**Supplementary Table 2: The definitions, characteristics, and reference values of the QIs in the QI system for blood collection agencies.**

| The first-tier QI | The second-tier QI | The third-tier QI | Reference interval | Property of the QI | Definitions or illustrations |
| --- | --- | --- | --- | --- | --- |
| I. Organizational Management　　　　 | (I) Personnel requirements　 | 1. Do qualifications of the blood collectors for NBS service meet the requirements? | – | Qualitative | The qualifications of blood collection personnel should meet the following requirements of the “Technical Specifications for Newborn Disease Screening”: (1) Have a technical secondary school education related to medicine and have been engaged in medical clinical work for >2 years and (2) Have received training in knowledge and skills related to NBS and obtained a technical qualification certificate. The training content includes the purpose, principles, methods, and network operation of NBS service; relevant knowledge of the collection, storage, and delivery of DBS; relevant information and file management for NBS. |
| 2. Did the blood collectors receive relevant training? | ≥1 | Quantitative | Blood collection personnel engaged in the NBS should receive at least one training on the knowledge and skills related to the NBS and obtain a technical qualification certificate. The training content includes the purpose, principles, methods, and network operation of NBS, relevant knowledge of the collection, storage and delivery of DBS, relevant information, and file management for NBS. Training means can be varied, such as training courses or academic conference at or above the county level. |
| (II) Institution construction requirements　　 | 3. Biosafety | – | Qualitative | Institution construction should meet biosafety. |
| 4. Does the blood agency regularly accept the quality control of the NBS centers? | – | Qualitative | The blood agency should regularly participate in the quality control of the NBS centers. |
| 5. Does the information management meet the specifications? | – | Qualitative | Blood collection agencies need to collect, analyze, and reflect relevant information about NBS. These information include the number of live births, the number of blood slices collected, the number of screenings, etc. |
| II. Process Management　　　　　　　 | (III) Publicity and health education　 | 6. Is there any publicity and health education for NBS? | – | Qualitative | The policies related to the NBS should be disseminated to the family members of newborns, and there should be signs of simple medical knowledge, such as publicity materials, publicity boards, publicity stands, etc. |
| 7. Does the informed consent process meet the requirements? | – | Qualitative | Before blood collection, blood collectors should truthfully inform the newborn’s guardians of the purpose, significance, screening disease types, conditions, methods, sensitivity, and cost of the NBS and obtain signed consent. |
| (IV) Blood collection　　　　　 | 8. Do the process of blood collection and DBS making meet the requirements? | – | Qualitative | The blood collection operation process should comply with the “Technical Specifications of Blood Collection for NBS”: (1) Before blood collection, blood collectors should well wash their hands and well wear sterile and talcum-free gloves. (2) The newborn’s heel should be massaged or heated and disinfected with 75% ethanol. (3) After the ethanol has completely evaporated, use a disposable blood sampling needle to puncture the inside or outside of the heel with a depth of <3 mm. Use a dry cotton ball to wipe off the first drop of blood, and start sampling from the second drop of blood. (4) Keep the filter paper in contact with blood drops, do not touch the heel skin, so that the blood will naturally penetrate to the back of the filter paper, avoid repeated blood drops, and collect at least three blood spots. (5) Hold the sterilized dry cotton ball and lightly press the blood collection site to stop bleeding. (6) Hang the blood slice flat and let it dry naturally to form a dark brown. Avoid sunlight and ultraviolet radiation, baking, volatile chemical substances, and other pollution. |
| 9. Is the blood collection registration card regulated filled? | 10 | Quantitative | The registration of the blood collection card should be completed and written clearly, that is, the content of the card includes the following information: blood collection unit, mother’s name, hospitalization number, contact information, newborn gender, gestational week, birth weight, date of birth, date of blood collection and the person who took the blood. |
| 10. Does the storage of NBS specimen meet the requirements? | – | Qualitative | The storage of NBS specimen should meet the requirements of “Technical Specifications of Blood Collection for NBS”: Put the qualified DBS in a sealed bag in time, and store them in a refrigerator at 2–8°C; If possible, they can be stored <0°C; All DBSs should be treated as infectious specimens; And special infectious specimens, such as specimens from patients with Acquired Immune Deficiency Syndrome, should be labeled and packaged separately.  |
| 11. Does the specimen delivery meet the requirements? | ≤5 | Quantitative | Specimens should be delivered within the specified time (5 days). |
| 12. Does the specimen handover meet the requirements? | – | Qualitative | The laboratory should fill in the specimen handover record form when receiving specimens. |
| 13. Does the specimen recollection records meet the requirements? | – | Qualitative | If blood samples are not collected on time due to special circumstances or unqualified specimens are returned and need to be re-collected, they should make an appointment in time or follow up to collect blood in time. |
| III. Outcome management　　 | (V) Informed notification | 14. Proportion of signed informed consent. | 0–100% | Quantitative | The number of signed informed consent forms as a percentage of the total number of screenings during the same period. |
| (VI) Quality of specimens | 15. Unqualified specimen rate. | <1% | Quantitative | (1) Unqualified DBS do not include specimens of special children collected within 24 hours (such as infants in the neonatal intensive care unit). (2) Examples of unqualified DBS include improper collection of specimens. Such specimens are insufficient blood volume; agglutination; smearing or contamination; insufficient filling in the ring; blood oversaturation; not completely dry before mailing; mold growth; or other reasons cannot be used for testing. (3) Qualified DBS is defined as the following: at least three blood spots, and each blood spot is >8 mm in diameter; blood drops naturally penetrate, and the blood spots on the front and back of the filter paper are the same; the blood spots are not contaminated ; there is no bleeding ring in blood spots. (4) Specimens with important information omission are considered as unqualified, too. The essential basic information on the DBS collection card includes blood collection unit, mother’s name, hospital number, residential address, contact phone number, newborn gender, gestational week, birth weight, date of birth, date of blood collection and the person who took the blood. Calculation formula: Number of unqualified DBS during the defined period/Number of test specimens during the defined period × 100%. |
| (VII) Archives preservation | 16. Does the preservation of archives meets the requirements? | – | Qualitative | The preservation of blood collection files should meet the requirements of the “Technical Specifications for Newborn Disease Screening”, that is, 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 should be kept for at least 10 years. |

NBS: Newborn screening; QI: Quality indicator.