

Identifying Enrollment Challenges and Discovering Research Opportunities in an Orthopaedic Trauma Consortium: The Value of a “Start-up” Registry

The Major Extremity Trauma Research Consortium (METRC)

www.METRC.org

PURPOSE

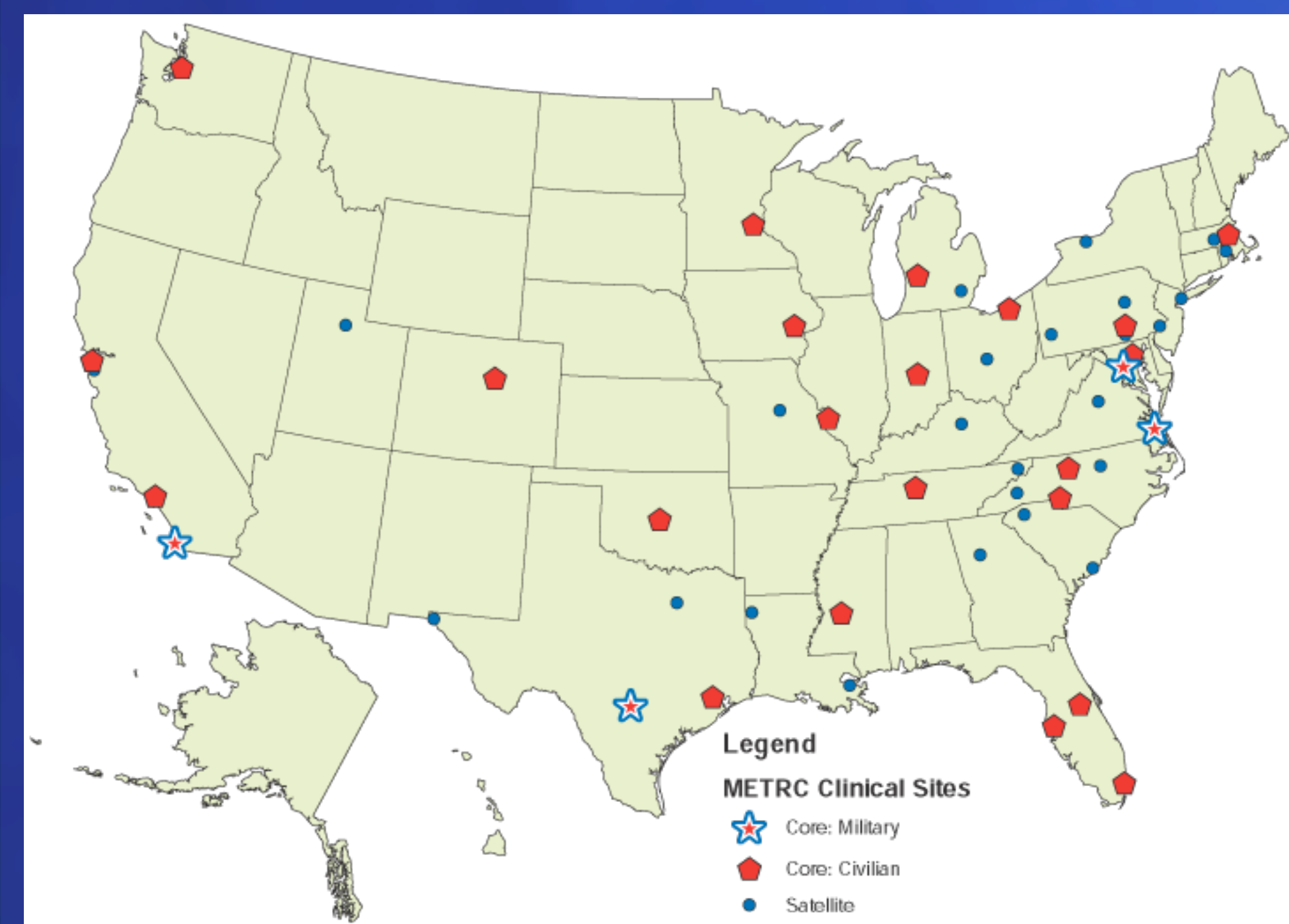
The Major Extremity Trauma Research Consortium (METRC) was funded to research major challenges to the successful care of and recovery from severe extremity trauma. To assist in the design of studies that are feasible and adequately powered, a registry was established. At the initiation of the Consortium, many of the centers did not have a registry, and those that did were not collecting data under a uniform protocol. We hypothesized that this registry would provide a good snapshot of the injuries treated by Consortium centers and would: (1) assist in making decisions regarding expansion of the Consortium to more centers; (2) identify recruitment challenges in competing projects; and (3) identify opportunities for additional studies based on the identification of high incident injuries that were not being researched by the Consortium.

ABOUT METRC

The overall goal of the METRC Consortium is to produce the evidence needed to establish treatment guidelines for the optimal care of the wounded warrior and ultimately improve the clinical, functional and quality of life outcomes of both service members and civilians who sustain high energy trauma to the extremities.

Anchored by a Data Coordinating Center at the Johns Hopkins Bloomberg School of Public Health and its Center for Injury Research and Policy, the Consortium includes 22 core Level I civilian trauma centers and 4 core Military Treatment Facilities (MTFs) – with the ability to expand patient recruitment to more than 30 additional satellite trauma centers.

LOCATION OF METRC CENTERS



METHODS

In 2010, an IRB-approved registry was established to assist the Consortium in determining the feasibility of future studies that could address critical research questions with adequate power. All core centers were asked to implement the registry via the REDCap distributed data system and maintain the registry for at least 365 consecutive days.

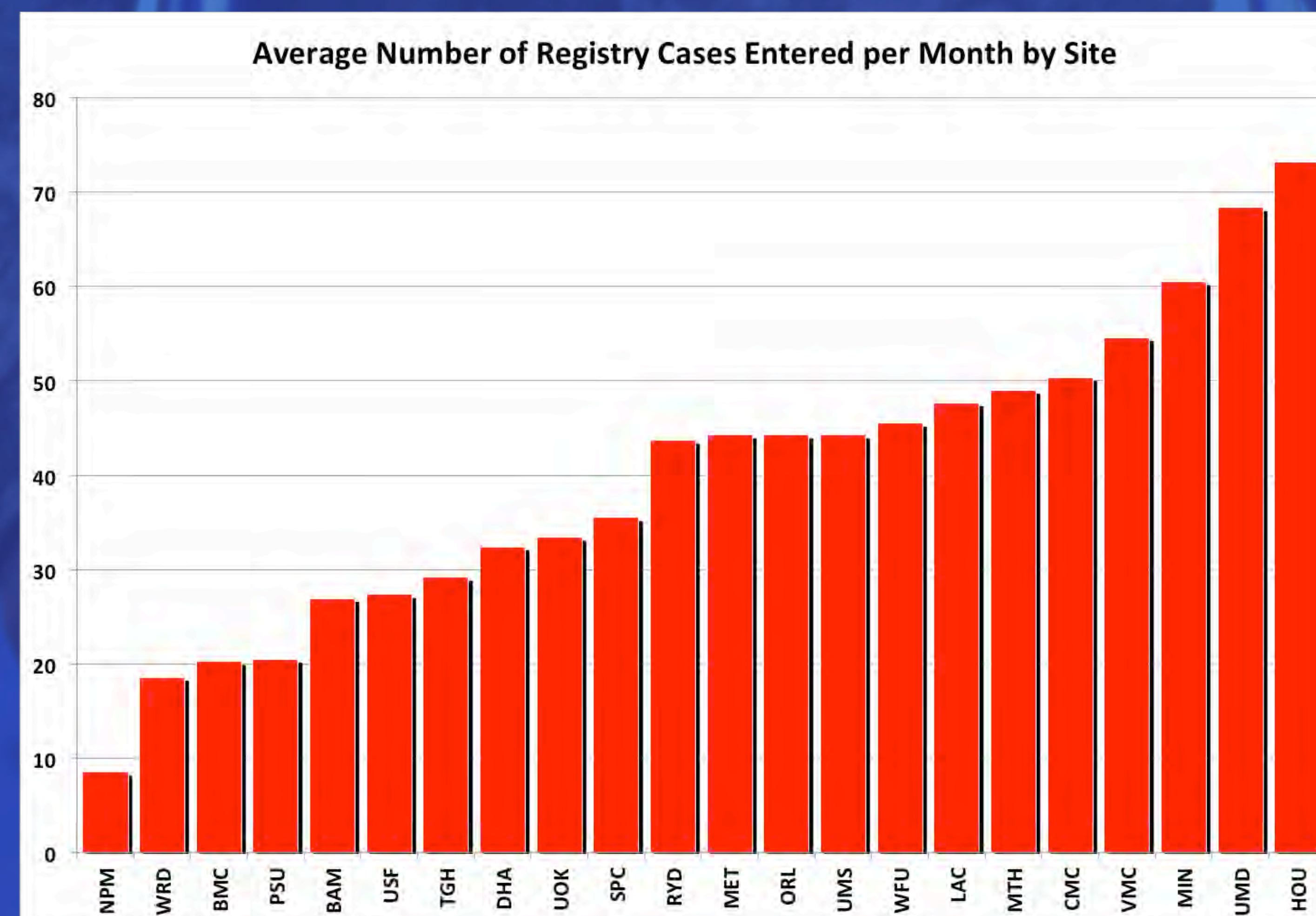
The registry contains a limited set of data on patients between the ages of 18 and 84 who were admitted with fractures requiring surgery of the upper or lower extremity, pelvis or acetabulum, and foot (calcaneus, talus or crush injuries only).

Excluded from the registry are hip fractures in patients 60 years or older and fractures to the wrist, hand, ankle, clavicle, patella, and the foot other than calcaneus/talus/crush.

RESULTS

As of August 15, 2012, 22 of the 26 core centers had implemented the registry and had entered cases for greater than 90 days; 18 of these centers have entered cases for 365 consecutive days. An additional 3 centers have just started to enter cases or are poised to begin; one center was unable to get the registry approved at its institution.

- A total of 11,972 patients have been registered across 22 trauma centers
- Data have been entered on 15,043 fractures (1.26 fractures per patient)
- The number of cases registered per month averages 36.4 across centers



The Table provides annual estimates of the number of ‘registry’ fractures treated per site and over the 22 core sites who have been contributing to the registry for at least 90 days.

- Over three quarters (77%) of all fractures are to the lower extremity
- Nearly one quarter (23%) of all fractures are open.
- Of the open fractures, 49% are Gustilo type III (33 % IIIA, 13% IIIB and 3% IIIC).
- An estimated 436 amputations (traumatic and surgical) are registered annually across the 22 sites (54 to the upper limbs and 382 to the lower limbs).

All Upper Limb Fractures	Average Per Site	Total for 22 Sites
Humerus	64	1417
11 A,B,C (% open)	24	536 (6%)
12 A,B,C (% open)	21	472 (22%)
13 A,B,C (% open)	19	409 (40%)
Radius/Ulna	69	1504
21 A,B,C (% open)	29	628 (28%)
22 A,B,C (% open)	40	876 (38%)
All Lower Limb Fractures	Average Per Site	Total for 22 Sites
Pelvis/Acetabulum	79	1729
61 A,B,C (% open)	38	826 (5%)
62 A,B,C (% open)	41	903 (2%)
Femur	144	3184
31 A,B,C (% open)	41	900 (3%)
32 A,B,C (% open)	72	1593 (19%)
33 A,B,C (% open)	31	691 (32%)
Tibia	195	4271
41 A,B,C (% open)	63	1379 (13%)
42 A,B,C (% open)	79	1730 (49%)
43 A,B,C (% open)	53	1162 (33%)
Foot	41	902
81 A,B,C (% open)	13	296 (27%)
82 A,B,C (% open)	25	546 (19%)
89 A,B,C (% open)	3	60 (55%)

CONCLUSIONS

The registry data have added value to the Consortium and its ability to plan for future studies. As can be seen in the Figure ... patients with type III tibia fractures are the subjects of several potentially competing METRC projects—driving the need for the addition of new centers. And, despite a high number of upper extremity, pelvic, and femur fracture patients, these injuries are currently the focus of few METRC studies. This information is being used to design future research.

The Consortium is currently in the process of expanding the registry to include information on nerve injuries.

ARE YOU INTERESTED IN PARTICIPATING IN METRC?

METRC is looking for centers that are interested in becoming involved as satellite centers. If you are interested in applying to become a satellite center, email admin@metrc.org or talk to Dr. Michael Bosse or Dr. Ellen MacKenzie.