Abstract

Purpose
The evolution of sterile compounding in the context of hospital patient care, the evolution of related technology, past incidents of morbidity and mortality associated with preparations compounded in various settings, and efforts over the years to improve compounding practices are reviewed.

Summary
Tightened United States Pharmacopeial Convention standards (since 2004) for sterile compounding made it difficult for hospitals to achieve all of the sterile compounding necessary for patient care. Shortages of manufactured injections added to the need for compounding. Non–hospital–based compounding pharmacies increased sterile compounding to meet the needs. Gaps in federal and state laws and regulations about compounding pharmacies led to deficiencies in their regulation. Lapses in sterility led to injuries and deaths. Perspectives offered include potential actions, including changes in practitioner education, better surveillance of sterile compounding, regulatory reforms, reexamination of the causes of drug shortages, and the development of new technologies.
Conclusion

Over the years, there have been numerous exhortations for voluntary better performance in sterile compounding. In addition, professional leadership has been vigorous and extensive in the form of guidance, publications, education, enforceable standards, and development of various associations and organizations dealing with safe compounding practices. Yet problems continue to occur. We must engage in diligent learning from the injuries and tragedies that have occurred. Assuming that we are already doing all we can to avoid problems would be an abdication of the professional mission of pharmacists. It would be wrong thinking to assume that the recent problems in large-scale compounding pharmacies are the only problems that warrant attention. It is time for a systematic assessment of the nature and the dimensions of the problems in every type of setting where sterile compounding occurs. It also is time for some innovative thinking about ensuring safety in sterile compounding.
Hopes are high for collaborative practice in Florida

Safety of high-dose intravenous labetalol in hypertensive crisis

Adverse drug reactions in the Veterans Affairs healthcare system: Frequency, severity, and causative medications analyzed by patient age
History is not bunk. The Founders of the United States, men like John Adams, Thomas Jefferson, George Washington and Benjamin Franklin, believed that history was the most important subject for all citizens of a free republic to study. Even those who know and remember many historical facts still repeat the mistakes of that past. The generation of politicians and military leaders in Europe of 1914 were well-versed in history. This blog is devoted to Learning the Lessons of the Past. Even more importantly, this blog is devoted to applying these lessons of the past to making decisions in the present and to planning for the future. This is what I mean by “historical thought.”

Brief history of sterile compounding. Sterile compounding evolved primarily in hospitals in the 1960s and 1970s. It involves preparations that are made in sterile environments (aseptically) by mixing, diluting, repackaging, or manipulating injectable products. The injections and infusions compounded in hospitals and other health systems include large-volume parenterals (LVPs) and small-volume parenterals (SVPs)."2 IV admixtures are those LVPs or SVPs to which injections have been added. In the past enforcement of pharmacy compounding has primarily resided at the state level through pharmacy and health boards. With the DQSA now in effect, the FDA also enforces USP compounding standards.