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GUEST EDITORIAL

Moving Toward Biospecimen Harmonization with Evidence-Based Practices

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Harmonization! Standardization! Common SOPs! These terms seem to be the mantra of today's biobanker and are certain to come up frequently next month at ISBER's 2014 Annual Meeting. Why do we care so much about these topics? They are the keys to being able to understand what we are really storing in our biobanks and being able to utilize and share biospecimens with some assurance that different tissues collected from different facilities on different days used similar procedures. The harmonization of biospecimen collection, processing, and storage procedures is particularly challenging and is rife with conflicting ideas about what ''should'' be done, what ''can'' be done, and what ''will'' actually be done at different facilities.

In the ''shoulds'' we wonder, for example, what is the best way to process the biospecimen? Is the ''best'' really different from the usual way at this facility? How do I know whether the ''best'' way is really best? What evidence is there for doing things one way versus another? Is there really one ''best'' way, or are there different best ways for different downstream uses of the biospecimens (''fit for purpose'' model)?

In the ''cans'' we wonder, can the facility purchase and utilize the reagents needed for the ''best'' way? Is it going to be possible to transport reagents and biospecimens as needed for a new procedure? Is there staffing available to process biospecimens according to different procedures? Is there even room in the physical space for an alternate storage vessel required by a new procedure? If it is simply not possible to implement every step of a new procedure, what will we ''sacrifice'' in terms of biospecimen quality?

And then we have the ''wills'' – what will really happen in the field when a new standard operating procedure (SOP) is implemented? Will timepoints be adhered to? Will instruments operate as expected? Will anyone actually read the SOP?

This is admittedly an intimidating set of challenges. What's a biobanker to do? Simply give up before starting? Absolutely not!

There is a growing number of tools for biobankers to access when dealing with harmonizing practices across facilities or starting new biobanking projects. These may include SOPs from other organizations, often posted for public use. Shared experience from other biobankers can be invaluable in evaluating a new SOP for adoption. Review articles and other publications can help us to understand the shoulds, cans, and wills of different biobanking procedures.

A disciplined approach has emerged in recent years to understanding the evidence base for using one SOP over another, and annotating biospecimens with information about how they were collected, processed, and stored. The NCI Biospecimen Research Database is a well-utilized, online literature database for biospecimen science. The ISBER Biospecimen Science Working Group has contributed a structured approach to annotating biospecimen procedures (SPREC[1]), while an NCI working group recommended an organized approach to including such information in publications (BRISQ[2]). The NCI BRN program[3] (Biospecimen Research Network) in the United States and the SPIDIA program[4] (standardisation and improvement of generic pre-analytical tools and procedures for in-vitro diagnostics) in the European Union have both addressed the need for basic and applied research to build the knowledge base in biospecimen science. In this issue of *Biopreservation and Biobanking*, NCI describes a new approach to building evidence-based procedures from idealized practices supported by literature references (Engel et al.[5]). Ideally, understanding the evidence underlying a procedure, including what may be compromised if the procedure is not followed, will help us to craft practical SOPs that will be fit for the purpose of the biospecimen and the capabilities of the collection facility.

If harmonization could be achieved internationally on biospecimen collection, processing, and storage procedures – as well as proper annotation of such in biobanks – the positive effects for research and development would be immeasurable. Challenges in disease biomarker identification and validation would be greatly reduced if work began with biospecimens that have been collected the same way. Development and validation of clinical assays performed on biospecimens would have one major area of challenge reduced if biospecimens were collected under common SOPs suited to the analytical needs of the assay. Ultimately, patients would benefit from more robust research and development enabled by improved and harmonized biospecimen procedures.

The ISBER community itself has been and continues to be a remarkable resource for working towards this harmonization in a truly international, collaborative manner. Many thanks go out to all of the ISBER members and leaders for

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the gifts of their time and talents in making this organization such an important part of growing the field of biobanking.

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