**Supplementary Table 4: The working tools of the QMIP-NBS for blood collection agencies.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Indicators** | **Questionnaires** | **Investigation methods** | **Scoring criteria** | **Scores** |
| **I. Organizational Management** |  |  |  |  |
| (I) Personnel requirements |  |  |  |  |
| 1. Do qualifications of the blood collectors for NBS service meet the requirements? | (1) The number of blood collectors who have a technical secondary school education related to medicine and have been engaged in medical clinical work for >2 years: . | Select a blood collection staff on the day of the survey, check his/her technical qualification certificate, academic qualifications, or job title, and assess his/her basic professional knowledge and skills on site. | In question (1), at least one blood collection staff meets the requirements to get 5 points, otherwise, no point is scored. |  |
| (2) Randomly conduct an on-site knowledge assessment of a blood collection staff, and the result is qualified: A. YES B. NO | Question (2) Choose A to get 5 points, and choose B to deduct 5 points. |  |
| 2. Did the blood collectors receive relevant training? | (1) The number of blood collectors engaged in NBS: , in which the number of blood collectors who receive at least one training on the knowledge and skills of NBS: . | View training records and qualification certificates or credits on site. | All NBS blood collectors have received at least one NBS training and have obtained training qualification certificates to score 20 points, otherwise, they will not be scored. |  |
| (II) Institution construction requirements |  |  |  |  |
| 3. Biosafety | (1) Provide employees with qualified and applicable protective equipment and equipment, including ethanol, gloves, disposable lancets, etc: A. YES B. NO | Check biosafety facilities on site. | Question (1) chooses A to get 5 points, and choose B to get no points. |  |
| (2) The handling and reporting mechanism for occupational exposure: A. YES B. NO | Question (2) chooses A to get 5 points, and choose B to get no points. |  |
| 4. Does the blood agency regularly accept the quality control of the NBS centers? | (1) Annually participate in the quality control from the NBS centers: A. YES B. NO | View the annual training plan and quality control plan of the participating NBS institutions, as well as the actual training records and quality control records. | Question (1) chooses A to get 10 points, and choose B to get no points. |  |
| 5. Does the information management meet the specifications? | (1) Collect and analyze relevant data of NBS: A. YES B. NO | View NBS information records, information management system on site | Question (1) chooses A to get 5 points, and choose B to get no points. |  |
| (2) Timely report relevant data of NBS: A. YES B. NO | Question (2) chooses A to get 5 points, and choose B to get no points. |  |
| **II. Process Management** |  |  |  |  |
| (III) Publicity and health education |  |  |  |  |
| 6. Is there any publicity and health education for NBS? | (1) The policies related to the NBS are disseminated to the family members of newborns and there are signs of simple medical knowledge, such as publicity materials, publicity boards, publicity stands: A. YES B. NO | View publicity related materials on site | Question (1) chooses A to get 10 points, and choose B to get no points. |  |
| 7. Does the informed consent process meet the requirements? | (1) Before blood collection, blood collectors truthfully inform the newborn’s guardians of the purpose, significance, screening disease types, conditions, methods, sensitivity, and cost of the NBS: A. YES B. NO | Interrogate two pregnant women and two blood collectors at the scene. | Calculate the score of each staff first, then add the scores of all staff to get the total score, and then divide by the number of people to get the average score. Question (1) chooses A to get 4 points, and choose B to get no points. |  |
| (2) There is guardian’s signature and date of signature when the child’s family members are screened after being informed: A. YES B. NO | Question (2) chooses A to get 4 points, and choose B to get no points. |  |
| (3) When the guardian does not agree to accept NBS, there is the guardian’s signature, date of signature, guardian’s current address and contact information: A. YES B. NO | Question (3) chooses A to get 4 points, and choose B to get no points. |  |
| (4) After NBS health education for the guardians of the child, if the guardian does not agree to accecpt NBS, inform them of the possible adverse consequences of the disease: A. YES B. NO | Question (4) chooses A to get 4 points, and choose B to get no points. |  |
| (5) In the medical (nursing) staff statement, the medical (nursing) staff’s signature and date of signature are included: A. YES B. NO | Question (5) chooses A to get 4 points, and choose B to get no points. |  |
| (IV) Blood collection |  |  |  |  |
| 8. Do the process of blood collection and DBS making meet the requirements? | (1) Sterile operation and unique sample ID: A. YES B. NO | View the specimen collection and DBS making process and collection records on site, and experts can ask questions during the operation. | Question (1) chooses A to get 10 points, and choose B to get no points. |  |
| (2) Collect heel blood and make DBSs according to the procedure: A. YES B. NO | Question (2) chooses A to get 20 points, and choose B to get no points. |  |
| (3) Randomly check 10 blood collection cards within 5 working days, among which, the number of blood collection cards taken within 72 hours to 7 days after birth: . | In question (3), randomly check 10 blood collection cards within 5 working days, and a sample that is collected within 72 h to 7 days after birth will get 3 points, and the blood collection time will be between 72 h and 7 days after birth. Otherwise, 3 points will be deducted for each specimen. |  |
| 9. Is the blood collection registration card regulated filled? | (1) The number of the blood collection card of which the registration are completed and written clearly: . | Check the blood collection card or information system on site, and spot check 10 blood collection cards and DBSs (blood spots are used for the following investigation of unqualified blood film rate) | Ten blood collection cards are registered to be standardized to get 40 points, and 5 points are deducted for each irregular registration. |  |
| 10. Does the storage of NBS specimen meet the requirements? | (1) The storage of NBS specimen: put the qualified DBSs in a sealed bag in time, and store them in a refrigerator at 2–8°C, or <0°C: A. YES B. NO | Check the temperature records of the specimen storage refrigerator and the identification of special infectious disease specimens on site. | Question (1) chooses A to get 5 points, and choose B to get no points. |  |
| (2) All DBSs are treated as infectious specimens: A. YES B. NO | Question (2) chooses A to get 10 points, and choose B to get no points. |  |
| (3) DBSs are sealed for preservation: A. YES B. NO | Question (3) chooses A to get 5 points, and choose B to get no points. |  |
| 11. Does the specimen delivery meet the requirements? | (1) Specimens are delivered within days. | View the specimen delivery records. | Specimens delivered within 5 days to get 20 points, otherwise, no point is obtained. |  |
| 12. Does the specimen handover meet the requirements? | (1) There is a specimen handover record form for receiving specimens: A. YES B. NO | View the handover records. | Question (1) chooses A to get 10 points, and choose B to get no points. |  |
| 13. Does the specimen recollection records meet the requirements? | (1) There is a record for specimens which are returned and need to be re-collected: A. YES B. NO | View the recollection records. | Question (1) chooses A to get 10 points, and choose B to get no points. |  |
| **III. Outcome management** |  |  |  |  |
| (V) Informed notification |  |  |  |  |
| 14. Proportion of signed informed consent. | (1) Randomly check the number of informed consent forms within 5 working days: , the number of signed informed consent forms: , and the proportion of signed informed consent forms: . | Check the medical history of the last week, count the number of informed consents, and count the total number of signed informed consents during the same period. | A proportion of 100% to get 20 points, otherwise no points to get. |  |
| (VI) Quality of specimens |  |  |  |  |
| 15. Unqualified specimen rate. | (1) The number of unqualified specimens: , and the rate of unqualified DBS: . | Check the blood collection card or information system, take blood collection cards and DBSs that have not been submitted for testing in a defined period, count the number of unqualified DBSs. Calculation formula: Number of unqualified DBS/10 x 100%. | If the rate is <0.5%, 20 points are scored. If the rate is between ≥0.5% and ≤1.0%, 5 points are scored. If the rate is ≥1%, no points are scored. |  |
| (VII) Archives preservation |  |  |  |  |
| 16. Does the preservation of archives meets the requirements? | (1) The preservation of blood collection files, such as files on the number of live births, the number of screenings, the registration information of neonatal blood collection, feedback test results, and follow-up data are kept for at least 10 years: A. YES B. NO | View the saved and backed up files. | Question (1) chooses A to get 8 points, and choose B to get no points. |  |
| (2) There are paper archives counters or electronic archives and information data preservation and backup procedures: A. YES B. NO | Question (2) chooses A to get 2 points, and choose B to get no points. |  |

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