SOPS – YOUR BIGGEST RISK TO PATIENT SAFETY? TIME TO RETHINK

by Martin Lush

Recently I had the privilege of working with a really committed group responsible for packing pharmaceuticals. I only wish the circumstances had been different. NSF Pharma Biotech was there to investigate the cause of a $28 million recall following a packaging error. The people were excellent and the equipment was adequate, but the procedures were awful! When we reviewed the SOPs covering critical activities (line setup, clearance and reconciliation), this is what we found:

- The average length of each SOP was 36 pages
- All SOPs referenced other SOPs, increasing error risk from 'distraction'.
- Each SOP required the user to 'jump' forward or backward in the same SOP, further increasing the risk of mistakes due to distraction.
- All SOPs consisted of solid text. Lots of words. Not a picture, diagram or schematic to be seen. In short, they were impossible to follow even if you were sitting in a soundproof room, let alone alongside the commotion of a busy, noisy packing line. The SOP's detail was overwhelming, confusing and unnecessary. We asked the author about involvement of the users. The answer? …'none'. 'Why so much detail?' we asked. 'We wanted to cover every eventuality to keep the inspector happy'. It seemed keeping the inspector smiling was more important than having a safe and reliable packing operation.
- SOP versions had also changed three times in just eight months, giving operators no chance of habituating the procedures. Additional details had been added in response to deviations, errors and mistakes. Instead of fixing the problem, the SOPs added more complexity and greater risk to create even bigger problems.

- As for 'check' signatures... Well, there were so many, nobody knew who was responsible for what. So many in fact that operators were forced to complete signatures at least 20 to 30 minutes after the task was complete.
- All three SOPs had been rushed in. Operators had been 'trained' by quickly reading through the SOP in the coffee room, not even on the packing line.

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Unfortunately, what we found -- SOP users doing the best they can with what they've got -- is not uncommon. **Many companies have simply forgotten about the core purpose of SOPs**, which is to ensure consistency in practice. In short, you get the same (consistent) result no matter who performs the task. Batch after batch. Month after month. This is why clear instructions and user involvement are so important.

During our 'Error Prevention' workshop we spend a lot of time talking about writing error-free SOPs; SOPs that ensure consistency, not confusion. These '**Five to Fix**' quick tips will start you on your way:

1. **Design documents** to be brain friendly and easy to read. Include pictures, schematics and/or process flows, all in logical order. Anything but words only. We know the brain only skims, rather than reads individual words. We also know our executive brain (used for focused thinking) can only manage 7 facts ±2. So, the more words and detail…the greater your risk of people not taking in or not remembering everything covered.
2. **Customise the level of detail** to the users and the task, including their background, education and experience. The better educated, the less 'how to' detail is required. Remember, in many cases 'less is more'.
3. **Let users design and write SOPs**, or at least review them. They must follow the directions and feel ownership of the procedures.
4. **Make SOPs easy to habituate.** Make sure you have the right 'triggers, routines and rewards'. If you don't know what these mean, have a listen to the recording of our free webinar on 'Changing Behaviours in the Workplace': **www.nsf.org/newsroom/webinar-changing-behaviors-in-the-workplace-how-to-educate-not-train**
5. **Provide alternatives to paper.** I watched a flight crew do a pre-flight check the other day with not one piece of paper in sight. The whole process was done using a tablet computer. One of our clients is already working on replacing SOPs with these as well. What they showed me was very impressive. One click took you to the process overview. Another click took you to a video demonstrating (in a way words can't) how to perform the task. It worked and the users loved it. Why are we so immersed in paper when there are better alternatives?

WHAT NEXT?

YOUR 'CALL TO ACTION'

Before we revisit our SOPs, we have to start facing the facts and stop kidding ourselves:

> SOPs are really expensive to write and administer. In fact about £18,000+ per SOP.

> Many expensive deviations and 483s are due to 'procedural non-compliance'. People don't follow SOPs because they can't. Their spirit is willing, but their brains are overwhelmed by the often difficult to use information in SOPs.

> Most incidents attributed to human error are nothing of the sort. The real root cause is over complexity of the SOP that's meant to help, but hinders.

> Most SOPs are so complex and poorly designed that only one thing is guaranteed: more errors and mistakes. So, ironically, the one thing we rely upon for 'consistency of practice' is actually increasing risk. We spend all this money and we get increased risk as our 'return on investment'. Surely things have to change?

If you want more **hints and tips on reducing errors** and getting more from your SOP system, I encourage you to attend one of our 'Error Prevention' sessions. I will share with you the latest best-in-class practices for error reduction. One of our clients saved over $2.5 million by applying some simple rules. You can achieve the same. Go to our website to find forthcoming dates and venues.**www.nsf.org/info/pharma-training**

Our Human Error Prevention training courses are also available in French, German and Italian. To request these services, contact us on **EUpharma@nsf.org**.

ANOTHER RESOURCE

If you want to keep up-to-date on the latest error prevention discussions, tools and techniques, join our 'Human Error Prevention' group on LinkedIn.

ABOUT THE AUTHOR

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