



SETTING HEALTHCARE'S ENVIRONMENTAL AGENDA

*Papers and Proceedings
from the October 16, 2000
Conference*



SHEA Conveners and Co-sponsors:

Kaiser Permanente

Health Care Without Harm

Catholic Healthcare West

American Nurses Association

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*U.S. EPA Office of Pollution Prevention
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INTRODUCTION

Charlotte Brody, RN
Co-Coordinator
Health Care Without Harm
April 20, 2001

Ambition, according to Webster's, means an eager or strong desire to achieve something. That definition provides an explanation for the ambitious name **Setting Healthcare's Environmental Agenda** for the one-day conference held on October 16, 2000 in San Francisco, California. The conference conveners, Kaiser Permanente and Health Care Without Harm, along with their co-sponsors Catholic Healthcare West, the American Nurses Association, Consorta Catholic Resource Partners, Premier, Catholic Health East, Catholic Health Initiatives and the U.S. EPA Office of Pollution Prevention and Toxics share a strong desire to transform the healthcare industry into a model of environmental responsibility.

This publication is one of the outcomes of **Setting Healthcare's Environmental Agenda** (SHEA). The authors first wrote these as white papers for the October 16th event. At SHEA, the white papers were discussed and refined in breakout groups attended by 10 or more conference participants. So these proceedings include documents that reflect not only each author's hard work, but also the opinions and experience of the healthcare industry leaders who were SHEA participants.

This book also includes excerpts from SHEA's three plenary speakers: Commonwealth President and Founder, Michael Lerner, Kaiser Permanente Chairman and CEO, David Lawrence and Catholic Healthcare West President and CEO, Lloyd H. Dean. The remarks of these three men inspired the audience on October 16th. Their presence at SHEA provided visible hope that the ambitions of the conference planners will turn into visible change in the healthcare industry.

The chapters in this document are a proposal for that change. Each one describes a problem area and proposes solutions based on the existing experience of healthcare providers. Each paper also includes resources that provide additional information on the topic. It is the ambitious hope of the SHEA co-sponsors that every reader will create institutional change and produce educational resources that make the information in this book out-of-date.

For the most important outcome of **Setting Healthcare's Environmental Agenda** will be the actions that are taken by SHEA participants and the readers of this book to improve the environmental practices of their own institutions. We hope that the ambition of the conveners and co-sponsors of SHEA will inspire ambitious achievements in every healthcare institution.

GREEN AND HEALTHY BUILDINGS FOR THE HEALTHCARE INDUSTRY

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INTRODUCTION

Just as health care professionals diagnose a patient's illness and prescribe appropriate treatment, so too are a growing number of building professionals diagnosing how buildings affect human health and the environment and prescribing strategies to minimize these impacts. This is in response to mounting evidence that buildings through their life cycle are significant causes of human illness and environmental degradation. According to the U.S. Environmental Protection Agency (EPA) and its Science Advisory Board (SAB), indoor air pollution is one of the top five environmental risks to public health.¹ This corroborates analyses that find that in the U.S., people spend on average 90% of their time indoors,² and that many common materials in widespread use emit dangerous compounds and harbor infectious molds, fungi and bacteria. For people confined indoors due to illness, and particularly for those with depressed immune systems, the consequences are significant.

Relative to the natural environment and resources, buildings represent a formidable sector. Building-related activities are responsible for 35% to 45% of CO₂ releases into the atmosphere,³ a precursor to global warming, and deplete the stratospheric ozone layer by using refrigerants and products, including some insulation materials, manufactured with ozone depleting compounds. Buildings use over 75% of polyvinyl chloride (PVC or vinyl),⁴ about 40% of raw stone, gravel, sand, and steel, and 25% of virgin wood. Buildings use about 40% of energy resources and 16% of water, while building construction and demolition generates about 25% of municipal solid wastes.⁵ Each of these impacts has direct or indirect consequences on

human health, the extent of which is becoming better understood as the interconnections between buildings, human health and environmental quality are subjected to rigorous analysis.

Recognizing these linkages, professional associations such as the American Institute of Architects (AIA) and the UIA/AIA World Congress of Architects have issued clear directives to incorporate sustainable design and green building strategies as basic and fundamental to standard practice.⁶ In addition, local, state and federal public policymakers are adopting green building guidelines, and corporations are establishing environmental building standards. These emerging strategies redefine the way buildings are designed, built, and operated, and extend the conventional notion of building performance to include human health and environmental quality as essential cornerstones of quality and value.

This shift in practice towards green and healthy buildings is fundamentally consistent with the core value of health care professionals – first, do no harm. To this end the healthcare profession should advocate for public health by providing services in facilities that do not degrade the health of individuals or of the general public. Furthermore, health care professionals should take responsibility for the environmental impact of health care delivery by initiating sustainable design, operation, and maintenance practices in their facilities.

The process of creating and maintaining dynamic healthcare settings is just beginning to be understood by owners and providers. They must learn that budgeting needs to change from first-cost to full cost accounting that, for example, extends a conventional balance sheet to include a value for health impacts and

the environment. They must grasp the concept of preventive maintenance and integrated, anticipatory design. Finally, they must embrace the concept of partnering with their suppliers and design professionals to continue to explore the linkages between the nature of the physical environment and the impact the environment—including the built environment—has on medical outcomes, user satisfaction and productivity.⁷

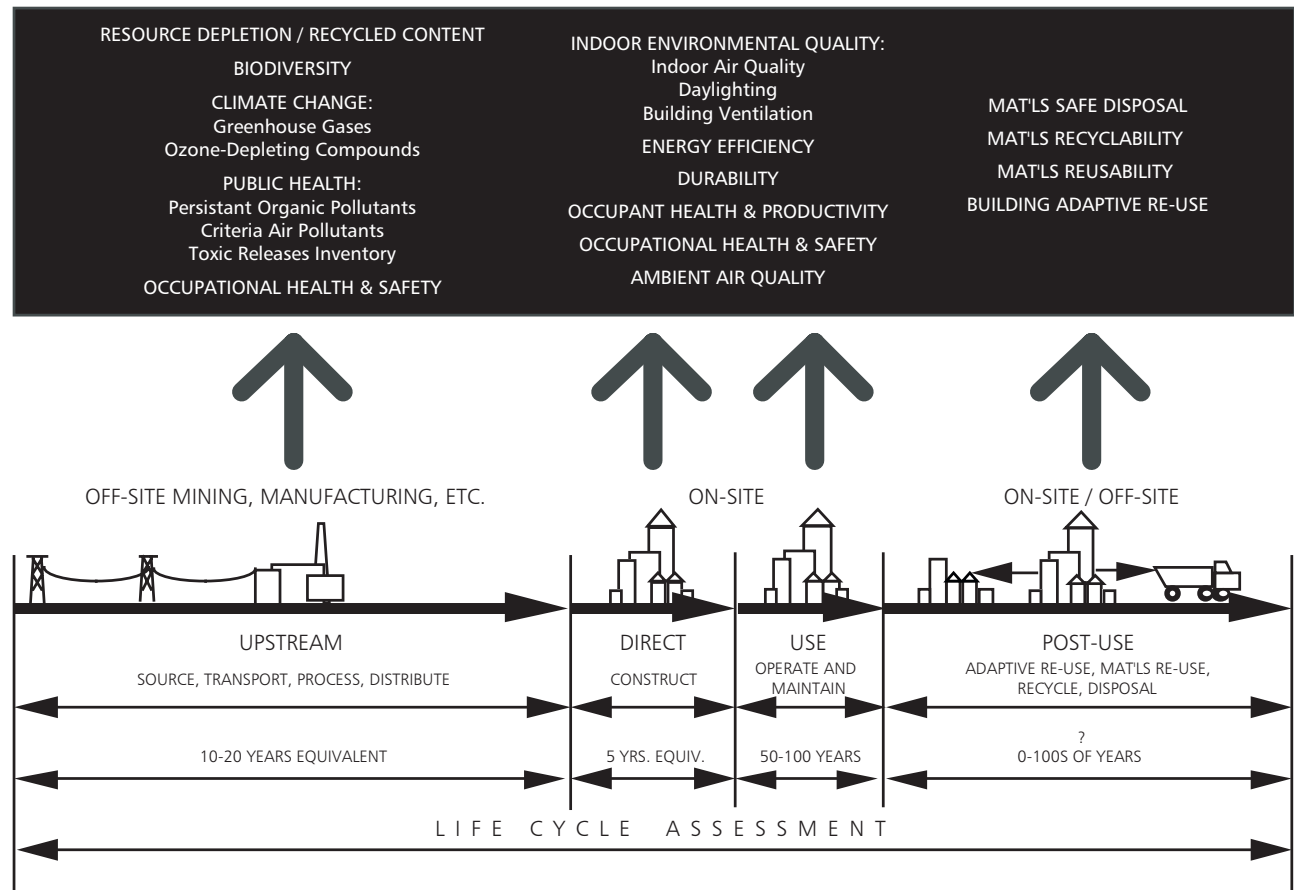
GUIDING PRINCIPLES

More than an optimization of any single component, sustainable design and construction represents the integration of materials and methods that, together, create the physical manifestation of a building. The entire life cycle of building materials and products, as well as the building as a whole relative to its physical, environ-

mental and human contexts on the local, regional and global scales, must be evaluated for environmental and health considerations (see Figure 1 below). We are informed by the U.S. EPA's findings that indoor air pollution is one of the top five environmental risks to public health, and by the U.S. Science Advisory Board's assessment of highest global environmental priorities: global climate change, loss of biodiversity, habitat destruction, and stratospheric ozone depletion. While not as obvious as to their affect on human health as indoor air quality, these indicators of environmental health at risk—rising global temperatures, increased exposure to ultraviolet radiation, and diminished supplies of natural resources—signal trouble for the human species. Establishing life cycle health and environmental considerations as evaluative criteria for design decisions and material and product specifications yield measurable benefits in enhanced patient

FIGURE 1: LIFE CYCLE ASSESSMENT OF BUILDING MATERIALS AND PRODUCTS

(Figure by CENTER FOR MAXIMUM POTENTIAL BUILDING SYSTEMS)



outcomes, improved worker productivity, and reduced operations and maintenance costs, to name a few. This recognition should trigger immediate review and modification of existing A/E Guidelines, standard procurement policies and specifications.

Upstream environmental and health impacts occur during the materials acquisition (source), transport, manufacture, and distribution life cycle stages of materials and products. These impacts can be equivalent to 10-20 years of a building's operation. In conventional economics, these impacts are called "externalities."

Construction of the building is the **Direct** life cycle stage. Its impacts are equivalent to about five years of building operation. The **Use** stage includes the operation and maintenance of the building and is typically assumed to be 50 years or more in Life Cycle Costing estimates. Owners are interested in payback periods during the expected life of the building, i.e., in how many years will savings in operational costs become equal to or greater than an initial investment in a particular improvement. Beyond a cost justification, investment in healthy building practices yields measurable results in medical outcomes for patients.

After the building's useful life, the building can be modified for "adaptive re-use" or the building's materials and products can be reused, recycled, or disposed. This is the **Post-Use** stage of materials and products. Reusing or recycling materials reduces burdens on landfills, conserves resources, and saves the contractor or owner the costs of landfill disposal. This is one example of "cost avoidance."

Case studies confirm that facilities can be greened with nominal, if any, additional costs. Design decisions and material choices that may represent higher first costs are recouped through savings in operations, maintenance and enhanced worker performance over the life of the building. Indeed, recent studies at major commercial/manufacturing facilities, such as Herman Miller's SQA Factory in Zeeland, Michigan and at government facilities such as the U.S. EPA's Research Facility in Research Triangle Park, North Carolina correlate superior indoor environmental quality (IEQ) with enhanced worker productivity.⁸ Because worker salaries represent the highest portion of a building's operational costs, a 1% improvement in productivity far outweighs any additional costs associated with green design features or healthy materials and prod-

ucts.⁹ Consistent with these findings and more germane to healthcare professionals, other research shows that improving the quality of hospital spaces can lead to decreased length of stays for patients.¹⁰ Clearly, establishing the highest achievable standards for indoor environmental quality (IEQ) is an important guiding principle for all healthcare facilities.

PROBLEM STATEMENT

Unique Characteristics of Healthcare Facilities

Healthcare facilities, averaging between 70 and 75 million square feet of construction per year,¹¹ have unique programming criteria that guide design decisions and material, product and equipment specifications. Understanding the complex of human health implications of these decisions is critical. For example, the Academy of Architecture and Health cites research indicating that natural lighting, indoor landscaping, rooftop gardens, solariums, and small atria have a health impact on hospital staff and can improve the feeling of well being and medical outcomes in patients. They recommend maximizing views of nature and landscaping from all patient environments, and increasing the use of skylights, interior transom windows, and natural light.¹²

In addition, these buildings undergo a high rate of change, as interior spaces are reconfigured, remodeled and outfitted with new furnishings and equipment reflecting changes in management and delivery systems.¹³ The result is an enormous amount of waste. Recognizing this trend, the International Facility Management Association (IFMA) Healthcare Council has tracked the development of flexible healthcare interiors based on building shell construction with universal distribution networks designed to minimize waste and accelerate schedules. According to an article in IFMA's *Facility Management Journal*, "The advantages of this approach are rapid project completion, clean and quiet installation, great flexibility and costs similar to those of conventional construction, but with significant lifecycle cost and operational savings."¹⁴

Representing a substantial share of annual design and construction activities in the U.S., the healthcare sector is well-positioned to highlight the potential that buildings have to reverse environmental decline and to create environments for people that enhance health, patient outcomes, and workplace performance. The

purchasing power represented by the healthcare industry can lead to industry partnerships to improve the health and environmental profiles of buildings *throughout their life cycle*. Recognizing this shared responsibility among designers, manufacturers, building owners, facility managers and public policymakers sets an agenda that will yield important outcomes, as manufacturers are encouraged to shift their practices in response to a growing demand for sustainable products and practices, and the allied building professionals are directed to implement green and healthy building practices.

Similarly, it is appropriate and timely to establish partnerships between the regulating and the regulated communities. Guidelines and regulations overseeing hospital design and construction should be evaluated based on their impacts on environmental quality and human health and revised so that they reflect these as priority considerations.

Indoor Environmental Quality

While poor air quality is commonly associated with outdoor air, air inside buildings is often worse. As buildings were constructed to tighter energy efficiency standards in the 1970's, the materials and compounds used to manufacture common building materials were found to have harmful emissions, with direct effects on people's health. In response, improved ventilation standards were established; however, numerous common building materials and products—standard specifications for commercial and institutional buildings—continue to be sources of indoor air pollution. Both improved ventilation rates and source elimination are necessary to achieve and maintain good indoor air quality.

According to the U.S. EPA, most sources of indoor air pollution come from materials and products used in the building such as adhesives, carpeting, upholstery, and manufactured wood products that emit volatile organic compounds (VOCs), including formaldehyde, a probable human carcinogen.¹⁵ Indeed, the construction industry is the primary end-user of formaldehyde-based products, representing 70% of its use.¹⁶ Health effects of poor indoor air quality include asthma, cancer, and reproductive and development effects, and are manifested in thousands of cancer deaths and hundreds of thousands of respiratory health problems.¹⁷

PVC (polyvinyl chloride) is another material manufactured into numerous common building products. Concerns about its effects on human health and environmental quality have been raised by many green building proponents as well as health practitioners. Recently, the U.S. Government's National Toxicology Program (NTP) expressed serious concern for the possibility of adverse effects on the developing reproductive tract of male infants exposed to very high levels of DEHP (diethylhexyl phthalate) that might be associated with intensive medical procedures. Also, the NTP expressed concern that exposure of pregnant women to current estimated adult exposure levels of DEHP might adversely affect the development of their offspring. Health Care Without Harm recommended that hospitals specify building products made without PVC.¹⁸ Consistent with this finding, substitutes should be specified for other building materials that contaminate indoor air, such as products manufactured with formaldehyde.

Obstacles to Green Building

Despite a growing recognition of the benefits of green building, many factors contribute to only a modest transformation of design and building practices to date. These include:

- **Resistance to change:** Innovation in the building industry lags behind virtually every other economic sector, with a few notable exceptions. The consolidation of ownership of natural resources and manufacturing infrastructure retards the competitive vibrancy that has become a distinguishing characteristic of other sectors such as telecommunications. In addition, professional academic training for architects and engineers has been slow to incorporate environmental and human health considerations into the core curriculum, so practitioners leave school without the benefit of this training.

Recommendation: Require the same level of innovation in your buildings as in your healthcare delivery systems; contract with design professionals with established credentials in green and healthy buildings; provide appropriate training to building-related professionals to implement the changed practice.

- **Fear of liability:** Introducing unfamiliar methods and materials raises liability concerns, especially when professional architects and engineers are required to stamp drawings.

Recommendation: Establish strategic academic and industry partnerships, invest in research, develop-

ment and demonstration projects, and monitor outcomes to reduce the liability risks. Compare the benefits of enhancing the environmental and health performance of buildings with the present liability of buildings that compromise environmental quality and human health. Consider that these present liabilities could be substantially expanded and increased as a more robust economic valuation of environmental quality and human health is codified and enforced.

- **Perception of higher costs:** Healthcare facilities typically operate for 30, 50, 100 years or more. An accounting system that artificially distinguishes the capital (first cost) budget from the operations and maintenance (O&M) budget hampers the ability to make decisions based on life cycle cost analysis.

Recommendation: Front-loading the design process and material and product specifications to create a green and healthy building and optimize cost performance over the life of the building is a sound investment. A study by the National Bureau of Standards concludes that in a typical office the labor cost of employees is 13 times the cost of the facility itself over its life cycle, including construction, furnishings, maintenance, and interest, while the cost of design is only about 1/50th the labor cost of people.¹⁹ Investing in design, materials and products that enhance productivity and improve health-related outcomes are quickly recouped and improve the bottom-line over time.

SOLUTION

Redefining buildings through their life cycle as integral parts of a healthy regional ecosystem, and as environments that directly impact human health, are basic principles of green building. Minimizing wastes, pollution, and toxics associated with the construction and operation of buildings and pursuing every opportunity to optimize indoor environmental quality are measurable performance goals. This agenda is consistent with the fundamental mission of healthcare professionals and should be reflected in their building portfolios.

The healthcare industry is appropriately positioned to invest in research and demonstration projects to evaluate, make recommendations and implement policies and procedures to enhance the therapeutic qualities of

healthcare facilities, and minimize material- and labor-intensive remodeling and renovation practices. Moreover, investments should extend to enhance the environmental performance of their buildings by adopting and implementing green building guidelines and establishing health and environmental performance parameters for all planning, design, specification, operations, maintenance, and post-use decisions.

IMPLEMENTATION

Short-Term Actions (Year 1)

1. Incorporate green and healthy buildings into the strategic plan, and implement corporate commitment through: establishing an in-house “green team” to review existing building-related policies and procedures, augmented by consultants as appropriate; developing green specifications; developing green housekeeping guidelines for building superintendent and custodial staff; engaging in legislative advocacy; establishing accountability protocols.
2. Require architects, engineers and contractors to specify commercially available, cost competitive materials and products as substitutes for products that compromise environmental quality and human health. Example substitutes are:
 - PVC-free products, e.g., flooring, wall covering, carpet backing, ceiling tile, plumbing pipe, roof membrane
 - Formaldehyde-free engineered wood products, e.g., oriented strand board, medium density fiberboard, plywood, furnishings
 - No/low VOC products, e.g., paints, adhesives, stains, finishes, floor coverings
 - Acoustical ceiling tiles that do not support growth of fungi and bacteria
 - Materials and products manufactured without ozone depleting compounds (CFCs, HCFCs and halon), e.g., insulation, refrigerants, fire suppressants
 - Treated wood manufactured without chromium or arsenic
 - Certified sustainably harvested wood products (as per Forest Stewardship Council)
 - Highest available recycled content steel and concrete to fulfill performance requirements
3. Provide and/or require attendance at green and healthy building training seminars for all building related staff and upper management.

4. Expand responsibilities of Environment, Health & Safety Department to include monitoring indoor air quality and ongoing commissioning of major operational systems.
5. Measure energy and water consumption, greenhouse gas emissions, and waste generation and establish efficiency goals based on baseline.
6. Review and modify, as appropriate, U.S. Green Building Council's LEED rating as a preliminary green building evaluative tool.
7. Establish reuse and recycling as prioritized tiers of the facilities' waste management practices.

Mid- to Long-Range Actions (Years 3-5)

1. Establish life cycle metrics for environmental, human health and natural resource performance to guide design decisions, material and product specifications and construction and operational protocols.
2. Design for the long-term (50-year+ building life expectancy).
3. Merge capital and O&M budgets to optimize life cycle costing.
4. Establish procurement policies and building material and product specifications consistent with the green and healthy metrics; provide for annual review/revision.
5. Establish partnership with regulators to review/revise regulations to reflect impacts on human health and environmental quality.
6. Establish an internal green and healthy building rating system, and/or adopt the U.S. Green Building Council's LEED with amendments to reflect particular priorities of healthcare facilities with focus on environmental health criteria and environmental exposures.
7. Establish permanent position to oversee compliance with green and healthy building standards and create a template for green building design, construction, operation and maintenance.
8. Provide ongoing green building training opportunities (on-site/off-site) for all building related staff and upper level management.
9. Integrate/balance resource flows (energy, water, materials) to enhance life-cycle efficiency.
10. Design for flexibility to facilitate operational changes, respond to changing user needs and minimize waste generation and labor requirements.

RESOURCES/ORGANIZATIONS

Architects/Designers/Planners for Social Responsibility (ADPSR)

Northern California Chapter
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CASE STUDIES

St. Mary's Hospital (NHS), Isle of Wight

A prototype 398 bed NHS facility opening in 1991 designed to be highly energy efficient; after nine years of operation the hospital's recorded energy consumption is 50% less than hospitals of comparable size.

Swindon Hospital (NHS)

www.carillionplc.com

This site describes the sustainable design of a new NHS hospital under construction in the UK utilizing the sustainable design principles of the Swedish organization The Natural Step, and includes a list of sustainable design principles being initiated in the hospital's construction and maintenance.

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One of the general themes in all the sessions was around commitment; that you must have commitments simultaneously at all levels of an organization.

This is something that cannot be achieved by a top down process. It must be a bottom up process, and a middle process and the top must support these initiatives. We also must have the commitment of our sponsors and of our boards. The commitment to safeguard the environment continues to grow as the link between human health and environmental quality is made clear. It is our core business to minimally impact the environment and to provide an optimum health and safe environment for our workers and our patients. Our ecological commitment exists because we impact the environment in the process of making people well.

THIS EXCERPT IS FROM THE REMARKS OF LLOYD DEAN, MA, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF CATHOLIC HEALTHCARE WEST AT SETTING HEALTHCARE'S ENVIRONMENTAL AGENDA ON OCTOBER 16, 2000 IN SAN FRANCISCO, CALIFORNIA.

MERCURY ELIMINATION

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PROBLEM STATEMENT

Mercury Pollution and the Healthcare Industry

Mercury is a naturally occurring heavy metal that is linked to numerous health effects in wildlife and humans. Mercury is neurotoxic and can damage the central nervous system, especially during fetal and childhood development.

Mercury exposure can cause tremors, impaired vision and hearing, paralysis, insomnia, emotional instability, neurological deficits during fetal development, attention deficit, and developmental delays.¹ Recent studies suggest that mercury may have no threshold below which adverse effects do not occur.

Mercury is a silvery-white liquid at ambient temperature and pressure, though it readily vaporizes and may stay in the atmosphere for up to a year. When released to the air, mercury is moved by global transport processes and deposited around the world. Mercury ultimately accumulates in lake bottom sediments, where it is transformed into a more toxic form, methylmercury, which builds up in fish tissue. Individuals with high methylmercury exposures from frequent fish consumption may have little or no margin of safety. The children of women who consume large amounts of fish and seafood during pregnancy are at highest risk of harm from methylmercury. A recent report estimated that each year about 60,000 children may be born in the United States with neurological problems that could lead to poor school performance because of exposure to methylmercury in utero.²

Fish consumption advisories due to mercury contamination are in place on thousands of water bodies across

the United States. Forty states have issued advisories on all or some of their lakes, streams and rivers. Mercury levels in the environment have been rising over the last century³ and parallel the rise in industrial activities.

Historically, mercury has been used in the medical setting, because of its uniform response to temperature and pressure changes. Typical uses include sphygmomanometers, laboratory and patient care thermometers and gastro-intestinal devices. Mercury compounds are also in preservatives, fixatives and reagents used extensively in hospital laboratories. Through medical waste incineration, healthcare facilities are recognized as the fourth largest source of mercury to the atmosphere.⁴ Hospitals are also known to contribute approximately 4-5% of the total wastewater mercury load.⁵

Because of the recognition that hospitals contribute significantly to the problem of mercury in the environment, in 1998, a memorandum of understanding was signed by the Environmental Protection Agency and the American Hospital Association. One of the key components of this agreement is to “virtually eliminate” mercury from hospitals by the year 2005.

The Vision: Moving up the Timeline, Mercury-Free by 2003

A variety of hospitals around the country have demonstrated that it is possible to practice mercury-free healthcare. Dana Farber Cancer Institute in Boston and St. Mary's Medical Center in Duluth, Minnesota are two examples. If sufficient resources are made available, the healthcare industry would be able to accomplish the following:

- Eliminate the purchase of any new mercury-containing equipment;

- Provide yearly training on mercury pollution prevention;
- Replace all mercury-containing equipment (sphygmomanometers, laboratory and patient thermometers, and gastrointestinal equipment);
- Eliminate the use of mercury-containing fixatives and reagents;
- Introduce a purchasing procedure that selects for products with the lowest levels of mercury for all hospital purchases with background mercury contamination;
- Replace all mercury-containing pressure gauges on mechanical equipment;
- Powerwash or replace plumbing systems;
- Eliminate the distribution of mercury thermometers to new parents;
- Establish fluorescent bulb and battery recycling programs; and
- Support legislation which prohibits the sale of mercury-containing equipment.

IMPLEMENTATION

14

All mercury elimination measures need a foundation of strong administrative support and financial resources. If, for example, a mercury reduction initiative is announced, and a mercury elimination taskforce developed, but the administration does not send representatives to taskforce meetings, the mercury reduction initiative will understandably be negatively impacted.

Alternatively, if the administration attends task force meetings but does not champion a budget, the initiative will be similarly impacted. Implementation of the ideal goal is dependent on both of these pillars. Without one or the other; the program will have less chance for success.

Another important success factor is the existence of an environmental “champion” within an institution. Support for these individuals is an excellent way to move a program forward.

Financial resources, administrative commitment and supported environmental champions are the foundation for building a long-term vision and a commitment to the process of employee, institutional and community-wide involvement and education. Education should be aimed at providing an understanding of the adverse impacts of mercury to the environment, public

health, and worker health and safety. Education on mercury-free alternatives is equally important.

Action steps

Initiation of a mercury reduction plan usually begins with an announcement of institutional support, and an invitation for interested employees to be part of a mercury pollution prevention taskforce. A taskforce will provide the most lasting and measurable impacts if it meets regularly and focuses on setting action steps to remove the largest sources of mercury first. The senior decision maker can have a positive impact on the reduction scenarios by providing management support for regular meetings, and financial support for implementation of those action steps necessitating funding. Timing and order of any action steps should be guided by the taskforce, but should include the following:

- Hold a mercury thermometer exchange;
- Provide annual mercury training/spill/labeling program;
- End the distribution of mercury thermometers to new parents and patients;
- End the purchase of new mercury-containing equipment and implement a mercury-free purchasing policy for vendors that includes reagents, and other background uses of mercury;
- Create a replacement plan and budget for elimination of mercury-containing equipment;
- Collect all wastes from processes involving the fixative B5 and designate a team to investigate the use of mercury-free alternatives;
- Set up a fluorescent bulb (and other mercury-containing bulb) recycling program;
- Establish a battery collection program;
- Develop a waste trap cleaning/replacement plan, and
- Implement a labeling and replacement plan for other mercury-containing devices (mechanical equipment).

First Steps

The first step for a mercury reduction team might include the identification of available educational resources, both internal and external to the hospital. Internally, these resources might include medical professionals and environmental services personnel. Externally, state and industry waste management resources are plentiful. Some mercury reduction teams have had early successes due to the order in which they prioritized their initiatives. Mercury sphygmomanometers frequently break and spill, incurring substantial clean-up costs. These might be a priority at one insti-

tution. Another institution may be at risk for wastewater fines for mercury, and here laboratory mercury reductions may be their priority. Different healthcare institutions will have different priorities, but prioritization is a means to achieve early successes.

Using your Group Purchasing Organization (GPO)

Purchasing is one of the most important departments in any hospital mercury reduction initiative. It is where the decisions are made as to what does or does not come into a facility. It is important to recognize that Materials Management is one of the first places to begin implementation of a mercury elimination policy through adoption of a mercury-free purchasing plan (with requisite education and training on mercury-free healthcare for purchasing staff). Yet, the role of purchasing in mercury-free medicine may frequently be subservient to the role of the individual institution's GPO. It is the GPO that offers the products that a hospital purchases. If a GPO offers mercury-containing equipment, or mercury products without disclosure of mercury concentrations, it may be contractually difficult to meet the objectives of an institutional mercury-free policy. The GPO therefore plays an important role in mercury-free healthcare. It is important to recognize this role and use this knowledge to empower hospital management. Hospital management must support the Purchasing Department during GPO contract negotiations, and demand mercury-free products and products with disclosure of mercury concentrations. Hospital management may also have to work collaboratively with other hospitals that use their GPO and together create a voice for mercury-free products. Such leadership will lend support to the GPO to call on manufacturers to disclose mercury concentrations.

Obstacles to Change

Mercury-free medicine is technically feasible, proven by the number of hospitals that have successfully implemented mercury elimination programs. These experiences have helped to identify obstacles and means to circumvent them, making the course that much easier for other hospitals attempting the same goal. Primary obstacles to be expected by the senior decision maker include:

1. LACK OF KNOWLEDGE BASE

The need for education to strengthen the general understanding of all staff on the impacts of mercury on the environment and on the health of hospital employ-

ees, patients and the public has already been emphasized. Education on the life cycle costs of mercury equipment is also extremely important when prioritizing where and when to replace mercury-containing equipment. These costs include hazardous material training, potential clean-up expenses, hazardous waste reporting requirements, and potential wastewater treatment fines.

There is also widespread misunderstanding of the accuracy of mercury-free equipment, especially among medical staff that has been trained on mercury equipment. It is important to educate medical staff on the availability of mercury-free equipment such as thermometers, gastrointestinal devices and sphygmomanometers that offer the same level of accuracy as the mercury product.

These are some of the examples that illustrate the need for an expanded knowledge base concerning mercury reduction and elimination. State and local governments have many conferences and training materials on mercury elimination. The resources provided with this paper should also provide a strong foundation for any mercury reduction initiative.

2. BUDGET

Cost containment is a reality in healthcare, and it may be difficult to defend any budget that includes staff time for mercury pollution prevention and equipment replacement costs (especially for properly functioning mercury-containing equipment). The aforementioned discussion on ancillary costs associated with mercury equipment may be useful. In addition, there are tremendous public relations benefits to any organization that begins a mercury reduction initiative. Mercury thermometer exchanges typically engender tremendous public support. Management interested in implementing a mercury reduction program may use innovative interdepartmental budgeting as it develops its program.

3. TIME

As with all programs, it is important to set and prioritize time for communication and meeting attendance for ongoing mercury pollution prevention task force initiatives. If consideration is not given to time management, it can have a tremendous negative impact on the program. It may be best to delay implementation than to begin and provide minimal attention to the program.

RESOURCES

Eliminating Mercury Use in Hospital Laboratories: A Step toward Zero Discharge: Public Health Reports, July/August 1999 Volume 114 p353-358.

Healing the Harm: Eliminating the Pollution from Healthcare Practices

Mercury Thermometers and Your Family's Health

How to Plan and Hold a Mercury Fever Thermometer Exchange

Making Medicine Mercury Free
Health Care Without Harm, P.O. Box 6806, Falls Church, VA 22040, (703) 237-2249; hcwh@chej.org

Mercury Use in Hospitals and Clinics. 20-minute video and guidebook. Minnesota Office of Environmental Assistance, 520 Lafayette Road N., 2nd Floor, St. Paul, MN 55155; (612) 296-3417; (800) 657-3843.

The case against mercury: Rx for pollution prevention. U.S. Environmental Protection Agency, Region V, Chicago, IL. 1995.

Medical waste pollution prevention. Keep mercury out of the wastewater stream. U.S. Environmental Protection Agency, Region V. Chicago, IL.

Mercury. Western Lake Superior Sanitary District. Duluth, MN.

Blueprint for Mercury Elimination. (38-page book of interest-free) Western Lake Superior Sanitary District ; 218-722-3336

INTERNET SITES

Health Care Without Harm, www.noharm.org.

Strategies to Achieve AHA's Vision of Healthy Communities, www.h2e-online.org

University of Massachusetts Lowell Sustainable Hospitals Project, www.sustainablehospitals.org

Reducing Mercury in Healthcare, Promoting a Healthier Environment
Monroe County, New York, Department of Health (also available in hardcover)
www.epa.gov/glnpo/bnsdocs/merchealth/about-merhealth.html

Mercury Use Reduction & Waste Prevention in Medical Facilities
Educational software for the Web by USEPA Region 5 and Purdue University
www.epa.gov/seahome/mercury/src/title.htm

(Massachusetts) Medical, Academic and Scientific Community Organization (MASCO)
www.masco.org/mercury

Massachusetts Water Resources Authority
www.mwra.state.ma.us

The Wisconsin Mercury Sourcebook contains chapters on Hospitals and Clinics
www.epa.gov/glnpo/bnsdocs/hgsbook/hospital.pdf

ENDNOTES

1. US EPA 1997, "Mercury Report to Congress."
2. National Academy of Sciences National Research Council, July 2000. "Toxicological Effects of Methylmercury."
3. Wisconsin Department of Natural Resources, 1996. "Mercury in Wisconsin's Environment: A Status Report."
4. USEPA 1997, "Mercury Report to Congress."
5. Personnel Communication, Western Lake Superior Sanitary District, Duluth, MN

18

A consistent ethic means that our healthcare organizations must change practices. At Catholic Healthcare West, we see a clear link between environmental responsibility and our basic mission, which is to provide quality healthcare services to all. There is a direct link between healing the individual and healing this planet. We will not have healthy individuals, healthy families, and healthy communities if we do not have clean air, clean water and healthy soil.

THIS EXCERPT IS FROM THE REMARKS OF LLOYD DEAN, MA, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF CATHOLIC HEALTHCARE WEST AT SETTING HEALTHCARE'S ENVIRONMENTAL AGENDA ON OCTOBER 16, 2000 IN SAN FRANCISCO, CALIFORNIA.

ENVIRONMENTALLY PREFERABLE PURCHASING

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INTRODUCTION

Environmentally preferable purchasing (EPP) is the act of purchasing products and services that have been found to be less damaging to the environment and human health than competing products and services. It includes the ongoing process in which a healthcare institution continually refines and expands the scope of its efforts to select environmentally sound products and services. A provider institution's decision to implement EPP is an important component of a larger system of healthcare industry practices that support the integrity of both business and environmental decisions.

Over the past several years, U.S. federal agencies have operated under a series of federal statutes and Presidential Executive Orders mandating the purchase of products and services that place fewer burdens on the environment (see insert). As a result, federal agencies are increasingly selecting products based on "green" criteria such as recycled-content percentages, energy and water efficiency ratings, lower toxicity, and the use of renewable resources. Many state and local governments are embarking on similar initiatives. The U.S. Environmental Protection Agency's (EPA) Environmentally Preferable Purchasing Program is assisting these efforts and documenting federal, state, and local government attempts to implement EPP strategies.

The growing interest in environmentally preferable purchasing is not limited to the public sector. Private sector companies are also investigating and purchasing environmentally preferable products and services. Although this is a new concept for some companies, others are beginning to resolve some of the challenges

encountered when incorporating environmental considerations into purchasing decisions. Through a variety of environmental and cost-savings initiatives – design for the environment, greening the supply chain, waste minimization, ISO 14000 certification, environmental accounting, and others, private sector companies are identifying, manufacturing and purchasing "green" products and services.

The EPA recommends selecting products that maximize beneficial environmental attributes and minimize adverse environmental effects consistent with price and performance considerations. The EPA encourages consideration of environmental impacts during each stage of a product's lifecycle – raw material acquisition, manufacture, packaging and distribution, use, and disposal. The environmental impacts include adverse effects to workers, animals, plants, air, water and soil. Other aspects to consider during the life cycle of a product include energy and/or water efficiency; recycled content; resource conservation; waste prevention; renewable material percentages and toxic material content.

Traditionally, private sector purchasing decisions have not been made to promote social, economic, or political objectives. Because private sector companies must sell quality goods at reasonable prices, they have historically examined a product's cost, performance, availability and impact on future profits. Due to heightened customer interest in "environmentally friendly" products and practices, an increasing number of private sector companies, such as Anheuser-Busch, Canon, IBM, Sony, Volvo and Warner Brothers, are adopting purchasing and production practices that promote specific social, economic and environmental objectives. Several consumer studies since 1994 have suggested

In October 1993, an **Executive Order, Federal Acquisition, Recycling and Waste Prevention**, initiated the EPA's work on environmental preferability by mandating the EPA to develop environmentally preferable purchasing guidelines for federal agencies.

Executive Order 13101 (September 1998), *Greening the Government Through Waste Prevention, Recycling and Federal Acquisition* defines environmentally preferable products as: "products and services that have a lesser or reduced effect on human health and the environment when compared with competing products or services that serve the same purpose. This comparison may consider raw materials acquisition, production, manufacturing, packaging, distribution, reuse, operation, maintenance, or disposal of the product or service."

that consumers are interested in purchasing environmentally friendly products, or products from environmentally conscious companies. As a result, several large, multinational companies believe producing "green" products and using "green" practices can distinguish a company from its competitors.

In addition, applying environmentally preferable purchasing principles often saves companies money. Examining environmental impacts through a product's life cycle can help companies identify opportunities to reduce costs, or in a cost-neutral situation, improve environmental performance. Additionally, companies employing environmentally preferable purchasing principles are significantly reducing their energy and water consumption, decreasing their use of natural resources, reducing waste and minimizing the use of potentially hazardous substances.

The implied mission of healthcare providers is to improve the health of people and the communities we serve. Issues that relate to the health of people and their communities are inherently linked to the health of the environment. It is becoming widely known that many of the medical products we buy, and practices we engage in, can cause damage to the environment and/or public health.

As a result, in June 1998, the American Hospital Association signed a Memorandum of Understanding (MOU) with the U.S. EPA in consultation with Health Care Without Harm, agreeing to work in voluntary partnership to:

- Virtually eliminate mercury waste generated by hospitals by 2005;
- Reduce overall hospital waste volume by 33% by 2005 and by 50% by 2010; and

- Jointly identify additional substances to target for pollution prevention and waste reduction opportunities.

This voluntary partnership has attracted the attention of many local government agencies as well as professional associations of physicians, nurses, environmental services directors, material managers, and representatives of product manufacturers and the waste management industry.

To date, a multi-disciplinary and multi-industry Environmental Leadership Council has been established to provide leadership in implementation of the MOU; stakeholder workgroups in twelve states have been formed to help meet the goals set out in the MOU; a manual, *Hospitals for a Healthy Environment*, is being written that will include chapters on Best Practices, Chemical Minimization, and Environmentally Preferable Purchasing; and a workplan for elimination of mercury in hospitals has been developed.

PROBLEM STATEMENT

Five areas that have been identified by Health Care Without Harm as focal points for EPP. They include:

- Mercury-containing products
- Polyvinyl Chloride (PVC)- containing products
- Reprocessed and Reusable products
- Green Building products
- Safer products for workers

In addition, Health Care Without Harm advocates waste minimization practices which can be implemented by the purchasing function through the selection of

products with reduced packaging and the procurement of items that are readily recyclable and/or made of recycled content.

The human and environmental impacts of each of these five areas are described in more detail in companion papers from the October 2000 Setting Healthcare's Environmental Agenda (SHEA) Conference. The companion papers identify strategies for increasing awareness of the effects of these products and practices, advocacy initiatives for public policy change, and strategies for reducing, replacing or eliminating non-preferable products in the healthcare setting. These papers and all of the breakout groups at SHEA identified environmentally preferable purchasing as a key strategy for success.

Purchasing departments are the central originating point for nearly every product or service procured for hospitals and healthcare providers. In the past, when healthcare organizations have attempted to purchase environmentally sound products and services, they have met four significant challenges:

- Resistance to change by end-users, even if the organization's philosophy supports EPP;
- Availability of few environmentally-sound alternatives; (the alternative's properties/ performance may be different from the products currently in use);
- Lack of availability of existing acceptable alternatives through the Group Purchasing Organization (GPO) for the institution;
- Affordability of environmentally-sound products and services (especially when compared on a unit-by-unit basis rather than a life cycle cost basis).

SOLUTION

Environmentally preferable purchasing faces challenges on several fronts, and therefore the solution requires a multi-pronged approach.

Overcoming Resistance to Change

Resistance to change in healthcare organizations is related to the stress of patient care, time constraint pressures, and the comfort of the familiar. Introducing environmentally preferable products and services can best be supported by education and the participation and creativity of staff at all levels. When given the opportunity to rethink practices and select new alternatives, staff members frequently take the initiative to

implement innovative ideas, which may produce unforeseen benefits. When new products are introduced into a hospital setting, it is essential that hospitals take the time to evaluate them, and work with the manufacturer to overcome any problems.

One way to overcome this resistance to change is to develop an Environmentally Preferable Purchasing (EPP) Team. This EPP Team should be comprised of individuals from different areas working together to foster a new purchasing culture. The team should coordinate its activities with the facility-wide environmental team and the product review committee(s). The leader of the team should be someone whose administrative responsibilities ensure the EPP project is fully implemented.

The diverse perspectives of members from various departments can challenge current practices and promote innovative solutions. If each department contributes to the process, there will be greater buy-in, and thus acceptance of changes in practices and products.

The EPP team should set specific goals and objectives, taking into consideration concerns or issues that the hospital is already facing (e.g., mercury spills, environmental violations, and worker safety issues). The goals should be quantifiable and have a timeframe for achievement.

Support from top management should be requested in the form of policies and procedures, and in the form of support for EPP language in Request for Proposals, job descriptions and performance evaluation criteria, etc. The EPP team should develop an educational program for the institution to be included in the new employee orientation process.

Availability of Alternative Products

While alternatives are not always easily found, it is important for a healthcare organization to communicate its desire for environmentally favorable products to suppliers and manufacturers. Feedback and demand are the driving forces behind the development of better products. In their effort to encourage the development of product alternatives, several healthcare organizations have inserted specific language regarding non-mercury and recycled content products into every Request for Proposal. Some of these organizations include Beth Israel Deaconess Medical Center (Boston, MA), Catholic Healthcare West (San Francisco, CA),

Catholic Health East (Newtown Square, PA) and Kaiser Permanente (Oakland, CA).

Hospital purchasing departments, by leveraging the product volume of the healthcare industry, are the ultimate drivers of the suppliers' business strategies. If hospital management emphasizes a desire for environmentally friendly technologies when making purchasing decisions, vendors will be motivated to invest in the design and production of environmentally safer products.

Organizing conferences for the vendor community and purchasing managers is one way to educate both groups on the importance of producing and selecting products that are more environmentally responsible.

Group Purchasing Organizations (GPOs)

Virtually every health system is a member of a Group Purchasing Organization (GPO). GPOs are able to combine the purchasing power of many providers to leverage the best prices from vendors. In order to achieve the best price possible, GPOs often limit available products to that of a "portfolio," analogous to a hospital formulary. It is essential to express the preference for environmentally preferable products to the GPO, so that these items will be included in any prospective portfolio. In some cases, the GPO may suggest alternative products that are currently available.

Just as important as influencing pricing, GPOs that represent a significant aggregated market, can influence suppliers and manufacturers on availability and cost of environmentally preferable products. Tactics such as including specific language in Requests for Proposals or on purchase orders that require disclosure of products containing mercury or PVC, or specifying recycled content or the recyclability of items have been used successfully by providers such as Catholic Healthcare West.

Another tactic that supports an environmentally preferable purchasing strategy requires that any contracted vendors be compliant with the voluntary International Standards Organization for environmental management systems known as ISO 14000/14001. The International Organization for Standardization (ISO), a non-governmental organization established in 1947, comprises a worldwide federation of national standards bodies from each of 100 countries. The organization's purpose is to facilitate the international exchange of goods and services by establishing standards and recon-

cing regulatory differences between countries. The ISO 14000 series is a voluntary set of standards intended to encourage organizations to systematically address the environmental impacts of their activities. ISO 14000 is a management system, not a performance standard. It provides a general framework for organizing tasks necessary for effective environmental management.

Alternative Product Pricing

Increased demand for environmentally preferable products can shift the demand curve and initiate a cycle resulting in better pricing. As companies ramp-up for large-scale production of environmentally designed goods and services, the research, development and production costs can be spread across a larger quantity of products. Increased production and falling prices will allow market expansion and will accelerate the process by which environmentally preferable products become general use items.

IMPLEMENTATION STEPS

EPP requires that healthcare organizations change their cultural mindset to be come more environmentally friendly. This culture change requires leadership and commitment. It begins with a vision of what the organization wants to achieve in terms of environmental responsibility. Considerations such as the resources consumed and waste produced during manufacturing of a product, the amount of packaging and its recyclability, product reusability and recyclability, and product safety all contribute to the overall sustainability of that product. Therefore, the healthcare purchasing vision needs to include the following components:

REDUCE –REUSE –RECYCLE –REDESIGN

Key tenets of this vision are the following:

- Prevent pollution at the source whenever and wherever possible
- Purchase products that can be reused or recycled
- Purchase products with fewer or no toxic ingredients
- Purchase energy efficient products
- Work with vendors and manufacturers to develop/redesign alternative products that are environmentally preferable
- Provide a healthier environment for patients, workers and the community

It is not necessary for healthcare organizations to reinvent the wheel in developing EPP programs. One model, developed and included in the Hospitals for a Healthy Environment manual, outlines the EPP process in a manner that creates buy-in and ownership from the outset. A flowchart from the Hospitals for a Healthy Environment *Environmentally Preferable Purchasing "How To" Guide* is provided at the end of this section.

There are many examples of healthcare provider organizations that have implemented EPP programs. These include Catholic Healthcare West, Kaiser Permanente, Beth Israel Medical Center, and Hartford Hospital. Some universities also act as good resources for information on EPP. The University of Massachusetts-Lowell has established a hospital sustainability project and related website. Several organizations have assembled lists of alternative products available to the healthcare industry. These are identified in the "Resources" section of this paper.

Finally, it is critical to continuously generate enthusiasm for, and awareness of, the EPP process. Whenever possible, use easily interpreted data as environmental indicators (such as recycled paper purchases saved 455 trees and 8,000 gallons of water this year). Label environmentally preferable products to educate staff and patients. Develop an awards program for employees who contribute to continuous improvement or have solutions to problems they have identified.

Our industry's commitment to a healthier community can be renewed and enhanced through advocacy of ecology-based purchasing decisions. By carefully selecting goods and services, healthcare organizations can significantly impact the overall quality and health of the environment.

RESOURCES

Websites

www.geocities.com/EPP_How_To_Guide – Hospitals for a Healthy Environment (H2E)

www.noharm.org - Health Care Without Harm

www.isogroup.iserv.net/iso14000.html – ISO 14000 standards

www.eli.org/isopilots.html

www.es.epa.gov/cooperative/topics/iso14000.html

www.epa.gov/opptimtr/epp/

www.epa.gov/OWM/pdfs/finalgu.pdf

www.sustainablebusiness.com/html/insider/

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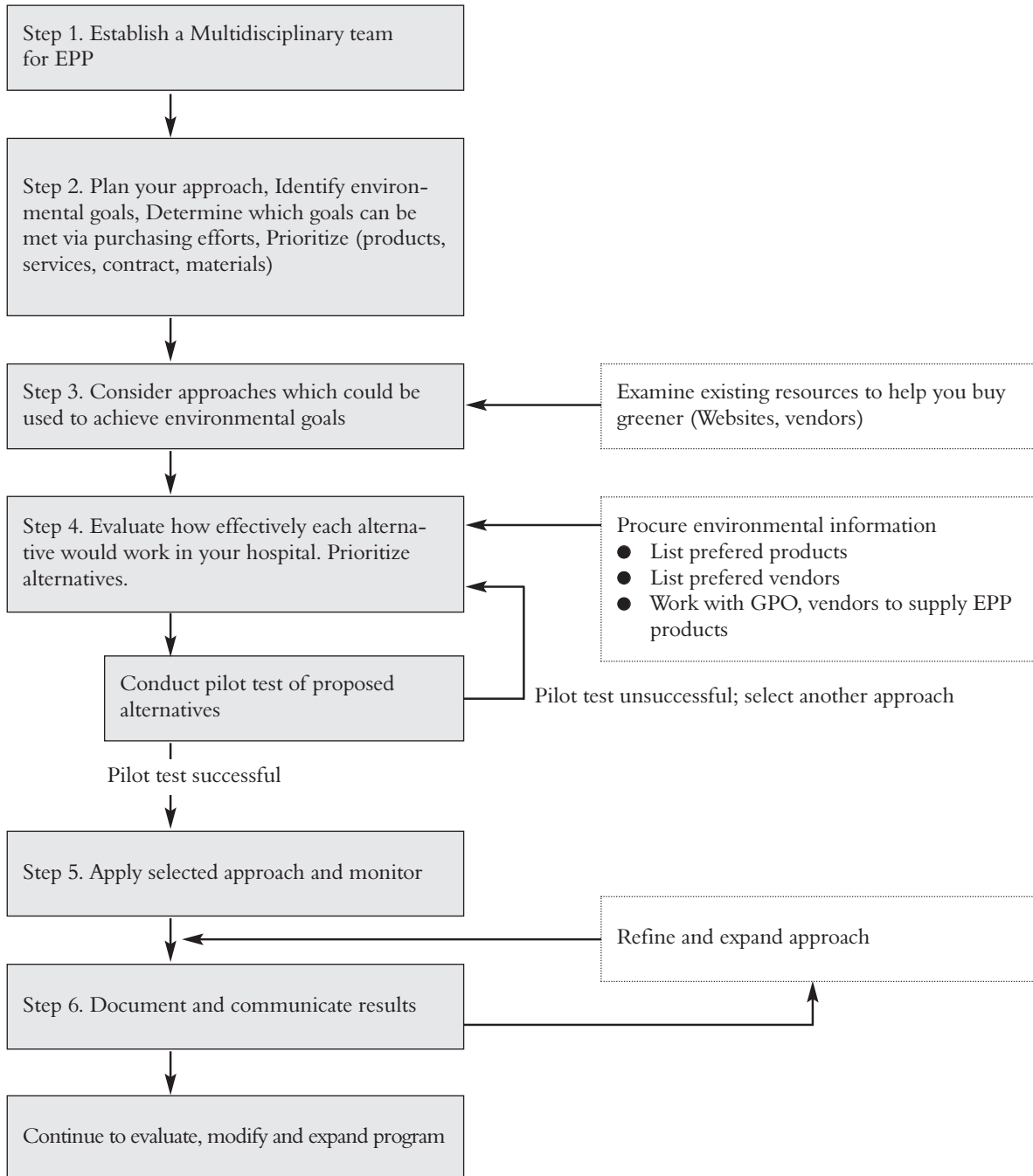
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NSF International, *Environmental Management Systems: An Implementation Guide for Small and Medium-Sized Organizations*, Ann Arbor, Michigan November 1996.

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Flowchart from the *Hospitals for a Healthy Environment*
Environmentally Preferable Purchasing “How To” Guide



We came into healthcare because we were driven by a desire to improve matters for the people we cared for. But at the same time we wanted to make things better for a community, for a population. Having lived in the world of public health for a long time before I joined Kaiser Permanente, I was often struck by how wide the gulf is between addressing the public's health and the individual patient's health. Part of the leadership challenge we have as we learn more about the environmental impacts of healthcare is that we have to marry those worlds. We need to create the institutions that allow us to bring together clinical practice, numerator medicine and public health.

THIS EXCERPT IS FROM THE REMARKS OF DAVID LAWRENCE, MD, CHAIRMAN AND CHIEF EXECUTIVE OFFICER OF KAISER FOUNDATION HEALTH PLAN & HOSPITALS AT SETTING HEALTHCARE'S ENVIRONMENTAL AGENDA ON OCTOBER 16, 2000 IN SAN FRANCISCO, CALIFORNIA.

PVC & HEALTHCARE

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INTRODUCTION

Polyvinyl chloride (PVC) is a chlorinated plastic polymer adapted for many different uses by the addition of fillers, stabilizers, lubricants, plasticizers, pigments, and flame retardants, depending on the intended application. The use of plasticizers (mainly phthalates) and stabilizers in rather high quantities constitutes a specific characteristic of PVC manufacturing compared to other types of plastic.¹ Lead and cadmium are widely used as PVC stabilizers for many applications, including construction and electric wire coating materials.

PVC is the most widely used plastic in medical products. It accounted for 27% of all plastic used in durable and disposable medical products in the U.S. in 1996. Approximately 445 million pounds of PVC were consumed in the manufacture of intravenous (IV) and blood bags, tubing, examination gloves, medical trays, catheters, and testing and diagnostic equipment in 1996.² Tubing, IV and blood bags, and gloves are the primary end-uses for PVC in disposable medical products. Other PVC products used in hospitals, which are not specific to healthcare, include office supplies and construction and furniture products (see Appendix 1 for a detailed list of products).

This white paper examines the life cycle hazards posed by PVC, with an emphasis on di-2-ethylhexyl phthalate (DEHP) exposures to patients and dioxin emissions from medical waste incinerators, and identifies methods and opportunities for reducing PVC use in hospitals.

PROBLEM STATEMENT

Concerns about the use of PVC in medical care fall into two categories: 1) potential impacts on patient health and safety from the use of PVC containing DEHP and 2) public health and environmental impacts from PVC production, use, and disposal.

Patient Health and Safety

PVC is a rigid plastic. To manufacture flexible PVC medical products, manufacturers add the plasticizer, DEHP.³ Some flexible PVC medical products contain more than 50% DEHP. DEHP does not chemically bind to the polymer (polyvinyl chloride). Instead, it lies in the polymeric matrix and leaches out under certain conditions, causing direct patient exposures. Because DEHP preferentially dissolves in fat rather than water, blood and feeding formulas contain higher concentrations of DEHP than other fluids, such as saline and amino acid solutions. The largest patient exposures occur during dialysis, extracorporeal membrane oxygenation, exchange transfusions, or repeated blood transfusions in newborns and preterm babies.⁴ Total parenteral nutrition (TPN) delivered through PVC tubing may also be a source of very significant exposure to DEHP.⁵

Though data from humans are sparse, the toxicity of DEHP has been extensively studied in various animal species. DEHP or its metabolites may cause toxic effects in various organ systems, depending on amount, route, and timing of exposures. Of particular concern, at exposure levels resulting from medical treatment with DEHP-containing medical devices, is toxicity to the developing male reproductive tract. Recently, the Expert Panel on Phthalate Esters from the National Toxicology Program's Center for the Evaluation of

Risks to Human Reproduction investigated the reproductive and developmental toxicity of DEHP and other related compounds.⁶ In their summary statement, the expert panel expressed “serious concern” for the possibility of adverse effects on the developing reproductive tract of male infants exposed to high levels of DEHP from medical procedures such as those used in neonatal intensive care units (NICUs). They also expressed “concern” that the exposure of pregnant and lactating women to ambient levels of DEHP, largely from dietary sources, might adversely affect their offspring. When DEHP exposures from the use of PVC medical devices are added to general dietary exposures during pregnancy, the risk of adverse effects obviously increases. The Panel also expressed “concern” that, if infants and toddlers are exposed to levels of DEHP substantially higher than adults, adverse effects might occur in the developing male reproductive tract.

Additional concerns have been raised about the potential role of DEHP exposure in liver failure frequently encountered by neonates receiving TPN as well as its potential contribution to the development of bronchopulmonary dysplasia in infants ventilated through PVC endotracheal tubes.^{7,8} These concerns deserve further investigation and remain unresolved.

Surprisingly, total DEHP exposure from concurrent use of multiple DEHP-containing medical devices has not been quantified. A Health Care Without Harm-sponsored study of PVC use in neonatal intensive care units found approximately 30 devices made of DEHP-containing PVC that are potential sources of DEHP exposure.⁹ Routine use of these devices will expose developing male infants to levels of DEHP and/or metabolites at or above levels known to cause testicular toxicity in studies in relevant animal species.

Public Health and Environmental Impacts of PVC Production and Disposal

PVC, DIOXIN, AND HEALTH CARE INSTITUTIONS

The public health and environmental impacts of PVC production and disposal result from: 1) release of dioxins and furans generated as by-products during the production of PVC feedstocks; 2) dispersion of plasticizers and metal stabilizers, including lead and cadmium, during use and after disposal; and 3) formation of hydrochloric acid and novel toxic compounds, including dioxins and furans when PVC is burned. PVC

recycling opportunities are limited, and when “recycled” PVC is actually down-cycled into products usually made from other materials, delaying, but not ultimately mitigating, disposal hazards. Efforts to recycle other types of plastics may be ruined by contamination with even small amounts of PVC, making strict segregation of PVC from the plastics waste stream essential, though this is often difficult to achieve in practice.

Chlorinated dibenzo-dioxins and furans are extremely potent, persistent, and bioaccumulative environmental toxicants that contaminate the general food supply. They are unintentionally formed during a variety of industrial processes, including the manufacture of PVC feedstocks and incineration of PVC. They cause their toxic effects at picogram to nanogram per kilogram (kg) body weight levels of exposure and are detectable at levels of concern in the general population and wildlife of most industrialized nations. Inuits and other northern peoples are also significantly exposed through their diet of marine fish and mammals, revealing the capacity of these compounds to travel far from their source.

The draft dioxin reassessment recently released by the US Environmental Protection Agency (EPA) reviews the contribution of PVC manufacturing and waste incineration to dioxin and furan emissions.¹⁰ According to calculations of the Vinyl Institute, reviewed and given a medium confidence rating by the EPA,¹¹ the production of PVC and its feedstocks result in air releases of 11.2–31.0 grams toxic equivalency (TEQ)¹² dioxins and furans per year. The EPA identifies municipal and medical waste incinerators as the leading sources of dioxin and furan emissions to air in the US: 1,250 and 488 grams TEQ annually, respectively.

Chlorine, carbon, and catalysts must be present in an incinerator in order for dioxins and furans to form.¹³ PVC is usually the largest chlorine source in municipal and medical waste incinerators. The relationship between chlorine inputs into an incinerator and dioxin and furan formation, however, depends upon combustion conditions.

For uncontrolled combustion, such as open burning of household waste, landfill fires, or building fires, a direct association between chlorine content of the combusted material and dioxin and furan formation has been established. For example, a study of the open burning of household waste showed that waste containing larger amounts of PVC (4.5% vs. 0.2%) produced substantially

larger amounts of dioxins and furans in air emissions (269 vs. 44.3 microgram/kg waste burned) and ash (7,356 vs. 489 microgram/kg waste burned).¹⁴

In modern, commercial waste incinerators, the rate at which dioxins and furans are formed and released depends upon chlorine inputs, incinerator design, operating conditions, the presence of catalysts, and pollution control equipment. In its draft dioxin reassessment the EPA concludes, based on studies of modern waste incinerators, that chlorine levels in feed are not the dominant controlling factor for rates of dioxin and furan stack emissions. Instead, according to EPA, the largest determinants are operating conditions — overall combustion efficiency, post-combustion flue gas temperatures, and residence times — and the presence of iron or copper catalysts that support dioxin synthesis.

However, for any given waste incinerator, according to the EPA, conditions may exist in which changes in chlorine content of waste feed will correlate highly with dioxin and furan emissions. These conditions may prevail during start-up or shut-down, changes in waste feed rate, or operational upsets. Although modern commercial waste incinerators are designed and intended to be operated to minimize release of dioxins, furans, and other hazardous air pollutants, they are, nevertheless, a significant source of dioxin and furan releases. For example, the EPA estimates that municipal waste and medical waste incinerators contribute 44 percent and 18 percent, respectively, of dioxin and furan releases to air from quantified sources.

Although the EPA concludes that incinerator operating conditions are the dominant controlling factor for dioxin/furan emissions, there is little doubt that chlorine content of the waste feed also plays a major role. Several laboratory and incinerator pilot studies have found a direct relationship between chlorine loading and dioxin and furan emissions.¹⁵ In addition, the EPA's conclusion appears to rest largely on an analysis of incinerator emissions data by Rigo, et al. (1995), which has serious methodological flaws.¹⁶ It is also important to note that the EPA conclusion refers only to stack gas emissions, which are a relatively small fraction of total dioxins and furans released from incinerators, and does not consider releases in fly ash, bottom ash, and water discharges.

When addressing dioxin and furan formation and emissions, prevention, rather than control, should be

the highest priority. As the US Congress stated in the Pollution Prevention Act of 1990, “pollution should be prevented or reduced at the source wherever feasible” and “disposal or other release into the environment should be employed only as a last resort and should be conducted in an environmentally safe manner.” Moreover, the US is among over 150 nations that recently concluded negotiating an international treaty intended to virtually eliminate production, use, and formation of Persistent Organic Pollutants (POPs), two of which are dioxins and furans.¹⁷

The primary source of dioxins and furans from the healthcare sector is waste incineration. Chlorine-containing products burned in incinerators provide the chlorine necessary for dioxin and furan formation. Methods for preventing healthcare-related dioxin and furan releases include:

- 1) ceasing all non-essential incineration as a means for chemically and physically transforming waste;
- 2) eliminating large sources of chlorine from incinerator waste feed by a) phasing out the use of PVC, and/or b) separating chlorine-containing products from the incinerator wastestream and sending it directly to a landfill; and
- 3) optimizing incinerator operating conditions for that portion of the waste stream that must be incinerated. Inasmuch as this is an end-of-the-pipe solution, however, it should be considered only as a last resort.

In summary, available data reveal a complex relationship among chlorine feed, design and operating conditions, and dioxin and furan emissions. It is certain that chlorine sources are necessary for dioxin/furan emissions, PVC products are the largest chlorine source, and incinerators with pollution control equipment are significant sources of dioxin/furan releases in stack gases, fly ash, bottom ash, and water discharges. Moreover, even modern, well-designed incinerators do not consistently operate at optimal combustion conditions. For these reasons, along with concern about other hazardous pollutants emitted from waste incinerators — including mercury, particulates, sulfur and nitrous oxides, and hydrochloric acid — Health Care Without Harm has taken the pollution prevention position that PVC use should be minimized, alternatives used when available without compromising patient safety or care, and all unnecessary waste incineration should be avoided.

DIOXIN TOXICITY

Rain, snow, and dust bring dioxin and furan emissions to the surface of the earth, often hundreds of miles from their point of origin, where they enter the food chain. Because dioxins and furans are environmentally persistent, bioaccumulative, and fat-soluble, their concentration biomagnifies as they pass up the food chain. Human exposure is primarily through food, with major sources including beef, dairy products, fish, pork, and breast milk.

Dioxins and furans are extremely toxic and potent environmental contaminants. They modulate and disrupt multiple growth factors, hormones, and developmental processes. In animals, dioxin causes cancer in multiple organ systems, sometimes at nanogram/kg body weight exposure levels. Prenatal exposure to dioxin in rodents substantially increases the risk of breast cancer later in life.¹⁸ Human epidemiological studies conclude that dioxin causes cancer in humans as well.¹⁹ The EPA draft dioxin reassessment estimates that as many as one in 1000 of the most highly exposed people in the general population are at risk of developing cancer because of dioxin.

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Dioxin also has widespread effects on reproduction and development, as shown in animal and human studies. Nanogram to microgram/kg body weight doses of dioxin on a single day during pregnancy cause permanent disruption of male sexual development in rodents, including delayed testicular descent, lower sperm counts, and feminized sexual behavior.²⁰ In primates, small dietary exposures to dioxin are associated with an increased risk and severity of endometriosis.²¹ A study in humans also shows higher levels of dioxin in women with endometriosis than in a control population.²²

Dioxin is particularly toxic to the developing immune system. Animal tests show that nanogram/kg doses given 1-4 times during pregnancy cause permanent alterations in the immune system of offspring.²³ Human studies also show an increased susceptibility to infection and changes in immune system parameters as a result of in utero exposure to ambient environmental levels of dioxin and dioxin-like compounds.^{24,25} Low levels of exposure during pregnancy also alter thyroid hormone levels in mothers and offspring, perhaps explaining neurological effects, including learning disabilities, that are seen in carefully conducted primate studies.²⁶

It is of particular concern that the general population, through ordinary dietary exposures, carries a current body burden of dioxin that is near or above the levels that cause adverse effects in animal tests. Moreover, breast milk contamination is such that the nursing infant, during vulnerable periods of development, is exposed to dietary levels of dioxin as much as 60-100 times that of adult exposures. Nonetheless, breast feeding remains far superior to formula feeding for a variety of reasons, and reducing breast feeding is not the appropriate public health response to a contaminated food supply. Rather, all possible steps should be taken to reduce breast milk levels of this contaminant by eliminating releases of dioxin to the environment.

SOLUTION:

ESTABLISH AND IMPLEMENT A PVC REDUCTION PROGRAM

Reducing PVC use in hospitals will involve educating staff on the need for change, gathering data, planning, assessing alternatives, and changing procurement policy. Specific steps include:

- establish a PVC reduction policy,
- educate staff on the lifecycle hazards of PVC and the toxicity of DEHP,
- collect data on PVC use in the hospital through audits and letters to vendors,
- identify PVC-free and DEHP-free alternatives, and
- develop and implement a PVC reduction plan.

Establish a PVC Reduction Policy

An organization wide PVC reduction policy is an important step towards reduction because it reflects senior management's support for action, signals staff to take the issue seriously, and signals vendors to market PVC-free products. The Tenet Healthcare and Universal Health Services memoranda of understanding with shareholders on reducing PVC use offer examples of model PVC reduction policy language (see Appendices 2 and 3).

Tenet Healthcare, for example, agreed to: "investigate the availability and utility of PVC-free and phthalate-free disposable medical products available in the marketplace"; "seek information on a regular basis from its suppliers of disposable medical products concerning whether their products are PVC-free and phthalate-free"; and "request its suppliers of disposable medical

products to aid in the development of and further advancements in PVC-free and phthalate-free disposable medical products.”

Educate Staff

Educational programs raise staff awareness of the hazards associated with PVC and DEHP-containing products and establish the reasons why staff should be concerned with the use of these products. Workshops, grand rounds, and conferences are all appropriate forums for promoting awareness of the life cycle hazards of PVC and toxicity of DEHP.

Collect Data

Data collection through audits and letters to vendors is a critical step because reducing PVC requires knowledge of its use and availability of alternatives. Catholic Healthcare West, for example, requires its group purchasing organization (GPO) to identify products that contain PVC. The principal end uses for PVC products in a hospital are:

- disposable health care products,
- office supplies,
- durable medical products (such as testing and diagnostic equipment),
- construction products, and
- furniture products and furnishings (see Appendix 1 for specific products).

PVC products range from critical healthcare devices, such as disposable intravenous (IV) bags and tubing, to bedpans and notebook binders, as well as basic construction materials and furnishings, such as water pipes and wall coverings.

Identify PVC- and DEHP-free Alternatives

Disposable PVC health care products divide into five broad categories: bags, tubes, gloves, trays,²⁷ and catheters. Bags (42.5%), tubes (43.0%), and gloves (12.5%) account for 98% of disposable PVC healthcare products.²⁸

A rigid plastic by nature, manufacturers add DEHP to make PVC flexible. DEHP-free PVC medical devices contain alternative softening agents (plasticizers). Non-PVC plastics used in medical devices, such as silicone, polyethylene, or polypropylene, are inherently flexible and do not contain plasticizers. Thus potential risks from plasticizer leaching are avoided.

Citrates and trimellitates have been substituted for DEHP as plasticizers in PVC medical products. Both may leach from PVC, although at different rates, depending on the nature of the solution in the bag. Citrates are less hazardous than DEHP, as indicated by their use as a food additive. Much less is known about the safety/hazards of the trimellitates, though some research indicates that trimellitates leach less than DEHP.^{29,30}

PVC bags package IV products, total parenteral nutrition (TPN) and enteral feeding formulas, and blood products (including packed red blood cells, fresh frozen plasma, and platelet rich plasma). PVC bags are also used to collect some bodily fluids. DEHP-containing PVC medical bags first became a matter of concern in the 1970s because of DEHP exposures from the use of blood and TPN bags. This concern led to the development of PVC-free platelet rich plasma bags, fresh frozen plasma bags, and TPN bags as well as a DEHP-free packed red blood cell bag.

Today, PVC-free bags are on the US market for all but one product, packed red blood cells. The PVC-free bags are cost- and technically-competitive with the PVC bags. For the packed red blood cells, a DEHP-free bag is on the market at a slightly higher cost than the PVC, DEHP bag. An unintended consequence of DEHP leaching from PVC bags is it acts as a preservative of red blood cells. DEHP extends the shelf-life of stored red blood cells by stabilizing the red blood cell membrane. The Food and Drug Administration does not regulate DEHP as an additive to red blood cells. The alternative plasticizer used in red blood cell bags is a citrate. Citrates, in fact, have a long history of use as a blood preservative. The shelf-life of blood in citrate-plasticized bags is similar to that of DEHP-plasticized bags.

PVC tubing conveys liquids — such as IV solutions and enteral formula — and gases — usually oxygen - to and from patients. PVC-free or DEHP-free tubing is on the US market for most medical applications. Silicone, polyethylene, and polyurethane are three alternative polymers frequently used in tubing applications. In most applications, at least one of these polymers can compete with PVC in terms of technical performance.

In fact, PVC tubing and catheters are actually poor technical performers in medical treatments that involve contact with human tissue longer than about three to

seven days. The leaching of DEHP not only exposes patients to the plasticizer, but also causes the product to become brittle and subject to cracking. For these reasons products like umbilical vessel catheters and gastrostomy tubes are no longer manufactured from PVC. Recent research suggests that significant levels of DEHP may leach out of nasogastric tubes within 24 hours. An analysis by researchers at Stockholm University of PVC nasogastric tubes used for 24 hours “showed that the section of the tube which had been inside the infant’s stomach contained only half as much plasticiser as the rest of the tube. Since this discovery, the [Swedish County] council’s medical board decided to substitute polyurethane tubes for the PVC ones.”³¹

In terms of economic performance, PVC-free tubing generally costs more than PVC tubing. In the next few years, however, plastics industry analysts expect metallocene polyolefins (polyethylene and polypropylene are polyolefins) to become cost-competitive with flexible PVC medical products.³²

Alternatives for disposable **PVC gloves** are also readily available. PVC is used primarily in the manufacture of examination gloves and has little market share in the surgical glove market. Latex is the other dominant material used in the manufacture of examination gloves. However, concerns with latex allergies have led hospitals and manufacturers to consider gloves made of different materials. For example, when Kaiser Permanente decided to phase-out the use of latex gloves it searched for PVC-free gloves, ultimately settling on gloves made of nitrile. While these are more expensive than latex and PVC gloves, Kaiser received a cost-competitive bid due the size of its contract. Reflecting growing demand, a diversity of latex- and PVC-free gloves are on the market today, although costs are slightly higher.³³

Given the availability of technically-competitive and often cost-competitive alternatives, and the hazards posed by DEHP, Lois Ember of Chemical & Engineering News concluded that:

“Balancing the slight harm to the vinyl chloride industry and the availability of cost-effective alternatives against studies — albeit ambiguous — that show potentially harmful health effects to humans dictates a prudent switch to non-PVC, DEHP-free alternatives.”³⁴

The environmental and human health advantages of most flexible, PVC-free medical devices are they do not contribute chlorine to incinerators and do not use plasticizers.³⁵ See Appendix 4 for a list of PVC- and DEHP-free health care products.

PVC-free construction and furnishing products

are widely available and are often cost-competitive. For example, PVC-free mattress covers and shower curtains are widely available and are cost-competitive with the PVC products. During renovations and new building construction, hospitals should specify PVC-free products. Construction productions, furnishings, and furniture products account for approximately 75% of all PVC end uses (see the Paper on Green and Healthy Buildings).

Develop and Implement a PVC Reduction Plan

A PVC reduction plan should include the following priorities:

1. first, target **disposable healthcare products**, especially within maternity departments, NICUs, and pediatrics, and **office supplies** for PVC elimination;
2. second, purchase PVC-free **furnishings, furniture products, and construction** products when purchasing new furniture, renovating existing departments, or constructing new wings or buildings; and
3. third, when buying new **durable medical products**, specify those that are PVC free.

These reduction priorities are based on the potential for patient exposure to DEHP, potential for the PVC product to be incinerated upon disposal, volume of PVC use, and availability of substitute products.

Disposable PVC healthcare products should be the first priority because of the potential for significant patient exposure to DEHP and because they may be incinerated at the end of their useful life. DEHP exposure is critical to consider, especially for fetuses, newborns, and toddlers who may be exposed to levels of DEHP known to cause harm in relevant animal models. Since DEHP is a reproductive and developmental toxicant, DEHP use in maternity departments, NICUs, and pediatrics is of particular concern. For maternity departments, NICUs, and pediatrics, health-care providers may decide that eliminating DEHP exposures in their particularly vulnerable patients justifies the higher cost for polyethylene, polyurethane, or

silicone tubing. While purchasing DEHP-free PVC products is an option for reducing DEHP exposure, it should only be considered an interim solution because it does not address the life cycle impacts of PVC (see Appendix 5 for a discussion of DEHP reduction options).

Office supplies are another priority for elimination because they may be incinerated upon disposal, cost-competitive alternatives are widely available, and hospitals usually can replace them easily under existing contracts.

PVC furnishings, furniture products, and construction products should be eliminated from new purchases, building renovations, and new building construction. For most of these products, cost-competitive, PVC-free alternatives are widely available³⁶ (for more details, see the paper on Green and Healthy Buildings).

Durable medical products pose the greatest challenge to reduction due to the lack of knowledge of their PVC content and availability of PVC-free devices. The primary use for PVC in durable medical products is as the housing — the rigid, outer plastic covering — for testing and diagnostic equipment. Since durable medical products have a longer use life than disposable medical products (such as IV bags) and result in little DEHP exposure, they are a secondary target for reduction. A first step in reducing PVC use in these applications would be to require vendors to disclose the PVC content in their equipment.

BARRIERS TO PVC REDUCTION

The primary obstacles to reducing PVC use are:

- lack of knowledge of PVC lifecycle hazards, hospital use of PVC, and the availability of PVC-free products;
- the “grandfathering” of medical products on the market prior to 1976;
- contracts, multi-year, single buyer, and bundled;
- limited number of PVC-free vendors;
- costs of transition and alternatives; and
- market opposition to change.

Lack of Knowledge

Most hospital staff are unfamiliar with the life cycle hazards of PVC, the extent to which they use PVC and

DEHP-containing products, and the availability of those that are PVC-free, limiting demand for alternatives. In Europe, where awareness of the life cycle hazards of PVC is greater than in the US, demand for PVC-free products is greater.

The “Grandfather” Clause³⁷

Marketing a new medical device requires approval of the Food and Drug Administration (FDA). However, a product that is “substantially equivalent” to devices marketed before May 28, 1976 avoids this strict regulatory scrutiny. The FDA does not require extensive testing of materials used to manufacture medical devices as long as the formulation does not substantially differ from that used prior to 1976. This procedure is not based on a scientific assessment of safety (testing). Rather, it is based on a Congressionally imposed presumption — as stated in section 510(k) of the Food, Drug and Cosmetics Act, as modified by the Medical Device Amendment of 1976 — that products and formulations on the market as of 1976 are presumed safe until proven unsafe. The burden is on the FDA to prove that such medical devices are unsafe before taking regulatory action.

Unfortunately, the law’s grandfathering provision has the effect of discouraging companies from innovating in product formulations. Under existing policies, manufacturers attempt to show that products are made of pre-1976 formulations, since any deviation from traditional product formulas requires more premarket testing and leads to more extensive FDA oversight. A product made of a new polymer would be required to undergo substantial premarket evaluation.

Contracts

To achieve lower per unit product costs, most hospitals purchase medical products through group purchasing organizations (GPOs). GPOs enjoy economies of scale because of large volume purchases, , commit to buy for the long-term (up to eight years), and occasionally agree to “bundled” contracts.

Purchasing through GPOs, however, may reduce purchasing flexibility and create impediments to innovation. By locking into long-term contracts with one vendor, GPOs — and the hospitals they represent — cannot change to another vendor before a contract expires without incurring a significant monetary penalty. Long-term contracts block immediate access to vendors of PVC-free products. For example, of the

three US market leaders in IV products,³⁸ only B. Braun McGaw markets a PVC-free bag. If a hospital decides it wants to purchase a PVC-free IV bag (and all the accompanying IV products), and its GPO has a long-term contract with Abbott Laboratories or Baxter Healthcare, it cannot purchase the PVC-free IV bag without incurring a monetary penalty.

The industry-wide practice of bundling contracts — where a vendor reduces the price of one product line if a buyer purchases another product line — further ties the hands of purchasers. For example, by switching to a different IV product manufacturer, a buyer may incur greater costs for pharmaceutical products, resulting in a net increase in expenditures.³⁹ Thus bundling and long-term contracts impede innovation by creating market barriers to new products.

The options available to healthcare organizations locked into long-term contracts include clearly stating their desire for PVC-free products to both their GPO and current vendors and finding individual departments within the hospital where product change is possible, such as NICUs. When contracts expire, healthcare organizations need to voice their desire to GPOs that they want a) single source contracts with manufacturers of PVC-free products or dual source contracts that include a vendor of PVC-free products and b) a clause added to new contracts that allows them to switch to products with better environmental performance.

Limited Number of PVC-Free Vendors

PVC-free products are on the US market in many product categories. However, the number of vendors of PVC-free products within each category may be limited. This is the case with both PVC-free IV bags (as noted above in the “Contracts” section) and PVC-free enteral feeding bags, where only one vendor sells the PVC-free product. The scarcity of vendors selling PVC-free products in the US is in sharp contrast to Europe. For example, at least seven corporations manufacture PVC-free IV bags in Europe,⁴⁰ whereas only one manufactures PVC-free IV bags in the US. At least four corporations manufacture PVC-free IV tubing in Europe, whereas none manufacture it in the US.

Corporations that sell in both the European and US markets often choose not to market PVC-free products in the US. Baxter International sells PVC-free IV bags in Europe, but not in the US.⁴¹ B. Braun McGaw,

whose corporate parent (B. Braun) markets PVC-free IV tubing in Europe, does not sell PVC-free IV tubing in the US. Fresenius sells a PVC-free peritoneal dialysis system in Europe, but not in the US. The combination of limited numbers of PVC-free vendors and long-term contracts can limit opportunities for a hospital to purchase a PVC-free product in the US (without incurring a monetary penalty for breaking a contract).

Costs

The potential monetary costs of product change come in two forms: transition costs for employees and potentially higher costs for alternative products. For some products, switching vendors requires training in the use of new equipment. The costs for some PVC-free products may be higher in the short-term but decline in the long-term, as costs of alternatives decrease with improved efficiency in production and through economies of scale.

Market Opposition

Transitioning away from PVC products is made more difficult by the vocal opposition of vested economic interests and their allies. Manufacturers with direct economic interests in continued PVC use include DEHP manufacturers, manufacturers involved in any stage of PVC production, and medical device manufacturers. Trade associations that have expressed support for continued PVC and DEHP use in healthcare include the American Chemistry Council (trade association of the chemical industry), AdvaMed (trade association for medical device manufacturers), and the Vinyl Institute. Think tanks that have expressed support for continued PVC and DEHP use in healthcare include the American Council on Science and Health, Competitive Enterprise Institute, and Reason Public Policy Institute.

Any hospital or healthcare organization that publicly announces a PVC reduction program should expect a visit from a trade association such as the Vinyl Institute or a manufacturer of PVC medical products. The broad arguments against the transition away from PVC and DEHP products are: 1) PVC incineration does not correlate with dioxin emissions and 2) DEHP is safe for use in healthcare products.

PVC advocates rely on the report by Rigo, et al to support their conclusion that PVC combustion does not correlate with dioxin production. This report, as discussed in endnote, has serious methodological flaws.

Other data support a correlation between PVC combustion and dioxin emissions (see “PVC, Dioxin, and Health Care Institutions” above for more details).

DEHP advocates rely on reports by the American Council on Science and Health (the “Koop Report”),⁴² Competitive Enterprise Institute,⁴³ and Reason Public Policy Institute to support their claim that DEHP is safe for use in medical products.⁴⁴ These reports conclude, as succinctly stated in the Koop Report, that “DEHP in medical devices is not harmful to even highly exposed people” (p. 2). The basis for this conclusion, as Schettler revealed in a letter-to-the-editor of *Medscape*, is a selective review of the scientific literature.⁴⁵

When all the scientific literature relevant to DEHP toxicity and exposure was evaluated by the independent Expert Panel on Phthalate Esters from the National Toxicology Program’s Center for the Evaluation of Risks to Human Reproduction, conclusions that differed dramatically from the Koop Report were reached. As noted above in “Patient Health and Safety,” the panel expressed “serious concern that exposure [to critically ill infants from medical devices] may adversely affect male reproductive tract development.”⁴⁶

CONCLUSION

PVC products pose two potentially significant hazards to humans across their life cycle. First, the use of PVC products in medical treatments may result in patient exposure to DEHP, a reproductive and developmental toxicant. Concerns about other potential health effects remain unresolved. Second, the production of PVC and its disposal in incinerators contribute to the formation and emission of dioxins and furans, extremely toxic and potent environmental toxicants.

Health care providers can change the material composition of products and can reduce the use of PVC by demanding safer and cleaner products. The availability of PVC-free umbilical vessel catheters, TPN bags, platelet rich plasma bags, and fresh frozen plasma bags, and DEHP-free packed red blood cell bags are all examples of how the market shifted when health care providers voiced concerns in the 1970s. The medical product market is shifting once again, especially in Europe where PVC-free bags and tubing are widely available. Some manufacturers have chosen to market PVC-free products in Europe, yet continue to sell the

PVC products in the US. The US market shows signs of incremental change, as indicated by Baxter’s decision to market PVC-free IV bags in the near future. However, without a clear signal from health care providers that they want PVC-free products, manufacturers will continue to delay the introduction of these products in the US.

RESOURCES

European Commission. 2000. Green Paper on Environmental Issues of PVC.

Webpage: <http://www.europa.eu.int/comm/environment/pvc/index.htm>

European Commission. 2000.

Five PVC studies:

1. The Influence of PVC on the Quantity and Hazardousness of Flue Gas Residues from Incineration
2. Economic Evaluation of PVC Waste Management
3. The Behaviour of PVC in Landfill
4. Chemical Recycling of Plastics Waste (PVC and Other Resins)
5. Mechanical Recycling of PVC Wastes

Webpage: http://www.europa.eu.int/comm/environment/waste/facts_en.htm

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ENDNOTES

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5. Loff S, Kabs F, Witt K, et al. Polyvinylchloride infusion lines expose infants to large amounts of toxic plasticizers. *J Pediatr Surg* 35:1775-1781, 2000.
6. See the National Toxicology Program's webpage: <http://cerhr.niehs.nih.gov/news/index.html>.
7. Loff S, Kabs F, Witt K, et al. Polyvinylchloride infusion lines expose infants to large amounts of toxic plasticizers. *J Pediatr Surg* 35:1775-1781, 2000.
8. Latini G, Avery G. Materials degradation in endotracheal tubes: a potential contributor to bronchopulmonary dysplasia. *Acta Pediatr* 88(10):1174-1175, 1999.
9. Rossi, M. *Neonatal Exposure to DEHP and Opportunities for Prevention* (Falls Church, VA: HCWH), 2000.
10. See US EPA, Report #: EPA/600/P-00/001Ab, March 2000
11. The EPA developed a three-part confidence rating scheme: "high" means the estimate is derived from a comprehensive survey; "medium" is based on estimates of average activity and number of facilities or a limited survey; and "low" is based on data judged possibly non-representative.
12. Since the toxicity of the various congeners of dioxins and furans varies, the toxicity of a given mixture of congeners is usually expressed as TEQs, where the most toxic form is assigned a value of one and the relative contribution of others is calculated accordingly.
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27. Trays are used to package surgical instruments, kits for surgical procedures, medical diagnostic kits, and admission kits.
28. Schlechter, M. *Plastics for Medical Devices: What's Ahead?* Norwalk, CT: Business Communications Company, Inc., 1996.
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33. For a list of products see: www.sustainablehospitals.org.
34. Lois Ember, "In the Name of Prudence, Switch", *Chemical & Engineering News*, March 15, 1999, p. 41.
35. A few PVC-free products do contain chlorine, including neoprene gloves, which are manufactured from polychloroprene.
36. Currently wire and cable coated with PVC is the most difficult of these products to replace.
37. The source for this section is: Health Care Without Harm, "Citizen Petition before the United States Food and Drug Administration," June 14, 1999 (Falls Church, VA: Health Care Without Harm).
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39. Another cost of change, discussed below, is transition costs for staff training.
40. See Lichtman, B, *Flexible PVC faces stiff competition*, European Medical Device Manufacturer, March/April, 2000; Rossi M and Muehlberger M, *Neonatal Exposure to DEHP and Opportunities for Prevention in Europe*, 2000 (Falls Church, VA: Health Care Without Harm); and The Federation of Swedish County Councils, 2000, *PVC in the Swedish Healthcare System*, Stockholm.
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44. Green K, *Phthalates and Human Health: Demystifying the Risks of Plastic-softening Chemicals*, Washington, DC: Reason Public Policy Institute, 2000.
45. "For example, the panel notes that the target organ for reproductive toxicity in the rat appears to be the testis and that young animals seem to be more sensitive than older animals. Inexplicably, however, the authors then fail to cite a single, readily available study of the effects of DEHP exposure on fetal or neonatal testes. Unmentioned are at least 4 studies demonstrating the particular sensitivity of the immature developing testis to the toxicity of DEHP." Schettler T, "Letter in Response to ACSH Report on Plasticizers," Medscape (www.medscape.com), May 26, 2000.
46. Page 105.

APPENDIX 1.

POLYVINYL CHLORIDE (PVC) PRODUCTS IN HOSPITALS

Disposable Health Care Products

BLOOD PRODUCTS AND TRANSFUSIONS

- apheresis circuits
- blood bags
- blood administration tubing
- extracorporeal membrane oxygenation circuits

COLLECTION OF BODILY FLUIDS

- dialysis, peritoneal: drainage bags
- urinary collection bags, urological catheters, and irrigation sets
- wound drainage systems: bags and tubes

ENTERAL FEEDING PRODUCTS

- enteral feeding sets (bags and tubing)
- nasogastric tubes, short-term use (usually for neonates)
- tubing for breast pumps

GLOVES, EXAMINATION

INTRAVENOUS (IV) THERAPY PRODUCTS

- catheters
- drip chambers
- solution bags
- total parenteral nutrition bags
- tubing

KIDNEY (RENAL DISEASE) THERAPY PRODUCTS

- hemodialysis: blood lines (tubing) and catheters
- peritoneal dialysis: dialysate containers (bags) and fill and drain lines (tubing)

PACKAGING, MEDICAL PRODUCTS

- film wrap
- thermoformed trays for admission and diagnostic kits, and medical devices

PATIENT PRODUCTS

- bed pans
- cold and heat packs and heating pads
- inflatable splints and injury support packs
- patient ID cards and bracelets
- sequential compression devices

Disposable Health Care Products (continued)

RESPIRATORY THERAPY PRODUCTS

- aerosol and oxygen masks, tents, and tubing
- endotracheal and tracheostomy tubes
- humidifiers, sterile water bags and tubing
- nasal cannulas and catheters
- resuscitator bags
- suction catheters
- ventilator breathing circuits

Office Supplies

- notebook binders
- plastic dividers in patient charts

Durable Medical Products

- testing and diagnostic equipment, including instrument housings

Furniture Products and Furnishings

- bed casters, rails, and wheels
- floor coverings
- furniture upholstery
- inflatable mattresses and pads
- mattress covers
- pillowcase covers
- shower curtains
- thermal blankets
- wallpaper
- window blinds and shades

Construction Products

- doors
- electrical wire sheathing
- pipes: water and vent
- roofing membranes
- windows

APPENDIX 2.

TENET HEALTHCARE CORPORATION, MEMORANDUM OF UNDERSTANDING WITH SHAREHOLDERS

LETTER AGREEMENT CONCERNING SHAREHOLDER PROPOSAL

This Letter Agreement Concerning Shareholder Proposal is entered into as of July 22, 1999, among the Sisters of St. Francis, Medical Mission Sisters and SEIU Master Trust (collectively, the “Shareholders”) and Tenet Healthcare Corporation (together with its subsidiaries, “Tenet”). As used herein, Tenet includes the operations of BuyPower, Tenet’s group purchasing operation.

RECITALS

- A. Between April 30, 1999, and May 3, 1999, each of the Shareholders submitted an identical shareholder proposal (the “Shareholder Proposal”) to Tenet requesting the Board of Directors of Tenet to adopt a policy of phasing out, at all of its health care facilities, the use of polyvinyl chloride (“PVC”)-containing or phthalate-containing medical products, where alternatives are available.
- B. Tenet is committed to conducting its business in a socially responsible and ethical manner that protects the safety of its patients and employees as well as the environment. Tenet recognizes that PVC plastic, a component of various medical products, may result in damage to the environment.

AGREEMENT

1. Tenet hereby agrees to investigate the availability and utility of PVC-free and phthalate-free disposable medical products available in the marketplace and periodically will review the state of the availability and utility of alternative products as technological advances result in the production of disposable medical products that do not contain PVC or phthalates. Tenet agrees to ask its top 25 suppliers about the availability of new medical products that do not contain PVC or phthalates at least twice a year and to report to back the Shareholders at least twice a year on the results of Tenet’s inquiry.
2. Tenet will develop an environmentally preferential purchasing policy for PVC-free and phthalate-free disposable medical products and utilize such products to the extent they are of a high quality, are of the same or better functionality as the products being replaced and are readily and reliably available at a reasonable price. Tenet further agrees to notify its vendors concerning its policy. Notwithstanding the foregoing, however, although Tenet will use its reasonable efforts to amend its supply contracts to allow Tenet to use alternative products that meet the above criteria, Tenet shall not be required to use alternative products if doing so violates the terms of such contracts. To the extent possible on commercially reasonable terms, Tenet will use its reasonable efforts to include in its future purchasing contracts a clause allowing Tenet to cease purchasing medical products containing PVC or phthalates under such contracts if there become readily and reliably available at a reasonable price alternative PVC-free and phthalate-free disposable medical products that are of the same or better functionality as the products being replaced.
3. Tenet will seek information on a regular basis from its suppliers of disposable medical products concerning whether their products are PVC-free and phthalate-free and concerning the availability of alternative products.
4. Tenet will request its suppliers of disposable medical products to aid in the development of and further advancements in PVC-free and phthalate-free disposable medical products.

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3. Tenet will seek information on a regular basis from its suppliers of disposable medical products concerning whether their products are PVC-free and phthalate-free and concerning the availability of alternative products.

4. Tenet will request its suppliers of disposable medical products to aid in the development of and further advancements in PVC-free and phthalate-free disposable medical products.

5. A representative or representatives of Tenet will be happy to meet with a representative or representatives of the Shareholders by no later than January 31, 2000, at a mutually convenient time and place, to discuss Tenet’s progress in achieving the goals set out in this Agreement and to further address the concerns expressed by the Shareholder Proposal.

6. In light of the terms of this Agreement, each of the Shareholders hereby withdraws its request that Tenet

APPENDIX 3.
UNIVERSAL HEALTH SERVICES,
MEMORANDUM OF UNDERSTANDING WITH SHAREHOLDERS

Universal Health Services (“UHS”) is committed to conducting its business in a socially responsible and ethical manner, which protects patient and employee safety and the environment. UHS recognizes that polyvinyl chloride (“PVC”) plastic, a component in various medical products, may result in damage to the environment. In light of these factors and in conjunction with a proposed shareholder resolution filed with the Company on December 21, 1998, UHS plans to investigate the utilization of PVC-containing items in their operations through the following measures:

- 1) The Company will investigate the availability and utility of PVC-free products available in the marketplace and will periodically continue its investigation as technological advances provide cost effective and high quality products. To aid in this process, Health Care Without Harm will provide UHS a list of items potentially containing PVC. Utilizing this information, the company will review its current supplies and request PVC-free alternatives from its suppliers, where appropriate.
- 2) To the extent that it is consistent with high quality and cost effective health care delivery, UHS will continue to explore the use of PVC-free products and utilize such products to the extent they are available. UHS agrees to formally request PVC-free alternatives from its suppliers to aid in the development of further advancements in PVC-free products.
- 3) The Company agrees to meet with representatives of the filing shareholders and Health Care Without Harm prior to June 30, 1999 in order to establish the timetable and benchmarks for the items listed above. UHS agrees to meet with the filing shareholders and other mutually agreed upon parties prior to October 31, 1999 to assess the Company’s progress.

The Company and the filing shareholders agree to announce this agreement through a mutually agreed upon joint press release to be distributed on May 19, 1999 in conjunction with the UHS Annual Meeting. The Company’s willingness to enter into this agreement furnishes the filing shareholders the sufficient evidence of goodwill on the Company’s behalf to allow the removal of the shareholder resolution from the Company’s proxy for the upcoming Annual Meeting. The filing shareholders hereby withdraw the shareholder resolution from the company’s proxy.

UNIVERSAL HEALTH SERVICES, INC.

CITIZENS FUNDS
On Behalf of Filing Shareholders

By: _____
Name: Kirk E. Gorman
Title: Senior Vice President, Chief Financial
Officer and Treasure
Date: April 19, 1999

By: _____
Name: Samuel Pierce
Title: Senior Social Research Analyst
Date: April 19, 1999

APPENDIX 4. PVC- AND DEHP-FREE DISPOSABLE HEALTH CARE PRODUCTS

PRODUCTS	PVC-FREE PRODUCTS	DEHP-FREE PRODUCTS
Blood Products, Transfusions, and Extracorporeal Membrane Oxygenation (ECMO)		
Apheresis Circuit		Citrate-plasticized circuit: Cobe
ECMO Circuit		None on the market, although the Cobe apheresis circuit is technically equivalent
Fresh Frozen Plasma and Platelet Bags	PO bag: Baxter Healthcare	
Packed Red Blood Cell Bag		Citrate-plasticized bag: Baxter Healthcare
Collection of Bodily Fluids		
Drainage Bags	PO bag: Dow Chemical Corp. (manufacturers films for use with drainage bags)	
Dialysis Products		
Hemodialysis, Blood Circuits		None on the market, although the Cobe apheresis circuit is technically equivalent
Peritoneal Dialysis, Bags and Tubing	Europe: PVC-free bags & tubing, Fresenius & B.Braun Japan: PVC-free bags, Terumo	
Enteral Feeding Products		
Enteral Feeding Set: Bags	Nylon, EVA, PE laminate bag: Corpak MedSystems	Kendall Healthcare
Enteral Feeding Set: Tubes		Corpak and Kendall Healthcare
Nasogastric Tubes (for 3 days or less)	Similar product: indwell tubes made from PUR or silicone, many manufacturers	
Gloves		
Examination Gloves	Nitrile or other polymers: many manufacturers	
Intravenous (IV) Products		
IV Bags	PP/PE copolymer, polyester, elastomer laminate bag: B. Braun McGaw	
IV Tubing	Europe: EVA or PO, many manufacturers	Budget Medical Products
Total Parenteral Nutrition	EVA bag: Baxter Healthcare	
Packaging, Medical Devices		
Trays for Admission and Diagnostic Kits, and Surgery	Acrylic, polycarbonate, polyester, polystyrene, steel: many manufacturers.	
Respiratory Therapy Products		
Endotracheal and Tracheostomy Tubes	Reusable tubes: many manufacturers; Silicone tube: Biovana Medical Technologies	
Oxygen Masks	Polyester mask: Vital Signs	
<p>Abbreviations: DEHP = di-2-ethylhexyl phthalate; EVA = ethylene vinyl acetate; PE = polyethylene; PO = polyolefin; PP = polypropylene; PUR = polyurethane; and PVC = polyvinyl chloride. Blank cell: no PVC-free or DEHP-free alternative product identified. Sources: The Federation of Swedish County Councils, PVC in the Swedish Healthcare System, 2000; Rossi, Neonatal Exposure to DEHP and Opportunities for Prevention, 2000; Rossi and Muehlberger, Neonatal Exposure to DEHP and Opportunities for Prevention in Europe, 2000; Sustainable Hospitals Project, www.sustainablehospitals.org.</p>		

APPENDIX 5.

DEHP REDUCTION OPTIONS

There are three routes for healthcare facilities to reduce or eliminate DEHP exposure from medical treatments. First, purchase a PVC-free product. Second, purchase a DEHP-free product. Third, purchase a DEHP-plasticized PVC product coated with an alternative substance to reduce DEHP leaching or off-gassing. Purchasing a PVC-free product practically ensures the product is DEHP-free because the alternative polymers — ethylene vinyl acetate, polyethylene, polypropylene, polyurethane, and silicone — do not require plasticizers for flexibility. In addition, PVC-free products avoid the life cycle hazards of PVC, including the use of a known carcinogen in the manufacturing process, vinyl chloride monomer, and the downstream formation of dioxin when vinyl is burned in a medical waste incinerator.

Using a PVC product plasticized with citrates or trimellitates, the primary alternative plasticizers to DEHP in medical products, reduces DEHP exposure but does not address the life cycle hazards of PVC. One option for reducing DEHP exposures is to use DEHP-plasticized PVC products coated with a thin layer of another material that prevents or reduces DEHP leaching. For example, PVC tubing bonded with heparin leaches less DEHP during ECMO than unbonded tubing.¹ While preferable to non-coated DEHP-plasticized vinyl, DEHP-coated products do not address off-gassing nor do they address the life cycle hazards of PVC.

1. Karle V, Short B, Martin G, et al. Extracorporeal membrane oxygenation exposes infants to the plasticizer, di(2-ethylhexyl)phthalate. *Crit Care Med* 25(4):696-703, 1997.

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This work is hard, the challenges are many, but the need is absolutely phenomenal. I am committed to the work that is being done here. And by working together, by staying the course, understanding that this journey is going to be a long one, we will be successful.

THIS EXCERPT IS FROM THE REMARKS OF LLOYD DEAN, MA, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF CATHOLIC HEALTHCARE WEST AT SETTING HEALTHCARE'S ENVIRONMENTAL AGENDA ON OCTOBER 16, 2000 IN SAN FRANCISCO, CALIFORNIA.

REPROCESSING SINGLE-USE MEDICAL DEVICES

Jan Schultz, RN
Jan Schultz & Associates
Roswell, GA

BACKGROUND

Single-use medical devices (SUDs) are usually made of non-renewable petrochemicals and/or metals. Most, but not all, SUDs are presented as sterile products, with the requisite barrier packaging material. Since the devices are intended to be used only once, both they and their packaging contribute to the solid waste stream. Few of these products are suitable for recycling, because they are considered biohazardous after use, are of composite material or have no after-market for the raw material. All are made of virgin material, in that federal regulations all but preempt the use of recycled material in medical devices that will be in contact with human tissue.

On the face of it, it seems that reusing these products makes good environmental sense, by reducing the consumption of non-renewable resources and reducing solid waste. Indeed, some have claimed such in marketing their reprocessing services to hospitals. However, it is important to note that the only reduction in solid waste is the delay in adding the original product to the waste stream. If the device is intended for sterile use, it must be packaged again, and the method chosen may have more mass than the original, which was specifically designed for that product.

The reuse of medical devices labeled as SUDs has become a common tactic for cost cutting in today's financially constrained provider community. This practice has gone on sub rosa for many years, with few institutions or professionals candidly acknowledging its presence. Over the past five or six years, an entire industry has grown up to service this need, in the form of third-party or commercial reprocessors.

Reuse of SUDs has gained the attention of the media, state and federal legislators and the U.S. Food and Drug Administration (FDA). At the request of the U.S. Congress, the General Accounting Office recently issued a report on the practice¹, finding that little data exist on problems with reuse, but that may be because of lack of means to identify adverse events. The report supports the general concern that there is a strong theoretical potential for patient harm and that the practice should be regulated.

Given the founding principles of HCWH, including "first, do no harm," should HCWH and this conference encourage the reuse of SUDs? And, if so, to what extent should environmental issues be part of the decision making process?

PROBLEM STATEMENT

Over the course of the last 25 years, many SUDs have entered the market. The decision to market an SUD rather than a reusable device may be made for several reasons:

- It may not be feasible to make the device out of reusable materials and achieve the desired function.
- It may not be possible to design a device to both achieve the desired function, and allow patient-safe reprocessing. That is, the device may not be able to be cleaned or sterilized repeatedly with no degradation in performance. A corollary to this is the issue of designing a product that can be reprocessed using the equipment and procedures currently available in the hospital setting. Requiring special equipment for reprocessing

could be a barrier to market entry and acceptance.

- Starting with an SUD may allow innovations to enter the market more quickly than they would if a carefully engineered reusable were required.
- Manufacturers may wish to control or limit their liability for product failure by making a product an SUD, rather than depending upon providers to do everything required for reprocessing and ongoing maintenance of a device. This would come into play when failure of the device in use might be harmful to the patient or the operator.
- Likewise, providers may require single-use designs for patient or staff safety reasons.
- Initially, in the old cost-plus health care reimbursement days, SUDs were preferred because they allowed direct pass through of expense to insurance payers.
- And, of course, SUDs may be more profitable to the manufacturer than well designed reusable products.

All of these reasons have or had legitimacy in our culture. However, the time has come to reevaluate those choices.

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Likewise, the reprocessing of SUDs has raised many questions. Some of them are related to the above issues:

- How does one ensure that an SUD that was not designed with cleaning or resterilization in mind is, indeed, safe for the next patient from both an infection control and functional perspective?
- How does one control the reprocessing of especially complex items to make sure that the desired results are achieved every time?
- Does the patient have a right to know that a device labeled as an SUD is being reused on them? Do they have a right to refuse without jeopardizing their care?
- What is the environmental impact of reprocessing? And, is this better or worse than continuing to use the SUD only once?
- In the end, does this process really save money for the institution? Experience has shown that this needs to be examined on a case-by-case basis both at the point of decision and within a year after reprocessing begins. Assumptions made at the time of decision may not play out in reality.

Under pressure from Congress and the media, the FDA issued final guidance on August 2, 2000 that will

address the first three questions on this list.² While the title of the document says “guidance”, the effect is regulatory, because the text explains how the agency will now interpret and enforce existing regulations to cover this practice. These regulations apply to all third-party reprocessors and hospitals, but do not apply to non-hospital affiliated clinics, ambulatory surgery facilities, or physicians or other providers’ offices. They also do not apply to opened, but unused SUDs that may be resterilized only, with no cleaning needed.

Hemodialyzer membranes are also exempted, even though they are commonly reused for the same patient, because they are already covered by other regulations.

The regulations effectively make it impractical for most hospitals to consider reprocessing SUDs themselves, because of the significant regulatory hurdles that must be negotiated to do so. Specifically, every hospital that does its own reprocessing of any device labeled as single-use (except opened but unused ones) must comply with all of the requirements of a manufacturer of medical devices, including:

- Registration as a manufacturer with the FDA
- Listing of any and all devices reprocessed at any facility within the health care organization
- Mandatory adverse event reporting for any reprocessed device
- Tracking of devices
- Correction of complaints or problems, with documentation
- Removal of defective product
- Labeling requirements as specified by other regulations
- Compliance with the Quality System Regulation (formerly known as GMP).

It is this last requirement that may prove the most difficult, in that it demands a total rethinking of the processing department, with control and documentation of procedures and supplies that are not usually seen in healthcare facilities. Third-party reprocessors are already subject to all of these regulations. Hospitals that reprocess will have to comply by August 1, 2001.

In addition, all reprocessors must meet the pre-market requirements for assuring the safety and efficacy of reprocessed medical devices. In most cases, this would mean submission of documentation of substantial equivalency with a device currently on the market (a so-called 510(k) submission, named for the section of the Food, Drug & Cosmetic Act that applies). A few

devices may require a pre-market approval submission (PMA), which is much more stringent. These later would be limited to devices that represent substantial risk to patient or provider safety when used as directed. The pre-market submission requirements are phased in over 18 months. Reprocessors need to submit for all Class III medical devices within 6 months; Class II, within 12 months; and, Class I, within 18 months. The work involved in amassing the information required for pre-market submissions is substantial and unfamiliar to hospitals. Third-party reprocessors have not had to comply with this part of the medical device regulations until now.

The good news of this regulation is that, once fully implemented, it will remove doubts about the safety and efficacy of devices that are approved for reprocessing. This will also eliminate the need for consideration of informed consent for those devices, as they will be assumed to be as safe and effective as the original. The net effect will be that hospitals choosing to reuse SUDs will probably do so only through a registered third-party commercial reprocessor.

The regulation does not address the other concerns noted for the reuse of SUDs. Therefore, the following scenarios are proposed for addressing this total issue:

SOLUTION

Scenario 1:

If resources were not an issue

In an ideal world, healthcare providers and institutions could move toward sustainability by having the following precepts in place, both institutionally and with the appropriate group purchasing organization (GPO):

1. We would have the following available when making a decision on any product:
 - The manufacturer's justification for making the device single-use, if it is so.
 - Life cycle environmental impact studies on the device and the technologies used to manufacture it, whether an SUD or reusable.
 - Accurate estimations of use-life, if reusable.
 - Valid life cycle costing of the alternatives in use.
 - GPO's would use their collective resources to evaluate this information, since no one hospital is likely to have the expertise to do so on every product.

2. We would choose SUDs only when the technology does not support making the product reusable, or the environmental impact is less than that of a reusable.
3. We would insist that mercury, PVC and DEHP not be used in manufacturing or construction of any medical device, whether reusable or an SUD.
4. We would reevaluate each of the SUD's currently used in our institution and, where it made sense, push manufacturers to develop reusable alternatives using the collective force of the market place.
5. We would not reprocess SUDs, nor send them to third parties for processing (See 2 above).
6. We would carefully control the use of products to prevent wastage of opened, but unused devices. This would involve staff and physician education, and perhaps some assistance from manufacturers with regard to packaging design, quantities in a package, and the provision of reusable devices as size determination trials for surgical implants.
7. For packaging of either an SUD or a reusable, we would choose the least amount of packaging (in terms of solid waste) that still provides protection of the contents (sterility barrier and physical protection, as needed).
8. We would choose all products (reusable or single-use) based on safety, efficacy and environmental impact, before considering cost.

Scenario 2:

Best case –leading to substantial results

The following steps could be taken to address environmental concerns associated with SUDs, while still taking the constrained resources of today's marketplace into account:

1. We would establish a working group within each institution or at the GPO level evaluate SUDs currently used within the system, beginning with the items used most often. This evaluation would ask the following:
 - a. Are there patient or worker safety issues that would preclude considering a reusable, if one were available (e.g. syringes and hollow bore needles need to remain disposable)?
 - b. Are there reusables on the market that should be considered as alternatives?
 - c. Is this a device that would lend itself to reprocessing, if such were available (e.g. the device is not deformed, damaged or consumed in use)?
 - d. Are there third-party reprocessors that can handle this device? One quick way to answer

that is to look at the listings of items from several third-party reprocessors (they must have these to comply with current FDA regulations).

2. Based on this evaluation of each product, we would determine any action steps needed to move toward reusables or reuse. This process will move quickly for some products and be slow for others. Starting with the high volume items may allow for some quick impact on solid waste and other environmental issues without having to complete the whole list of purchases first.
3. If third-party reprocessing were an option for a product, we would ask the status of their pre-market submission process. We would prefer to wait until the FDA has fully implemented the regulation to assure that patients will not be harmed. We will deal only with FDA registered reprocessors.
4. We will consider packaging in every product evaluation, including that from third-party reprocessors of SUDs. We will provide feedback and attempt to influence manufacturers to minimize packaging and use environmentally friendly materials (preferably recyclable) in packaging.
5. We would communicate to all suppliers that we would prefer reusable products when they can meet the patient care need. We would ask corporate levels of manufacturers to tell us why specific products are made disposable, to heighten the awareness of our concern. We would indicate that we would not expect reusables to cost more, when considering total use-life and reprocessing costs.
6. We would carefully control the use of products to prevent wastage of opened, but unused devices. We would continue or initiate staff and physician education in areas such as the OR, L&D and the ED, to encourage opening only those devices that will be used, rather than preparing for a worst case scenario each time. We would provide feedback to manufacturers with regard to packaging design, quantities in a package, and the provision of reusable devices as trials for implants.
7. If our community has a recycling program, we will provide separate waste containers in areas of high usage to capture paper and other clean, recyclable packaging material from both SUDs and reusable products.
8. We would survey what SUDs are being reprocessed in-house, remembering to consult all departments and considering all devices, not just those initially sold as sterile.

9. If currently reprocessing SUDs in-house, we would develop a phase-out plan to comply with August 1, 2001 deadline. In rare circumstances, some institutions may decide to register as manufacturers and comply with the regulation.

Scenario 3- Quick fixes for some impact now

At a minimum, every institution should be doing the following:

1. If a commercial reprocessor is currently processing devices, we would ask the status of their pre-market submission process. We would prefer to wait until the FDA has fully implemented the regulation before initiating any new reprocessing of items to assure that patients will not be harmed. We will deal only with FDA registered reprocessors.
2. We would communicate to all suppliers that we would prefer reusable products when they can meet the patient care need. We would ask corporate levels of manufacturers to tell us why specific products are made disposable, to heighten the awareness of our concern. We would indicate that we would not expect reusables to cost more, when considering total use-life and reprocessing costs.
3. We would continue or initiate staff and physician education in areas such as the OR, L&D and the ED, to encourage opening only those devices that will be used, rather than preparing for a worst case scenario each time. We would provide feedback to manufacturers with regard to packaging design, quantities in a package, and the provision of reusable devices as trials for implants.
4. If our community has a recycling program, we will provide separate waste containers in areas of high usage to capture paper and other clean, recyclable packaging material from both SUDs and reusable products.
5. We would survey what SUDs are being reprocessed in-house, remembering to consult all departments and considering all devices, not just those initially sold as sterile.
6. If currently reprocessing SUDs in-house, we would develop a phase-out plan to comply with August 1, 2001 deadline. In rare circumstances, some institutions may decide to register as manufacturers and comply with the regulation.

RESOURCE ON CURRENT FDA ACTIVITY

The FDA Center for Devices and Radiological Health website at: www.fda.gov/cdrh

- Click on “pre-market issues” to see what is involved in 510(k) process.
- Click on “post-market issues” to see the regulations regarding registration, listing, tracking, reporting, corrections and removals, and the Quality System regulation.

ENDNOTES

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2. Division of Enforcement III, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration. Guidance for Industry and for FDA Staff- Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals. August 2, 2000. Available at www.fda.gov/cdrh/comp/guidance/1168.pdf.

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Just as we have responsibility for providing quality patient care, just as we have responsibility for keeping our facilities and technology up to date, we have a responsibility for providing leadership in the area of the environment. The stakes are extraordinarily high. We have to keep folding these questions and these considerations back into our leadership. We have to incorporate them into our incentives, into what it is we're held accountable to do, how we measure our impact. We all know the old saw "no margin, no mission." But as a colleague said, without the mission I don't want to get up in the morning. Competing effectively is a need that we all have, but it isn't what healthcare is about. It's about improving the health of the communities we serve.

THIS EXCERPT IS FROM THE REMARKS OF DAVID LAWRENCE, MD, CHAIRMAN AND CHIEF EXECUTIVE OFFICER OF KAISER FOUNDATION HEALTH PLAN & HOSPITALS AT SETTING HEALTHCARE'S ENVIRONMENTAL AGENDA ON OCTOBER 16, 2000 IN SAN FRANCISCO, CALIFORNIA.

OCCUPATIONAL HEALTH AND SAFETY

Susan Wilburn, MPH, RN
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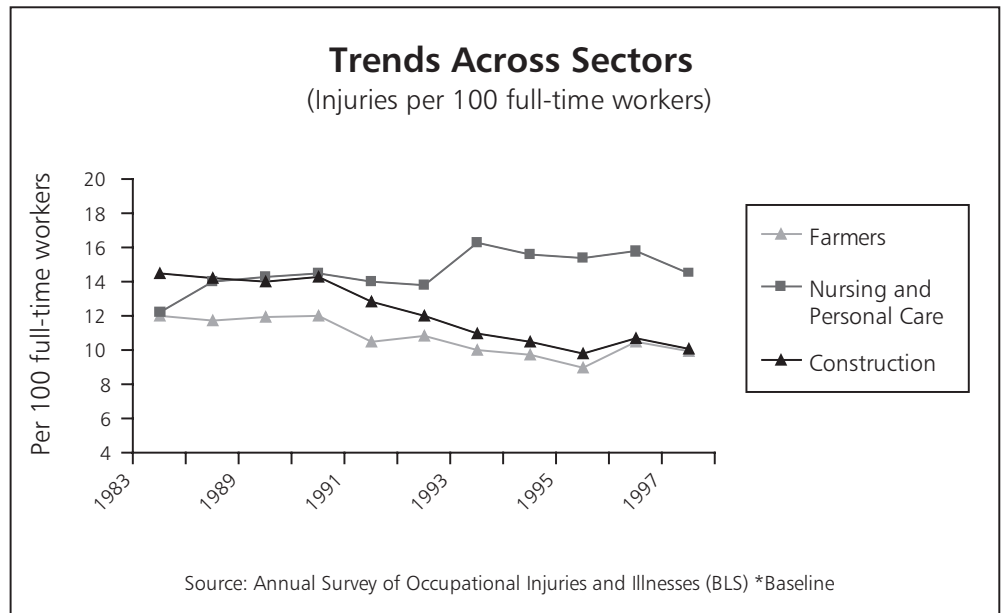
BACKGROUND

The Healthcare Workforce

While healthcare workers toil tirelessly to heal and comfort the nation's ill, little attention has been focused on securing the health and safety of these critical workers. Healthcare workers currently represent 8% of the U.S. workforce. Over 10 million people are employed in healthcare industries in occupations ranging from doctors to pharmacists to dental assistants, dietary and maintenance workers. Nearly 80% of the healthcare workforce is female.¹

Healthcare is rapidly becoming one of the most dangerous industries in the United States. The rate of occupational injury and illness to healthcare workers surpassed all other industries combined in 1991.² While the rate of injury to all workers has declined since 1991, the rate of injuries to healthcare workers has continued to climb. It is now more dangerous to work in a hospital than in construction and more dangerous to work in a nursing home than in a mine.³

Healthcare has lagged behind other industries in progress towards protecting workers. The first federal Occupational Safety and Health Administration (OSHA) Standard aimed specifically at protecting healthcare workers was the 1991 Bloodborne Pathogens Standard.⁴ The second standard to protect healthcare workers, the OSHA Tuberculosis Standard, remains bogged down by politics after 8 years in progress.⁵ Reasons for this lack of attention to healthcare worker health and safety may include the focus on curative rather than preventive health in the hospital environment, the focus on patient safety over worker safety, and the focus within the field of occupational health on traditionally male occupational hazards rather than those impacting female workers.⁶



PROBLEM STATEMENT

Hazards in the Healthcare Environment: Identification and Control

There is growing recognition that few workplaces are as complex as a hospital.⁷ Other healthcare settings, such as dental offices and nursing homes, present similarly complicated work environments. In healthcare settings, workers face a variety of occupational hazards, classified in the following five categories:⁸

- Biological/Infectious hazards (bacteria such as Tuberculosis, and viruses such as, HIV, Hepatitis B and Hepatitis C can be transmitted by contact with infected patients or contaminated body secretions/fluids)
- Chemical hazards (medications, solutions, or gases such as ethylene oxide, formaldehyde, glutaraldehyde, waste anesthetic gases, nitrous oxide, chemotherapeutic agents, laser smoke and aerosolized medications such as Pentamidine)
- Physical hazards (ionizing radiation, lasers, noise and electricity)
- Ergonomic/Biomechanical hazards (such as patient transfers and lifting)
- Psychosocial hazards (short staffing, stress, mandatory overtime and shift work)

Hierarchy of Controls

It is possible to prevent or reduce healthcare workers exposure to these hazards. The industrial hygiene hierarchy of controls is a recognized method to apply control measures for primary prevention of occupational injury and disease.⁹ The following hierarchy is listed in order from most to least effective:

Elimination of hazardous materials and dangerous activities (needleless IV systems, no lifting)

Substitution of Less Hazardous Materials and Systems (substitute oxidizing chemicals such as paracetic acid for glutaraldehyde, nitrile gloves for latex or vinyl gloves)

Engineering Controls - use of technical means to isolate or remove hazards (lifting devices, safer needle devices such as those that retract or self-sheath after use; ventilation)

Administrative Controls - policies that limit workers' exposure to hazards (appropriate allocation of

resources to prioritize health and safety, safe staffing, education programs and equipment)

Work Practice Controls (eliminating recapping of needles, lifting team, no lift policy)

Personal Protective Equipment (PPE) - barriers and filters between the work and the hazard (gloves, respirators and masks, goggles, gowns, etc.)

Serious Hazards

BACK INJURIES AND MUSCULOSKELETAL DISORDERS (MSDs)

Low back injuries are the leading occupational health problem affecting healthcare workers and are increasing among nurses and nurses' assistants. Hospitals and nursing homes are the top two workplaces for days away from work due to back injuries. The primary risk factor for low back disorders among nursing personnel is lifting and transferring of patients. Other jobs at risk for musculoskeletal injury include transport workers, housekeeping and environmental services. The NIOSH lifting equation indicates that the average worker can routinely lift no more than 51 pounds.¹⁰ Healthcare workers are routinely asked to lift beyond safe loads without adequate staffing support and lack access to lifting devices.¹¹

According to research conducted at the University of Wisconsin, of the 38% of nurses with back injuries, 12% are considering leaving the profession thus contributing to the current nursing shortage.¹² The 1996 Institute of Medicine Report: *Nurse Staffing in Hospitals and Nursing Homes: Is it adequate?*, discusses the relationship between staffing and back injuries and recommends lifting devices and teams.¹³

LATEX ALLERGY

Latex gloves have been used to prevent transmission of many infectious diseases to healthcare workers. However, latex is hazardous to some healthcare workers, resulting in a range of health effects from minor dermatitis to asthma, life-threatening anaphylaxis and respiratory arrest, similar to a bee sting allergic reaction.¹⁴ Data indicate that 8-12% of the healthcare worker population that use gloves are sensitized to natural rubber latex compared with 1-6% of the general population.¹⁵ The FDA has reported five healthcare worker deaths related to latex glove use.¹⁶

Powdered latex gloves present an additional hazard because the latex proteins in the glove attach to the glove donning powder and become aerosolized.¹⁷ A latex allergic patient or sensitive worker cannot be safe in a powdered latex environment.

Because the only effective treatment for latex allergy is the complete avoidance of contact with latex-containing products and powder, alternative glove barrier materials are needed. Finding adequate barrier protection without harming the worker, the patient or the environment is a challenge that lies at the intersection between environmental and occupational health. Vinyl gloves are the most common and least expensive substitute for latex exam gloves. Vinyl is an adequate barrier, if the glove is intact, according to the CDC; however vinyl gloves break down easily and are environmentally toxic.¹⁸ Other synthetic alternatives include nitrile, polyurethane, neoprene and tactylon. Although latex has been considered the “gold standard”, other synthetic materials provide superior chemical barriers for handling chemotherapeutic agents and other chemicals such as glutaraldehyde.¹⁹

NEEDLESTICK INJURIES

An estimated 600,000- 800,000 needlestick injuries (nsi) occur annually in the United States.²⁰ About half of these injuries go unreported. An average hospital incurs approximately 30 worker nsi per 100 beds per year.²¹ Most reported nsi involve nursing staff, but lab staff, physicians, housekeepers, and other healthcare workers are also injured.²² Some of these injuries expose workers to bloodborne pathogens, including Hepatitis B, Hepatitis C, and HIV. Infection with any of these pathogens is potentially life-threatening.

The risk of infection from hepatitis is much greater than the risk from HIV and while there is an immunization to prevent Hepatitis B, and post-exposure prophylaxis and treatment for HIV, there is currently no recommended prophylaxis or effective treatment for Hepatitis C. The only solution is to prevent exposure.²³ Safer devices have been shown to reduce needlestick injuries by 80%.²⁴ Frontline healthcare worker involvement is essential for a comprehensive analysis of injury hazard, the selection of clinically appropriate devices and for the successful implementation of a change to safer products.²⁵

VIOLENCE

Of the medical professionals, nurses suffer the largest number and the highest rate of non-fatal workplace violence. Healthcare patients are the source of more than half of nonfatal workplace assaults, with current and former co-workers accounting for 8%. Mental health and emergency departments are typically the most noted areas for violence; however, all departments in healthcare settings are at risk.²⁶

CHEMICAL HAZARDS

Glutaraldehyde, one of many chemical hazards in the healthcare workplace, is a potent sensitizer that causes occupational asthma.²⁷ Many of the drugs used to treat cancer are themselves known carcinogens.²⁸ Ethylene oxide, a cold sterilizing agent is a carcinogen and a reproductive toxin that causes miscarriage.²⁹ Cleaning agents and materials and their methods of use are increasingly implicated in asthma. Despite the existence of OSHA chemical hazard communications, most healthcare workers are unaware of the risks of these agents and the appropriate control measures.

ORGANIZATION OF WORK

Changes in work organization resulting from restructuring, downsizing, and layoffs within the healthcare industry are resulting in decreased staffing levels, increased workloads and time pressures, and longer hours of work.³⁰ Because of the nature of their work, healthcare workers also face unique stressors including: exposure to illness and death; the need to provide adequate patient care; and shift work. Exposure to such stressors has been found to be related to numerous health problems, including headaches, digestive problems, heart disease, injuries (including back and nsi), fatigue and depression.³¹

THE SOLUTION

Recommendations for a Safe and Healthy Work Environment

The participants at the Setting Healthcare’s Environmental Agenda Conference adopted the following principles and goals for worker health and safety recognizing that a cultural shift may be necessary. This shift should be towards a culture that values the health and safety of healthcare workers equally with patient safety and quality of care. A systematic occupational safety and health program must be in place in

order for an organization to successfully recognize and control occupational hazards.

The overriding issue for healthcare worker health and safety is the same as for patient safety: sufficient and appropriate levels of staffing. Inadequate staffing became a major problem in the 1990s as cost containment drove decision-making. Inadequate staffing results in an increased risk of medical errors as well as injury to workers.

1. Adopt the principles from the World Health Organization Safe Injection Global Network (SIGN): “a safe injection does no harm to the recipient, does not expose the healthcare worker to any risk and does not result in waste that is dangerous for the community” and expand them to safe healthcare practices:

A safe healthcare practice does no harm to the recipient, does not expose the healthcare worker to any risk and does not result in waste that is dangerous for the community.

2. Management Leadership - Visible top management leadership provides the motivating force for an effective health and safety program. “The most significant finding in terms of enhancing compliance and reducing exposure incidents was the importance of the perception that senior management was supportive of the bloodborne pathogen safety program. When employee safety is considered and valued, employees feel valued.”³² An organization’s commitment to health and safety is demonstrated by the assignment of responsibility and allocation of appropriate resources for the health and safety program. Adequate staffing (patient care and occupational health program staff), and materials for hazard controls are essential tools for safety. It is important to recognize that the business of providing quality healthcare to patients requires safe and healthy employees and that what is unsafe for workers is probably unsafe for patients.
3. Employee Participation - Involve frontline workers in an interdisciplinary process for the evaluation of hazards and the selection and implementation of control measures. Joint labor-management health and safety committees are effective vehicles provided they have the support and authority to implement decisions. Utilizing the considerable expertise of frontline workers increases the probability that the most appropriate safety devices and

work practice controls will be selected and increases the likelihood that staff will be more accepting of new devices and practices.

The SHEA health and safety work group emphasized that a successful joint labor-management effort, as is required by the 1999 amendments to the OSHA Bloodborne Pathogens Standard for device selection, should incorporate the following principles:

- The committee has the authority to make and implement decisions in a timely manner.
 - The committee reviews and analyzes exposure, illness and injury data.
 - Training is provided to committee members for effective participation.
 - Frontline staff chooses frontline staff representatives to the committee.
 - Committee meetings occur during paid work time.
 - The Health and Safety Committee has linkages to other institutional committees including product evaluation and purchasing.
4. Encourage reporting and recording of work-related symptoms, injuries and “near misses.” Address issues that contribute to under-reporting by eliminating blame for injuries and other disincentives. Ensure prompt and immediate response to reported injuries and identify and address needs for institutional change. Utilize illness and injury data as a corrective feedback loop.
 5. Prioritize prevention by utilizing the industrial hygiene hierarchy of controls. Focus on eliminating hazards and implementing engineering and work practice controls to prevent exposure to hazards.
 6. Advocate for research on prevention and enforceable standards.
 7. Incorporate an analysis of the impact on worker health and safety prior to the implementation of job changes, restructuring, new technology, new procedures, products, chemicals and medications. Request a NIOSH Health Hazard Evaluation when unknown products and procedures are initiated. Pay attention to the “canaries.” Healthcare workers with work-related illness and injury may be the harbinger of risk for all healthcare workers and an indication of an unsafe environment for patients and/or the community.

IMPLEMENTATION

Back injury prevention: implement a no-lifting policy.

Latex safety: eliminate latex and vinyl exam gloves; eliminate powdered latex gloves and provide synthetic alternatives for sterile glove uses. Utilize synthetic gloves only in food preparation. Dietary workers should never wear latex gloves.

Needlestick injury prevention: establish a needlestick injury prevention committee with frontline healthcare worker involvement in the evaluation, selection and implementation of safer needle devices.

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RESOURCES ON THE WORLD WIDE WEB

Bloodborne Pathogens (Safer Medical / Needle Devices)

Bloodborne Facts, fact sheets provided by OSHA entitled,

- Repeating Exposure Incidents
- Protect Yourself When Handling Sharps
- Hepatitis B Vaccination -Protection For You
- Personal Protective Equipment Cuts Risk

www.osha-slc.gov/OshDoc/data_BloodborneFacts/

Occupational Safety and Health Administration (OSHA). Needlestick Injuries. Includes final text of the 2000 amendments to the Bloodborne Pathogens Standard (29 CFR 1910.1030) www.osha-slc.gov/SLTC/needlestick/index.html

Food and Drug Administration (FDA) Safety Alert: Needlestick and Other Risks from Hypodermic Needles on Secondary I.V. Administration Sets-Piggyback and Intermittent I.V. www.osha-slc.gov/SLTC/needlestick/fdaletter.html

NIOSH Alert - Preventing Needlestick Injuries in Healthcare Settings
Publication No. 2000-108. Publication Date: 11/99 www.cdc.gov/niosh/2000-108.html

NIOSH Guidelines for Selecting, Evaluating, and Using Sharps Disposal Containers.
Publication No. 97-111, 1998. (To order, call 1-800-35NIOSH). www.cdc.gov/niosh/2000-108.html

California OSHA Sharps Injury Control Program. Include a listing of safer needle devices available on the market. www.ohb.org/sharps.htm

Training for the Development of Innovative Control Technologies (TDICT) Project. Includes needlestick device safety feature evaluation forms. www.tdict.org/criteria.html

ECRI: evaluation of needlestick devices. <http://healthcare.ecri.org/site/whatsnew/press.releases/980723hdneedle.html>

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Methicillin Resistant Staphylococcus Aureus: Facts for Health Care Workers. 1999.

www.cdc.gov/ncidod/hip/aresist/mrsahcw.htm

Ergonomics

Working Safely with Video Display Terminals. U.S. Department of Labor Occupational Safety and Health Administration. (OSHA 3092). 1997 (Revised)

www.osha-slc.gov/SLTC/ergonomics/index.html

OSHA Ergonomic Standard - Effective 2001

www.osha-slc.gov/ergonomics-standard/index.html

Hazardous Chemicals/Gases

Managing Hazardous Materials Incidents Volume I & II Emergency Medical, Services and Hospital Emergency Departments, U.S. Department of Human Services, Public Health Service, Agency for Toxic Substance and Disease Registry. Volume I and II Publication Date: 1/1/92

<http://aepo-xdv-www.epo.cdc.gov/wonder/prevguid/p0000018/0000018.htm>

<http://aepo-xdv-www.epo.cdc.gov/wonder/prevguid/p0000019/0000019.htm>

Formaldehyde

CPL 2.2-52- Enforcement Procedure for Occupational Exposure to Formaldehyde (Information Date: 11/20/90)

This instruction provides uniform inspection procedures and guidelines to be followed when conducting inspections and issuing citations for workers potentially exposed to formaldehyde.

www.osha-slc.gov/OshDoc/Directive_data/CPL_2-2_52.html

Nitrous Oxide

NIOSH Hazard Controls (HC29) - Control of Nitrous Oxide During Cryosurgery, Publication No. 99-105. Publication Date: 1/99. U.S. Department of Health and Human Services. NIOSH.

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Controlling Occupational Exposure to Hazardous Drugs.\OSHA Technical Manual (TED 1-0.15A), Section VI, Chapter 2, (1999, January 20), 35 pages. Describes medical surveillance, handling, transporting, storing, and disposal of hazardous drugs. Appendix VI:2-1, contains common drugs considered hazardous. Appendix VI:2-2, contains aerosolized drugs considered to be hazardous.

www.osha-slc.gov/dts/osta/otm/otm_vi/otm_vi_2.html

Hospital Investigations: Health Hazards OSHA Technical Manual (TED 1-0.15A), Section IV, Chapter 1, (1999, January 20), 11 pages.

Deals briefly with the hazards of anesthetic agents and antineoplastic drug exposures in the hospital setting.

www.osha-slc.gov/dts/osta/otm/otm_vi/otm_vi_1.html

Hazardous Waste

OSHA Compliance Directive:

CPL 2-2.59A — Inspection Procedures for the Hazardous Waste Operations and Emergency Response Standard (Hazwoper), 29 CFR 1910.120 and 1926.65, Paragraph (q) : Emergency Response to Hazardous Substance Releases (Information Date: 4/24/98)

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American College of Allergy, Asthma, and Immunology. Latex Allergy home page includes Guidelines for the Management of Latex Allergy and Safe Latex Use in Health Care Facilities.
<http://allergy.mch.edu/physicians/ltxhome.html>

Latex Allergy links
www.netcom.com/~nam1latex_allergy.html

Stress

NIOSH Stress at Work.
www.cdc.gov/niosh/99-101pd.html

Tuberculosis

Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities. @ October 28, 1994. Morbidity and Mortality Weekly Report, 43(RR-13); 1-132. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention.
<http://aepo-xdv-www.cdc.gov/wonder/prevguid/m0035909/m0035909.htm>

TB: Respiratory Protection Program in Health Care Facilities - Administrator's Guide. Publication No. 99-143. Publication Date: 9/99.
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www.osha-slc.gov/OshDoc/Directive_data/CPL_2_106.html

Workplace Violence

OSHA Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers.
www.osha-slc.gov/SLTC/workplaceviolence/guideline.html

Miscellaneous

American Nurses Association (ANA)
www.nursingworld.org

Occupational Safety and Health www.nursing-world.org/dlrwa/osh

Needlestick Injury Prevention
www.needlestick.org

Pollution Prevention

www.nursingworld.org/rnnoharm

National Institute for Occupational Safety and Health (NIOSH) Guidelines for Protecting the Safety and Health of Health Care Workers.

www.cdc.gov/niosh/pdfs/88-119.pdf

OSHA. Worker Rights Under the Occupational Safety and Health Act of 1970.

www.odhs.gov/as/opa/worker/rights.html

OSHA. Employer Responsibility.

www.osh.gov/as/opa/worker/employer-responsibility.html

OSHA. Nursing Home Electronic Compliance Assistance Tool (eCAT). AA virtual nursing home walk-through for health and safety.

www.osha-slc.gov/SLTC/nursinghome_ecat/index.html

American College of Occupational and Environmental Medicine (ACOEM)

Guidelines for Employee Health Services in Health Care Facilities.

www.occenvmed.net

Sustainable Hospitals Project (SHP)

The Sustainable Hospitals Project at the University of Massachusetts - Lowell has a web-based clearinghouse for selecting products and work practices that eliminate or reduce occupational and environmental hazards, maintain quality patient care, and contain costs.

Information about latex-free medical gloves, safer needle devices, alternatives to polyvinyl chloride products (PVC), and mercury-free products are included at:

www.uml.edu/centers/LCSP/hospitals/

Health Care Without Harm (HCWH)

www.noharm.org

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We are living in what E.L. Wilson would call an Age of Extinctions.” We are driving biodiversity back 65 million years to its lowest level of vitality since the end of the age of dinosaurs. The four great drivers are climate change, ozone depletion, toxic chemicals, and habitat destruction. It’s not just about the polar bears that are being born with both male and female sexual organs because of chemical exposure. It’s not just about dolphins, sharks and whales. It’s also about the human family. Many people numb themselves to this reality, because it’s a greater reality than human beings can easily live with or want to live with.

But the fact of the matter is that those in healing professions know that we really cannot help a patient if we participate in the psychic numbing. A global environmental health movement is emerging because there are too many of us unwilling and unable to live with psychic numbing in the face of the realities of all the people we know who not someday, but today, are suffering from learning disabilities, endometriosis, immune disorder, infertility, early medistatic breast cancer and all the rest. The question is whether healthcare professionals can begin to recognize the environmental consequences of our operations and set our own house in order. This is no trivial question. The fact that it plays out with little issues, like eliminating mercury thermometers and medical waste incineration, and all the technical aspects of transforming one of the greatest industrial centers in the world. The fact that it plays out in that detail shouldn't blind us to what it is that we're actually doing. And so I would suggest to you that what we're doing here, in this concrete work that we're doing, is setting in order the house of healthcare. Ghandi said, “Be the change that you want to see.” We gather in the healthcare community to clean up our house with a vision that part of what we're doing is to act on behalf of our families. So there are a few less learning disabilities. A few less young mothers with breast cancer. That can then become a beacon, and that beacon can transform what it means to be human in the next century and help us support the kind of world we'd like to live in.

THIS EXCERPT IS FROM THE REMARKS OF MICHAEL LERNER, PHD, PRESIDENT AND FOUNDER OF COMMONWEAL AT SETTING HEALTHCARE'S ENVIRONMENTAL AGENDA ON OCTOBER 16, 2000 IN SAN FRANCISCO, CALIFORNIA.

WASTE MANAGEMENT & HEALTHCARE

Kathy Gerwig
Kaiser Permanente
Oakland, CA

PROBLEM STATEMENT

As healthcare providers, we are responsible for promoting health. Yet, in the process of delivering healthcare, American hospitals **generate 4 billion pounds** of waste each year. The environmental consequences of this waste include the following:

- **Cancer and reproductive effects** caused by the release of toxins, notably dioxins and mercury, from medical and solid waste incinerators,
- **Global warming and other climate change** caused in part by the emission of greenhouse gases from the combustion of waste, and
- **Human health hazards and explosions** caused by the generation of methane gas from the decomposition of organic materials in landfills.

Other environmental issues garner more excitement or fear. But no environmental initiative is more fundamental to building and sustaining environmentally responsible healthcare at the facility level than effective waste management. The polluting work practices of the healthcare industry can be changed with the support of senior leadership, starting with those responsible for the management of our waste.

There is a direct link between the health of the environment and the health of the people to whom we provide healthcare. We can promote health by taking actions to protect the environment. Reducing the amount and toxicity of our waste is the critical foundation for this effort.

THE ISSUES

Waste costs money, can result in regulatory violations and fines, and can impact employee and patient safety. Yet it is commonly treated as an operational issue not requiring the attention of senior management. In the healthcare industry, waste management has been primarily focused on regulatory compliance and recycling programs. We can take steps to better manage materials, not just at the point of purchase, but also during use and disposal following their useful life.

Key waste management issues that are prompting decision-makers to become involved include:

1. Some municipal landfills have banned waste from hospitals due to fears of bloodborne pathogens and infectious disease exposures. Some haulers are charging higher rates to transfer hospital waste due to additional processing activities.
2. Community activism to eliminate medical waste incinerators and their accompanying pollution and more stringent emission requirements for incinerators have resulted in numerous incinerators being closed. Managers need to identify other options for treatment and disposal.
3. Public fear of medical waste (e.g., syringes found on beaches, low-level radioactivity and exposure to potentially infectious material) impacts public policy.
4. Labor union concerns related to handling, transporting, and treating/processing waste can surface in contract negotiations and through grievance processes.
5. Consolidation of medical waste haulers has resulted in only one national medical waste disposal firm, Stericycle. Fewer treatment options and fewer haulers are already leading to higher costs.

6. News reports documenting unauthorized access to confidential documents and prescriptions found in waste containers around hospitals and pharmacies have resulted in the promulgation of regulations in California and other states.

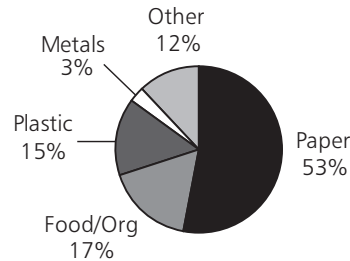
THE BENEFITS OF WASTE MANAGEMENT

There are many compelling reasons to manage waste more responsibly in healthcare:

- Reduce **environmental impacts**. By reducing the toxicity and volume of waste, we reduce the toxicity and volume of air, soil and water pollutants.
- Improve **employee safety**. By reducing the amount of waste that has to be collected and treated as hazardous or infectious waste, you reduce the risk of exposure to employees handling these materials.
- Improve **patient safety**. Through improved segregation and management of waste streams, and reduction in the number of potentially harmful materials present in the care environment, the risks to patients are reduced. Additionally, educating patients about proper disposal of waste generated from patient-administered treatment in the home (e.g., syringes used for insulin injections) can improve patient safety and the safety of municipal trash collectors.
- Protect **confidentiality**. Secured waste management and recycling systems and processes can prevent sensitive documents from being mishandled or misused.
- Decrease **operating costs**. It is conservatively estimated that operating costs can be reduced by up to 20% by minimizing the volume of solid waste sent to landfills. This savings can be redirected to providing healthcare services.
- Additional benefits include: contributions to licensure and accreditation requirements including Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Environment of Care standards; enhanced public image for healthcare; and improved employee morale.

ABOUT WASTE

In 1998, the Environmental Protection Agency (EPA) and the American Hospital Association (AHA) signed a Memorandum of Understanding to reduce total waste volumes in the health care industry by 33% by 2005 and 50% by 2010. This voluntary initiative is intended to drive change toward more responsible waste management.



More than half of the solid waste at healthcare facilities is paper and cardboard

A Note on California's Confidentiality Law ("SB19")

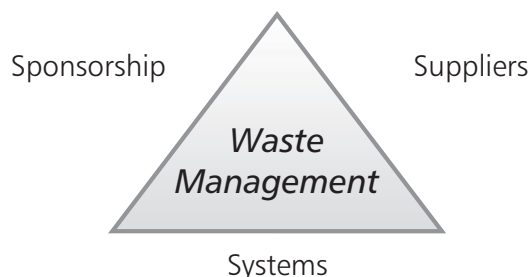
A law took effect on January 1, 2000 in California that has impacted healthcare waste management and recycling programs statewide and has also raised consumer awareness about waste management issues in healthcare. The federal Health Care Financing Administration (HCFA) and some states are reviewing the issue for possible regulatory action. The law contains the following directive:

'Every provider of health care . . . who creates, maintains, preserves, stores, abandons, or destroys medical records shall do so in a manner that preserves the confidentiality of the information contained therein. Any provider . . . who negligently disposes, abandons, or destroys medical records shall be subject to the provisions of this part.'

Civil Code Section 56.101.

IDEAL SCENARIO FOR WASTE MANAGEMENT TO BE SUCCESSFUL

For waste management and minimization to be successful and sustainable, program sponsorship, appropriate systems, and a connection to suppliers are required.



“Sponsorship” includes top management leadership, supportive policy statements, assigned resources including designated staff to lead waste management initiatives, labor union support, meaningful performance measures that are tracked, and a clear message to staff that waste management and minimization is an expectation for everyone at the healthcare facility. Sponsors also ensure that clear and effective procedures are implemented. Ultimately, sponsorship also means that each employee and physician takes responsibility and ownership in the success of the program.

“Systems” means managing waste as a resource, evaluating technology for maximum operational benefit and minimum environmental impact, having the necessary facility space and equipment, creating reuse and donation programs, establishing tracking and reporting mechanisms, and exploring opportunities in recycling markets.

“Suppliers” refers to educating targeted suppliers about waste minimization, and asking them to contribute to the effort through offering reusable options, redesigning for product material reduction, packaging reduction and providing recycled materials. Suppliers also refers to working with waste haulers and recyclers in alignment with the institution’s environmental policies.

IMPLEMENTATION

Steps senior managers can take to drive change

1. **Understand your organization’s waste streams.** Ask for a report that establishes a baseline of the volume and disposal costs of these categories, by facility:
 - regulated medical waste (biohazardous waste)
 - hazardous waste (e.g., chemicals, mercury)
 - solid waste (trash)
 - recyclables (especially paper and cardboard)
 - construction and demolition debris
 - industrial waste water (for water conservation purposes)
2. **Know where your waste is going.** Are you sending medical waste to an incinerator or an autoclave? If the waste is sent to an autoclave, is it then retired in a landfill or burned in a municipal waste incinerator? Are there community issues related to incineration? Where is the landfill and are there health/community issues related to that operation?
3. **Establish performance metrics** for waste management that drive reduction in toxicity and volume. Make the metrics specific, achievable, meaningful and measurable.
4. **Do not tolerate wasteful practices.** Change expectations about material use. For example, senior managers can reduce paper use by letting staff know that they expect to receive double-sided materials, and that they support practices that reduce paper use overall. Said another way, it should not be an acceptable business practice to waste materials. Wasteful practices, including single-sided copies and over-production of reports, should be viewed as an irresponsible use of the organization’s resources with corresponding outcomes.
5. **Establish policies for handling construction and demolition debris.** In California, 28% of the volume of landfill waste is from construction/demolition debris. Much of this waste can be diverted from landfills by reusing salvageable items and by recycling materials. Also in California, 800 hospital-buildings will be replaced, retrofitted, demolished or discontinued as hospitals by 2008 to com-

ply with seismic regulations. The potential volume of waste from this activity is staggering.

6. **Build waste minimization infrastructure into new buildings.** Ensure that architects allow room for waste segregation and recycling within units and at the loading dock.
7. **Analyze the issues surrounding disposables versus reusables** at your facilities. Most of these decisions are made by a variety of departments and it is rare that management looks at the impact of these decisions on the overall waste volumes and toxicity. By establishing policies to evaluate how disposables are used, the facility-wide impact of departmental decisions can be assessed.
8. As a management supporter or sponsor of the waste management effort, **ask questions, stay involved,** and establish attainable goals. Recognize and award accomplishments for achieving these goals.

Steps stakeholders can take to drive change

1. **Establish Standards for Waste Management:** Comprehensive standards for appropriate waste management in the healthcare industry do not exist today. There are numerous laws, regulations, and accreditation guidelines, but the industry lacks comprehensive performance standards that focus on toxicity and volume reduction. The ISO 14001 series of international standards requires the implementation of Environmental Management Systems (EMS). EMS includes establishing and publicizing an environmental policy, determining impacts, setting targets, and taking action to meet targets. In addition to ISO, another organization that promotes environmental standards is CERES (Coalition for Environmentally Responsible Economies). CERES, through the Global Reporting Initiative, aims to measure and report environmental, social, and economic performance. Stakeholders (including waste generators, regulators, waste haulers, public health advocates) should evaluate the appropriateness of encouraging haulers and generators to join CERES, apply for ISO 14000/14001 certification, or at least establish EMS-like systems.

In addition to certification programs, standards can be encouraged through the use of resolutions by professional and state associations (e.g., medical associations). Facilitated through Health Care Without Harm, stakeholders could prepare a template resolution for use nationally.

An entity that establishes standards for healthcare is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In the Environment of Care standards, there may be an opportunity to enhance the waste management protocols to promote minimization and reduce environmental impact.

Finally, individual healthcare organizations (waste generators) should adopt standards within their organizations to reduce the volume and toxicity of their waste streams.

2. **Enhance Performance:** Many healthcare institutions have not embraced waste minimization and toxicity reduction. This is evidenced by the small number of organizations that have assigned responsibility for environmental stewardship, including waste management, to specific personnel. Assigning responsibility for waste minimization is a critical step in enhancing performance. This assignment can be accomplished without adding staff if savings from waste minimization are returned to the program. Assigning performance-based accountability at all levels is also critical to sustaining gains.

Another way to enhance performance is for stakeholders to share information and resources among hospitals or systems. Encouraging “green teams” to communicate with each other, sharing return-on-investment and volume/cost reduction data, and reporting on transferable local initiatives will raise the national level of performance.

3. **Develop Continuing Education Modules:** Physician and nursing continuing education programs offer opportunities to educate the medical community on waste minimization. Other healthcare professionals that require ongoing training are industrial hygienists, certified safety professionals, and facility engineers. Stakeholders can develop certified training modules, including web-based training, to reach these audiences. Certification

will be feasible if the training modules clearly demonstrate the connection waste minimization has to patient care and patient safety.

4. **End Incineration:** Only a very small portion of medical waste is required by law to be incinerated. Public health advocates and environmental experts hope to eliminate those requirements and end incineration of medical wastes. This outcome can succeed if state laws which require incineration are changed and through education of medical waste generators and the portion of the public who now prefers the aesthetics of incineration for medical waste.
5. **Build Partnerships:** Waste minimization involves many stakeholders, including state and metropolitan hospital associations, HMOs, regulators, labor unions, group purchasing organizations, professional societies, and manufacturers of medical supplies. Utilizing the information and tools available now, these stakeholders can be engaged to support the opportunities listed above.

RESOURCES

The actual implementation of waste minimization and management programs can be delegated to operational staff, and is best supported by “green teams” or other groups that represent a cross section of staff. There are numerous resources for waste management:

Web Sites

<http://www.epa.gov/epaoswer/non-hw/reduce/wstewise/main.htm>

EPA’s WasteWise site offers links and information to help organizations reduce solid waste. They have an on-line fact sheet specific to hospital waste reduction.

<http://www.noharm.org>

Health Care Without Harm is a campaign working to reduce pollution in health care without compromising safety or quality.

<http://www.papercoalition.org>

The Recycled Paper Coalition strives to conserve natural resources and reduce waste by purchasing environmentally-preferred paper products and by using paper more efficiently.

<http://www.ciwmb.ca.gov/>

California’s Integrated Waste Management Board web page offers hyperlinks to the State’s waste reduction programs that aim to divert 50% of waste from landfills.

<http://www.stopwaste.org>

Alameda County Waste Management Authority & Source Reduction and Recycling Board is an agency that promotes source reduction and recycling. They have tools applicable nationally.

Publications/Guidebooks

American Hospital Association, *An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities*. Cost: \$29.95 (member), \$50 (nonmember); order number 057-007. To order call (800) AHA-2626. For more information contact: American Society for Healthcare Environmental Services, (312) 280-4458.

Kaiser Permanente, *Waste Minimization Starter Kit*. Cost: \$150. Tool kit including instructions, poster, fact sheet, training slides, and tent cards. To order, call 510-987- 4737.

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