College of Physicians & Surgeons of Alberta

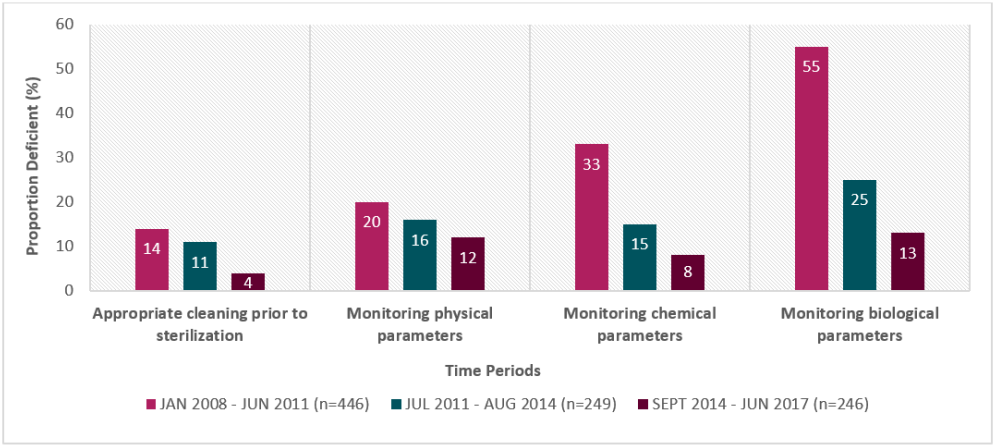
MDR assessments are improving sterilization practices in medical clinics

The College's Infection Prevention and Control (IPAC) program started assessing the quality of medical device reprocessing (MDR) in non-accredited medical clinics in 2008. Early on, they found a significant number of clinics were not meeting sterilization standards. They also identified a number of breaches to patient safety.

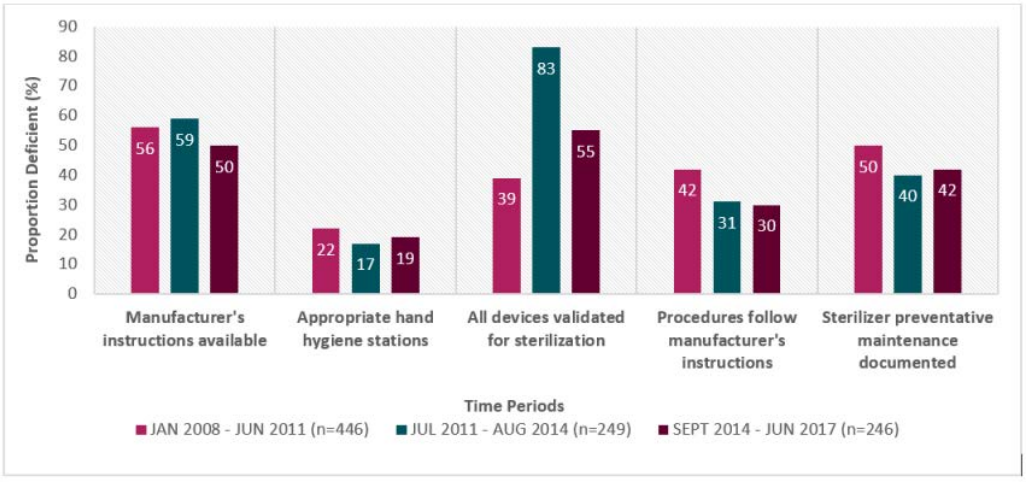
The program recently reviewed all completed assessments (941 in total) between 2008 and 2017. The analysis found over the years, an increase in standards adoption in medical clinics as well as improved sterilization practices.

Although some limitations existed in the review, the impact of IPAC assessments is promising.

Medical clinics are significantly improving their compliance to critical sterilization standards



Many standards still have room for improvement



Over time, there is a clear pattern of improvement

Category of Comparison (N = number standards compared between time periods)	Mean Difference (% deficient T_1 - % deficient T_2)	
	Jan 2008 – Jun 2011 vs Jul 2011 – Aug 2014	Jul 2011 – Aug 2014 vs Sept 2014 – Jun 2017
General (N=11)	**+ 2.8%**	**+ 6.6%**
Cleaning (N=11)	**+ 1.5%**	**+ 4.7%**
High Level Disinfection (N=13)	**+ 14.6%**	**+ 12.5%**
Sterilization (N=21)	**+ 10.4%**	**+ 7.6%**

* Standards that changed over time (e.g., withdrawn, added, revised) were not compared

Top 10 deficiencies (in last 308 assessments)

1. Clinic's sterilizing devices not validated/approved for sterilization
2. Efficiency testing not done on ultrasonic cleaners
3. Device manufacturers' validated reprocessing instructions were unavailable
4. No training process documentation for MDR staff
5. No logs of sterilizer maintenance
6. Ultrasonic cleaners not being used as per manufacturer's instructions
7. Reusable gloves not adequately cleaned and disinfected
8. Sharp tipped devices were unprotected in peel pouches
9. Sterilizer not regularly maintained as per manufacturer's instructions
10. Incomplete MDR policies & procedures

Review Limitations

- IPAC program did not monitor for consistent assessment approaches between 2008 and 2016. Today, the program controls assessment quality with annual assessor training and standardized reporting.
- IPAC program did not monitor or control data integrity prior to 2013, and did not go back to clean past assessment data.
- Results only include clinics that completed an assessment. Some clinics chose to stop performing sterilization prior to their assessment (most likely due to non-compliance with the standards).
- The review could not compare standards revised, withdrawn, or added over time.
- IPAC program assessed less than 30 clinics performing high-level disinfection (HLD) since 2014, and was unable to present time-based comparisons for most HLD standards.
- Reports only capture "routine" CPSA MDR assessments. Joint AHS/CPSA reports issued during investigation of public concerns are not included in this analysis.

Questions

If you have any questions about this information, please email ipac@cpsa.ca.