# STOP II TRIAL
# QUARTERLY PROGRESS REPORT FOR NON-RANDOMIZED PATIENTS RECEIVING TRANSFUSIONS

*** AFFIX PATIENT LABEL HERE***

A1. Person completing form (Name):_____ (Initials): | | | |

A2. Date of interview (Month/Day/Year): ___ ___/___ ___/___ ___ ___ ___

A3. Person interviewed (Choose **ONE** for person providing majority of answers to sections B-F):

☐ 1. Patient ☐ 2. Parent ☐ 3. Legal Guardian ☐ 4. Other → A3.a (specify): _____

A4. Were address and telephone information verified for this patient? ☐ **1. NO** ☐ **2. YES**

**QUESTIONS IN SECTIONS B THROUGH D ARE TO BE ANSWERED BY THE PERSON INTERVIEWED; QUESTIONS IN SECTIONS E THROUGH G ARE TO BE ANSWERED BY MEDICAL PERSONNEL.**

## B. MEDICATIONS

B1. Is the patient currently taking, on a regular basis, any medications prescribed by a physician?

☐ **1. NO** ☐ **2. YES** ↓

| **B1.a TYPE OF MEDICATION:** (CHECK **NO** OR **YES** FOR EACH OF B1.a1-6) | **1. NO** | **2. YES** | **B1.b HOW MANY MONTHS HAS PATIENT BEEN TAKING THE MEDICATION?** |
|---|---|---|---|
| 1. Penicillin | ☐ | ☐ | 1. ☐☐☐ |
| 2. Other antibiotic | ☐ | ☐ | 2. ☐☐☐ |
| | | ↓ B1.a2.a SPECIFY:_____ | |
| 3. Folate | ☐ | ☐ | 3. ☐☐☐ |
| 4. Hydroxyurea | ☐ | ☐ | 4. ☐☐☐ |
| 5. Iron Chelators (Desferoxamine) | ☐ | ☐ | 5. ☐☐☐ |
| 6. Other | ☐ | ☐ | 6.a ☐☐☐ |
| | | ↓ B1.a6.a SPECIFY:_____ B1.a6.b SPECIFY:_____ | 6.b ☐☐☐ |



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## C. CLINICAL EVENTS

Since the last quarterly report (or entry interview if this is the first quarterly report) on ___/___ ___/___ ___ ___ ___, has the patient been seen by a doctor or nurse for any of the following:

| C1.a Event | USE CODES 1. NO 2. YES | C1.b Total # of unique events | C1.c # treated at your institution | C1.d What was the date of the most recent event? (Month/Year) | C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center |
|---|---|---|---|---|---|
| 1. **Stroke/TIA** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| *(**PROBE**: An event which a doctor called a stroke or cerebrovascular accident (CVA) which involved loss of consciousness, paralysis, visual, speech, or motor difficulties)* | | | | | |
| 2. **New Onset of Seizures** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| *(**PROBE**: Any fits or convulsions that were not associated with a stroke or meningitis (brain infection))* | | | | | |
| **IF RESPONSE TO C1.a1 or C1.a2 IS YES, SUBMIT QUASI-ADJUDICATION NEUROLOGICAL EVENT FORM Q30, NEUROLOGICAL EVALUATION REPORT, MRI REPORT, CT SCAN REPORT (IF DONE), AND SUPPORTING HOSPITAL SUMMARIES** | | | | | |
| 3. **Meningitis** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| *(**PROBE**: Infection of the brain)* | | | | | |
| c1.f3 **IF YES,** Date of discharge | ___ ___/___ ___/___ ___ ___ ___ | | | | |
| 4. **Head Injury with loss of consciousness** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| c1.f4 **IF YES,** Date of discharge | ___ ___/___ ___/___ ___ ___ ___ | | | | |
| 5. **Splenic Sequestration*** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| *(**PROBE**: Enlargement of the spleen with trapping of blood in it)* | | | | | |
| 6. **Aplastic Crisis*** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| *(**PROBE**: A drop in the blood count which required a transfusion)* | | | | | |
| 7. **Hand-Foot Syndrome*** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| *(**PROBE**: Pain, tenderness, with or without swelling, in the hands and/or feet only)* | | | | | |
| 8. **Vaso-occlusive pain event for which the patient was hospitalized*** | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| *(**PROBE**: An acute episode of pain in the arms, legs, back, chest, and/or abdomen, lasting at least two hours for which no other explanation was found)* | | | | | |

| C1.a Event | USE CODES 1. NO 2. YES | C1.b Total # of unique events | C1.c # treated at your institution | C1.d What was the date of the most recent event? (Month/Year) | C1.e Where was patient seen for the most recent event? 1 = STOP II Center 2 = Non-STOP II Center |
|---|---|---|---|---|---|
| 9. **Fever*** *(**PROBE**: A temperature greater than 101° F (39° C)* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| 10. **Septicemia*** *(**PROBE**: An infection in the blood stream)* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| 11. **Acute Chest Syndrome/Pneumonia *** *(**PROBE:** An infection or blockage of blood flow in the lung(s))* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| 12. **Osteomyelitis*** *(**PROBE**: Infection in the bones)* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| 13. **Priapism*** *(**PROBE**: A painful, unwanted erection of the penis lasting more than one hour)* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| 14. **Transfusion reaction** *(**PROBE**: Complication of a transfusion within 2 weeks after the transfusion was given* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| 15. **Other*** *(**PROBE**: Was the child seen for any other clinical events? What events?)* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | _____ |

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C1.a15.a. IF YES, Specify:

_____

_____

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| C2.a Procedure | USE CODES 1. NO 2. YES | C2.b Total # of unique procedures | C2.c # performed at your institution | C2.d What was the date of the most recent procedure? (Month/Year) | C2.e Where was patient seen for the most recent procedure? 1 = STOP II Center 2 = Non-STOP II Center |
|---|---|---|---|---|---|
| 1. **Transfusion** *(**PROBE**: Injection of blood into the bloodstream)* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |
| 2. **Surgery*** *(**PROBE**: An operation or a medical procedure requiring general anesthesia)* | ☐ | ☐ | ☐ | __ __/__ __ __ __ | ☐ |

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C2.a2.a. IF YES, Specify:

_____

_____

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C3. Does the patient currently have a portacath? ☐ **1. NO** ☐ **2. YES**

**NOTE: FOR VISITS AT A NON-STOP II STUDY SITE, ASK PARENT TO SIGN A MEDICAL RECORD RELEASE FORM FOR EACH UNIQUE EVENT AND REMEMBER TO SUBMIT MEDICAL RECORD REVIEW FORM (FORM 16R)**

## D. NEUROLOGICAL SIGNS AND SYMPTOMS

D1. Has the patient developed a new neurologic problem, been hospitalized for a neurological event, or been seen by a neurologist because of a new neurologic problem?

☐ **1. NO** ☐ **2. YES**

D1.a. Please give brief details:

_____

_____

_____

## E. OTHER MEDICAL CONDITIONS

### (SECTIONS E – G TO BE COMPLETED BY MEDICAL PERSONNEL)

| Since the last quarterly report was the patient **newly** diagnosed with: **(CHECK NO OR YES FOR EACH OF E1 - E17)** | **1. NO** | **2. YES** |
|---|---|---|
| E1. Leg ulcers | ☐ | ☐ |
| E2. Aseptic necrosis | ☐ | ☐ |
| 2.b If Yes, specify location(s) _____ | | |
| E3. Sickle cell retinopathy | ☐ | ☐ |
| E4. Chronic lung disease | ☐ | ☐ |
| 4.b If Yes, specify type _____ | | |
| E5. Asthma | ☐ | ☐ |
| E6. Chronic heart disease | ☐ | ☐ |
| 6.b If Yes, specify type: _____ | | |
| ☐☐☐.☐☐ **OFFICE USE** | | |
| E7. Chronic liver disease | ☐ | ☐ |
| 7.b If Yes, specify type: _____ | | |
| ☐☐☐.☐☐ **OFFICE USE** | | |
| E8. Chronic renal disease | ☐ | ☐ |
| 8.b If Yes, specify type: _____ | | |
| ☐☐☐.☐☐ **OFFICE USE** | | |
| 8.c If Yes, is patient receiving dialysis? | ☐ **1. NO** | ☐ **2. YES** |
| E9. Iron overload | ☐ | ☐ |
| 9.b If yes, highest ferritin level (ng/ml) ☐☐☐☐☐ | | |
| E10. Diabetes | ☐ | ☐ |
| E11. Rheumatic fever | ☐ | ☐ |

| | 1. NO | 2. YES |
|---|---|---|
| E12. Tuberculosis | ☐ | ☐ |
| E13. Cancer | ☐ | ☐ |

13b. If Yes, specify type: _____

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| | | |
|---|---|---|
| E14. Priapism | ☐ | ☐ |
| E15. Elevated blood lead level (blood lead level ≥ 15 mg/dl?) | ☐ | ☐ |
| E16. New red cell antibody | ☐ | ☐ |

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E16.a. SPECIFY:
a1. _____
a2. _____
a3. _____
a4. _____

| | | |
|---|---|---|
| E17. Any other chronic medical condition? | ☐ | ☐ |

17.a. If Yes, specify type: a1. _____
a2. _____

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## F. VACCINATIONS

F1. Since the last quarterly report, has the patient received Hepatitis B vaccination?

☐ 1. NO ☐ 2. YES

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F1.a Date of vaccination (Month/Day/Year)
___ ___/___ ___/___ ___ ___ ___

## G. GENERAL

G1. Is the patient seen for most of his/her clinical events at a NON-STOP II study site because of third party payment restrictions, distance from clinic, some other reason? ☐ 1. NO ☐ 2. YES

Signature of Study Coordinator: _____ Date: ___ ___/___ ___/___ ___ ___ ___