Multiple data elements are necessary to provide up-to-date information for quality review and outcomes analyses as HCT evolves. Databases must have specificity yet flexibility in customizing data elements. Purchased proprietary applications are used by many HCT programs, but are limited by lack of cost-efficient configurability for center-specific needs. We sought to develop an HCT research application allowing evolution for program and scientific growth without major developmental costs. We identified 5 features essential for a functional HCT database including: 1) Uniform data capture; 2) Center-specific adaptability; 3) Rapid report generation; 4) Accurate, current data; and 5) Productivity tracking.

Between August 2010 and March 2012, our team of IT developers, programmer analysts, data managers, and a HCT physician planned, developed, tested, and launched a new database "BRAIN" (Blood and Marrow Transplant Research Analysis and Information Network). This required assessment of essential data, mapping and migration of data from a legacy database, and interface creation to available center systems. Legacy data was reviewed, standardized, and imported to BRAIN. Electronic interfaces connect institutional systems including lab results and medications via the Moffitt data warehouse to BRAIN. Additionally, discrete data such as staging and disease prognostic factors entered by clinicians into the electronic medical record interface with BRAIN reducing potential reporting errors or missing data elements. These interfaces, along with manual abstraction, enhance data for center specific analyses and electronic submission to CIBMTR via AGNIS. A dashboard identifying data manager specific CIBMTR forms due creates a proficient process of tracking forms. Thus, with the advancement of interfaces within the application and the mapping of this discrete data to the CIBMTR, productivity and accuracy are enriched. To date, two forms are submitted to the CIBMTR via AGNIS. Continuing efforts to map AGNIS-ready forms and development of a simple query tool will allow further growth and functionality within the application.

BRAIN fulfills a program need for cost efficiently, managing evolving data, enhancing data consistency, minimizing labor for data entry, making data easily assessable within the institution, and ensures current and accurate data submission to outside regulatory reporting agencies.

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Female Fertility After Allogeneic Stem Cell Transplantation in Denmark. A National Cohort Study

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Background: It is well known that female fertility is impaired after allogeneic stem cell transplantation (SCT), however, more female patients become long term survives, and wish to have children of their own. Data regarding pregnancies and child births are scarce. The aim of this study was to determine the proportion of female patients obtaining documented pregnancy and motherhood following SCT.

Methods: We obtained data regarding pregnancies and child births in consecutive female transplant recipients from our center. The patients were treated with SCT in the period from 1976 to 2012. Data was obtained through the national centralized access to the patients' medical records including specialist treatment. Patients less than 17 years of age at the time of analysis were excluded. In total, 161 women were included in the analysis. The median age at SCT was 17.2 years, and 31.4 years at analysis. Of the 161 women, 24 (15%) died in the observation period, the surviving 138 women were observed median 12.3 years (0.5-36).

Results: Of the 161 women, 20 (12.3%) had at least one documented pregnancy (i.e. fertile). One of the 20 women which experienced pregnancy is dead and never gave birth. Thirteen (8%) woman obtained motherhood: 8 had one child, 5 had two children. All children born were healthy. Among the women with a pregnancy, 9/20 (45%) had non-malignant hematological disease, and 11/20 (55%) had malignant disease, among the non-fertile women the numbers were 36/141 (25%) and 106/141 (75%), respectively ($P = .66$). Of the woman with motherhood, 7/13 (54%) had non-malignant disease, whereas 38/148 (26%) of the remaining women had non-malignant disease ($P =$ 0,029).

Total body irradiation (TBI) was given to 7 (54%) of the women with completed delivery, at a dosage of 200 cGy in 2 and 850-1200 cGy in 5 patients.

The median age at HSCT was not different among fertile and non-fertile women, 18.6 (2.3-33) years and 16.7 (0,2-34,6) years respectively ($P = .91$).

Among evaluable patients, chronic graft versus host disease (GvHD) was documented in 4/18 (22%) of the fertile women, and 43/116 (37%) of the non-fertile women, $P =$ 0,22.

Conclusion: Not all women are infertile following allogeneic SCT, despite treatment with TBI chemotherapy and chronic GvHD. However, only 8% obtained motherhood, emphasizing the need for fertility conservation procedures. The current study benefits from centralized access to patient information ensuring a high quality of accurate and complete data.

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Retrospective Data Review of Blood and Marrow Transplant (BMT) Medicare Coding to Analyze Coverage and Reimbursement Claims

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The number of hematopoietic cell transplants (HCT) for Medicare beneficiaries has dramatically increased, heightening the need to address Medicare coverage and reimbursement. Previous analysis of CMS claims data by ASBMT and NMDP suggested variability by HCT programs (HCTP) in coding and billing. Addressing these issues may be critical to ensure financial solvency for HCTP and continued HCT access for Medicare beneficiaries.

The Sarah Cannon Blood Cancer Network (SCBCN), consisting of 5 FACT accredited HCTP, analyzed Medicare claims data submitted by SCBCN between 1/1/11 and 12/31/11. 120 HCT were performed on 119 patients (pts): 69 men and 50 women, median age 67 years (range 28-79) with Multiple Myeloma (62), Lymphoma (35), Acute Leukemia (17) and other (5). There were 23 allogeneic (allo) HCT (MS-DRG-14), 2 of which were outpatient with an average length of stay (LOS) of 30 days (0-123) for related and 25 days (5-55) for unrelated; 12/23 were < 20 days. Inpatient coding for autologous (auto) HCT was split among three MS-DRG because of a change in 2012 from MS-DRG- 15 (71) and to MS-DRG 16—with complication/comorbidity (cc) (18) and MS-DRG 17—without cc (8) with average LOS 18 days (2-39); 55/97 were <20 days. Of 18 pts assigned DRG16, all appeared to have codes supporting increased complexity. Of 8 pts assigned DRG17, 5 had codes that might have supported billing under DRG 16. Among 23 allo pts, 7 were missing the code defining donor source as related or unrelated including both patients who received outpatient allo HCT. Revenue code 819, which reports charges for donor cell acquisition, was reported in 18 cases with a 40-fold variance in range of charges. Interestingly, this code was also submitted in 46 of 97 auto cases.

Conclusion: Significant opportunities may exist for using the proper MS-DRG for auto pts (which has substantial revenue implications) and the use of revenue code 819 for allo HCT (which has substantial implications for future rate setting). Programs can significantly increase future payment rates by understanding their current Medicare billing practices and identifying opportunities for improvement. Further investigation will focus on estimation of costs as compared with reimbursement for Medicare beneficiaries.

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CIBMTR Data Management Training Survey 2012

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Purpose: Effective training of data managers (DM) is instrumental to assure accurate, quality data. The National Marrow Donor Program (NMDP) and the Center for International Blood and Marrow Transplant Research (CIBMTR) network provide training resources and liaisons for each transplant center in order to assist in proper completion of the CIBMTR data collection forms. The University of Maryland Greenebaum Cancer Center's (UMGCC) Blood and Marrow Transplant (BMT) team utilizes the CIBMTR electronic training resources and liaisons, as well as other alternative training methods. Our team was interested in assessing the effectiveness of DM training methods and to enhance the CIBMTR DM training model.

Method: The UMGCC BMT team developed an anonymous, twenty-question survey on the various training methods implemented at 138 NMDP and CIBMTR-affiliated transplant centers in the U.S. The survey consisted of quantitative and qualitative questions pertaining to demographics, prior DM experience, and training.

Results: Seventy DMs responded to the survey. Participant ages were well distributed with 29% of participants 18 to 34 years, 39% 35 to 49 years, and 33 % 50 to 64 years. Most respondents (66%) reported that they had been a CIBMTR DM for greater than 5 years. Half (51%) participated in monthly internal assessments and 57% worked at centers that performed over 100 transplants per year. When asked about training to become a DM, 51% reported having less than 1 week of training and 88% reported not being extremely satisfied with his/her DM training. Thirty percent had no previous experience with BMT-related information when they became a DM and most (53%) were not audited prior to independently completing CIBMTR forms. Training to complete CIBMTR forms ranged from none to training received from multiple sources. At the time of the survey, 54% were not familiar with the current CIBMTR training model.

Conclusion: The CIBMTR DM Training Methods Survey shows that CIBMTR DMs vary by age, previous experience, and levels of training. Based on the data, it is evident that a training model, which incorporates specific procedures and methods, would be of value to CIBMTR DMs and the data they report. Standardized DM training would improve the accuracy and quality of data, which would contribute to the knowledge learned from hematopoietic stem cell transplant research.

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Standardizing Standard Operating Procedures' (SOP) Manual to Benchmark Cell Processing Laboratory (CPL) Performance

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Background: Healthcare SOPs are now standardized. There are a few hundred routine CPL policies/procedures (P/P) and maintaining SOP Manual (SOPM) becomes a daunting task. SOP of any two labs would not only differ on how to achieve the same task but no two SOPM would equally cover all topics required by regulatory and/or accrediting agency (R/AA).

Amongst the R/AA, JC, OSHA, CLIA, CAP, AABB, FACT & FDA all have oversight claims on the lab, including lab practices and SOPs. Failure to abide may result in catastrophic outcome from citation to shut down and insurance disapproval.

Objective: R/AA have common minimum standards-patient safety is the prime concern, and it may be possible to standardize R/AA requirements so that SOPM for every CPL is identical in content, achieving uniformity across the board.

Methods: In 2008, our CPL had a management change and became an independent lab with a cGMP facility. We inherited SOPs from two departments, a total of 161 policies plus 204 forms. There was confusion and duplication with two dissimilar SOPs and formats, also previous P/P had not been updated to current regulatory guidelines.

Early in 2010, we merged the two sets into integrated, practical and regulatory-compliant documents with novel formatting to distinguish one from the others. FDA regulations took precedence over other R/AA.

FDA, FACT, CAP and the JC's guidelines were keenly scrutinized prior to addressing the merger. SOPs were sorted into three broad categories: Quality Management, Cell Processing and cGMP.