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Quality Enhancements of your Biorepository Through Continuous Metrics Review

Beaumont

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Background

Ensuring the highest quality of biobanking services and operations, the Beaumont Health System BioBank has developed the following plan to guide our full range of Quality Assurance (QA), Quality Control (QC), and Quality Improvement (QI) activities. Setting and following policies with overarching properties covering sample collections, communications, monitoring and improvement reviews. The BioBank QA monitoring encompasses pre-analytical variables, consenting, sample processing to storage times, specimen analytic quality and fiscal operations. A robust specimen management system was needed to help support our specimen collection oversight as well as to report performance metric data. Biomaterial Tracking and Management (BTM, Daedalus Software) was procured to support the managing of specimens and the associated data.

Process

Quality Management (QM) is reviewing each investigator collections and associated specimen metrics giving light to the success and pitfalls in the day to day operations. With these metrics key indicators or targets and thresholds are defined.

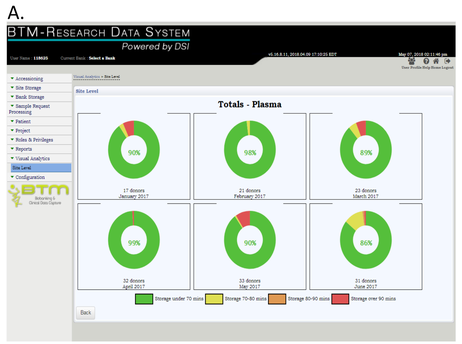
Consenting has daily oversight with monthly reporting from our research administration. Additionally, consent audits with associated charts are reviewed for correct data entry and pathologic findings. Since our operation includes the collection of DNA derived from whole blood from every BioBank subject, sample integrities of nucleic acids are measured and quality purity are documented and reviewed. An additional QA that is reviewed daily and monthly is our sustainable output for commercial contracts.

Planning-

All personnel have the appropriate education and experience, and receive the training for the type and complexity of variable collections. We ensure proficiency for individuals who conduct specimen collection, and perform quality control procedures to report analytical results promptly and proficiently.

Biospecimens- Thresholds are set to meet the needs of downstream application of the biospecimens and the realistic operational process. Time from operating room (O.R.) to freezer for all sample types and all collections are monitored from the time the samples leave the OR to the placement in storage (Serum ≤ 60 min., plasma ≤ 70 min., paraffin and frozen tissue ≤45 min.). Consent and storage box units are self audited for accuracy *(box audit results are reported and errors are corrected at the time of discovery).*

A.



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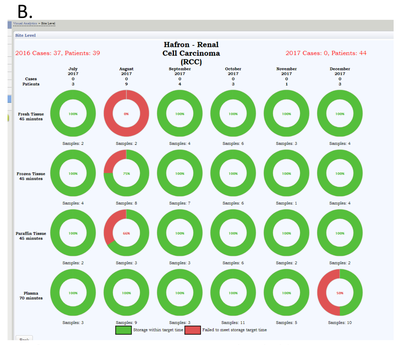


Figure 1. **(A)** BTM generated monitor for total plasma samples time form O.R. to freezer Jan.- June 2017, percent threshold were met at 91.1 %. **(B)** BTM generated metrics for Renal Cell Carcinoma collected July-December 2017. August 2017 warranted an internal review of collected fresh, frozen and paraffin tissue that did not meet the time cut off, followed by corrective action plan. The remaining four month showed a vast improvement, although a new threshold decline in the plasma collection for the month of December was noticed.

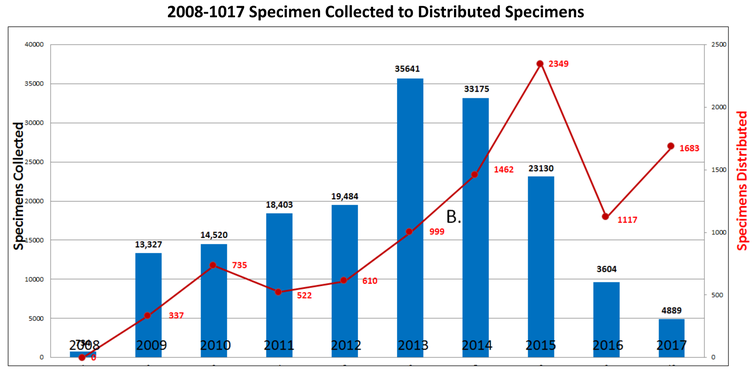
Teamwork-

Teamwork is at the back bone of the BioBank operation, deploying communication between BioBank staff, operating rooms, surgeons and pathology during day to day operations. Achieving optimal handling of patient's specimens and identify needs for remedial training or continuing education with the resulting of the internal metrics. In-services are scheduled between departments that interact with the BioBank to review processes, and to educate on the goals and quality initiatives as they relate to the larger Beaumont Health System.

Monitoring-

Time metrics are compiled by using our specimen management software BTM. Real time data can be extracted from specific collection time frames for a given specimen and/or project. This data is compiled quickly with a visual analytic tool designed to generate easy to read graphics for our QA. (*Figure 1.)* A standard operating procedure (SOP) which defines the quarterly review of BTM data entry scrutinizes patient identification within a chart and is compared to the specimen management system. This self inspection ensures the efficiency and accuracy of the data associated with our biospecimens. Another monitor involves the monthly assessment of the 260/280nm ratio of extracted DNA samples from whole blood (WB). The measured ratio for each sample is compared to the "ideal" value of 1.8. Both of these values are reported and discussed at our laboratory meetings. With the ongoing need for sustainability, a monthly review of specimen accrual with the percent of specimens collected for commercialization along with the number of donors consented is compiled and reported. Monitoring the distribution of these biospecimens sheds awareness to a focused and revenue generating collection process.

A.



B.

2016-2017 Consented donors to Commercialized Cases

	2016			2017		
	Total Donors	Commercialized	% Commercialized	Total Donors	Commercialized	% Commercialized
January	54	2	3.70%	19	11	57%
February	60	5	8.30%	25	15	60%
March	52	9	17.30%	25	19	76%
April	62	12	19%	34	24	71%
May	34	14	41%	37	29	78%
June	33	14	42%	33	26	78%
July	15	11	73%	32	18	56%
August	34	4	11%	32	20	62%
September	26	21	80%	28	11	39%
October	20	3	15%	28	17	60%
November	16	10	62%	43	26	60%
December	25	12	48%	30	34	110%

Figure 2. **(A)** *Beaumont driven collection accruals from 2009 through 2013 shows a specimen growth of 37% , compared to operational changes of sustainability-commercial contract driven collection decreasing the accruals in 2016 by 30 thousand.* **(B)** Targeted commercial collection started in 2016 with an increase of overall commercial donors from 117 to 250 in 2017, hence a percent donor to successful commercialized distribution at 35 % (2016) up to 67% in 2017.

Review-

Metrics are under active surveillance on a weekly basis by the section supervisor or designee with a monthly secondary review by the Scientific Director or designee. If monitors fall below the targeted threshold for 2 consecutive months an internal meeting to trouble shoot and resolve problems is scheduled (if after 4 consecutive months below the 75% threshold, a meeting with the Primary Investigator and/or other relevant departments [Pathology, etc.] is scheduled to discuss the collection and a corrective action plan).(*Figure 3.)* Consenting data is overseen and reported by self-audits and research institute administration. Deviations as well as patient safety incidents are recorded followed by corrective actions plans. This significantly reduced deviations in 336 consents to a low percent error of 0.6% in 2017. Specimen distribution (starting in 2016), an overall change in the BioBank collections operation occurred to include providing specimens for the NIH CPTAC initiative as well as commercial partners. This forced our targeted collections to meet the requirements of the specified contracts, hence giving way to a operational change decreasing our consented donors and subsequent samples. Consequently, increasing our percent consented donors whose samples were commercialized up to 67%, with a shift in revenues up by 40%. *(Figure 2.)*

Sample integrity within the scope of ideal nucleic acid, analytics is compiled for each DNA extracted WB, ratio data is charted to account for percentage of specimens within the 260/280 ratio. Extracted buffy coat DNA is purified using the MaxWell 16 SEV instrument (Promega) percent DNA ratio is reported for 2017 showing the threshold of quality at 93.1 % of the samples were within the range of 1.7 or > 2.1.

Figure 3. Pancreatic collection metrics Jan.- June 2017. Frozen and paraffin tissue samples fell below our thresholds for more than 2 consecutive months. Review of process reveals circumstances beyond our control (specimens are sent to frozen section room and the BioBank must wait for diagnostic review prior to receiving a portion of the tumor), hence targeted times may need to be adjusted or a process changed to meet the thresholds. Thresholds for specimen Ischemic time is set against Best Practice models (ISBER, NIH) tissue samples ≤ 30 min. ≤ 60 min.

Improvements-

All the mentioned monitors are discussed individually to determine whether the processes can be improved and brought into line with our stringent ideal metrics. If necessary, corrective action must be taken and properly documented to show QA improvements. Over the course of the 10 years of the Beaumont BioBank quality downfalls have been teased out due to vigorous metric review followed by process improvement plans. Sample handling requirements may shift due to unforeseen work flow out of the control of the BioBank. Sustainability has forced continuous review of evolving customer projects and needs, hence shedding light on fiscal operations aligning with QM.

Conclusion

The quality management plan sets the framework for the implementation and documentation of a continuous QI program within the BioBank. This allows the BioBank to continuously monitor and improve its daily activities. The value of the BioBank is defined and supported by the quality of these biospecimens and in turn provides the resulting research.

Acknowledgment

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