

Outpatient Connection



SUDs can be reprocessed with reasonable assurance of safety and effectiveness

Dr. Daniel Schultz, Director, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA), testified recently that based on their investigations, he considered reprocessed, single use devices (SUDs) to be safe. Dr. Schultz said, "I believe FDA currently has many tools to ensure the safety, effectiveness, and manufacturing quality of reprocessed, single-use devices (SUDs). FDA has been actively engaged in the SUD reuse issue for some time, and our efforts have included research, outreach, pre-market review, inspections, and compliance investigations. We have held numerous public meetings and conferences with industry, healthcare professionals, and consumers over the years to determine the extent, magnitude, and changing nature of this practice. FDA has carefully evaluated and conducted research to develop the scientific basis for addressing SUD reprocessing. We have inspected third party reprocessors, evaluated and investigated reports of patient injuries, and reviewed numerous pre-market submissions. Taken together, the Agency believes that these efforts have provided, and will continue to provide, reasonable assurance of safety and effectiveness of reprocessed SUDs for patients. The reprocessing of SUDs is legally permissible in the United States under the FD&C Act. Currently, only Class I and II SUD device types have been cleared by FDA for reprocessing. No Class III SUDs have been cleared/approved for reprocessing. As of August 1, 2006, reprocessed SUDs must prominently and conspicuously bear the name, abbreviation, or symbol of the reprocessor on the device itself, on an attachment to the device, or on a detachable label, depending on the physical characteristics of the device and whether the device has been marked by the OEM. FDA has received a total of approximately 434 reports on adverse events. The final analysis of the reports found that the types of adverse events reported to be associated with the use of SUDs were the same types of events that also are being reported for new, non-reprocessed devices. Therefore, it was unclear whether the device, the medical condition of the patient, the medical procedure, or other confounding factors caused or contributed to the adverse event. On September 25, 2006, FDA published two rules: the direct final rule for Medical Devices; Reprocessed Single-Use Devices; and a proposed rule for Medical Devices; Reprocessed Single-Use Devices. These amendments will help ensure that reprocessors submit the data, needed to demonstrate that their device is substantially equivalent to the predicate device. For the complete report, visit: www.fda.gov/cdrh/reuse/

OPERATINGRoom

O.R. managers walk the line between finance and clinical practice

by Jeannie Akridge

Managing an operating room takes deep clinical knowledge, years of experience, a heart of gold, and a head for business. It's a high-stress, high-profile position that demands dedication, leadership skills and an innate ability to adapt.

The 2006 *Healthcare Purchasing News* O.R. Management Salary Survey shows an overall average salary across all O.R. management titles of \$70,269, about a 3.4% increase over last year, but many would argue it's still not enough.

Highest earners by title for 2006 were Surgical Services Directors/Managers, who comprised 17 percent of our respondents, and commanded an average salary of \$84,077, up more than \$8,000 over last year. O.R. Directors and Managers, who comprised 36 percent of respondents, earned on average \$80,036 in 2006, up almost 4 percent over 2005. What's more, one-third of respondents earned \$80,000 or more and just under 10 percent earned hefty, but well-deserved salaries of \$100,000 or more in 2006. The 18 percent of our survey respondents who claimed the title of O.R. Materials Manager earned the lowest salaries, at \$41,786.

Same as last year, 80 percent of our respondents experienced a salary increase over the previous year. Also encouraging, only 2.6 percent said their salaries had decreased from the prior year, compared with 4.5 percent who reported a salary decrease in 2005. For those reporting increases, the average amount of the increase was 4.1 percent, also the same as last year. Unfortunately, the number who expect to receive a bonus as part of their compensation continues to decline yearly. Twenty percent of respondents expected a bonus in 2005, versus 16 percent who expect one in 2006.

A question about job security raised some interesting dynamics for O.R. management professionals. Although the number who said they felt "very secure" in their current position increased to 55 percent

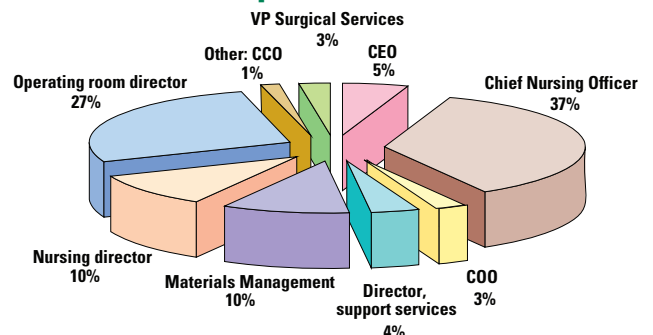
compared to 47 percent in 2005; the number who felt "somewhat insecure" in their position has been rising steadily since 2004's low of 1.85 percent to 12 percent in 2006. Those who felt "somewhat secure" in their position totaled 34 percent in 2006, compared to 46 percent in 2005. In all, 88 percent felt at least "somewhat secure" in their current position, compared to 92 percent last year.

O.R. management professionals continue to play an increasing role in purchasing decisions for their department. In fact, 83 percent of respondents said that they recommend and/or specify products to be purchased for the O.R. Another 81 percent said they evaluate products, 75 percent determine the need for such products. Fifty-eight percent of respondents are members of a purchasing group or committee. There was also an 8.5 percent increase from 2005 in the number of O.R. management professionals who approve/authorize purchases (56%). Only 2.6 percent said they were *not* involved in any way in the hospital's purchasing decisions.

Top product areas specified by O.R. management include O.R. supplies/equipment (96%), drapes (91%), gloves (88%), patient warming equipment (88%), orthopedics (82%), disposable kits and trays (81%), endoscopy/endoscopic products (80%), lighting systems (78%), sterility assurance products (78%) and dressings (77%).

When asked what they would like to see more coverage of in *Healthcare Purchasing News*, popular answers included: O.R. equipment (66%) and O.R. suites (55%), followed closely by surgical instrument tracking (48%), surgical

O.R. Personnel report to:



instruments (46%), storage solutions (39%), surgical apparel and drapes (39%), minimally invasive surgery (38%), inventory control (36%), surgical error tracking software (36%), and infection control (34%).

While O.R. managers and directors are often chosen based on clinical skills and years of experience in the O.R., the lines between business and clinical functions are continually being crossed. Janet Tidwell, RN, MSN, MSHA, CNOR, director surgical services, Hendersonville Medical Center, Hendersonville, TN, said that the most challenging aspect of her job is “balancing the needs of the department with available capital dollars.” Like a growing number of her counterparts, Tidwell returned to school to obtain a master’s degree to help her with the business aspects of her position. She says that tighter capital budgets have intensified the need to effectively justify each purchase.

Who they are

Those working in O.R. management have definitely earned their stripes. More than a third of respondents have worked in the O.R. for 25 years or longer, and they earned an average salary of \$77,981. All told, 64% of respondents have worked in the O.R. environment for 15 years or more, bringing the average number of years worked in the O.R. to 17.4 years.

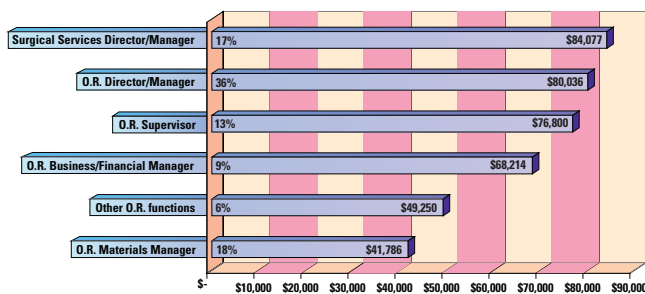
Looking at how long O.R. management professionals have worked at their current facility tells a different story. One-third of respondents have worked in their current facility for between two and five years. Highest earners were those with a 6-9 year tenure at their current facility at \$77,389. On average, these O.R. managers have worked 10.2 years at their current facility.

For our 2006 survey, “Associate’s Degree” was most often reported as the highest level of education (44%) and these respondents earned on average \$66,176, a 15 percent increase over 2005. Salaries increased incrementally with higher education levels, topping out at almost \$90,000 for the 17 percent of respondents with a post-graduate degree.

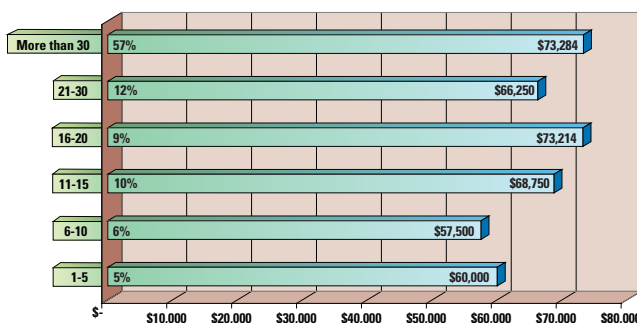
The average age of our O.R. management respondents continues to hover around 50 years old. This year our average O.R. management

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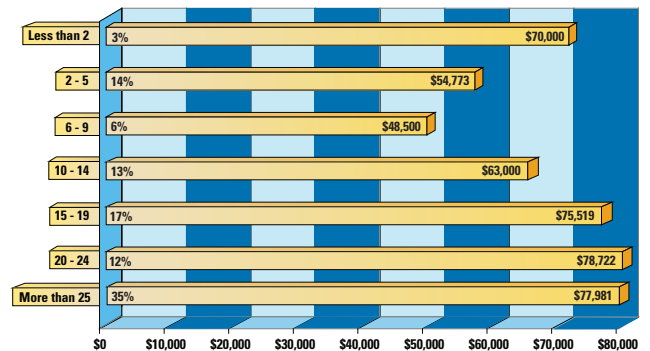
Salary vs Job Function



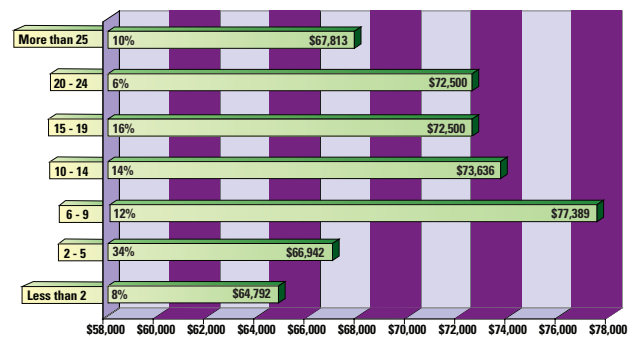
Salary vs Number of Employees in Dept.



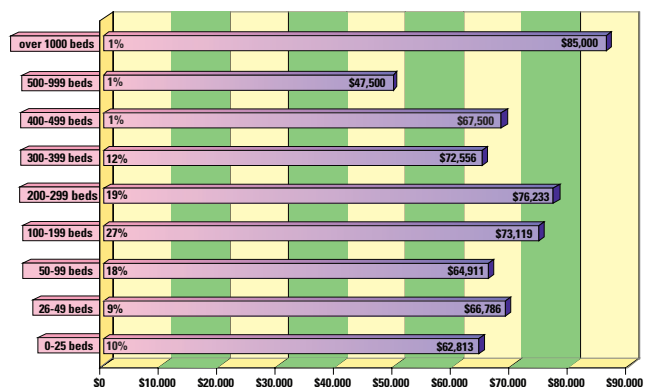
Salary vs Years in O.R.



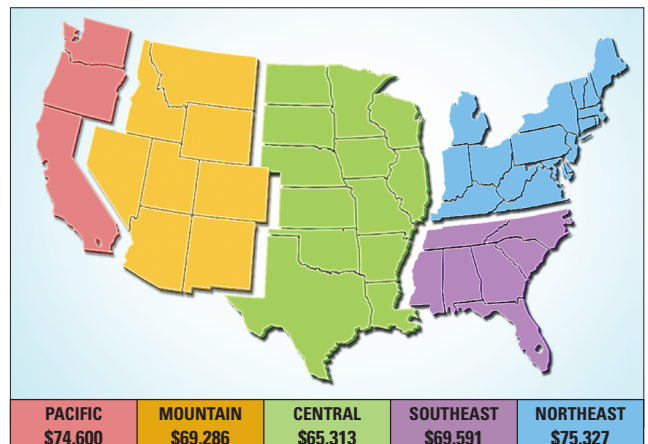
Salary vs Years at Facility



Salary vs Number of Beds



Salary vs Region



SALARY from page 27

professional is 49, compared to 48 in 2005, and 51 in 2004. We had 15 percent more respondents than last year who were between the ages of 46 and 50, totaling 35 percent.

Although females continue to dominate the O.R. management profession, we had a few more males answer our survey this year to comprise 28 percent of respondents, almost 10 percent more than last year. While the O.R. has historically been an area that defied national trends by paying female managers more than males, (for 2005 females earned \$10,000 more than their male counterparts), our 2006 survey shows that male O.R. management professionals are now making slightly more than females at \$69,905 versus \$69,162.

Where they work

Similar to last year's findings, a majority of 73 percent of respondents work in a standalone hospital, while 22 percent work for a multi-facility hospital. In addition, 86 percent work in a non-profit facility. Though just 3 percent work in a government-owned facility, they were the highest paid, at an average of \$82,500, versus \$71,186 for those working in non-profit facilities. For-profit facilities paid the least, at just \$60,833.

Just over half of respondents work in a rural facility earning on average \$69,212, but the 27 percent who work in suburban facilities were paid the most at \$76,857.

By region, facilities in the Pacific U.S. have historically paid their O.R. management professionals the highest salaries, but this year the Northeast region boasts top pay at \$75,327, barely edging out the Pacific's \$74,600 average salary. Though more than a third of our respondents work in the Central U.S. region, they are the lowest earners at \$65,313.

The average number of O.R. suites in our respondents' facilities increased to 10.7, up from 8.5 in 2005. The number of employees in the average O.R. department also increased. Fifty-seven percent of respondents work in a facility that has more than 30 employees, compared to 48 percent in 2005.

We added a question this year about number of O.R. turns and our respondents reported an average of 10 O.R. turns per day per suite.

Regarding O.R. turns at her facility, Tidwell noted, "We are trying to decrease turnover time to increase physician satisfaction and to decrease overtime not necessarily to increase number of cases a day."

In an interesting approach to efficiency, Tidwell said her department is "working on crew training—taking information from aviation and applying it to the O.R. setting."

Those working in O.R. management reported most often to the Chief Nursing Officer (37%) or to the O.R. director (27%), according to our 2006 survey. Ten percent of respondents report to Materials Management.

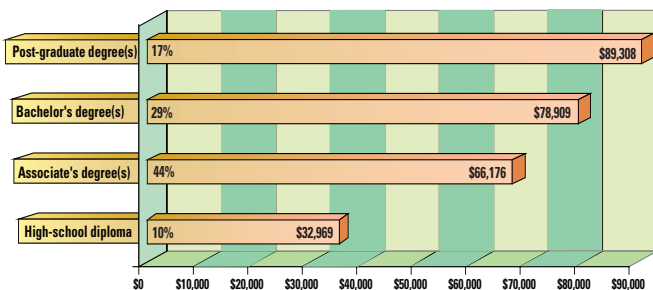
When asked which functions report to the O.R. director at their facility, the top answer by far was PACU, at 95 percent – last year just 22 percent of respondents said that PACU was headed by the O.R. director. At the same time, there was a 28 percent drop in the number of O.R. directors responsible for anesthesia services, for a 2006 total of 42 percent. More than 80 percent of respondents said that sterile processing functions report to their facility's O.R. director, about the same as last year. We also saw a 12 percent increase in the number of facilities in which central services reports to the O.R. director, for a 2006 total of 49 percent.

The number of facilities in which decontamination functions fall under the direction of the O.R. continues to decrease at a rate of about 10 percent each year for a 2006 total of 63 percent. Also down, was the number of respondents who said that medical equipment cleaning/disinfection was headed by the O.R. director, from 57 percent in 2005 to 33 percent in 2006.

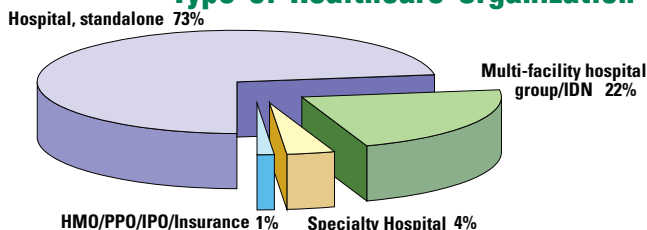
We added a category of "outpatient surgery" for this year's survey, and 79 percent of respondents said it was under the control of the O.R. director at their facility. Another new category of "endoscopy services" was indicated by 18 percent of respondents as falling under the direction of the O.R.

As with most of healthcare, O.R. management is ultimately about the patient. When asked what she liked best about her job, Tidwell, who says she has "responsibility for everything in the O.R. world", said it was the "staff interaction", and "seeing changes being made to improve patient care" that give her the greatest satisfaction. "Patient safety initiatives have been our main priority—implementing all of the ones that have anything to do with surgical patients." **HPN**

Salary vs Education



Type of Healthcare Organization



Salary vs Type & Location of Facility

TYPE OF FACILITY		
For profit	12%	\$60,833
Government-owned	3%	\$82,500
Non-profit	86%	\$71,186
LOCATION OF FACILITY		
Rural	51%	\$69,212
Suburban	27%	\$76,857
Urban	22%	\$64,559

Salary vs Gender

