New research is offering clues for methods to get rid of prions without damaging delicate instruments.

Inactivating prions on surgical instruments has been seen as difficult. Current methods rely on harsh chemicals or extended sterilization cycles that can damage or destroy instruments.

Three reports published this year provide evidence on gentler methods that could be effective. None is cleared in the U.S., but some are starting to be available in Europe.

Prions are misshapen proteins that cause disease without the help of DNA or RNA. The misfolded particles cause spongy holes and inflammation in the brain that are hallmarks of transmissible spongiform encephalopathies such as Creutzfeldt-Jakob disease (CJD) and mad cow disease.

Prions attach tightly to surfaces and have been considered hard to remove with usual sterilization and disinfection techniques. But researchers are making progress.

One significant advance—scientists for the first time have an animal model they can use to measure the effectiveness of prion inactivation methods. The model assumes a worst-case scenario with no cleaning.

Using the model, researchers now have solid data on treatments recommended by the World Health Organization (WHO). Two of three methods tested—soaking in sodium hydroxide or sodium hypochlorite—were effective in a study by French researchers funded in part by the Steris Corporation. The third method, an extended prevacuum sterilization cycle of 134°C for 18 min, on its own, was not. But in an important finding, simply immersing the item in water made this extended cycle much more effective.

“A simple cleaning step followed by sterilization in water in a gravity-displacement-type sterilizer [at 21°C for 20 min] is probably more effective than anything else that has been recommended,” says Gerald McDonnell, PhD, senior director of technical affairs for Steris and a co-author of a study led by Fichet of France. This method would not be appropriate for heat-sensitive items, however.

Highlights of other findings:

Alkaline cleaners
Alkaline detergents showed great promise in activating prions in all 3 studies, though they are not cleared for this claim in the U.S.

“The message we are hearing loud and clear is that alkaline cleaners are very effective against prions, and they have much better materials compatibility than sodium hydroxide,” notes Martin Favero, PhD, director of scientific and clinical affairs for Advanced Sterilization Products (ASP), a Johnson & Johnson company.

A Steris alkaline cleaner used in the pharmaceutical industry actually degrades prions and does not harm instruments, Fichet and colleagues found. Steris is making the product available in Europe for medical devices under the brand name, HAMO 100.

A German study led by Yan and funded by ASP also found an alkaline detergent showed a “significant reduction” in infectivity, whether the terminal method was disinfection or sterilization. The detergent was tested at 70°C. It has since been tested at 50°C with similar results, Favero says.

Vaporized hydrogen peroxide
Also promising is vaporized hydrogen peroxide (VHP) sterilization.

VHP combined with cleaning completely removed prion infectivity in the Fichet study—a significant finding because it doesn’t damage surfaces, including electron-
ic equipment. Steris does not currently have a VHP technology with governmental approvals for health care sterilization. Steris has used its VHP technology to decontaminate buildings with anthrax.

A modified cycle of ASP’s Sterrad system, which uses hydrogen peroxide gas plasma, also was effective in reducing prion contamination. When accompanied by precleaning with an alkaline detergent, the modified cycle with 4 injections (basically a double cycle) resulted in complete inactivation of prions. These experiments used the industrial model Sterrad 100 GMP because it could be programmed. The next step will be to test a hospital-type Sterrad unit using the same protocol, Favero says.

Other cleaners
Other cleaners had mixed results. Two Steris products, Environ LPH, a general surface phenolic disinfectant, and Klenzyme, an enzymatic cleaner, were effective against prions. Cleaning with Klenzyme followed by gravity-displacement steam sterilization at 121°C for 20 min eradicated prions, according to the Fichet report.

ASP’s enzymatic cleaners, on the other hand, seemed to have no effect. Favero said scientists do not yet know why the enzyme formulations had different results.

Peracetic acid
The Steris System 1 and its proprietary formulation, Steris 20, which use peracetic acid, partially reduced the risk of prion transmission, Fichet et al found. The Yan study found another peracetic acid formulation (0.35% at 5 min) had no effect on prions.

Though work is still to be done, results suggest there is a broader range of choices beyond the methods recommended by WHO, says Favero, and there now is a scientific basis for evaluating how well those methods work.

References

