get 2 points, and choose B to get no points. |  |
| (5) There is a quality control rule for the collection and making process of DBS: A. YES B. NO | Question (5) Choose A to get 2 points, and choose B to get no points. |  |
| (6) There is a quality control rule for the acceptance of DBS samples: A. YES B. NO | Question (6) Choose A to get 2 points, and choose B to get no points. |  |
| (7) Does the biosafety SOP comply with the relevant laboratory biosafety guidelines (refer to “WS/T 442-2014 Clinical Laboratory Biosafety Guidelines”): A. YES B. NO | Question (7) Choose A to get 2 points, and choose B to get no points. |  |
| 26. Is the performance of laboratory measurement systems checked regularly? | (1) The laboratory periodically (every 2 years) verifies the analytical performance of the confirmed measurement systems: A. YES B. NO | Check the performance verification records or related materials of the detection system on site. | Question (1) Choose A to get 4 points, and choose B to get no points. |  |
| 27. Is internal quality control for testing performed regularly? | (1) Number of testing items which has the internal quality control: . | View the quality control records (including original quality control data). | Question (1) If the number of test items is ≥2, 3 points are scored, and <2 is not scored. |  |
| (2) The frequency of internal quality control for Phe testing: . | For questions (2) and (3), the quality control frequency of each plate is ≥1 time to get 3 points, and the frequency of <1 plate is not to be scored. |  |
| (3) The frequency of internal quality control for TSH testing: . |  |
| (4) The number of the concentration level in each plate for quality control: . | Question (4), if the quality control level of each plate is ≥2 concentrations, 3 points are scored, and if the quality control level of each plate is <2 concentrations, no point is scored. |  |
| 28. Does the internal quality control for PKU and TSH laboratory testing meet the requirements? | (1) There is quality control chart for internal quality control: A. YES B. NO | View the quality control charts, out-of-control analysis records or reports, and corrective measures in the most recent year. | Question (1) Choose A to get 4 points, and choose B to get no points. |  |
| (2) There are analysis records or reports of the reasons for the loss of internal quality control: A. YES B. NO | Question (2) Choose A to get 4 points, and choose B to get no points. |  |
| (3) There are corrective measures after the loss of internal quality control: A. YES B. NO | Question (3) Choose A to get 4 points, and choose B to get no points. |  |
| 29. Does the CV of Phe testing meet the requirements? | (1) For Phe, the accumulated CV% are in control for at least half a year: A. YES B. NO | View relevant statistical reports or survey reports, quality control information in the most recent year. | Question (1) Choose A to get 9 points, and choose B to get no points. |  |
| (2) For Phe, the accumulated CV% are not >1/3 of the total allowable error of the EQA: A. YES B. NO | Question (2) Choose A to get 9 points, and choose B to get no points. |  |
| 30. Does the CV of TSH testing meet the requirements? | (1) For TSH, the accumulated CV% are in control for at least half a year: A. YES B. NO | View relevant statistical reports or survey reports, quality control information in the most recent year. | Question (1) Choose A to get 9 points, and choose B to get no points. |  |
| (2) For TSH, the accumulated CV% are not >1/3 of the total allowable error of the EQA: A. YES B. NO | Question (2) Choose A to get 9 points, and choose B to get no points. |  |
| 31. Status of the participation of EQA. | (1) The number of NBS testing items participating in NCCL EQA activities each year: . The participating frequency of EQA for PKU: . The participating frequency of EQA for TSH: . | Check the participating records of the EQA this year or the previous year, and use the annual as the statistical cycle to count the number of NBS testing items that participated in the EQA. | If the number of items is equal to 2, 10 points are scored, and 10 points are deducted for <2 items. 5 points for each item whose participation frequency is ≥1 time per year, 5 points are deducted for 0 participation. |  |
| 32. EQA passing status of the Phe testing. | (1) Obtained a certificate: A. YES B. NO | View related materials of this year’s or previous year’s EQA. | Question (1) Choose A to get 10 points, and choose B to deduct 10 points. |  |
| 33. EQA passing status of the TSH testing. | (1) Obtained a certificate: A. YES B. NO | View related materials of this year’s or previous year’s EQA. | Question (1) Choose A to get 10 points, and choose B to deduct 10 points. |  |
| (IX) Posttesting quality control |  |  |  |  |
| 34. Rate of timely issued testing reports. | (1) The number of the quarterly □ or yearly □ issued reports: , in which the number of the reports issued within 5 working days from the date of receiving qualified DBS samples: , the percentage of reports issued by the laboratory within 5 working days from the date of receiving qualified DBS samples to the total reports: . | Check the information system or relevant statistical reports or survey reports; quarterly or yearly as the statistical cycle, count the number of the issued reports and the number of the reports issued within 5 working days from the date of receiving qualified DBS samples, calculated the rate according to the calculation formula: rate of timely issued testing reports = the number of the reports issued within 5 working days from the date of receiving qualified DBS samples/the number of issued reports in a statistical cycle×100%. | If the rate is 100%, 10 points are scored. If the rate is between ≥90% and <100%, 5 points are scored. If the rate is between ≥80% and <90%, no points are scored. If the rate is <80%, 5 points are deducted. |  |
| 35. The standardization of testing reports. | The test report should contain the following information: | Check the information system and testing report (mainly look at the template). |  |  |
| (1) the mother’s name: A. YES B. NO | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) child’s age: A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| (3) child’s birth date: A. YES B. NO | Question (3) Choose A to get 2 points, and choose B to get no points. |  |
| (4) identification number: A. YES B. NO | Question (4) Choose A to get 2 points, and choose B to get no points. |  |
| (5) date of sampling, testing, and report issued: A. YES B. NO | Question (5) Choose A to get 2 points, and choose B to get no points. |  |
| (6) screening testing results: A. YES B. NO | Question (6) Choose A to get 2 points, and choose B to get no points. |  |
| (7) tester and results reviewer’s signature: A. YES B. NO | Question (7) Choose A to get 2 points, and choose B to get no points. |  |
| (8) The reviewer has intermediate or above technical titles/positions: A. YES B. NO | Question (8) Choose A to get 2 points, and choose B to get no points. |  |
| 36. Are there quality control measures when issuing reports? | (1) The process of report issuance includes quality control measures to reduce errors, such as a review of the test results, a review of sample information, etc.: A. YES B. NO | On-site inquiry/observation of laboratory personnel how to ensure the quality of the inspection report. | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) There is SOP document for the quantitative and qualitative judgment of the screening results of neonatal genetic metabolic diseases: A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| (3) Do the quantitative and qualitative judgments of the screening results of neonatal genetic and metabolic diseases meet the SOP documents formulated by the institution: A. YES B. NO | Question (3) Choose A to get 2 points, and choose B to get no points. |  |
| (4) There is quality control rule for the recall process of NBS positive specimens: A. YES B. NO | Question (4) Choose A to get 2 points, and choose B to get no points. |  |
| 37. Notification rate of children with positive PKU testing results. | (1) The number of notified children with positive PKU screening results in the quarter: , and the total number of children with positive PKU screening results during the same period: , notification rate of children with positive PKU testing results: . | Check the relevant records, such as telephone records and other information records; take quarter as the statistical cycle, count the number of notified children with positive PKU screening results in the quarter and the total number of children with positive PKU screening results during the same period, calculated the rate according to the calculation formula: notification rate of children with positive PKU testing results = the number of notified children with positive PKU screening results during the same period/the total number of children with positive PKU screening results in a statistical cycle×100%. | 20 points are scored for the notification rate of 100%, and 20 points are deducted for the notification rate <100%. |  |
| 38. Notification rate of children with positive CH test results. | (1) The number of notified children with positive CH screening results in the quarter: , and the total number of children with positive CH screening results during the same period: , notification rate of children with positive CH testing results: . | Check the relevant records, such as telephone records and other information records; take quarter as the statistical cycle, count the number of notified children with positive CH screening results in the quarter and the total number of children with positive CH screening results during the same period, calculated the rate according to the calculation formula: notification rate of children with positive CH testing results = the number of notified children with positive CH screening results during the same period/the total number of children with positive CH screening results in a statistical cycle×100%. | 20 points are scored for the notification rate of 100%, and 20 points are deducted for the notification rate <100%. |  |
| 39. Recall rate of children with positive PKU test results. | (1) The number of the quarterly □ or yearly □ children with positive PKU screening results: , in which the number of recalled children with positive PKU screening results: , recall rate of children with positive PKU test results: . | Check the relevant records, such as telephone records and information system; take annual or quarter as the statistical cycle, count the number of children with positive PKU screening results and the total number of recalled children with positive PKU screening results during the same period, calculated the rate according to the calculation formula: recall rate of children with positive PKU test results = the number of recalled children with positive PKU screening results during the same period/the total number of children with positive PKU screening results in a statistical cycle × 100%. | If the rate is >90%, 20 points are scored. If the rate is between ≥80% and <90%, 10 points are scored. If the rate is between ≥70% and <80%, 5 points are scored. If the rate is between ≥60% and <70%, 2 points are scored. If the rate is <60%, no point is scored. |  |
| 40. Recall rate of children with positive CH test results. | (1) The number of the quarterly □ or yearly □ children with positive CH screening results: , in which the number of recalled children with positive CH screening results: , recall rate of children with positive CH test results: . | Check the relevant records, such as telephone records and information system; take annual or quarter as the statistical cycle, count the number of children with positive CH screening results and the total number of recalled children with positive CH screening results during the same period, calculated the rate according to the calculation formula: recall rate of children with positive CH test results = the number of recalled children with positive CH screening results during the same period/the total number of children with positive CH screening results in a statistical cycle × 100%. | If the rate is >90%, 20 points are scored. If the rate is between ≥80% and <90%, 10 points are scored. If the rate is between ≥70% and <80%, 5 points are scored. If the rate is between ≥60% and <70%, 2 points are scored. If the rate is <60%, no point is scored. |  |
| 41. Positive predictive value of PKU screening testing. | (1) The number of the quarterly □ or yearly □ recalled children with positive PKU screening results: , in which the number of confirmed children with positive PKU screening results: , positive predictive value of PKU screening testing: . | Check the relevant records, such as telephone records and information system; take annual or quarter as the statistical cycle, count the number of recalled children with positive PKU screening results and the number of confirmed children with positive PKU screening results during the same period, calculated the rate according to the calculation formula: positive predictive value of PKU screening testing = the number of confirmed children with positive PKU screening results during the same period/the number of recalled children with positive PKU screening results in a statistical cycle × 100%. | If positive predictive value is >0.08, 5 points are scored. If the value is between ≥0.05 and <0.08, 2 points are scored. If the value is <0.05, no point is scored. |  |
| 42. Positive predictive value of CH screening testing. | (1) The number of the quarterly □ or yearly □ recalled children with positive CH screening results: , in which the number of confirmed children with positive CH screening results: , positive predictive value of CH screening testing: . | Check the relevant records, such as telephone records and information system; take annual or quarter as the statistical cycle, count the number of recalled children with positive CH screening results and the number of confirmed children with positive CH screening results during the same period, calculated the rate according to the calculation formula: positive predictive value of CH screening testing = the number of confirmed children with positive CH screening results during the same period/the number of recalled children with positive CH screening results in a statistical cycle × 100%. | If positive predictive value is >0.08, 5 points are scored. If the value is between ≥0.05 and <0.08, 2 points are scored. If the value is <0.05, no point is scored. |  |
| 43. False negative rate of PKU screening testing. | (1) The number of the quarterly □ or yearly □ confirmed PKU patients: , in which the number of PKU patients with negative screening results: , false negative rate of PKU screening testing: . | Check the information system or relevant statistical reports or survey reports; take annual or quarter as the statistical cycle, count the number of confirmed PKU patients and the number of PKU patients with negative screening results during the same period, calculated the rate according to the calculation formula: false negative rate of PKU screening testing = the number of PKU patients with negative screening results during the same period/the number of confirmed PKU patients in a statistical cycle×100%. | If the false negative rate is <0.3, 5 points are scored. If the rate is between ≥0.3 and ≤0.8, 2 points are scored. If false negative rate is >0.8, no point is scored. |  |
| 44. False negative rate of CH screening testing. | (1) The number of the quarterly □ or yearly □ confirmed CH patients: , in which the number of CH patients with negative screening results: , false negative rate of CH screening testing.: . | Check the information system or relevant statistical reports or survey reports; take annual or quarter as the statistical cycle, count the number of confirmed CH patients and the number of CH patients with negative screening results during the same period, calculated the rate according to the calculation formula: false negative rate of CH screening testing = the number of CH patients with negative screening results during the same period/the number of confirmed CH patients in a statistical cycle×100%. | If the false negative rate is <0.3, 5 points are scored. If the rate is between ≥0.3 and ≤0.8, 2 points are scored. If false negative rate is >0.8, no point is scored. |  |
| (X) Follow up |  |  |  |  |
| 45. Positive (or negative) follow-up rate. | (1) The number of the follow-ups: , in which the number of positive follow-ups: , the number of negative follow-ups: , the positive follow-up rate: , the negative follow-up rate: . | Check the relevant statistical reports or survey reports; randomly check the follow-up records for 1 month, count the number of follow-ups and the number of positive follow-ups and the number of negative follow-ups. The positive (or negative) follow-up rate = the number of positive (or negative) follow-ups/the total number of follow-ups. | If the rate is between ≥90% and ≤100%, 3 points are scored. If the rate is between ≥60% and <90%, 2 points are scored. If the rate <60%, no point is scored. |  |
| (XI) Preservation of testing files and specimens |  |  |  |  |
| 46. Does the storage of testing files meet the requirements? | (1) The original data of each test result includes standard curve, quality control results, screening results: A. YES B. NO | View the testing files on site. | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) Laboratory testing files are kept intact and backed up electronically or with paper data in a timely manner and kept for 10 years: A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| 47. Does the specimen storage meet the requirements? | (1) The specimens are stored at 2～8℃ (the laboratory can be stored <0℃ if conditions permit) : A. YES B. NO | Check the storage conditions of the specimens on site; randomly check 10 samples. | Question (1) Choose A to get 10 points, and choose B to get no points. |  |
| (2) Randomly check 10 samples, and the number of samples that have undergone NBS within 5 years: . | In question (2), randomly check 10 samples, find 1 sample that has undergone NBS within 5 years, and get 1 point; if not find 1 sample that has undergone NBS within 5 years, then 1 point will be deducted. |  |
| **III. Diagnosis and treatment management** |  |  |  |  |
| (XII) Case diagnosis |  |  |  |  |
| 48. The standardization of medical records. | (1) All positive screening tests have a clear confirmed diagnosis: A. YES B. NO | View diagnostic medical records on site. | Question (1) Choose A to get 2 points, and choose B to get no points. |  |
| (2) The case writing is standardized, and the content of the diagnostic medical record includes the date of assessment of the screening results, the date of diagnosis/case treatment, the date of treatment/intervention (if feasible), the confirmed diagnosis results, and the treatment results of the case (Intervention, no intervention, follow-up disappearance): A. YES B. NO | Question (2) Choose A to get 2 points, and choose B to get no points. |  |
| 49. Rate of standard diagnosis of PKU. | (1) The number of standardized diagnoses of PKU in the number of children with positive PKU screening results: , the number of children with positive PKU screening results: , rate of standard diagnosis of PKU: . | Randomly check the relevant medical records; count the number of standardized diagnoses of PKU and the number of children with positive PKU screening results, and calculate according to the formula: Rate of standard diagnosis of PKU = PKU standard diagnosis number/ the number of children with positive PKU screening results × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
|  |  | The samples of this spot check are suitable for the investigation of **the following** diagnosis and treatment quality management indicators. **Random sampling rules**: |  |  |
|  |  | (1) Number of random samples: 10 random samples (cases/records) are selected for institutions with a screening volume of 30,000–50,000; 15 samples are randomly selected for institutions with a screening volume of >50,000–100,000; 20 samples are randomly selected for institutions with a screening volume of >100,000. |  |  |
|  |  | (2) Quantitative characteristics: random check of cases after 2014, and proportionally check different age groups, that is, the number of cases of children under 1-year-old in the random check should not account for 50% of the total number of random checks; cases of children aged 3–5 should account for the random check 30% of the total; cases of children over 6 years old should account for 10% of the total number of random checks, if <10%, cases of children aged 3–6 years old for a supplement. |  |  |
| 50. Proportion of PKU patients diagnosed at the newborn stage. | (1) The number of PKU patients who were screened and diagnosed during the neonatal period (28 days after birth): , the number of PKU children: , proportion of PKU patients diagnosed at the newborn stage: . | View case records in the information system; count the number of confirmed cases of PKU children in the neonatal period, and the number of confirmed cases of PKU children who are randomly checked, and calculate as follows: the number of children with PKU diagnosed in the neonatal period/the number of children with diagnosed PKU × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 51. Rate of standard diagnosis of CH. | (1) The number of standardized diagnoses of CH in the number of children with positive CH screening results: , the number of children with positive CH screening results: , rate of standard diagnosis of CH: . | Randomly check the relevant medical records; count the number of standardized diagnoses of CH and the number of children with positive CH screening results, and calculate according to the formula: rate of standard diagnosis of CH = CH standard diagnosis number/ the number of children with positive CH screening results × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 52. Proportion of CH patients diagnosed at the newborn stage. | (1) The number of CH patients who were screened and diagnosed during the neonatal period (28 days after birth): , the number of CH children: , proportion of CH patients diagnosed at the newborn stage: . | View case records in the information system; count the number of confirmed cases of CH children in the neonatal period, and the number of confirmed cases of CH children who are randomly checked, and calculate as follows: the number of children with CH diagnosed in the neonatal period/the number of children with diagnosed CH × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| (XIII) Treatment and follow-up |  |  |  |  |
| 53. Proportion of standard treatment for PKU patients. | (1) The number of children with PKU who were treated according to the “Technical Specifications for Newborn Disease Screening”: , the number of children diagnosed with PKU: , proportion of standard treatment for PKU patients: . | View case records in the information system; count the number of children with PKU who were treated according to the “Technical Specifications for Newborn Disease Screening” and the number of children diagnosed with PKU. The calculation formula is as follows: the number of children with PKU treated in accordance with the “Technical Specifications for Newborn Disease Screening”/the number of children diagnosed with PKU × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 54. Proportion of PKU patients starting treatment from the neonatal period. | (1) The number of children with PKU who started treatment during the neonatal period: , the number of children diagnosed with PKU: , Proportion of PKU patients starting treatment from the neonatal period: . | View case records in the information system; count the number of children with PKU who started treatment during the neonatal period and the number of children diagnosed with PKU. The calculation formula is as follows: the number of children with PKU who started treatment during the neonatal period/the number of children diagnosed with PKU × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 55. Proportion of PKU patients regularly monitored Phe levels. | (1) The number of children with PKU who have Phe regularly monitored: , the total number of treated children with PKU: , proportion of PKU patients regularly monitored Phe levels: . | View case records in the information system; count the number of children with PKU who have Phe regularly monitored and the total number of treated children with PKU. The calculation formula is as follows: the number of children with PKU who have Phe regularly monitored/the total number of treated children with PKU. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 56. Proportion of PKU patients regularly evaluated physical development status. | (1) The number of children with PKU undergoing regular physical development assessments at the age of 3 months: , The number of children with PKU: , proportion of PKU patients regularly evaluated physical development status: . | View case records in the information system; count the number of children with PKU undergoing regular physical development assessments at the age of 3 months and the number of children with PKU. The calculation formula is as follows: The number of children with PKU undergoing regular physical development assessments at the age of 3 months/The number of children with PKU. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 57. Proportion of PKU patients regularly evaluated for mental development status. | (1) The number of children with PKU undergoing intelligent development assessments at 1 year, 3 years, and 6 years of age: , the number of children diagnosed with PKU: , proportion of PKU patients regularly evaluated for mental development status: . | View case records in the information system; count the number of children with PKU undergoing intelligent development assessments at 1 year, 3 years, and 6 years of age and the number of children diagnosed with PKU. The calculation formula is as follows: The number of children with PKU undergoing intelligent development assessments at 1 year, 3 years, and 6 years of age/The number of children diagnosed with PKU. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 58. Proportion of standard treatment for CH patients. | (1) The number of children with CH who were treated according to the “Technical Specifications for Newborn Disease Screening”: , the number of children diagnosed with CH: , proportion of standard treatment for CH patients: . | View case records in the information system; count the number of children with CH who were treated according to the “Technical Specifications for Newborn Disease Screening” and the number of children diagnosed with CH. The calculation formula is as follows: the number of children with CH treated in accordance with the “Technical Specifications for Newborn Disease Screening”/the number of children diagnosed with CH × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 59. Proportion of CH patients starting treatment from the neonatal period. | (1) The number of children with CH who started treatment during the neonatal period: , the number of children diagnosed with CH: , Proportion of CH patients starting treatment from the neonatal period: . | View case records in the information system; count the number of children with CH who started treatment during the neonatal period and the number of children diagnosed with CH. The calculation formula is as follows: the number of children with CH who started treatment during the neonatal period/the number of children diagnosed with CH × 100%. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 60. Proportion of CH cases with regularly monitored FT4/TSH levels. | (1) The number of children with CH who have FT4/TSH regularly monitored: , the total number of treated children with CH: , proportion of CH patients regularly monitored FT4/TSH levels: . | View case records in the information system; count the number of children with CH who have FT4/TSH regularly monitored and the total number of treated children with CH. The calculation formula is as follows: the number of children with CH who have FT4/TSH regularly monitored/the total number of treated children with CH. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 61. Proportion of CH patients who are regularly evaluated for physical development status. | (1) The number of children with CH undergoing regular physical development assessments at the age of 3 months: , The number of children with CH: , proportion of CH patients regularly evaluated physical development status: . | View case records in the information system; count the number of children with CH undergoing regular physical development assessments at the age of 3 months and the number of children with CH. The calculation formula is as follows: The number of children with CH undergoing regular physical development assessments at the age of 3 months/The number of children with CH. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 62. Proportion of CH patients who are regularly evaluated for mental development status. | (1) The number of children with CH undergoing intelligent development assessments at 1 year, 3 years, and 6 years of age: , the number of children diagnosed with CH: , proportion of CH patients regularly evaluated for mental development status: . | View case records in the information system; count the number of children with CH undergoing intelligent development assessments at 1 year, 3 years, and 6 years of age and the number of children diagnosed with CH. The calculation formula is as follows: The number of children with CH undergoing intelligent development assessments at 1 year, 3 years, and 6 years of age/The number of children diagnosed with CH. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| (XIV) Treatment effect |  |  |  |  |
| 63. Proportion of PKU patients with normal physical development status. | (1) The number of children with PKU with normal physical development at the age of 1 year: , the total number of treated children with PKU: , proportion of PKU patients with normal physical development status: . | View case records in the information system; count the number of children with PKU with normal physical development at the age of 1 year and the total number of treated children with PKU. The calculation formula is as follows: the number of children with PKU with normal physical development at the age of 1 year/the total number of treated children with PKU. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 64. Proportion of PKU patients with normal mental development status. | (1) The number of children with PKU with normal intellectual development indicators at the ages of 1, 3, and 6: , the total number of treated children with PKU: , proportion of PKU patients with normal mental development status: . | View case records in the information system; count the number of children with PKU with normal intellectual development indicators at the ages of 1, 3, and 6 and the total number of treated children with PKU. The calculation formula is as follows: the number of children with PKU with normal intellectual development indicators at the ages of 1, 3, and 6/the total number of treated children with PKU. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 65. Proportion of CH patients with normal physical development status. | (1) The number of children with CH with normal physical development at the age of 1 year: , the total number of treated children with CH: , proportion of CH patients with normal physical development status: . | View case records in the information system; count the number of children with CH with normal physical development at the age of 1 year and the total number of treated children with CH. The calculation formula is as follows: the number of children with CH with normal physical development at the age of 1 year/the total number of treated children with CH. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| 66. Proportion of CH patients with normal mental development status. | (1) The number of children with CH with normal intellectual development indicators at the ages of 1, 3, and 6: , the total number of treated children with CH: , proportion of CH patients with normal mental development status: . | View case records in the information system; count the number of children with CH with normal intellectual development indicators at the ages of 1, 3, and 6 and the total number of treated children with CH. The calculation formula is as follows: the number of children with CH with normal intellectual development indicators at the ages of 1, 3, and 6/the total number of treated children with CH. | The rate reaches 100% to get 30 points, 90–100% gets 20 points, 80–90% gets 10 points, 50–80% does not score, and <50% deducts 5 points. |  |
| (XV) Medical record management |  |  |  |  |
| 67. Are there archives established for each PKU patient? | (1) The PKU specialist archives and management rules are established and the medical records of children with PKU are established and properly managed: A. YES B. NO | View PKU specialist files and medical records on site. | Question (1) Choose A to get 5 points, and choose B to get no points. |  |
| 68. Are there archives established for each CH patient? | (1) The CH specialist archives and management rules are established and the medical records of children with CH are established and properly managed: A. YES B. NO | View CH specialist files and medical records on site. | Question (1) Choose A to get 5 points, and choose B to get no points. |  |

DBS: Dried blood spot; EQA: External quality assessment; NBS: Newborn screening; QMIP-NBS: Implementation procedure for quality management of the NBS network.