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Clean Room Sterilization Process Improvement

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to the Nebraska Hospitals Association Quest for Excellence Awards

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Honorable Mention: Nancy Hicks-Arsenault, Theresa May

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CCH CHERRY COUNTY Hospital and Clinic

Leadership/Planning:

Cherry County Hospital (CCH) is a Critical Access Hospital in rural North-Central Nebraska, with a service area that extends throughout Cherry County (the largest county in Nebraska) and into South Dakota. The patients who rely on the services provided at CCH are our friends, neighbors, and loved ones. With that in mind it is easy to strive toward our mission of "Providing Personalized, Quality, Progressive Health Care.[1]" This mission statement is not just a line in an employee handbook. It is something that is lived every day; by the team members who not only serve our patients, but who live and serve in our community.

This mission statement is the basis for our strategic plan which was put into place by the hospital administration in April of 2021, with the assistance of the Senior Leadership Team (SLT). The strategic plan is built on the five pillars: People, Quality, Service, Growth, and Finance. The goal related to the Quality Pillar is transparency for quality and safety reporting, and meeting or exceeding national standards. The objectives also discuss transparency of quality reporting. This transparency is an important goal, as it allows for the entire facility to come together; and pool their resources to manage a problem, to find a suitable solution.

Too often, departments can be considered a silo; cut off from the rest of the facility. If a quality metric is found to need improvement, the burden of improving that process can feel to rest solely with the one specific department where the concern was identified. In contrast, encouraging transparency of those quality metrics can help to include other team members in the improvement process. This is fundamentally important, as most quality improvement projects must span departments to truly be effective. In line with that goal of transparency, the Clean Room Sterilization Process Improvement at CCH included not only the pharmacy

department, but also: improvements and process changes from environmental services and maintenance, input and improvement plans from quality and infection control, and support and guidance from the administration and Chief Executive Officer (CEO) at Cherry County Hospital.

Process of Identifying Need:

The positive and negative pressure rooms utilized for sterile compounding are certified semiannually by an outside company, AT analytical. This testing is in compliance with current standards[2]. The results of this testing are reported to the Director of Pharmacy. This position was held by four different individuals between the years of 2015 and 2022, at which point a fifth director assumed the role. The fragmentation in methods, resulting from repeated change in department management, allowed for utilization of processes in dire need of revision. Our cleanroom sterilization was one of these processes.

When AT analytical completed their report for the spring of 2022, the viable and particle counts in the compounding rooms did not pass initial testing. These were retested after interventions and subsequently passed; however, this prompted a review of past reports to identify the full scope of the event. AT analytical was contacted to request past reports. A representative issued access to the Director of Pharmacy for the AT analytical website, where report information could be pulled. A compilation of the initial findings from the previous recertification reports was completed and reviewed. It is noted that these are initial findings only; as the hoods have been retested in response to these results, to maintain compliance.

Information dating back to 2019 was available, which predates the cleanroom construction. Reviewing these reports revealed that an ongoing issue with viable and particle counts has been occurring since the initial construction of the cleanrooms (see chart in

Appendix B). The importance of passing particle and viable counts is related to product contamination rates. If the cleanroom environment is not appropriately maintained, it could cause infections in our patient population, due to an increased possibility of microbial contamination in the prepared intravenous product.

It is also important to note that the problematic counts were located in the surrounding rooms, not in the Compounding Aseptic Isolator/Compounding Aseptic Containment Isolator (CAI/CACI or hoods) where the compounding actually occurs. The United States Pharmacopeia (USP) general chapter <797> is considered the standard for compounding sterile medications[3]. This chapter has previously allowed for compounding in a CAI that is not located in an International Organization for Standardization (ISO) class 7 buffer area, under certain conditions[2]. This is considered an appropriate method for compounding. The new USP regulations which become official on November 1st, 2023 also allow for compounding outside of a cleanroom, if in a primary engineering control[2, 4].

As stated, in certain situations, it is considered appropriate and within current best practice to compound without the additional security of a dedicated buffer room beyond the hood; however, the USP <797> recommendations are stated to be the minimum standards to follow for safety[2]. Therefore, it is still in the best interest of our patients to strive to adhere to the most sterile environment possible when compounding. Any risk for contamination could potentially lead to infection in our patients.

The CCH team has been directly involved in the care of numerous patients struggling with infections. Whether it be Methicillin-Resistant Staphylococcus Aureus (MRSA) bloodstream infections, pneumonia, infected joint replacements, or urinary tract infections (UTIs) the

healthcare professionals of Cherry County Hospital have been there through them all. These infections can result in time away from work or family, multiple surgical visits, intensive care transfers, and multiple other stressors for these individuals and their loved ones. Having seen firsthand the difficulties that these occurrences present to patients, it makes the decision to strive for excellence during compounding suite sterility an easy choice for the wellbeing of our patients.

Process Improvement Methods:

Multiple interventions were performed to combat the low particle counts and high viable counts reported for the cleanrooms. These include: stricter garbing practices and training, medication storage removed from the cleanrooms, re-varnishing the doors, examining the air handler and vents, and increased cleaning. These interventions were undertaken by the Director of Pharmacy and pharmacy staff, with direct collaboration with Clint Assarsson the Head of the Maintenance Department and the entire Environmental Services Team under the direction of Ashely Sandoz, the Director of Ancillary Services.

Another process improvement put into practice, is the effort made to integrate more premixed solutions into our facility workflow. This allows for not only decreased risk of contamination, and longer storage; but also mitigates the risks of compounding errors. For added patient protection, the premixed bags tie into our barcode scanning security in the electronic health record (EHR). Another option used, for medications not purchased in premixed solutions, are the Baxter Mini-Bag Plus Containers. These adaptor bags allow point of care compounding outside of pharmacy business hours. This point of care mixing is also within

approved practice per USP <797>, as these immediate use options are considered outside the scope of compounding restrictions[2].

In addition to the above stated interventions, one novel practice implemented was the use of the Tru-D SmartUVC device for disinfection of the cleanroom suite. Tru-D uses ultraviolet light to disinfect surfaces, and is available from PDI Healthcare[5]. This device was initially purchased by CCH amid the Coronavirus Disease (COVID-19) public health emergency, to disinfect rooms after exposure to patients with the SARS-CoV-2 virus. While reviewing the most comprehensive cleaning processes available at CCH, this novel device was added to our processes to enhance the level of sterility attained in the compounding environment.

Chuck Dunn, the President at Tru-D SmartUVC was contacted to discuss the feasibility of using this device with regards to the safety of our cleanroom equipment; specifically the High Efficiency Particulate Air (HEPA) filters located in the CAI, CACI, and built into the air handling system of the rooms. Mr. Dunn provided information via email which discusses the application of ultraviolet (UV) systems to HEPA filters[6] which can be generalized to our use in the cleanroom suite. Mr. Dunn discussed that the application of UV light, as is done during a treatment with the Tru-D device, should not cause concern for harm to the filter[6]. This intervention would not have been an effective process improvement if the stability of the HEPA filter were impaired during the disinfection of the cleanroom environment.

Using the past AT analytical reports, it was possible to review the impact of the executed interventions. After the Tru-D device was added to the workflow, the viable counts passed on both the fall 2022 resample, and the spring 2023 initial results. Infection control data compiled by Theresa May (RN, Infection Control) was also reviewed. The infection rates of the

facility have not indicated an issue with regards to compounded sterile preparations (see graphs in Appendix C). This will be discussed in more detail in the results section.

In an effort to align with our objective of transparency, the information related to this project was compiled first as a Corrective Action Plan, which was reviewed with Tony Lee at AT analytical. Next, this was addressed as a PDSA (plan, do, study, act) quality initiative which was discussed at the daily safety huddle for department heads. It was also presented at the Pharmacy and Therapeutics Committee meeting, and the Quality Assurance Committee meeting. The entire process, and results, were also discussed in depth with Theresa May in Infection Control. This discussion allowed for brainstorming of any additional data which would be beneficial to track, related to the sterility of compounded products. The consensus was that viable and particle counts in the cleanroom suite would be the most reliable measure of infection risk.

Results:

The infection control data gathered is not specific to detecting sterility in compounded medications. There are multiple factors which contribute to the data for the infections rates which were reviewed for this project. That being said, two data points were selected which would be most relevant to the monitoring of compounded product sterility; these are nosocomial infection occurrences and surgical infection occurrences. During discussion with our infection control nurse, most of the nosocomial infections for CCH referenced in this review are related to urinary tract infections; which are likely not related to compounding processes. However, if an issue were to arise from breaches in compounding sterility, the nosocomial infection rates would likely identify this occurrence. Additionally, the surgical infection rates

were chosen, as compounded antibiotics are commonly utilized for pre-operative and/or post-operative prophylaxis. Again, if an issue were to arise with our compounded preparations, these rates would likely trend to an increase in events; prompting review and identification of the source.

The infection control data was reviewed from 2021 through June 2023 (see graphs in Appendix C). It was thought this range would give a good indication of the instances prior to the introduction of Tru-D disinfection, and any improvements seen after. The graphs show normal variation in occurrences. This is expected, as our interventions only apply to compounding sterility which is not the only contributing factor for this data source. However, of note, the surgical infections in 2022 were at zero from August through December. This is likely an interesting correlation, rather than a causation; however, regardless of the reasoning, five months of no surgical infections is certainly a positive report.

The outcome measures related to the results of the particle and viable counts from our recertification reports have improved greatly. As stated, the spring 2023 recertification report showed both particle and viable counts passing on the initial report. The cleanroom suite was taken from three years of requiring resampling, to an initial passing rate. This was done through the efforts of our multidisciplinary team and through multiple interventions looking at our entire process from start to finish.

The new USP <797> regulations which take effect on November 1st, 2023 introduce new testing requirements. They state that surface sampling in the areas of compounding must be completed at least monthly[2]. Adding these new testing processes to our cleanroom sterilization process, along with the implementation of the Tru-D system, allows for our facility to be in a

state of preventative identification of any sterility concerns; rather than a reactive state, as we had previously been. The process measure of the frequency of required sterility testing has increased from twice a year, to 12 times a year[2]. This is an increase of 500%. This increased testing will ensure that environmental sterility is reviewed periodically, to allow for timely identification of any concerns. This has led to an estimated increased cost of $2,400 per year, just in supplies, for our facility.

Ultimately, the implications of hospital acquired infections can, in severe cases, lead to patient fatalities. This potential outcome is an unacceptable cost. Above and beyond this personal aspect of cost, are the financial and legal implications of tainted compounded products. To stratify these risks, a review of the "largest public health crisis ever caused by a pharmaceutical drug[7]" will be discussed. The New England Compounding Center (NECC) was the source of a nationwide fungal meningitis outbreak in 2012[7]. Barry Cadden, the owner of NECC at the time of the outbreak, was sentenced to fourteen and a half years in prison, and was ordered to pay $1.4 million in forfeiture with $82 million in restitution[8]. Several pharmacists, and other employees of NECC were also charged and found guilty in relation to the outbreak[7]. While this is an extreme case with regards to this type of incident, the implications are still relevant even here in rural Nebraska.

Increased surface sampling and new disinfection processes are a commitment, and a cost from both a supplies and personnel standpoint. Yet, they are an investment in our mission, and our vision for the facility and the quality of the healthcare offered by Cherry County Hospital.

Lessons Learned, Replicability, Sustainability:

Disinfection with ultraviolet light is an intervention which could be implemented into many facilities' standard operating procedures, to maintain a sterile environment for compounding. Within the ever changing environment of compounding regulations, the ultimate goal of all contributors is patient safety. Keeping a clean compounding environment is integral to achieving that goal.

Improving viable and particle counts at CCH did not happen overnight. It required implementing change on multiple levels, from storage to cleaning; and all the processes were important enhancements towards the goal. Some of the initial changes did not get CCH to a full passing result. The fall 2022 report, while the particle counts were improved, still failed viable counts. This was a blessing in disguise; as this lead to more brainstorming, and the introduction of the Tru-D device to our process. The take away from this project is that there is always something else that can be done to improve the quality of healthcare provided to our patients. It is an ongoing process, and it is a group effort.

Going forward, policies are being rewritten to include the new steps to our cleanroom cleaning processes. These new policies will look to the updated USP chapter <797>, and will incorporate Tru-D disinfection. Training will be completed by compounding staff, and kept on file in accordance with the industry standards of <797>[2]. We anxiously await the fall 2023 recertification testing by AT analytical, and continued sterility results to enhance our service to our patients.

Appendix A

Glossary

CACI – Compounding Aseptic Containment Isolator

CAI – Compounding Aseptic Isolator

CCH – Cherry County Hospital

CEO – Chief Executive Officer

COVID – Coronavirus Disease

EHR – Electronic Health Record

HEPA – High Efficiency Particulate Air

ISO – International Organization for Standardization

MRSA – Methicillin Resistant Staphylococcus Aureus

NECC – New England Compounding Center

PDSA – Plan, Do, Study, Act

SLT – Senior Leadership Team

USP – United States Pharmacopeia

UTI – Urinary Tract Infection

UV – Ultraviolet

Appendix B

Date	PEC Certification	HEPA filter leak test	Pressure Diff	Viable Count	Particle count	AC/H	
8/8/2019	P						
3/19/2020	P	F	P	F	F	P	
10/20/2020	P	F	P	F	F	P	
4/15/2021	P	P	P	F	F	P	
9/24/2021	P	P	P	F	F	P	
4/14/2022	P	P	P	F	F	P	
10/13/2022	P	P	P	F	P	P	
4/3/2023	**P**	**P**	**P**	**P**	**P**	**P**	Humidity P, Temp Distressed*

Complied Results from AT Analytical of initial recertification results from Fall 2019 – Spring 2023

P = pass

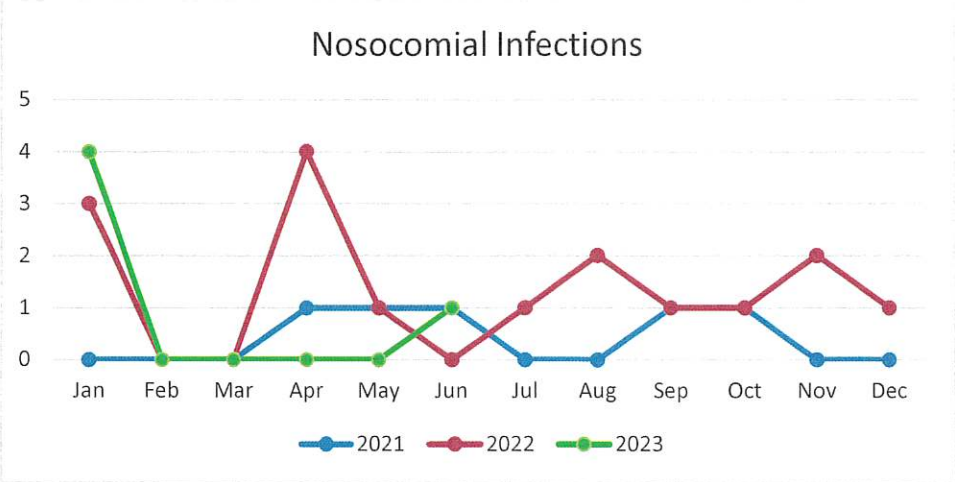
F = fail

Viable count indicates microbial growth identified in the compounding rooms.

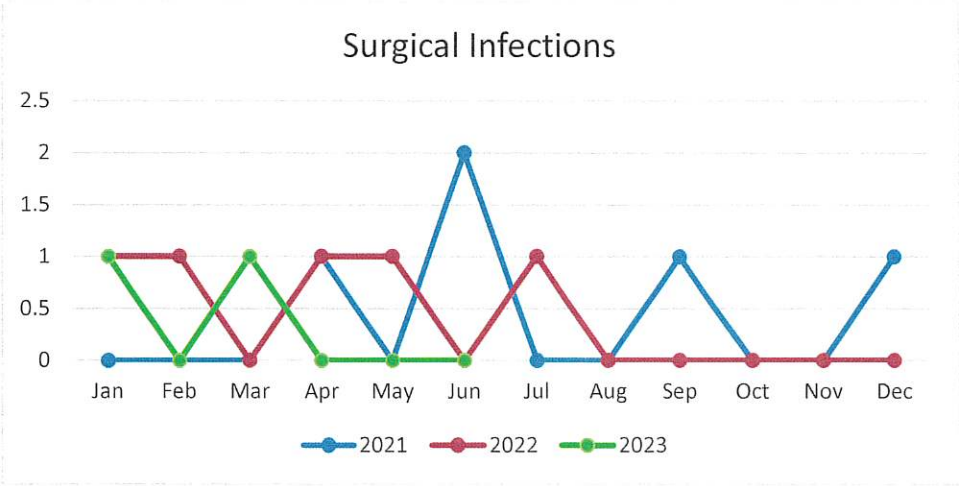
Particle count indicates that dust or other particles are present in the air, in the compounding rooms, which could lead to contamination concerns. These particles should be removed by filtration, in relation to the air exchanges done in the compounding room environment.

*The distressed temperature was addressed by adjusting the temperature control in the hood rooms. After adjustment, this was again within normal limits by pharmacy staff review. This was not considered a fail, as the temperature range is a suggestion in USP <797>, not a requirement.

Appendix C



Nosocomial Infection rates from January 2021 – June 2023. Per infection control, most of this data represents UTIs. This graph shows normal fluctuation as is expected. If concerns for compounded product sterility were present, the number of infections would be expected to increase outside of the normal fluctuation. No concerns were identified based on this data.



Surgical Infection rates from January 2021 – June 2023. This graph shows normal fluctuation as is expected. This data is used as a potential indicator of concern for compounded product sterility. No concerns were identified based on this data. Of note, there were no surgical infections reported from August of 2022 – December of 2022.

References

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CLEAN ROOM STERILIZATION PROCESS IMPROVEMENT

Cherry County Hospital, Critical Access Hospital, Valentine, NE

CCH CHERRY COUNTY Hospital and Clinic

Background

- 23 bed, Critical Access Hospital in North-Central Nebraska
- Reports from hood recertification were pulled dating back to 2019
- Particle and Viable counts were the target for improvement

Date	Viable Count	Particle count
3/19/2020	F	F
10/20/2020	F	F
4/15/2021	F	F
9/24/2021	F	F
4/14/2022	F	F
10/13/2022	F	P
4/3/2023	P	P

Aims

- Ensure the most sterile environment possible for continued compliance and best practice, for the safety of our patients

Plan

- Stricter garbing practices and training
- Medication storage removed from cleanrooms
- Use of point of care proprietary systems (ex. Baxter Mini-Bag Plus Containers)
- Re-varnishing the doors
- Examining air handler and vents
- Increased cleaning
- Implementation of Tru-D UVC disinfection device

Picture: Tru-D. Accessed 31 July 2023. https://tru-d.com/

Measure

- Viable Counts, Particle Counts from AT analytical which take into account surface sampling and air sampling
- Reviewed Infection Control Rates for Surgery and Nosocomial Infections
- Increased surface sampling going forward

Results

- Spring of 2023 was the first time, since 2019, that the *initial* report for the hood recertification received full passing marks

Picture: LabWrench Accessed 31 July 2023. https://www.labwrench.com/equipment/9022/nuaire-pharmagard-nr797

Next Steps

- Updating policies to reflect the new cleaning processes which will incorporate Tru-D device
- Updating policies to adhere to new USP 797 requirements for surface sampling

Team

- Michelle Connot, Chris Bitner, Clint Assarsson, Nancy Hicks-Arsenault, Theresa May, Ashley Sandoz