

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

STANDARD OPERATING PROCEDURE (SOP) #101

SOP #101	Title: Identification of Subjects for the Burn Model System National Database	
Approved: BMS Project Directors	Effective Date: 10/18/2013	
Attachments: None	Revised Date: 9/30/2015	
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 subjects into the NDB.

Scope:

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

Responsibilities:

BMS staff responsible for identifying and enrolling subjects 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;
4. They agree to scheduled follow-up assessments at 6, 12, 24 months, and every five years post-burn.

Inclusion Criteria for Model System Burn Patient:

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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 primary 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 (effective date of this criterion: 8/13/2013).
 - Autografting is considered wound closure; those patients that have only xenografting or allografting are not eligible.
 - 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.
 - If there is reasonable expectation that follow-up care at the model system can occur, the patient will be enrolled.
 - Once the patient meets inclusion criteria and is enrolled into the study, the subject should be retained even if she/he is subsequently transferred to another facility or moves to a different catchment area.

Training requirements:

Staff who are responsible for recruitment and enrollment of subjects 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.

8/7/15—Edited to clarify the number of days from discharge that consent should occur.

9/30/15—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.

6/13/17—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.

Review schedule:

At least every 5 years