Quick, Easy, Fast, and Cheap!

Using Excel to Eliminate Risk of Errors, to Standardize Reports, and Support the Triple Aim of Improved Accessibility and Patient Outcomes at Less Cost

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Why are we here…

Purpose:

As healthcare strives to accomplish the Triple Aim - improved accessibility and patient outcomes while using fewer resources - capitalizing on opportunities for continuous improvement is a necessity. Using Excel spreadsheets as a tool during the testing process is an easy and effective way to support this Aim by maintaining quality outcomes while still gaining efficiency in daily processes.

This presentation outlines how BloodCenter of Wisconsin's Diagnostic Laboratories learned to manage Excel workbooks within their document control process to improve quality and efficiency, reduce potential risk, and maintain compliance.

Why are we here…

Objectives:

1. Demonstrate how Excel functionality can benefit the testing process, improving both efficiency and quality.
2. Share best practices on how to maintain control over spreadsheets while still supporting functionality.
3. Convey strategies that build your laboratory's capacity and knowledge base in Excel in order to sustain and expand upon improvements.

Why are we here…

Takeaways

- To identify where Excel workbooks can be beneficial in reducing errors by exploring potential risks.
- Excel functionality that can easily be applied to laboratory testing.
- The value of implementing standard work, with clear development of roles and responsibilities, for review and control of Excel workbooks.
- The importance of managing Excel workbooks to avoid unauthorized content changes that have the potential to impact testing processes and results.
- Real lessons learned regarding the challenges and successes around harnessing the benefits of Excel functionality while still maintaining compliance and quality.

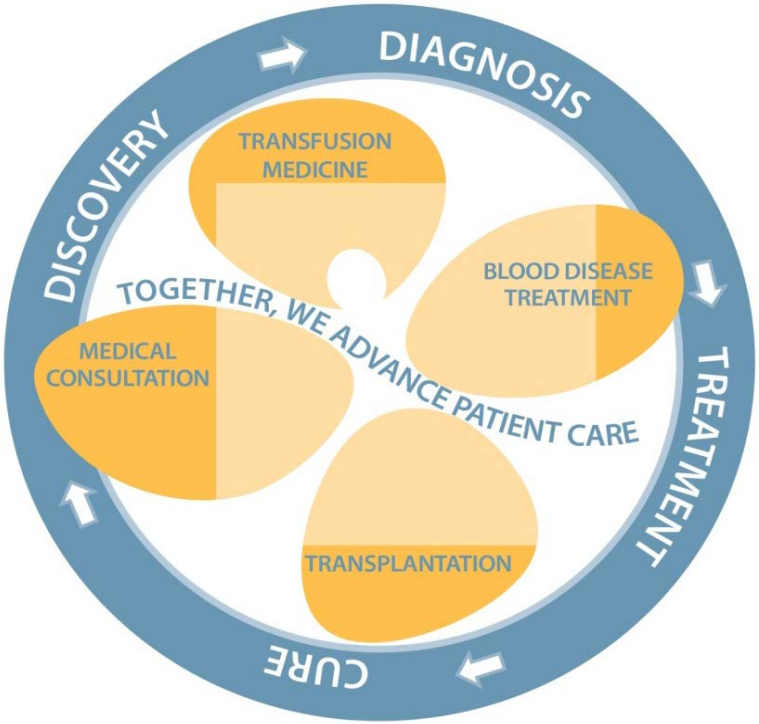
BloodCenter of Wisconsin

Mission:
BloodCenter of Wisconsin advances patient care by delivering life-saving solutions grounded in unparalleled medical and scientific expertise.

Vision:
Together we will become the blood center without equal, discovering new ways to save more lives.

Values:
Excellence – To strive to be the best
Integrity – To bring honesty and responsibility to all we do
Learning – Dedication to acquire and share new knowledge and skills
Respect – To affirm each person's dignity and worth
Innovation – To create new knowledge and solutions
Service – To anticipate and exceed customer expectations

Serving patients and the community through



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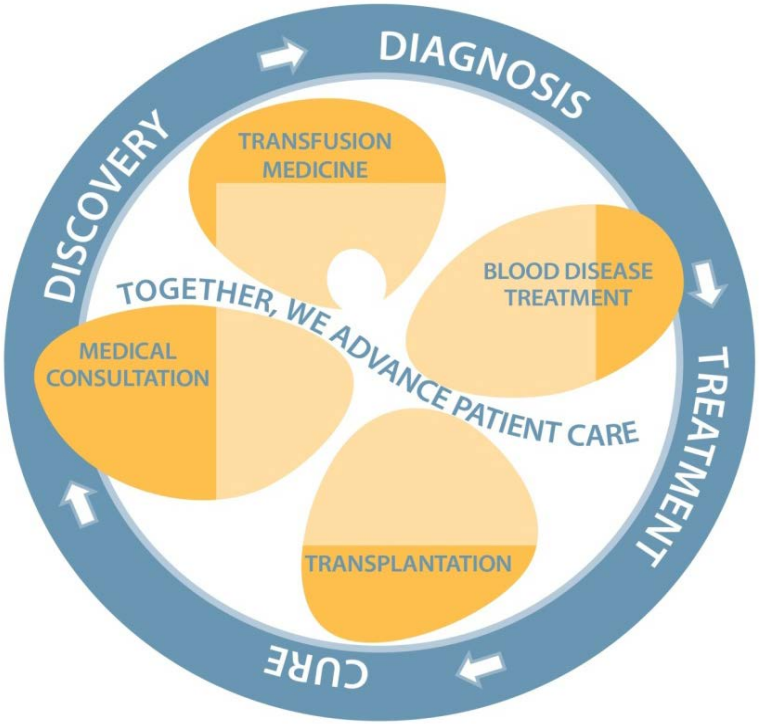
Multifaceted Care

- Blood Services
- Medical Science Institute
- Blood Research Institute
- Organ and Tissue Donation
- Diagnostic Laboratories

Serving patients and the community through our

Continuum of Care



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Diagnostic Laboratories

- Use innovative tests and unparalleled expertise to help physicians **deliver better care to the patient**.
- Comprised of multiple areas of expertise
  - Hematology Lab (HEM)
  - Histocompatibility Lab (HLA)
  - Immunohematology Reference Lab (IRL)
  - Molecular Diagnostics Lab (MDL)
  - Molecular Oncology Lab (ONC)
  - Platelet Immunohematology Lab (PNIL)
  - Transfusion Services (located in Children's Hospital of Wisconsin)

  - Product Development Lab
  - Applied Research Lab

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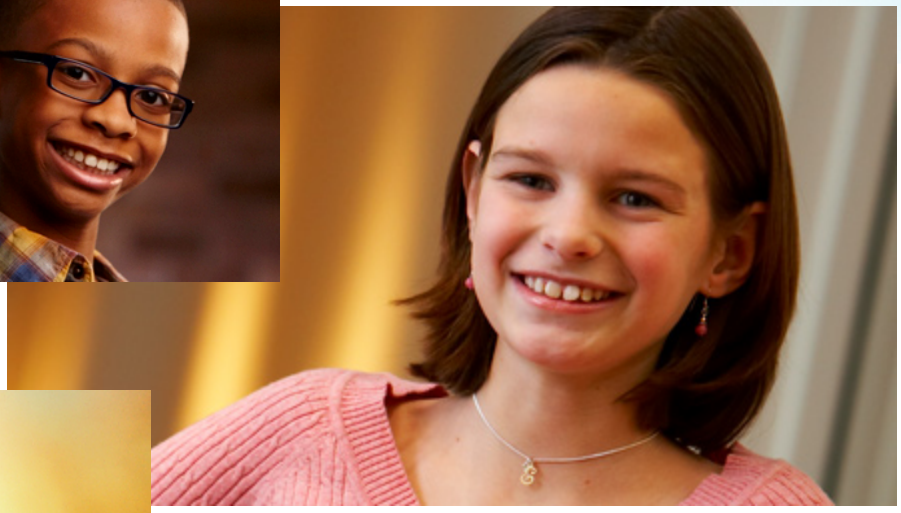
Find your foundation…

Everything we do starts and ends with **patient care**:







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Documentation

- Laboratory testing requires documentation:
  - Patient names
  - Lot numbers
  - Expiration dates
  - Calculations
  - QC information
  - Temperatures
  - Test results

Documentation

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  - Temperatures
  - Test results

Challenges and Risks to Documentation

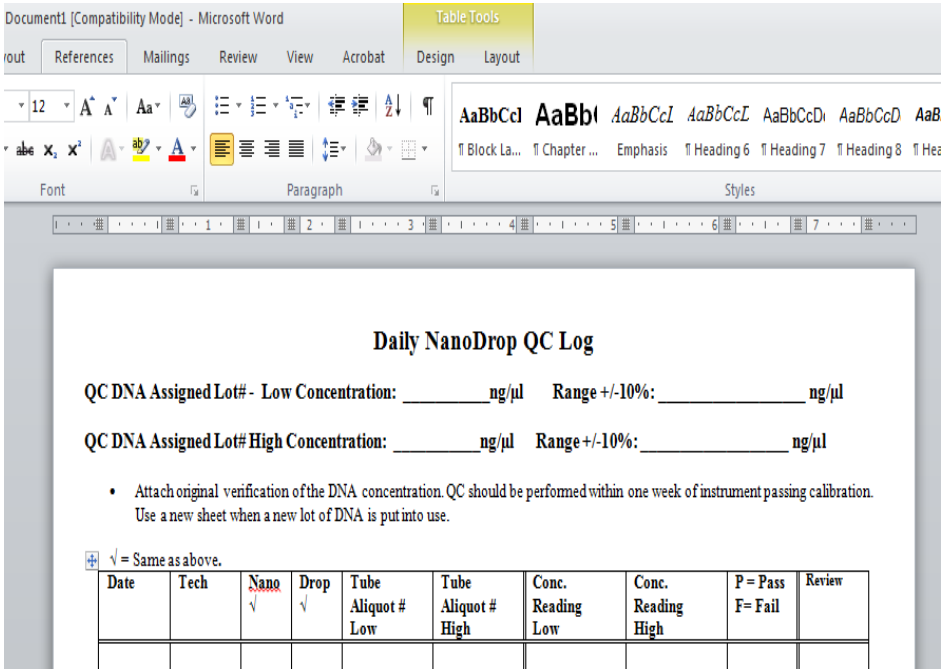
- Time consuming:
  - Repetitious information
  - Information can span multiple worksheets
  - Complex testing may require more documentation

- Transcription and Calculation errors:
  - Transpose long or similar lot numbers
  - Transpose numbers in results
  - Fields erroneously left blank
  - Misspell patient names
  - Miscalculate a formula

Documentation at BCW

Controlled Word document forms available in hard copy

Controlled Word document forms available from electronic drive



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Finding Opportunity in the Challenges

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Wouldn’t Excel Be Better?

Benefits

- Built in formula functionality for calculations and repeat values
- Built in visual management features
- Workbook feature to contain all applicable worksheets (better organization)
- Existing program on all PCs with no additional cost

Challenges

- Unsure of compatibility with our document management system
- Ensuring version control
- Protecting content and formulas
- Different user ability levels
- Availability of PCs near bench top

Functionality – Creating Content

- Majority of functionality comes from **basic or common** Excel functions:
  - Calculations: Basic math functions such as =, -, +, /, ( ), SUM
  - Repetitive information: = (other cell locations), links to other workbooks
  - Required fields: Visual management with conditional formatting, cell shading
  - Long number sequences: Barcode scanning
  - Clean look: If, Then function to eliminate error messages

- Synergy of Excel content with SOP content

Functionality – Protecting Content

- Control over inadvertent edits
  - Content: Lock cells on the worksheet or workbook level
  - User Flexibility: Protection options to allow users some customization in use

Validation / Qualification

- This was the most challenging part of the process, due to so many considerations and the need to ensure quality and compliance:
  - Should these be treated as software or as a controlled document?
  - Should these be required to have a full validation plan or is a qualification of functionality sufficient?
  - If we only require a qualification, how do we document?
  - How do these decisions above impact existing, validated spreadsheets already in use?
  - Who should be responsible?

Validation / Qualification

Made the decision to version control the Excel forms using our existing document management system.

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Validation / Qualification

That decision came with benefits and challenges that influenced other decisions along the way:

Benefits:

- Documented approval of content within each version
- Annual review of content
- Better control over locations of published files
- Standard across all of BCW and not just the labs
- Ability to “flag” functional Excel files in the system

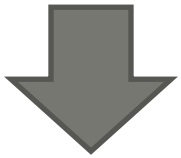
Challenges:

- Existing spreadsheets needed to be incorporated into system
- Compatibility of document management system
- Made people uncomfortable/took some control away from the labs

Validation / Qualification

Required **documented evidence** that the functionality and content of the Excel document had been verified prior to publication of a new version.

To allow flexibility based on the workbook content, we did **not** specify how this documented evidence should look.



This led to each area documenting this evidence in different ways and left us more prone to formatting and logic errors.

Validation / Qualification

Creating standard work helped enforce roles, responsibilities, and expectations and decreased our amount of re-work.

Excel-type QSD Checklist - DLQ

Instructions Ensure that each of the following areas are verified and properly addressed for all Excel-type QSDs *before preparing approval copies and/or master copies*, as listed.

Before Printing Approval Copies			
Complete	NA	Formatting the Workbook:	Notes:
☐	☐	Each worksheet contains the title of the QSD.	
☐	☐	Each worksheet contains the name of the tab. *(Applicable only to workbooks with more than one tab.)*	
☐	☐	Each worksheet contains a compliant QSD footer.	
☐	☐	Print settings are set based on the use of the document.	
☐	☐	Instruction worksheet included in the workbook. *(Applicable only if the entire workbook will not be printed each time the Excel QSD is used.)*	
Complete	NA	Protecting the Workbook:	Notes:
☐	☐	Each tab/worksheet is password protected.	
Complete	NA	Overall Formatting & Functionality of Workbook:	Notes:
☐	☐	*Excel-type QSD Checklist - Departmental* form completed by the department and included in the DCR packet.	

Upper Checklist completed by: _____ Date: _____

Before Printing Mastering Copies			
Complete	NA	Protecting the Workbook:	Notes:
☐	☐	Each *tab/worksheet* is password protected.	

Lower Checklist completed by: _____ Date: _____

Excel-type QSD Checklist - Departmental

Instructions Ensure that each of the following areas are verified and properly addressed for all Excel-type QSDs ***before requesting approval copies from DLQ***. If a line is not applicable to the Excel-type QSD, check the "NA" box and **include justification** in the "Notes" field.

The checklist MUST be completed using the file saved in DMS.

If **ANY changes** are made after the checklist is finished, a new checklist must be completed and submitted with the DCR packet before approval copies are created.

Complete	NA	Formatting the Workbook:	Notes:
☐	☐	Each worksheet contains the title of the QSD.	
☐	☐	Each worksheet contains the name of the tab. *(Applicable only to workbooks with more than one worksheet.)* **Note:** While not required, it is best practice to delete any unnecessary, empty worksheets from the workbook.	
☐	☐	Each worksheet contains a compliant QSD footer *(which includes copyright, page numbers, QSD number, effective date, and version number)*:	
☐	☐	Formatting is appropriate to the functionality of the workbook *(i.e. - cells formatted as "number" vs. "text," columns are wide enough to view inputs, etc.)*. **Important**: This includes ensuring that all formatting (*especially conditional formatting*) is compatible with the file **as stored in DMS** (.xls, .xlm, .xlt extensions).	
☐	☐	Print settings are set based on the use of the document. *(It is easiest to view this using Print Preview or by printing the document.)*	
☐	☐	Instruction tab included in the workbook. *(Applicable only if the entire workbook will not be printed each time the Excel QSD is used.)*	

Excel-type QSDs - Standard Work and Helpful Hints

Table of Contents

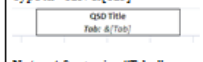
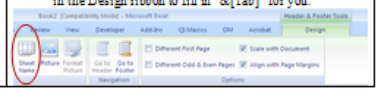
- Instruction Tab
- Adding the QSD Title and Tab Name to the Document
- Margins
- Locking and Unlocking Cells
- Protecting the Sheets
- Print Set Up - Print Areas and Scaling
- Linking Cells to other Workbooks
- Saving the Workbook
- Uploading a File Directly into DMS

Instruction Tab The following is standard wording to include in the instruction tab of -7 and -4 Excel QSDs.

"This workbook contains a total of [*insert number of tabs, including instruction tab*] tabs and is designed for [*insert appropriate tab name(s)*] tab(s) to be printed out as a single, complete record."

Adding the QSD Title and Tab Name to the Document The title and tab name can be entered into Row 1 of each sheet manually or they can be placed in the workbook header.

To place it in the workbook header:

Step	Action
1	Double click in the header area.
2	Type in the QSD title.
3	Hold "Alt" and hit "Enter" to move to the next line.
4	Type in "Tab: &[Tab]"  **Note:** After typing "Tab:," you can hit the "Sheet Name" button in the Design ribbon to fill in "&[Tab]" for you. 

Initial Training - User Level

- Group level:
  - Held training multiple open training sessions on Excel functionality to create a common baseline knowledge among all staff

- Individual level:
  - Questions and training specific to the test were fielded by the applicable area's super user, management, or primary trainers.
  - More advanced Excel training was offered by request

Initial Training – Super User Level

- Group level:
  - Held training multiple open training sessions on Excel functionality to create a common baseline knowledge among all staff
  - Held training sessions to communicate **roles**, **responsibilities**, and **expectations** (including the use of our Qualification Checklists).

- Individual level:
  - More advanced Excel training was offered by request or level of need.

Sustainability

- **Software**:
  - Excel software is a common, available program
  - Excel is usually upgraded as part of an OS update

- **Training**:
  - Many people have a basic level of understanding already
  - Additional training incorporated into assay training and competency as the forms are part of the testing process
  - More advanced training offered by request and through “tips and tricks” guides tailored to the labs’ most common questions

Sustainability

- **Content**:
  - Maintained by the lab and subject matter experts
  - Simplicity in design makes content easier to update and maintain even after creator transfers out or leaves BCW
  - Spreadsheets are called out in SOPs as related documents
  - Annual review of content

Efficiency Gains and Avoiding the Cost of Quality

- Decrease in overall documentation time:
  - Decreased transcription time of lengthy information, especially with lot numbers and expirations
  - Decreased repetition in transcription
  - Decreased time needed to calculate reagent volumes based on number of samples
- Cost of Quality
  - Corrected Reports
  - Customer Dissatisfaction
  - Rework to correct error, investigate root cause, and implement actions to prevent additional errors in the future

Celebrating Successes

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What we did well…

- Identifying pain points and brainstorming solutions to address them
- Recognizing the need for flexibility in the document control process
- Identifying experts in the work to create the content
- Communicating among the lab areas to highlight what worked well and what was painful
- Maintaining version control and protecting the content

Learning through Failures

Great Start

Unforeseen Challenges

A Flooded Tent & Lessons Learned

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What we could have done better…

- Establishing roles and responsibility at the beginning
- Establishing expectations at the beginning
- Creating standard work around qualification and validation
- Creating standard work between lab areas
- Assessing employees understanding of Excel
- Documenting “tribal” knowledge
- Better compatibility between software (aging document control system)

Questions?