EDITORIAL

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If it ain't broke, what are we trying to fix? Reprocessing devices labeled "for single use only"

The FDA wants to regulate the reprocessing of single-use devices

WITH LITTLE FANFARE, the hospitals and doctors' offices of America just got saddled with an extra layer of Federal bureaucracy, the people who pay for health care got hit with massive extra expense, and the companies that make health care equipment stand to make a lot more money. At issue are devices that physicians and hospitals have traditionally reprocessed (cleaned, tested, and sterilized) for further service.

On August 2, 2000, the Food and Drug Administration (FDA) released a guidance document[1] that proposes to regulate the reprocessing of single-use devices as "remanufacturing."[2] It will subject hospitals that reprocess these devices, as well as third-party reprocessors, to the same regulatory standards that the original manufacturers of the devices must meet, including premarket testing.

This is the government's response to scary claims by some consumer advocates and device manufacturers that reuse of devices labeled "for single use only" constitutes a threat to patient health and safety.

The FDA and the General Accounting Office (GAO), in their own analyses, found this charge to be without foundation.[3] Nevertheless, the FDA, at the urging of Congress, decided to regulate anyway because the perception that there could be a risk might undermine public confidence in our health care system.

REASONS FOR THE SINGLE-USE LABEL

Why would the device manufacturers suddenly start labeling devices as "single-use only?" Several reasons come to mind.

Economics. A precipitating event in this controversy was a relatively recent practice by manufacturers to relabel devices (such as surgical saw blades) from multiple use to single use only.[3] Hospitals continued to reprocess these devices just as they always had. Furthermore, if a device that has previously been used safely up to five times (especially an expensive one, such as a lumenless cardiac electrophysiology mapping catheter or a radiofrequency ablation catheter)[4] now can only be used once, the manufacturer can sell five times as many catheters and make five times as much money. Not a bad day's work for just adding a phrase to the label.

Product liability. If an injured party can successfully sue the deep-pocketed manufacturer of a product used in a medical procedure that caused an injury, that's scary, especially since the manufacturer has no control over what happens to the product once it is shipped to the hospital or physician who purchased it.

Safety. Some devices cannot be adequately cleaned without damaging them to the point of unreliability. For example, certain gastrointestinal biopsy forceps don't work as well after cleaning and sterilization, and some studies suggest that they really can't be adequately cleaned.[5] On the other hand, many devices can be safely reprocessed and reused.[6–8]

WHY SHOULD WE CARE?

The GAO acknowledged in their recent report that there is no evidence that reprocessing of single-use devices is a threat to public health.[3] One thing neither the GAO nor

the FDA included in their respective reports is a recommendation for the development of criteria for application of the "single-use only" label. Why should providers or anyone else care?

It is wasteful. Hospitals and physicians are currently operating under strong mandates to eliminate unnecessary costs from their procedures and practices. It is clearly wasteful to discard an expensive piece of equipment that can be safely and economically reused.[9] When the cost of using a serviceable, safe, reprocessed item is less than the cost of using a new one, why would we not want to do this? Cost-effectiveness is one of the linchpins of health care reform, and we must continue to increase it.

It will consume resources better directed toward quality improvement. Maintenance and improvement of quality are the hallmarks of modern health care. Current initiatives throughout the system to track and prevent errors are a part of this, and providers must keep the pressure on to assure that there are resources to beef up these efforts.

Such initiatives provide the data which prove the safety of current reprocessing methods, and we should not consume the valuable resources that fuel this process by arbitrarily driving up the expenses associated with clinical practice.

It will generate more medical waste. Recycling is one of the cornerstones of modern waste management. Medical waste is a particularly nasty byproduct of the health care system, for which nearly every practical method of disposal has come under serious criticism. A better solution is to reduce the generation of waste through recycling.

It is not necessary. As the GAO report on reprocessing confirmed, there is no evidence that reprocessing and reuse of single-use devices, as it is now practiced, has produced any significant problems.[3]

Even new devices occasionally fail, and nothing suggests that reprocessed devices fail at a greater rate than new ones.[10] Infection from inadequately sterilized devices is a theoretical problem that has not been encountered in practice. So why institute a process that will definitely add cost but cannot improve quality?

FDA RULING WAS A COMPROMISE

The involvement of the FDA came about in an attempt to find a compromise between banning the reuse of single-use devices vs doing nothing in response to the issues raised by the device manufacturers. On the face of it, this makes sense, because the focus of FDA oversight would be on patient safety rather than on economic benefits for the manufacturers. Reprocessing, whether by hospitals or third-party reprocessing companies, would be permitted, but it would only be allowed to occur under strict FDA supervision. There are several reasons why this compromise is not optimal.

These devices are not really remanufactured. To refer to the process of cleaning, testing, and resterilization by the term "remanufacturing," as the FDA does,[2] is more than a little pretentious, not to mention misleading. Throughout modern history, hospitals have been and remain in the business of resterilizing equipment used in the operating room and elsewhere, and this is not at issue. It is only understandable in the context of what the FDA wants to require of those who reprocess equipment marked, arbitrarily in many cases, "for single use only." The proposed requirements are essentially the same as those posed to the original manufacturers, including premarket testing, etc.

The GAO found no evidence of a problem

Furthermore, the FDA has classified the reprocessed equipment to be overseen into minimal (class I), intermediate (class II), and high (class III) risk. Included in the class II category are blood pressure cuffs. On the face of it, this seems ludicrous, and the whole business could use a dose of common sense.

No evidence there is a problem. If there is no problem (as confirmed by the GAO),[3] how will we know if the FDA process has been successful? If after a few years there have been no infections, for example, is someone going to claim that the FDA's oversight process is responsible for that?

New bureaucracy. The FDA is restricting its initial oversight to hospitals and third-party reprocessors. They acknowledge that many of the same activities they plan to regulate also take place in physicians' offices, but

they do not as yet have the manpower to deal with these settings.[1] You can bet they will correct that as quickly as they can.

Additional burdensome regulation. Hospitals and physicians' offices already carry a heavy regulatory burden. They get inspected by multiple federal and state agencies as well as by accrediting organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee on Quality Assurance (NCQA). If there were a way to combine some of these inspections, that would at least be somewhat helpful.

Conflicting message. The government has a hard time getting agreement among its various departments and agencies as to what they really expect of health care providers, and many conflicting messages and initiatives, not all of which are clearly articulated, keep pouring forth. Are we supposed to be cost-effective or to avoid any activity that might have the nefarious purpose of saving money? Are we supposed to protect the environment or load it up with perhaps five times the amount of waste we now generate?

The whole business could use a dose of common sense

HOSPITALS, OFFICES WILL HAVE TO CHOOSE

It seems pretty clear that, at least for the present, hospitals that currently reprocess certain equipment will have some choices to make. If they wish to continue reprocessing, they will need to gear up to meet the new FDA requirements. The other choices are to stop doing the procedures altogether (unacceptable), use the equipment only once and discard it (expensive and wasteful), or to send out the used equipment to third-party reprocessors. While none of these options is particularly attractive, the last one may be the least of the evils for hospitals. The best option for individual physicians' offices, when it comes to that, is less clear. Cost and turnaround time (especially for expensive equipment) are the main problems with the last option, and hospitals will need to carefully consider the relative importance of these and other factors in making their decisions.

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