

**Burn Model System
National Data and Statistical Center**

STANDARD OPERATING PROCEDURE (SOP) #101

SOP #101	Title: Identification of Participants for the Burn Model System National Database	
Approved: BMS Project Directors	Effective Date: 10/18/2013	
Attachments: None	Revised Date: 12/12/2023	
Forms: None	Review Date:	
Review Committee: BMS Project Directors		

Introduction:

This policy and procedure addresses the established criteria to determine eligibility for enrollment and participation in the BMS National Database (NDB).

Purpose:

To institute standard inclusion / exclusion criteria for identifying and enrolling potential participants into the NDB.

Scope:

Current BMS centers which are identifying and enrolling participants into the NDB.

Responsibilities:

BMS staff responsible for identifying and enrolling participants into the NDB (e.g., BMS researchers or clinicians, research assistants, study coordinators).

Policy:

As of 8/1/2009, the study group criteria for the BMS NDB is as follows:

Case Definition:

A patient with a burn injury at one of the Burn Model System Centers is eligible for participation in the BMS NDB if:

1. They are a patient with a burn injury that is treated at one of the NIDILRR-funded BMS Centers.
2. They meet the criteria listed below;
3. They sign a Consent Form

Inclusion Criteria for Model System Burn Patient:

1. $\geq 10\%$ TBSA, ≥ 65 years of age and with burn surgery for wound closure;
2. $\geq 20\%$ TBSA, 0-64 years of age and with burn surgery for wound closure;
3. Electrical high voltage/lightning with burn surgery for wound closure;
4. Hand burn and/or face burn and/or feet burn with burn surgery for wound closure [surgery for wound closure does NOT need to occur on the

hand/face/feet area that qualifies the subject for inclusion]; OR

Met Burn Model System inclusion criteria prior to the change in such criteria that was made on 8/1/2005 (for tracking follow-up of already enrolled subjects)

And;

- Received acute care treatment in the Burn Model System Center from the time of burn (outpatient or inpatient) for primary burn wound closure. Surgery for closure of burn wound must occur within 30 days of burn injury. This includes day number 30.
 - Burn wound closure surgeries include:
 - Autografting (this includes cultured epithelial cells and skin suspensions)
 - Amputation
 - Flap closure
 - Adjacent tissue transfer
 - Or placement of acellular dermal matrix for eventual autografting
 - Of note: xenografting and allografting are not eligible.
 - When potential participant is eligible due to placement of acellular dermal matrix for eventual autografting, the placement of acellular dermal matrix must occur within 30 days of burn injury. Approach for consent of these potential participants should occur after the hospital stay that included autografting, and must occur within 30 days of the discharge from the hospital stay that included autografting.
- As of 2010, frostbite/cold, TENS/Steven Johnson, necrotizing fasciitis, meningococemia, and other skin disease are not eligible types of burns to be included in the national database. Therefore, the burn etiologies that are eligible to be included are: fire/flame, scald, contact with hot object, grease, tar chemical, hydrofluoric acid, electricity, radiation, UV light, flash burn, and other burn (other burn includes steam burns, etc). In 2017 it was determined that abrasion should not be considered as an eligible other burn, but that friction burns are eligible (which should be included in the “other burn” category when they meet other inclusion criteria (surgery for wound closure, burn in critical area, and/or TBSA%).
- Consent should occur within 30 days of discharge from the model system clinical unit (either from the acute care unit or inpatient rehab unit).
- In addition to acute care, will be provided comprehensive rehabilitation services at the Burn Model System Center, including: psychiatric, physical, occupational, recreational, psychological, vocational, or other traditional rehabilitation therapies throughout the care of the burn injury.
 - Once the patient meets inclusion criteria and is enrolled into the study, the participant should be retained even if she/he is subsequently transferred to another facility or moves to a different catchment area.

Exclusion Criteria for Model System Burn Patient:

1. Patients who are in law enforcement custody at admission to the BMS Center or who are taken into custody at discharge from the BMS Center are not eligible for the BMS study and should not be approached for consent.

Training requirements:

Staff who are responsible for recruitment and enrollment of participants into the BMS NDB should be familiar with these criteria.

Compliance:

Only participants that meet these inclusion criteria will be enrolled into the BMS NDB. These criteria should be reported in publications related to analysis of the NDB data, but do not need to be stated exactly as above.

References:

None

History:

1/2/2014—Edited to clarify which types of burns are eligible and not eligible.

4/14/2014—Edited to clarify what types of burns are included in “other burns” and clarify some wording issues.

8/7/2015—Edited to clarify the number of days from discharge that consent should occur.

9/30/2015—Edited to clarify that surgery for wound closure does not need to occur on the critical areas of hand/face/feet. Updated to replace all references to NIDRR with NIDILRR.

6/13/2017—Edited to clarify that road rash and abrasions are not eligible burns. Friction burns are eligible types of burns for enrollment into the BMS National Longitudinal Database.

12/15/2021—Edited to change “primary” treatment to “acute care”, to clarify that amputation is considered a type of wound closure and therefore that people with their burn wounds amputated are eligible, and to remove window for surgery to occur within 30 days after burn. Language updated from “subjects” to “participants”.

8/10/2022—Edited to reinstate window for surgery to occur within 30 days after burn.

11/21/2022—Edited to include exclusion criterion of incarceration at discharge.

9/18/2023—Edited to clarify type of surgery required for eligibility.

12/12/2023—Specified approach period for people who are eligible because dermal matrix was placed within 30 days of discharge.

Review schedule:

At least every 5 years