

BACKGROUND

Studies that evaluate UGIB in electronic healthcare data typically rely on inpatient diagnostic codes for outcome identification. Use of hemoglobin (HGB) lab test results might increase detection of UGIB that do not lead to hospitalization.

OBJECTIVES

To evaluate whether use of HGB test results increases UGIB identification using non-steroidal anti-inflammatory drugs (NSAIDs) as a test case.

METHODS

From the Mini-Sentinel distributed database, we identified patients ≥18 years old who initiated prescription NSAIDs in 3 Data Partners between January 2008-April 2013. Availability of HGB test results was examined before and after NSAID initiation. Numbers of events and cumulative incidences within 30 days after NSAID initiation were calculated for 4 mutually exclusive outcome definitions: (1) inpatient UGIB diagnosis (standard claims-based definition without lab test results); (2) non-inpatient UGIB diagnosis AND ≥3 g/dL decrease in HGB; (3) ≥3 g/dL HGB decrease alone without UGIB diagnosis in any clinical setting; (4) non-inpatient UGIB diagnosis, without ≥3 g/dL HGB decrease. In secondary analyses, we reviewed all coded diagnoses in patients with outcome 3 to scan for codes indicative of potential UGIB and assessed distributions of specific UGIB diagnoses in patients with outcomes 1, 2, and 4.

Table 1. Hemoglobin Laboratory Result Value Availability within 365 days before and within 30 days after starting an NSAID, Overall and by Site

Hemoglobin Result Value Availability ^{a, b, c}	Overall (N = 2,289,772)	Site 1 (N = 95,182)	Site 2 (N = 1,121,061)	Site 3 (N = 1,073,529)
Available at any time within 365 days before to 30 days after NSAID Initiation				
Yes	1,036,294 (45.3)	47,947 (50.4)	625,961 (55.8)	363,075 (33.8)
No	1,253,553 (54.7)	47,235 (49.6)	495,864 (44.2)	710,454 (66.2)
Timing of Availability				
Before NSAID Initiation Only	747,640 (32.7)	34,034 (35.8)	426,798 (38.1)	286,808 (26.7)
After NSAID Initiation Only	132,507 (5.8)	6773 (7.1)	92,987 (8.3)	32,747 (3.1)
Both before and after NSAID initiation	156,072 (6.8)	7140 (7.5)	105,412 (9.4)	43,520 (4.1)
Care Setting where Laboratory Specimen was Obtained				
Before NSAID initiation only^{a, b, c}				
Emergency department	83,503 (11.2)	N/A	83,503 (19.6)	N/A
Inpatient	40,320 (5.4)	4548 (13.4)	33,407 (7.8)	2365 (0.8)
Outpatient	707,746 (94.7)	32,661 (96.0)	389,710 (91.3)	285,375 (99.5)
After NSAID initiation only^{a, b, c}				
Emergency department	17,007 (12.8)	N/A	17,007 (18.3)	N/A
Inpatient	3069 (2.3)	470 (6.9)	2276 (2.4)	323 (1.0)
Outpatient	117,434 (88.6)	6442 (95.1)	78,537 (84.5)	32,455 (99.1)
Both before and after NSAID initiation^{a, b, c}				
Emergency and Emergency				
Emergency and Emergency	12,344 (7.9)	N/A	12,344 (11.7)	N/A
Emergency and Inpatient				
Emergency and Inpatient	12,650 (8.1)	N/A	12,650 (12.0)	N/A
Emergency and Outpatient				
Emergency and Outpatient	21,957 (14.1)	N/A	21,957 (20.8)	N/A
Inpatient and Emergency				
Inpatient and Emergency	6315 (4.0)	N/A	6315 (6.0)	N/A
Inpatient and Inpatient				
Inpatient and Inpatient	14,016 (9.0)	524 (7.3)	13,227 (12.5)	265 (0.6)
Inpatient and Outpatient				
Inpatient and Outpatient	14,217 (9.1)	1177 (16.5)	12,768 (12.1)	272 (0.6)
Outpatient and Emergency				
Outpatient and Emergency	22,056 (14.1)	N/A	22,056 (20.9)	N/A
Outpatient and Inpatient				
Outpatient and Inpatient	18,123 (11.6)	1030 (14.4)	16,820 (16.0)	273 (0.6)
Outpatient and Outpatient				
Outpatient and Outpatient	118,695 (76.1)	6135 (85.9)	69,481 (65.9)	43,079 (99.0)

^a Only Site 2 has emergency department laboratory test results available in the Mini-Sentinel Distributed Database
^b Outpatient setting reflects outpatient and "unknown" locations considered together because Mini-Sentinel Data Partners have stated that laboratory results with the setting variable populated with "unknown" are primarily outpatient laboratory test results
^c The N in each setting do not add to the N for the "Any" setting or "Overall" numbers because the same individual could have had HGB results from more than one setting (i.e., same individual could be counted in different settings)

RESULTS

We identified 2,289,772 NSAID initiators (Figure 1); 45% had ≥1 HGB result available within 365 days before or 30 days after NSAID initiation. Only 7% had results before and after (Table 1). Of 7,637 potential outcomes identified from all 4 definitions, outcome 1 accounted for 22%, outcome 2 for 1%, outcome 3 for 34%, and outcome 4 for 43% (Table 2). Potential cases identified by outcome 3 were mostly associated with codes for non-UGIB or other non-hemorrhagic conditions. Outcomes 1, 2, and 4 were associated with similar distributions of specific UGIB codes.

Figure 1. Study Flowchart

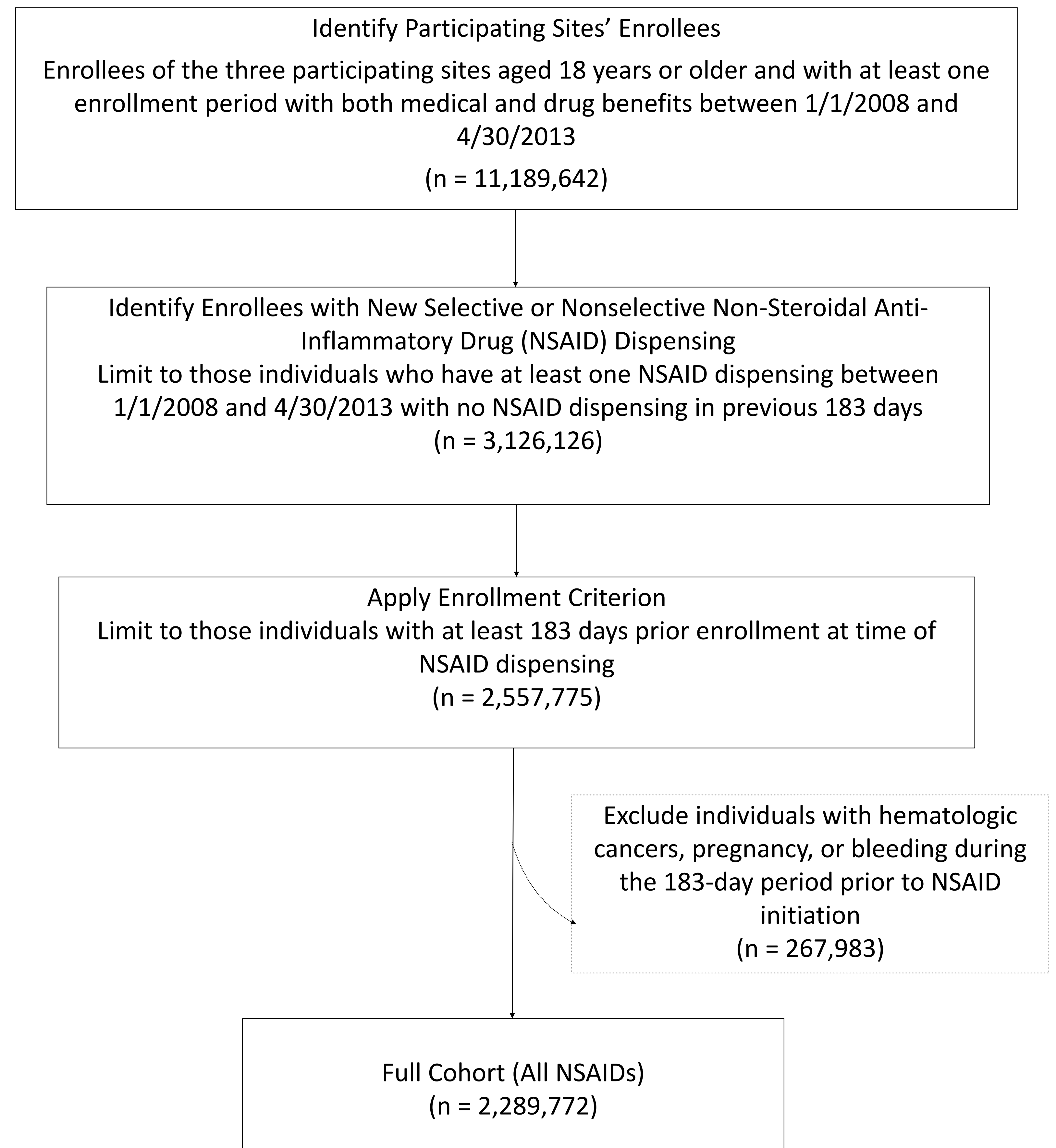


Table 2. Upper Gastrointestinal (UGI) Bleeding Outcomes within 30 Days after NSAID Initiation using Varied Outcomes Definitions, Overall and by Site

Outcome	Bleeding Outcomes Definition ^a	Data Partner Site			
		All Sites	Site 1	Site 2	Site 3
1	Inpatient diagnoses (with or without an observed HGB drop ≥ 3 g/dL)	1657 (21.7)	30 (11.7)	520 (14.9)	1107 (28.4)
2	Non-inpatient diagnosis with drop in HGB ≥ 3 g/dL	58 (0.8)	2 (0.8)	41 (1.2)	15 (0.4)
3	Observed drop in HGB ≥ 3 g/dL (no coded UGI bleeding diagnosis)	2619 (34.3)	148 (57.6)	2160 (61.9)	311 (8.0)
4	Non-inpatient diagnosis without observed drop in HGB	3303 (43.3)	77 (30.0)	769 (22.0)	2457 (63.2)
1 – 4	Total bleeding outcomes	7637	257	3490	3890
Outcome	Bleeding Outcomes Definition Excluding Outcome 3 ^a	Data Partner Site			
		All Sites	Site 1	Site 2	Site 3
1	Inpatient diagnoses (with or without an observed HGB drop ≥ 3 g/dL)	1657 (33.0)	30 (27.5)	520 (39.1)	1107 (30.9)
2	Non-inpatient diagnosis with drop in HGB ≥ 3 g/dL	58 (1.2)	2 (1.8)	41 (3.1)	15 (0.4)
4	Non-inpatient diagnosis without observed drop in HGB	3303 (65.8)	77 (70.6)	769 (57.8)	2457 (68.7)
1, 2, 4	Total UGI bleeding outcomes without Group 3	5018	109	1330	3579

^a Mutually exclusive groups

CONCLUSION

Using HGB result values in combination with UGIB diagnoses identified few additional potential UGIB cases and with unknown specificity. The use of HGB result values alone did not improve identification of potential UGIB events. The use of non-inpatient diagnostic codes may increase UGIB outcome detection, but would require validation.

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