KAISER PERMANENTE

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Re: **Evaluation of Antimicrobial Property Claims in Finishes and Fabrics**

Situation

The recent prevalence of new products in the marketplace that tout the benefits of antimicrobial properties in finishes and fabrics, (such as paint, carpet, ceiling tile, privacy curtains and patient gowns), has prompted National Facility Services (NFS) to request that National Environmental, Health & Safety, in conjunction with the National Infection Prevention and Control Steering Committee, provide recommendations regarding the usefulness of these finishes and fabrics. We do not recommend environmental surface finishes or fabrics that contain antimicrobials for the purpose of greater infection control and the subsequent prevention of hospital acquired infections. This position is subject to change as additional scientific-based evidence becomes available.

Background

Manufacturers of products and finishes aimed at the health care market are aggressively marketing their products, implying that their products' antimicrobial properties are effective at controlling and preventing infections. Specific products that have come to market include paint, carpet, ceiling tile, privacy curtains, door handles and fixtures and patient gowns. These products have come to the attention of NFS Capital Projects' design teams and their alliance partners, including medical equipment consultants, architects and engineers. Since Kaiser Permanente has no established position regarding the usefulness or the potential adverse effects of these products, the teams lack guidance regarding whether these products should be specified in construction and remodeling projects. It should be noted that these products usually command a significant premium over products without antimicrobial claims.

The federal Environmental Protection Agency (EPA) registers and regulates antimicrobial agents under the Federal Insecticide, Fungicide and Rodenticide Act

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(FIFRA).[1] The products considered here fall into the category of non public health products, as opposed to public health products that include sterilizers, disinfectants, sanitizers and antiseptics/germicides (which are also regulated by the Food and Drug Administration).

EPA registration requirements establish that the product will not cause adverse effects to human health or the environment; that the product labeling and chemical composition comply with FIFRA requirements; that data is available to support efficacy claims against specific microorganisms; and that the label includes specific data detailing the required elements for safe and effective use and the hazards associated with the product.

The EPA, under FIFRA, regulates these products and prohibits manufacturers from making a public health claim for any product distributed or sold unless the product has been approved and registered by the EPA or is exempt from registration. They also require that the product conform to the "truth in advertising" laws.

The label claims must be examined carefully when considering whether the antimicrobial properties are for the preservation or stability of the product itself, to prevent staining or odors, or to actually prevent infection.

Implication of antimicrobial properties for infection prevention must be evaluated in light of the modes of transmission and infection. Appendix I contains a detailed summary of the mechanics of the chain of infection. Briefly, if one of the "links" in the chain is broken, no infection can occur.

The pathogenic agent must live in a reservoir that serves as a continuing source of contamination. In turn, the reservoir must have a "portal of exit" for transmission to take place. Although healthcare environments are frequently re-contaminated with a potentially wide array of organisms, appropriate hand disinfection by healthcare personnel mitigates the transfer (portal of exit) from such surfaces to patients. Further, the way in which an agent leaves the reservoir (or the "mode of transmission") must be consonant with the "portal of entry" and the host through which the agent enters must be susceptible to infection. This means that if the agent in question is transmitted through blood, it must contact directly an open lesion or mucous membrane of a host that is not immunized to the agent. Likewise, if the agent is transmitted through air, by droplet nucleii, it must enter through the airway of a non-immunized or immuno-compromised host.

Further, the antimicrobial action of surfaces can only effectively treat the first cell layer of pathogenic material. Any more than that and the only effective way of deactivating the agent is through mechanical debridement, (or mechanical cleaning), of the surface to remove the bioburden. Thus, cleaning surfaces with an approved environmental cleaner is

[1] **40 CFR 152:** Provides EPA with the authority to oversee the registration, distribution, sale and use of pesticides. The act applies to all types of pesticides including insecticide, herbicides, fungicides, rodencides and antimicrobials.

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the only effective means of reducing the bioburden on environmental surfaces, which can then be disinfected to prevent infection.

Assessment

The products discussed here are all considered inanimate surfaces, including the patient gowns. Evidence based guidelines direct that mechanical cleaning with detergent and water are required before disinfection is performed with the goal of preventing infection transmission. Transmission of airborne infectious agents would not be in any way prevented by antimicrobial agents in surface finishes or fabrics since their route of transmission is from the reservoir to the host's airway. Effective control of airborne pathogens must occur in the air itself, not on surfaces.

Recommendations

Review of current scientific literature reveals no evidence that environmental surface finishes or fabrics containing antimicrobials assist in preventing infections. (Only one study was found and it was for a different, clinical application of silver-impregnated fabrics.[2] The fabric was shown to be effective in treating atopic eczema when worn on the skin for several weeks. No studies were found linking anti-microbial fabrics to their effect in preventing health care acquired infections from wearing a gown in the patient setting.) Far more effective is the implementation of strict hand hygiene and environmental surface cleaning and disinfection.

In addition, some of these products contain impregnated silver particles, a heavy metal that is an environmental toxin. Whether these materials leach enough silver ions into rinse water upon cleaning or into the soil upon disposal has not been assessed here; however, it would be prudent to prevent a known hazardous material from entering into a product's life cycle during manufacture, use, maintenance or final disposal.

It is our considered opinion that due to the unproven benefits of anti-microbial health care finishes and fabrics such as paint, carpet, ceiling tile, privacy curtains and patient gowns, coupled with their increased cost and potential environmental concerns, these products do not recommend themselves for use in health care facilities for the purpose of greater infection prevention and control. This position is subject to change as additional scientific-based evidence becomes available.

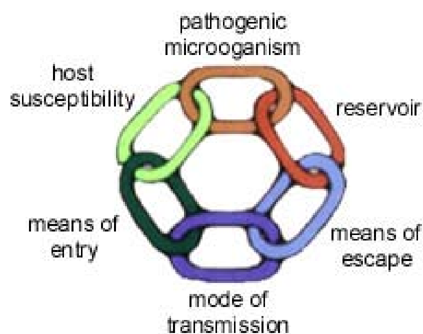
[2] Gauger A, Mempel M, Schekatz A, Schafer T, Ring J, Abeck D, "Silver-coated textiles reduce Staphylococcus aureus colonization in patients with atopic eczema," *Dermatology*. 2003;207(1):15-21.

Appendix I: A Discussion of the Mechanics of the Chain of Infection[3]

In order to fully understand the most effective means of preventing the spread of infections, it is necessary to understand the basic modes of transmission. Transmission of infections requires three elements:

- A source of infecting microorganisms
- A susceptible host
- A means of transmitting the microorganism

Figure 1: The Chain of Infection



Courtesy of the University of Minnesota Department of Environmental Health and Safety

The concept of the "chain of infection" displayed in Fig. 1 includes more than just the pathogenic agent, the host, and the mode of transmission. It recognizes that the agent has a reservoir serving as a continuing source of contamination. It also recognizes that the agent must escape from the reservoir in excretions or secretions (also called a "portal of exit.") for transmission to take place. In order to infect a susceptible host, the agent must enter through mucus membranes, breaks in the skin, or other means (also called a "portal of entry"). So, if you break one link in the chain by eliminating the reservoir or immunizing the host, there is no possibility of disease transmission.(Kennamer, 2002)

Source of Infectious Agents

The most common source of infectious agents is the patient's own endogenous flora. These microorganisms typically do not harm us and are often beneficial in that they may prevent the colonization of our skin or gut with pathogenic organisms. However, when a patient's immune system is weakened or there are new portals of entry, such as central venous or urinary catheters, these organisms become opportunistic pathogens. Other sources of infectious agents may be inanimate objects such as food, instruments, or even environmental surfaces. For environmental surfaces to be a source of infection, typically the patient's immune system must be severely compromised. [*emphasis added*]

[3] Excerpted from George Byrns' unpublished chapter "Introduction to Infection Control" for an upcoming industrial hygiene textbook. Reprinted with permission of the author.

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Other patients, personnel, or visitors may serve as important sources of cross-contamination. These sources of infections are typically the most easily preventable.

Susceptible Host
Patient susceptibility varies greatly, since some may be immune; while others may develop asymptomatic carrier state, and some may develop clinical disease. The most important host factors affecting susceptibility are age, underlying disease, and current treatments (antimicrobial drugs, immunosuppressive agents, irradiation, surgery, anesthesia, catheterization, etc.).

Means of Transmission
The five main routes of infection transmission are:

- Contact (Direct or Indirect)
- Droplet
- Airborne
- Common Vehicle
- Vector borne

Direct versus Indirect Contact
Contact transmission may be direct, for example, person to person contact, or indirect when a person contaminates an object and another person comes in contact with that object.

Droplet versus Airborne
Microbes can be released into the air from human sources as droplets or droplet "nuclei." Droplets, produced by such activities as coughing or sneezing, are relatively large in size (> 5µm in diameter). Once released, they either settle out of the air or dry out and become droplet nuclei. It is estimated that these particles become desiccated after traveling no more than approximately 3 feet. The particles are now much smaller in size (<5µm) and are capable of going deeper into the respiratory system once inhaled. Fortunately most microorganisms do not survive this drying process and can not be transmitted at a distance of greater than 3 feet. There are some notable exceptions; tuberculosis and measles survive the drying process and because of the small size of the droplet nuclei, may remain suspected in the air for considerable periods of time. This is why it is critical to have patients with airborne infections isolated in rooms with proper mechanical exhaust under negative pressure relative to the corridor.(AIA, 2006)

Other sources of airborne or droplet transmission
Soil, water, dust, and decaying organic matter may be released into the air creating potentially infectious aerosols. For this reasons, special care must be taken during renovation projects and in the placement of building fresh air inlets. A special concern is the location of aerosol generating equipment such as cooling towers. Water borne disease may occur if these towers are located in close proximity to building fresh air intakes since they may be contaminated with *Legionella pneumophilia* bacteria.(CDC, 2003)

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Vector and Vehicle Transmission
Vectors are living transmitters of disease. For example, West Nile Disease requires a mosquito to transmit the viral agent from a bird reservoir or another infected host to a susceptible host. Vector-borne nosocomial transmission is rare in the US. This may not be true in some developing countries were screened windows and other public health necessities may be absent.

Vehicles are non-living transmitters of disease. For example, inadequate disinfection or sterilization of medical devices may result in nosocomial infections. Other potential vehicles include: contaminated food, water, or medications. These are uncommon causes of nosocomial infections, but they may result in large scale outbreaks. This is particularly worrisome if the contamination occurs at a pharmaceutical manufacturing plant. Water systems may be contaminated with *Legionella pneumophilia*, and this can make even showering risky for certain susceptible patients. There is a wide variety of medical equipment that may serve as vehicles of disease such as dialysis systems, hydrotherapy tanks, endoscopes and endoscope re-processors, and even dental lines. These may become contaminated with chlorine-resistant gram negative bacteria that may cause nosocomial illness or death.(CDC, 2003)

References:

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