Comprehensive Prevention Achieving Enhanced Safety and Improving Infection Prevention and Detection

Policy Proposal

American Medical Devices and Diagnostics
Manufacturers' Association (AMDD)
HAI / Safety Working Group

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Concrete Measures to Achieve Enhanced Healthcare Safety & Infection Control

Dear Concerned Healthcare Leader & Stakeholder:

Since the mid-1990s a shift towards early intervention and prevention has become a central feature of public healthcare policy across the developed world. This paradigm shift resulted from the emergence of a common recognition among countries as to the significance of this issue. As a result, healthcare authorities across the global are now working on establishing a comprehensive set of new national policies and programs focused on early intervention and prevention.

A critical component of a comprehensive prevention-oriented policy addresses Healthcare-Associated Infections (HAI), which specifically aim on enhancing patient and healthcare worker (HCW) safety. HAI are preventable infections to patients and healthcare workers acquired while in a clinical setting or facility. For example, although the spread of multi-drug resistant organisms (MDROs) in hospitals may appear intractable, a number of practical infection prevention practices, such as hand hygiene, safety-engineered devices and materials, contact isolation, environmental hygiene, and active surveillance in hospitals, have been shown to significantly reduce the spread of these pathogens.

HAI is widely recognized as a significant healthcare issue. The World Health Organization (WHO) has identified HAI as a leading cause of preventable morbidity and mortality. The cost of treating avoidable HAI is substantial and could be significantly reduced with the implementation of comprehensive guidelines and mandates targeting enhanced infection control. In addition, the implementation of comprehensive guidelines and mandates to better enhance safety for patients and HCWs by lowering the risk of foreseeable accidents and injuries and preventable infection would also yield positive outcomes including improvements in the quality of care; reductions of avoidable accidents and injuries; as well as effective controls on unnecessary healthcare costs.

Recognizing the significance of the issues facing Japan's healthcare, the American Medical Device & Diagnostics Association (AMDD) HAI Working Group presents the following recommendations to make a meaningful difference to caregivers, patients and the public. To achieve this will require the commitment, collaboration and leadership of key healthcare and policy stakeholders in Japan. It is for these reasons that we request your support and active participation.

With sincerest regards,

William Bishop
Chairman, HAI/Safety Working Group
American Medical Device & Diagnostics Association (AMDD)

Achieving Enhanced Safety and Improving Infection Prevention and Detection

Background

Since the mid-1990s early intervention and prevention has become a central feature of public policy across the developed world. Healthcare systems in Japan and around the world, including governments, employers, payers and individuals, are seeking new solutions to promote health while more effectively managing increasing costs of care. Advances in technology enable healthcare providers to detect problems and move patients into preventive treatment before their disease becomes more severe or leads to more costly complications or worse to less effective treatment outcomes.

By shifting from a treatment to a prevention-oriented paradigm and implementing a comprehensive set of new national policies and programs focused on prevention, early detection, early intervention, and wellness, the Government of Japan has in recent years improved health outcomes, boosted long-term healthcare cost efficiency and increased the productivity of the workforce.

As seen in the Cabinet Office's report "New Health Frontier Strategy", the government of Japan has increased efforts to address the challenges of an aging population and its impact on patients, the economy, and society as a whole. The Government of Japan has recognized that preventive care is important to the health and welfare of Japanese citizens. The Healthy Japan 21 plan focuses on the prevention of lifestyle-related diseases and the Basic Plan for the Promotion of Cancer Control includes important provisions for the early detection and prevention of cancer. Further, in April 2008 all of Japan's prefectural governments launched their own prevention policies.

One good example of success if the Japanese government's nationwide program to provide free diagnostic screening for the Hepatitis C virus over the past several years that has resulted in over 100,000 infected people to have been discovered, giving them the chance to seek treatments to eliminate the virus before it causes liver cancer. Another good example is the continued funding of a National Women's Cancer Initiative offering fee breast cancer test for women 40, 45, 50, 55, 60 years of age and cervical cancer test for women 20, 25, 30, 35, 40 years of age since the FY2009 Supplement Budget.

The toll of workplace injuries and illnesses is also a significant problem in need of national policies. For workers in every industry and in every sector of the economy, the prevention of avoidable and foreseeable accidents and injury is taken for granted as a matter of occupation health and safety under the law. Though Japan has made progress in shifting health care resources increasingly toward a prevention-oriented

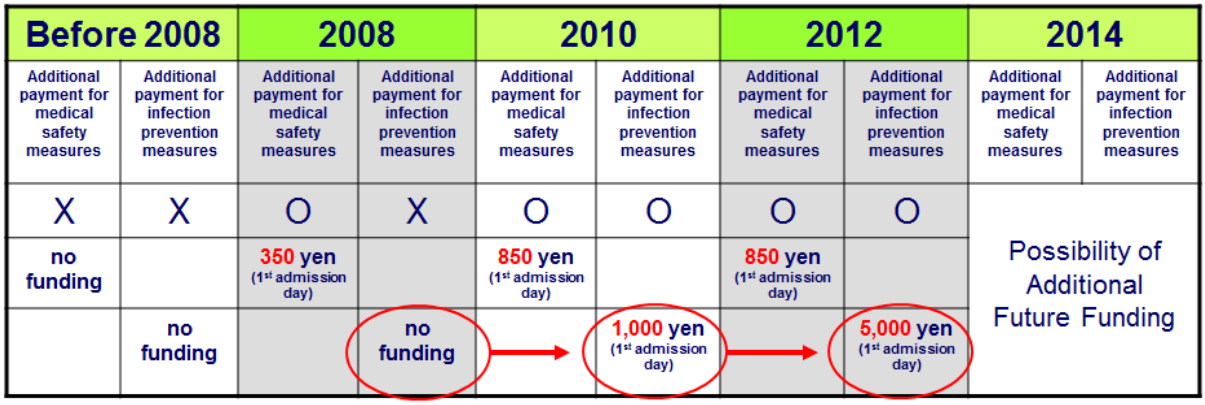
paradigm by focusing on wellness and the early detection and treatment of disease, comprehensive guidelines and mandates for enhanced safety and infection control for patients and healthcare workers (HCWs) have not been implemented hand-in-hand with these efforts.

Implementing comprehensive guidelines and mandates to better enhance safety for patients and healthcare workers by lowering the risk of foreseeable accidents and injuries and preventable infection would yield three positive outcomes; it would raise the quality of care; reduce avoidable accidents and injuries; and act as an effective control on healthcare costs. The World Health Organization (WHO) has identified healthcare associated infections (HAIs) as a leading cause of preventable morbidity and mortality. The cost of treating avoidable HAI is substantial and could be reduced significantly with enhanced safety and infections control.

The safety of HCWs is invaluable not only for workers themselves but also for their families, workplaces, communities, industrial sectors and nation as a whole. For the prevention of foreseeable accidents, it is necessary for the government, employers, workers and all parties concerned to comprehensively and systematically implement preventive measures in an integrated manner.

Fundamentally, employers have a responsibility to eliminate or control any foreseeable workplace risk. For HCWs, sharp object injuries are a foreseeable workplace risk and have been identified internationally as being a significant problem for HCWs, particularly needle stick injuries (NSIs). The most considerable risk from NSIs is transmission of blood-borne viruses (BBVs) such as hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV). The risk is dependent on the prevalence of the viruses in the general population; the transmission rate (higher with HBV and HCV than HIV); and vaccination coverage for HBV.

However the missing component in the recent focus and shift to a prevention-orientated paradigm has been policies specifically directed at the enhancement of patient and healthcare worker safety and the prevention of HAIs. In the 2012 medical fee revision, the hospital fee for infection control efforts was considerable raised. Although the requirements include activities such as holding regular conferences, they do not include specific activities to recognize the actual status of and countermeasure for the prevention, reduction and control of HAIs.



The following 6 sections have been compiled to provide a background, current data and recommendations targeting the implementation of enhanced safety and infection prevention, reduction and control measures in the healthcare setting.

Section I: Infection Prevention – Current Situation and Issues
Section II: Infection Prevention/IVD
Section III: Skin Antisepsis
Section IV: Healthcare Worker Safety
Section V: Medical Devices in Infection Prevention
Section VI: Infection Control in Home Healthcare

Section I: Infection Prevention – Current Situation and Issues

An increased focus on prevention could yield both cost and health benefits. Improving the quality of care is essential for countries to be successful in improving health outcomes and reducing the expense that accompanies the treatment of preventable conditions. Reining in avoidable costs, like those incurred to treat HAIs, will make resources available to address other healthcare needs and will improve the overall quality of care for all.

The government should implement healthcare initiatives that expand access, improve quality and enhance efficiency by removing avoidable costs through prevention, early diagnosis, improved health information technology and the appropriate use of technology solutions. A comprehensive, target-oriented and enforceable approach to reducing HAIs is a necessary component of these goals.

High Occurrence Rate of Preventable HAI

Healthcare-associated infection (HAI), also known as a nosocomial infection, is an infection that a patient contracts while receiving treatment for another condition in a healthcare facility. Although HAIs are preventable, it is also a leading cause of preventable morbidity and mortality. The World Health Organization (WHO) reports that HAIs affect hundreds of millions of patients worldwide each year. Their prevalence in hospitals is 5-10% in developed countries and in some cases over 25% in developing countries[1]. Moreover, HAIs result in massive avoidable healthcare costs. In the U.S., the overall direct medical costs associated with treating HAIs ranges from $28.4 billion to $33.8 billion each year[2]. Similarly the Organization for Economic Co-operation and Development (OECD) study of three countries reveals that HAIs added $7-8 billion annually to healthcare costs in the countries surveyed[3]. Additionally, one study of the impact of HAIs on hospital stays showed that the average number of days in the hospital for cases with an HAI was 20.6 compared to 4.5 for cases without an HAI, and costs 6 times as much on average[4]. Many of these infections are preventable and therefore healthcare institutions across the globe can, and should, implement comprehensive strategies to reduce HAIs.

Background

World-wide HAIs are serious public health problems that affect both developed and developing countries, and the impact of HAIs are threatening hard-won gains in human health and life expectancy. Additionally, HAIs have serious adverse economic impacts by driving up the costs of healthcare. This is particularly important at a time when nations around the world are designing and implementing strategies to address the

increasing costs of healthcare. HAIs can result from inadvertent exposure to pathogenic bacteria, viruses, fungi or spores. Exposure may be caused by transmission from contaminated healthcare workers' hands, environmental surfaces, patient-to-patient contact and catheter insertion and maintenance practices.
Many of these infections are resistant to treatment with antibiotics, leading to serious illnesses, debilitating post-treatment effects and in some cases, death. Some bacteria that cause HAIs can survive in the healthcare environment including on medical devices, surgical tools, unwashed hands, and the clothing of hospital personnel, and are easily transmitted from patient-to-patient when healthcare professionals do not observe good infection control practices. Patients in intensive care units who are treated with medical devices such as central venous catheters, ventilators and urinary catheters as well as those with open wounds, or who are otherwise immune-compromised, are at much greater risk of contracting these infections and, are at risk for serious complications due to their already vulnerable status..

For example, the trend of occurrence of in-hospital infection differs depending on the scale of the hospital. Horan, et.al reports there was an average of 33.5 infection cases per 1,000 patients for in-hospital infection if fifty-one hospitals in the U.S. with 80 to 1,200 beds.

- More than 500 beds (University hospital) 41.4 cases
- Less than 500 beds (educational hospital) 33.8 cases
- (non-educational hospital) 22.2 cases

This study indicates that larger hospitals and educational hospitals that execute more complicated high-level medical treatment tend to have a higher incidence of in-hospital infection than others.

The occurrence ratio of in-hospital infection is higher in intensive care units. Kim, et.al (2000) reported that the occurrence ratio in ICUs was about 4 times (10.7%) compared with general nursing wards (2.6%). Constantinni, et.al also reported that the infection ratio in ICUs was 26.9% and its ratio increased by prolonging of length of stay. These results indicate that the longer a patient stays in ICU, the higher the risk of in-hospital infection. Clearly, effective measures for infection control and prevention require a comprehensive approach. The control of infectious disease can yield multiple benefits. Reducing the spread of infection through comprehensive detection/prevention enhances patient QOL, lowers the risk of injury to healthcare workers and reduces overall medical expenditures. Indeed, the savings can be substantial as demonstrated in a "Summary report of MRSA HAI Surveillance in 2008" by Kobayashi H., et. al. [5]

Table 4: Medical expense with and without MRSA infection

	wo MRSA	w MRSA
Number of Patients	56,859	167
Average days in Hospital	15.05	81.12
Medical expense Patient/day (yen)	53,532	58,744

Total medical expense for MRSA infection

1.	Total number of in-patient per day		37,057
2.	Rate of inpatient become MRSA		0.6%
3.	Total MRSA infection		222/day
4.	From Table 4, medical expense	w MRSA	58.744 x 81.12 = 4,765,313.3
		wo MRSA	53,532 x 15.05 = 805,656.60
5.	Difference		4,765,313.3 – 805,656.6 = 3,959,656.7
6.	Total = difference x incident/day x 365 days		3,959,656.7 x 222 x 365 = ca. 320 billion (yen)

Active Surveillance

By knowing the carrier of infectious disease pathogens in advance, healthcare workers and facilities are better able to take appropriate preventative actions to control and prevent the spread of infection. Healthcare workers are able to take precautions if they know that a patient is a carrier of an infectious pathogen whereby preventing the pathogen from spreading.

Special infection prevention programs such as decontamination before surgery can help to protect patients. Active surveillance is most effective when all hospital inpatients are screened at the time of admission. At the very least, active surveillance should be used for ICU and ER patients and for all high risk patients such as those patients who are immune-compromised or undergoing long-term hospitalization. Active surveillance is not intended to serve as a substitute for the "diagnosis of infection"; rather, active surveillance has been found to be an effective tool healthcare facilities can use for the detection and control of infectious pathogens such as MRSA, VRE, HIV, and Hepatitis Viruses.
The government should support the reduction of HAIs by employing comprehensive infection prevention practices. The following are six guiding principles:

1. Comprehensive Strategy

- An HAI prevention strategy must be comprehensive in nature, including "bundles" of proven infection control practices, education and cultural change. It should

consider the impact that enabling technologies, like rapid molecular diagnostic testing and novel medical devices, have in improving patient safety and reducing HAIs. Information technology should also be utilized to enhance HAIs surveillance and prevention implementation.

2. Defined Targets for Healthcare Institutions

- Reasonable HAIs prevention targets should be set and achieved over defined time periods that are measurable. Wherever possible, baseline HAI incidence rates should be established using standardized measurement systems to allow measurement of hospital-specific progress toward achieving prevention targets.

3. Coordinated Effort at the Government Level and the Institutional Level with Stakeholder Support

- Prevention will require a concerted effort by all healthcare institutions, with engagement and leadership from policy-setting bodies at different levels of Government, and with the support of stakeholder organizations with missions support best practices in health care and to reduce HAIs. This support is needed for the development and implementation of efforts to reach the prevention targets.

4. Incentives to Promote Compliance with HAI Prevention Targets

- Incentives, which include both rewards and penalties, must be implemented and linked directly to progress toward achieving the prevention targets. Every healthcare facility should develop and maintain a comprehensive HAI control and reduction plan that is consistent with current standards of care and best practices. Facilities that fail to develop, implement, and maintain a current HAI control and reduction plan should face sanctions until they are compliant.

5. Adequate Resources

- Adequate resources, appropriate for the overall infrastructure of each country, should be applied to Government efforts, international efforts, and local/institutional efforts. This also included identifying and prioritizing gaps in HAIs research.

6. Active surveillance, early screening, detection and monitoring of infection in the healthcare setting

- Implementation of active surveillance of infectious pathogens such as multi-drug resistant organisms and bacteria as well as the well-known pathogens, MRSA, VRE, HIV, and Hepatitis Virus.

- Reimbursement rewards for facilities that implement active surveillance as well as rewards for the periodic environmental monitoring on microbial contamination such as MRSA.

Examples of the Most Recognized HAIs

MRSA

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a particularly prevalent HAI. People can be colonized with MRSA but show no sign of clinical infection. The most recent population-based estimates of MRSA colonization are approximately ~ 1% from 2001, but in patients who are in healthcare facilities the colonization rate can be 10 ~ 15%. MRSA carriers can serve as a source of MRSA that can be passed along to vulnerable populations in the hospital or to healthcare professionals who then transmit it to those in their care. In the hospital, colonization and infection with MRSA is often acquired during or after surgery or by patients in the ICU, and can lead to systemic infections in the bloodstream which are difficult to effectively treat. For example, one patient who contracted MRSA after minor laparoscopic surgery became septic and spent four months in an intensive hospital care battling her infection. C. *difficile*, VRE and other pathogens which can cause HAIs are equally serious public health problems. Studies have found that MRSA alone causes more than 94,000 cases of invasive infections in the U.S. annually, and close to 19,000 deaths[6].

Clostridium difficile

C. difficile infection (CDI) is caused by toxin-producing strains of the *C. difficile* bacteria in the intestine. About 3% of healthy adults are carriers of *C. difficile, but this rate is higher in patients and elderly people being treated in hospitals with antibiotics. Antibiotics kill many of the normal gastrointestinal bacteria, allowing C. difficile* to grow unchecked which causes *C. difficile* infection (CDI). Symptoms of the infection can include severe diarrhea, nausea, abdominal pain, loss of appetite, dehydration, fever, bowel inflammation and in its worse cases, colonic perforation, sepsis, and death.

VRE

HAIs caused by vancomycin-resistant *enterococci* are increasingly common and difficult to treat. *Enterococci* are bacteria that are normally present in the human intestines. Vancomycin-resistant *enterococci* are, as the name suggests, resistant to vancomycin and many other antibiotics, leaving patients infected with VRE with few treatment options. As with MRSA and *C. difficile*, patients may become colonized with VRE, but show no signs of clinical infection. Ultimately, some of these carriers will be at risk of infection from VRE, particularly if their immune systems are weakened from cancer or cancer treatments or following surgery. Symptoms from VRE infection are related to the type of infection that the pathogen causes which include sepsis,

bloodstream, urinary tract and surgical site infections. In 2007, CDC estimated that *enterococci* caused about 1 out of every 8 infections in hospitals, of which about 30% were caused by VRE.

Examples of Nosocomial infections include:

CAUTI

Constantini, et. al reported UTI with catheter was 18.4% and UTI without catheter was 3.1% in ICU ($P<0.001$). Retention of urinary catheter correlates 6 times of non-retention.

CRBSI

CDC reported CRBSI at the following in 1991.

- Occurrence of infection with PV line insertion is 0~2 cases/1000 days at any types.
- Occurrence of infection with CV insertion is 2~30 cases/1000 days and rather higher infection occurrence is burn ICU and pediatric ICU
- Insertion of CV line correlates higher risk of in-hospital infection.

VAP

Constantini, et.al reported VAP without ETT was 3.3% and VAP with ETT over 48 hours was 42.4% in ICU ($P<0.001$). Retention of ETT with mechanical ventilation correlates 13 times of non-intubation. Fagon, et.al reported prolongation of MV increase of the risk of VAP occurrence ration (6.5% - 10 days, 19% - 20 days, 28% - 30 days). VAP occurrence ratio/day was approximately 1% ($1\pm$ 0.76%).

SSI

The risk factor with related SSI is the contamination of surgical wounds.

- Class 1 (RI 0): clean wound = $<$1% of SSI risk
- Class 2 (RI 1): semi clean wound = about 10% SSI risk
- Class 3,4 (RI 2,3): contamination, infection = $>$30% SSI risk

SSI is differentiated between inner related (by normal inhabitant) case and outer related (any contaminations) case.

Example of Disinfection and Sterilization Guidelines
CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Introduction:
- Disinfection and sterilization are essential for ensuring that medical and surgical instrument do not transmit infectious pathogens to patients.
- 'Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization. Failure to comply with scientifically-based guidelines has led to numerous outbreaks.'

Sterilization Practice: Monitoring
- 'The sterilization procedure should be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilizing conditions and indirectly the microbiolobic status of the processed items.'
- 'Steam and low temperature sterilizers (e.g. hydrogen peroxide gas plasma, peracetic acid) should be monitored at least weekly with appropriate commercial preparation of spores. If a sterilizer is used frequently (e.g. several loads per day), daily use of biological indicators allows earlier discovery of equipment malfunctions or procedural errors and thus minimizes the extent of patient surveillance and product recall needed in the event of a positive biological indicator.'

ANSI · AAMI ST79:2006: Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities
10.4 Overview of sterilization process monitoring
- 'Sterilization process monitoring devices include physical monitors, CIs, and BIs. Each of these devices plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance.'

JAOM Practice Guideline 2008
- 7.III.8 : Process of Sterilization assurance with adequate indicator is essential

JMDA Guideline of Sterilization Assurance in health care facilities 2005
- 1.1.4 : Routine monitoring and control

Section II: Infection Prevention via IVD Devices

Healthcare-associated infection (HAI) can be prevented or at the very least the incidence rate significantly lowered through the implementation of many of the recommendations covering sharp object handling and safety, single-use devices and the issues of reuse and reprocessing and HAI prevention presented in previous sections.

Infection Detection/IVD Diagnostics

Infection prevention and detection is possible when using the appropriate IVD testing. Early detection of infectious disease is important for patient treatment. The quicker an infection is detected, the speedier the treatment and the sooner the patient is able to recover. All patients, in a healthcare setting, run the risk of acquiring an infection, especially patients with compromised immune systems, infants, the elderly, patients recovering from an illness or operation and patients hospitalized for long-term medical care.

In all cases, proper diagnosis is fundamental to appropriate medical treatment. For example bloodstream infections, often potentially fatal, can only be detected by blood culture. To save lives, the rate of blood culture testing per bed for in-hospital patients should be increased to provide faster detection and more accurate diagnosis of bloodstream infections and sepsis.

Patient safety is paramount; however, the provision of a safe and healthy working environment is also a fundamental right of every employee in Japan, including healthcare workers. Occupational health and safety legislation aims to protect persons from all types of hazards and risks arising from work activities. Therefore it is reasonable to expect that healthcare workers in Japan should be protected from the hazard of occupational exposure to the environmental microbial contaminations such as MRSA and the subsequent risk of acquiring a potentially life threatening blood-borne disease such as hepatitis B, hepatitis C or HIV/AIDS.

Especially in hospital emergency departments, doctors and nurses and other healthcare workers suffer with high frequency the risk of acquiring a potentially life threatening blood-borne disease. Patients also suffer the risk of the environmental microbial contaminations such as MRSA in healthcare settings.

The elimination of workplace hazard and risk is a fundamental principle of occupational health and safety legislation. Every infectious disease able to be acquired at work is a foreseeable hazard faced by healthcare workers. All employees in the healthcare

sector have the right to work without concern of experiencing an infectious disease at work. The risk of occupational exposure to the environmental contamination and blood-borne pathogens can be and must be eliminated.

Against these risks IVD testing for patients and healthcare workers as well as for the testing of the environments within hospitals is exceptionally effective in detecting and monitoring the status of infection. Prevention measures must include the implementation and use of effective active surveillance and IVD testing combined with relevant training and education.

The government should coordinate, support and fund as necessary the practices of appropriate IVD testing to detect and monitor infectious disease for patients, healthcare workers and the environments within hospitals. The following are guiding principles:

1. Infectious Disease Prevention

Implementation of a national infectious disease prevention program that is driven and initiated by the Government of Japan/MHLW.

- Implementation of HIV testing similar to the guidelines recommended by US Centers for Disease Control (CDC).
- Better national coordination and implementation of HCV testing program currently administered by local governments.
- And other measurers deemed necessary

2. Recognition and rewards for active surveillance, early screening, detection and monitoring of infection in the healthcare setting.

- Enhance rewards for hospitals implementing robust testing programs for the early detection of infectious disease. Elements would include POC, blood culture, and other rapid detection measurement.
- And other measurers deemed necessary

3. Recognition and rewards for the appropriate maintenance of IVD Instruments in hospital laboratories as well as investments in on-site microbiology testing such as culture handling growth and analysis.

- Reimbursement rewards for facilities to both maintain and purchase necessary on-site IVD instruments, blood culture handling and analysis and microbiology testing equipment.

Without a well-funded and sustainable shift in policy by the Government to assist in the systemic implementation of infection detection and prevention, efforts to shift the prevention-orientated paradigm in Japan will not be possible nor will the multifaceted benefits of enhanced quality of care and patient QOL, reduced risks to healthcare workers and overall healthcare cost savings this shift would yield.

Section III: Skin Antisepsis

The prevention and control of infections represent one of the most significant safety initiatives for a healthcare organization. Infections can be acquired in any healthcare setting, transferred between organizations, or brought in from the community. Because infections are a significant safety risk for patients and healthcare workers (HCWs), infection prevention and control must be high on every organization's list of priorities.

Hand in hand with robust hand hygiene and environmental disinfection, skin antisepsis is fundamental to the prevention of healthcare-associated infection and is a critical component of effective infection prevention and control program. While many antiseptics have been used over the years, clorhexidine gluconate (CHG) is increasingly becoming the standard of care for skin antisepsis for the prevention of HAIs on a global basis.

CHG is a broad-spectrum skin antisepsis compound that, when used in appropriate concentrations, has rapid and long-term antiseptic properties. A large and growing base of scientific evidence supports the efficacy of CHG in reducing both gram-positive and gram-negative bacteria. As a result, CHG is increasingly considered the standard of care of skin antisepsis in countries with developed infection control practices. The overwhelming body of clinical evidence supporting the safety and efficacy of CHG has led to growing awareness and adoption globally. CHG is recommended in HAI guidelines in a growing number of countries and is a compulsory component of the patient care "bundles" or interventions for prevention of the most costly and deadly device-related HAIs—catheter-related bloodstream infections (CRBSIs), surgical site infections (SSIs), and ventilator-associated pneumonia (VAP).

While allergic reactions can occur, according to the WHO, the U.S. Centers for Disease Control and Prevention (CDC) and other influential health organizations, CHG is considered to be both safe and effective. Many key Japanese opinion leaders favor use of CHG to prevent all device-related infections.

In Japan, although there are some guidelines recommending that using 0.5% chlorhexidine solution is equal to using a 10% povidone iodine or 70% alcohol solution for skin antisepsis, there is no specific national guideline to recommend the specific use of applications of more than 0.5% chlorhexidine.

Those leading infection prevention in Japan recognize the CDC guidelines and are aware of the Institute for Healthcare Improvement (IHI) care bundles, while some health institutions are following these recommended practices. However, actual practice is often inconsistent with these recommendations because of the fear of

allergy and the perceived relatively high cost of single-dose applicators. To better ensure infection prevention in Japan, evidence-based general skin antisepsis protocols should include, at a minimum, those globally recognized best practices being employed worldwide to reduce and prevent HAIs.

In line with the aforementioned, basic skin antisepsis guidelines for Japan should include, at a minimum, the following 4 protocols:

1. **Skin antisepsis for the insertion and maintenance (dressing changes) of central venous catheters, peripherally inserted central catheters (PICCs) and peripheral catheters (arterial or venous).**

- Preparation of clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion, and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives.[7,8,9]
- Preparation of clean skin with an antiseptic (70% alcohol, tincture of iodine, an iodophor, or CHG) before peripheral venous catheter insertion[7,8]. CHG may be more effective in preserving the IV site, increasing its longevity, decreasing sample (blood) contaminant, and preserving sample integrity.

2. **Skin antisepsis for patient presurgical bathing and presurgical skin prep.**

- Use a 2% chlorhexidine wash for daily skin cleansing to reduce the chance of SSI.[7,,10,11,12]

3. **Skin antisepsis for surgical skin prepping (pre-operating room, and can be inclusive of cut-down procedures for the placement of central venous catheters [CVCs], such as tunneled dialysis catheters, and subcutaneous ports).**

- Use of 2-4% chlorhexidine as an antimicrobial agent for surgical skin prepping (not for use on eyes, ears, mucous membranes).[13]

4. **Single-dose applicators for skin antisepsis**

- Single-dose applicators; 1) eliminate contamination of multi-use bulk solution bottles, 2) increase compliance with skin antisepsis guidelines; 3) reduce the need for skin antisepsis solution, durable materials and sterile reprocessing; 4) reduce procedure time; 5) lower both the director cost of skin antisepsis practices and indirect costs (labor and time).
- While single-dose applicators are not specifically called for in the CDC guidelines, they have the earlier-mentioned benefits.

Section IV: Medical Safety

1. Prevent Needle Stick and Sharp Object Injuries

Needle stick and sharp object injuries pose a serious occupational risk to healthcare workers. The provision of a safe and healthy working environment is a fundamental right of every employee in Japan. Duty of care provisions within occupational health and safety legislation aim to protect people for all types of hazards and risks arising from work activities. Therefore, it is reasonable to expect that healthcare workers should be protected from exposure to dangerous blood-borne viruses, including hepatitis B and C viruses and HIV. Even the smallest puncture of the skin can expose a healthcare worker to more than 30 blood-borne pathogens, bacteria, and parasites, [14] any of which can cause serious potentially life-threatening infections. The majority of these injuries are suffered by nurses and doctors and occur in patient rooms and operating rooms. However, other medical staff can also become victims. Ancillary staff such as hospital orderlies, cleaners and laundry staff, and other downstream workers also suffer needle stick injuries.

In the European Union, where few regions have adopted mandatory needlestick prevention requirements, it is estimated that there are more than one million needlestick injuries each year[15]. Additionally, results survey conducted by the Royal College of Nursing in 2008 showed that almost half (48%) of nurses had been stuck by a needle or sharp that had previously been used on a patient during their career and 10% had sustained an injury in the last year.[16]

In the United Sates, the Centers for Disease Control and Prevention estimates that healthcare workers in hospital settings sustain over 380,000 percutaneous injuries involving contaminated sharp objects annually[17]. This estimate does not include non-hospital settings, and one estimate places the total annual U.S. percutaneous injuries from sharp objects in healthcare settings at over 500,000.[18]

In Japan, it is estimated that 450,000 to 600,000 sharp object injury occur every year which means one in two doctors or nurses experience sharp object injuries every year. According to the Research Group of Occupational Infection Control and Prevention, in Japan in 2012, 52% of nurses and 35% of doctors experienced sharp object injuries,

with the increasing percentage for doctors. Categorized by profession, incident rates (number of needle stick injuries per year for profession A) / (number of staff in profession A) x (100) were 9.7 for residents, 4.1 for doctors, 3.5 for nurses, and 3.0 for clinical technologists, with the degree of risk being higher for doctors[18]. In terms of the number of reported cases, in 2010 the incidence of needle stick injuries was 6.4 per 100 occupied beds, with a significantly higher ($p<0.01$) rate of 7.9 at university hospitals compared with 5.3 at other hospitals[19]. There has been a notable increase in the number of sharp object injuries caused by suture needles and pre-filled cartridge needles (insulin injection pen needles). The delay in the universal utilization of safety-engineered devices was pointed out in a recent report as a persistent problem in Japan.[19]

Needle stick and other sharps injuries generate significant cost for healthcare systems and can result in great stress for the injured healthcare workers and their families.[20]

Independent studies show that the majority of needlestick injuries are preventable through the implementation and use of safety engineered medical devices (SEMD) combined with relevant education and training programs for healthcare employees[21-25]. Unlike many countries, Japan has yet to adopt a nationally consistent approach to the use of SEMD in healthcare settings either through prescriptive legislation or policy. Guidelines, awareness and education campaigns and other non-legislative initiatives alone have generally proven ineffective in preventing needlestick injuries to healthcare employees.[25]

Today, many international jurisdictions have taken steps to amend Occupational Health and Safety Legislation and include provision for mandatory use of safety engineered needles and sharp objects in medical workplaces[26-29]. To reduce the exposure of healthcare workers to infections disease comprehensive prevention legislation and/or regulations should include four key elements:

1. **Education and training of healthcare workers on infection prevention techniques**

- In order to encourage compliance with infection control guidelines, it will be necessary to develop infection prevention education and training programs targeted to healthcare workers including proper disposal.

2. **Mandate safer working practices**

- Employers must develop and implement an exposure control plan to eliminate or minimize worker exposure to blood-borne pathogens if workers are required to handle, use or produce an infectious material or organism or are likely to be exposed to a place of employment.

3. **Require the use of medical devices incorporating needle protection technology**

- The use of devices with safety-engineered technologies can greatly reduce the incidents of needlestick inquires and exposure to blood-borne pathogens. Healthcare facilities should be required to adopt and regularly evaluate engineering controls designed to prevent percutaneous injuries.

4. **Eliminate the use of needles where safe and effective alternatives are available**

- The use of devices that eliminate the need for needles should be encouraged whenever possible in order to reduce the potential for occupational exposure to blood-borne pathogens due to percutaneous injuries from contaminated sharp objects.

2. Avoid Reuse of Single-Use Devices

Generally, single-use medical devices (SUDs) are designed to be disposed of after one use and should not be reused under any circumstance. The one-time use of a SUD ensures function and sterility and prevents cross-contamination and infection[39]. Only SUDs that have gone through appropriate reprocessing, including cleaning, functional

testing, repackaging, relabeling, disinfection and sterilization, should ever be reused. However some healthcare personnel are unaware of, do not understand, or do not adhere to the guidelines for appropriate use of SUDs products.[30-41]

Inappropriate reuse of SUDs poses a serious health risk to patients. In the US, the reuse of syringes has led to the contamination of injectable products and resulted in patient-to-patient transmission of infectious disease and more than 30 outbreaks of HBV and HCV. [42-46]

Comprehensive reuse prevention efforts should include five key elements:

1. Enforcing compliance with best practice infection prevention guidelines

- The transmission of infectious disease in healthcare settings can be prevented through adherence to basic infection prevention principles. There is a need to develop enforceable national regulations to ensure outpatient facilities adhere to Standard Precautions and aseptic technique.

2. Increasing oversight of healthcare facilities to ensure implementation of the best practices

- The need for the development of national enforceable standards for oversight to enhance inspection and regulation of healthcare facilities. There is a need to develop national standards for oversight to enhance inspection and regulation of healthcare facilities.

3. Enhancing education and training of healthcare workers on infection prevention techniques

- In hospital settings, infection control personnel are employed to conduct surveillance, monitor practices, and provide education and training on appropriate infection control practices. However, specific infection control resources have traditionally been lacking in outpatient settings. In order to address the inconsistencies in adherence to infection control guidelines, the development of infection prevention education and training programs that include the proper use and handling of SUDs and that are targeted to healthcare workers in outpatient settings.

4. **Encouraging the adoption of technologies to prevent reuse of single-use devices (SUDs)**

- There is a need to support efforts to enhance uptake of existing technologies designed to prevent reuse as well as the development of new technologies to address this problem.

5. **Conducting outreach efforts to enhance patient awareness of appropriate use of single-use devices**

- There is a need to develop initiatives that empower patients to ask questions about the appropriate use of needles, syringes and other-use devices.

The practice of reusing and reprocessing SUDs raises legal and ethical questions. These pertain to liability for harms to patients, informed consent to treatment with reprocessed SUDs, duty to notify patients of past exposure to harm, and the appropriate balancing of the economic benefits of reuse against risks to the health and safety of patients. These questions focus on matters of law. In the absence of regulation and legal precedents, however, ethical principles must be used to guide decisions. Patients who are exposed to risks (especially undisclosed or poorly understood risks) may experience psychosocial problems such as heightened anxiety about their health and distrust in care providers, institutions, and regulators.

Although the reuse of SUDs is considered to be a cost-saving measure, the liability risks associated with it may lead to higher costs to health care facilities if patients who are harmed after using unclean or degraded devices successfully sue for damages. If scientific evidence reveals harms from the reprocessing and reuse of SUDs, patients may need to be informed of the risks proactively or retroactively, as circumstances warrant.

The small numbers of studies that have considered the clinical outcomes associated with the use of reprocessed SUDs are of variable quality and provide insufficient evidence to establish safety and efficacy. The use of several types of reprocessed SUDs is cost-saving if it is assumed that there are no adverse effects. There are insufficient data to establish the cost-effectiveness of re-using SUDs. Legal, ethical, and psychosocial issues require consideration by those who fund and use SUDs.

Section V: Medical Devices in Infection Prevention

1. Closed vs. Open Systems

Many nosocomial infections occur when medication/fluids are administered via an intravascular device[47]. A common example of infections caused by exposure to air and contamination via intravenous (IV) systems are bloodstream infections (BSIs). BSIs have a significant influence on patient outcomes because these infections can either be the patient's primary cause of death. A surveillance study by the International Nosocomial Infection Control Consortium (INICC), conducted in intensive care units (ICUs) in Latin America, Asia, Africa, and Europe, demonstrated that the mortality rate of patients with BSIs was 29.6%. [48]

Most bloodstream infections and their associated risks can be prevented. The use of innovative medical products can play an effective role in BSI prevention. For example, closed intravenous systems have a proven record of reducing BSIs, thereby potentially improving patient safety and reducing costs of associated longer hospital stays and treatment. In a closed IV system, the fluid is not exposed to the outside air, which significantly reduces the risk of contamination and infections. Studies have shown that BSI rates were reduced when changing from an open to a closed system. In Mexico, the BSI rate was reduced by more than 80%[49], in Argentina by 64%[50], in Italy by 61%[51] and in Brazil by 55%[52]. The results of a clinical study conducted in Argentina demonstrate that the mortality rate associated with BSIs can be reduced by 91% if patients receive fluids via a closed IV system.[53]

The reduction of BSI rates lowers costs by shortening ICU length of stay and reducing the use of antibiotics and other medications required to treat BSIs. Studies conducted in Mexico and Brazil have shown that reducing BSI rates may lead to significant cost savings.[54,55] Recognition of closed system safety innovation through higher reimbursement would also encourage the use of newer closed system devices over existing older open system devices that sacrifice safety for a lower unit cost.

In Japan, the medical fees set for many types of cases do not assume use of closed systems; indeed, there is no distinction between open and closed systems in medical fee reimbursement schedules. As a result, medical institutions must bear the additional associated costs of purchasing and using advanced closed system medical devices. The pricing rules for Special Treatment Materials also lack incentives for using closed systems: the distinction between open and closed systems is not established in existing reimbursement categories. This results in the pricing of closed system devices that are designed for enhanced safety and infection control being set at the same level as the older, less innovative, and less safe open systems.

Recommendations:

- The Japanese government should encourage hospitals to make the use of innovative medical products, such as closed intravenous systems, an integral part of hospital infection control policy.
- Revise medical fees to reflect the cost and use of closed system medical devices in both inpatient and outpatient settings.
- Establish a clear distinction between open and closed systems through the creation of new functional categories.
- Reimbursements should be revised upward to encourage the use of the safer closed intravenous system.
- In order to facilitate appropriate use, clinical usefulness and economics should be taken into account through a medical economics approach.

2. Preventing BSIs by Using Appropriate Devices

Potential Factors in Catheter Infection

Catheter-associated infections include exit, tunnel, pocket and bloodstream infections.[4] In the U.S., these kinds of infections extend the length of hospital stays by an average of 12 days and result in an additional cost of some $18,432 per patient[56]. As reported by the U.S. Centers for Disease Control (CDC), some 250,000 bloodstream infections (BSIs) resulting from central vascular catheter (CVCs) have been estimated to occur annually,[59] with an estimated death rate of some 12–25% (30,000–62,500) as a result of catheter-related bloodstream infections (CRBSIs). The prevention of CRBSIs is important for improving patient outcomes, and depends on having appropriate medical care, product guidelines, and infection control.

Examples of the potential factor related to the catheter infection risk include:

1. The length of time catheters remains inserted.
2. The frequency with which catheters are inserted and removed.
3. The use of multiple-lumen catheters.
4. Immunosuppression.[57]

Local infection often arises in such areas as the catheter insertion site, or the tunnel for, or pocket of an implanted port, and can occur concurrently with a BSI. The indications include local oppressive pain, the sensation of heat, sweating, hardened areas, and pus discharge. These can be identified by visual examination and by lightly tapping the dressing over an insertion site, tunnel, and port pocket.

Should any abnormality be detected, the dressing should be removed and the site carefully inspected.[58]

Evaluating Catheter-related BSIs[3]

- Regularly check catheter insertion sites
- Observe a patient's general condition (including for fever, chills, sweating, malaise, lassitude, muscular pain, weakening, tachycardia, changes in consciousness, and sharp pain)
- Pay attention to immunosuppressed patients, because symptoms of infection do not show
- When infection is suspected, promptly start treatment (with blood culture, antibiotics) as instructed by the doctor. It has been estimated that fatalities exceed 50% for patients not treated within 24 hours of the onset of infection[58]

Reduce CRBSIs with Needleless Systems[5]

Use of needleless systems has been included in the 2011 CDC guidelines for preventing intravascular catheter-related infections: "a split septum valve may be preferred over a mechanical valve due to increased risk of infection with some mechanical valves."[60] The recommendation was added because the CDC found evidence that the structure of needleless systems affects the incidence of CRBSIs.[61] A study provides strong evidence that both positive- and negative-pressure mechanical valves are linked to increases in CRBSIs, in conditions where the CRBSIs, surveillance methods, and infection prevention measure are the same.[62] When switching from a split septum (Interlink®) to a positive- or negative-pressure mechanical valve, an increase in CRBSIs was observed in all ICUs and wards. In addition, switching the valves back to a split septum (Interlink® or Q-Syte™) resulted in a significant decrease in CRBSIs in 14 ICU rooms. When planning the introduction of a closed type IV needleless system, hospital staff should keep an eye on CRBSIs to ascertain whether they result from use of mechanical valves.[62]

Efficacy of PICCs in Reducing CLA-BSIs

The peripherally inserted central catheter (PICC) is a central vascular catheter (CVC) that is inserted through elbow, forearm, or upper arm veins and places the catheter tip into the central vein. According to Morikane et al. (2009), it has been reported that PICC procedures reduce the rate of central line-associated bloodstream infection (CLA-BSI) by approximately 45% compared with that of CVC procedures through the subclavian vein or internal jugular vein. In addition, the total cost of treatment per hospitalization decreases, given that the CLA-BSI-related cost of antibiotics (some ¥410,000 per infection) and additional hospitalization (about 22 days per infection) can be avoided.

Further, use of PICCs not only reduces the incidence of infection on insertion, but can ensure safety. The anti-reflux PICC reportedly decreases the risk of catheter occlusion caused by the anti-reflux valve, which is designed to resist backflow when the catheter is not being used.

In Japan, medical fees are set without taking into account the possible use of medical devices to prevent CR-BSI, and the pricing rules for Special Treatment Materials also lacks incentives for developing such devices.

Moreover, according to Japan's Special Treatment Materials system, PICCs are classified as central venous catheters, which are further divided into subcategories, such as standard type and antithrombotic type. In April 2010, when the anti-reflux valve PICC was introduced, the reimbursement that was set for the standard type catheter (single lumen: ¥1,740; multilumen ¥2,870) was revised to ¥13,800. However, following the 2012 revision, the reimbursement is now set at ¥12,900. As a result of the revisions that have taken place, the gap has closed between the price of a single lumen anti-reflux PICC (basic kit: ¥16,000; microintroducer kit: ¥24,000) and the reimbursement. This, in turn, has reduced the incentive for hospitals to purchase PICCs, since hospitals where the DPC/PPS system has been introduced, avoid using expensive products, even if they help prevent infection.

In the case of double lumen anti-reflux PICCs (basic kit: ¥32,000; microintroducer kit: ¥40,000), the gap between the hospital purchasing price and the reimbursement is significant. Therefore, for financial reasons, hospitals will avoid using these catheters, setting aside necessity and high clinical efficacy. Although the material costs will rise with the use of PICCs, overall, use of these catheters will put downward pressure on the cost of both medical insurance and medical care, given the fees derived from medical treatment and the management of complications, while patient safety is ensured.

3. The Closed System Urinary Catheter – Preventing Catheter-Associated Urinary Tract Infection (CAUTI)

Urinary tract infections (UTIs) the most common type of nosocomial infections, accounting for over 40% of all nosocomial infections, in hospitals and nursing homes and catheter associated urinary tract infections (CAUTIs) constitute 80% of all nosocomial urinary tract infections (UTIs).[63] Although CAUTI may not be directly associated with increased mortality, CAUTI is responsible for raising hospital costs, prolonging length of stay, and complicating the recovery of critically ill patients.

To prevent urinary tract infections, a closed drainage system (a sterilized sealed unit in which the catheter, tube and drainage bag are secured) should be used, and urine flow must be unobstructed. Maintaining a closed system requires that the catheter and drainage tube are not disconnected unless absolutely necessary. The catheter, tube and collection bag are secured, preventing bacteria from entering the catheter tube. It has been reported that by employing the closed system catheter, the rate of urinary tract infections decreased by 42%[64].

Examples of Benefits

- Cases of urinary tract infections were reduced by 23% when closed urinary catheters were used.[65]
- Clinical results reflected a reduction of 90% to the frequency of urinary tract infections when closed urinary catheters were used[66]

Safety Benefits

- Accidental detachment of the urinary catheter and the collection bag occurs at a rate of 26%, which increases the risk of urinary tract infection (UTI) by 92%. If a closed urinary catheter system is used, the detachment rate will be reduced by 19%, contributing to reducing cases of urinary infection. [67]

Cost Benefits

- It is estimated that 25% of hospitalized patients receive an indwelling urinary catheter, amounting to 3,482,000 patients68. A study has shown that it costs 73,000 yen to treat one patient for UTI69. Calculating the estimated healthcare cost savings using the closed system urinary catheter would be as follows:

  3,482,000 (patients) x 73,000 yen x 10% x 23% = 5,846,278,000 yen

  10%: The rate of UTI of hospitalized patients
  23%: The reduction rate of UTIs by use of closed system urinary catheter

Section VI: Infection Control in Home Healthcare

As described in its policy for Comprehensive Reform of Social Security and Taxes, the Government of Japan, it light of its super-aging population, aims by 2025 to establish an effective and efficient medical and care services system through 'differentiation and strengthening of, and cooperation between, hospitals ' and by establishing an 'integrated community care system'.

The general concept behind 'the integrated community care system' is to improve in-home medical care and smooth cooperation between medical care and long-term care. To achieve this vision a seamless coordination, as well as paradigm shift, between healthcare institutions and the community, and between medical care and long-term care will be necessary.

Within the revisions of the medical service fees adopted in fiscal 2012, 'improved regional cooperation between medical and long-term care, and improved home healthcare' was prioritized. In addition, a budget of 150 billion yen was allocated to advance home medical care.

As the medical setting in the future will shift from healthcare institutions to home healthcare, out-patient, or long-term care, infection control must also shift focus to not only prevent existing nosocomial infection, but consider prevention measures toward a wider spectrum of healthcare-associated infections (HAIs).

For nosocomial infection control measures within the revised medical fee for fiscal 2012, a modification was made to the additional fee for infection control by placing it under a separate rating system from the existing medical safety measures additional fee. Furthermore, the additional fee for infection control 1 may be added from the first day of the in-hospital stay through the community infection control measures additional fee scheme, with consideration that a linkage is established between the healthcare institutions, reflecting the continuous strengthening of infection control measures. On the other hand, although there is recognition of the importance of infection control measures in settings such as out-patient treatment, post- hospitalization, home healthcare and home nursing care, consideration as to how best to address these are just at an early stage.

It is noteworthy that a revision was made to the 'long-term care insurance' in fiscal 2012. The category of 'oral function and maintenance' was newly established, with a provision of an additional long-term care fee in recognition that proper oral care was effective in the prevention and treatment of aspiration pneumonia. From the viewpoint of infection control, this is an important policy measure. Future health care

will shift from institution-centric, to the home, where patients will be able to receive the required medical and care in a familiar environment with a peace of mind. Thus it will become vital to strengthen infection control measures in home care settings.

1. Infections in the Home Healthcare Setting

Among infectious diseases that occur in the home care settings are; aspiration pneumonia, bed sores, urinary tract infections, which can occur in high frequency, and lead to become serious health issues for the elderly, or for those who are immunocompromised. In addition, the following afflictions can frequently attach patients who are receiving home healthcare; scabies, superficial mycosis, candidiasis, influenza, herpes, gum disease, such as; gingivitis and periodontitis, chlamydia, conjunctiva inflammation, and legionella infection. Although there is no detailed study, statistics show that elderly patients admitted to the hospital within one year reflect that roughly half (48.9%) suffered from respiratory infection; including pneumonia and bronchitis. Those suffering from urinary tract infection accounted for 33.8%, a significantly high number. [70]

A report shows that three major bacteria; pneumococcal, hemophilus influenza, and Moraxella catarrhalis, are largely responsible for community-acquired pneumonia among the elderly[71]. Further analysis of these patients revealed they were confined to bed in a home care setting and aspiration was largely related to pneumonia. The pneumococcal organism was the bacteria most frequently found to be the cause. Another report indicates that in comparison to patients who require minimum care, there is a higher rate of isolation frequency due to the infection of pseudomonad aeruginosa or methicillin-resistant Staphylococcus aureus (MRSA)[72]. A large majority of home care elderly patients have a history of hospitalization, close observation and precautions against MRSA and multiple-drug-resistant pathogens (MDRP) should be taken at home settings as well.

MRSA

It is known that patients released from the hospital, returning home and professional healthcare workers can be colonized with MRSA a particularly prevalent hospital acquired infection (HAI), but show no sign of clinical infection for an extended period of time[73]. Health-acquired (HA-MRSA) exists within the general environment. There is a study which notes that the majority of MRSA discovered within the community, or general public environment, is HA-MRSA[74]. However, recently a report has shown that HA-MRSA low-risk individuals, who have no record of hospitalization or out-patient treatment, are infected by different strain of MRSA[75]. This particularly MRSA is referred to as community-acquired MRSA or CA-MRSA[76]. In Japan, of 818 children in nursery and kindergarten, 35 children (4.3%) were reported to be carrying MRSA,

evidence that MRSA colonization is not restricted to the healthcare setting.[77]

Multi-drug resistant pseudomonas aeruginosa (MDRP)
MDRP is a nosocomial infection which occurs at a number of healthcare institutions, however there are no reports of the infection being found in communities. However, pseudomonad aeruginosa can remain on the hands of healthcare workers, urine tract catheters, and the surrounding environment of patients such as; the sink area. When colonization occurs, it is resistant and extremely difficult to eliminate. Thus, strategies to increase and monitor adherence are important components of MDRP control.

2. Infection control and medical device use in home settings

Although at a home setting, patients and their care providers will expect the same quality of treatment; in both method and technique, as in an institutional healthcare setting. To effectively advance home healthcare, in addition to the integrated community care system, there will be a necessity to properly prepare the care environment, as well as the utilization of medical devices which deliver necessary medical treatment.

Medical devices in home healthcare vary in function and complexity. Syringes, portable perfusion pumps, automated peritoneal perfusion equipment, dialysis liquid supply equipment, oxygen enrichers; are a few examples of devices that can be found in a home healthcare setting. Medical devices require a level of proper maintenance and management. The people who use these devices may be the care recipient themselves, a family member, or a lay care provider. It is important that there is initial training, education and instructions provided by a healthcare institution.

Home healthcare involves, and is supported by numerous service providers; such as medical care professionals, health and welfare, as well as the patient and his family, or care providers. Consequently, infection control must be observed not only within the home environment, but within the integrated community, respective healthcare facilities, as well. Daily maintenance and management of medical devices should be made by the care recipient themselves or by a care provider, family member. In addition, a periodical routine maintenance and inspection of the device should be undertaken by the manufacturer or rental company to further ensure safety.

Dialysis of hemodialytic home care patients

According to a report which surveyed 18 cases of individuals who were receiving their hemodialytic treatment in home settings, revealed a variation in the level of cleanliness in the room where dialysis was conducted. Dialysis equipment, a medical device, is managed by a biomedical equipment technician and a manufacturer, thus there is no risk directly related to the home setting environment. Furthermore, through guidance, training provided by healthcare institutions on the blood vessel needling techniques, and management of dialysis devices, safety is ensured. As a result, among the surveyed 18 cases, there were no incidents of infection from the needle site. [78]

3. Current environment and challenges of infection control in home healthcare

A survey was conducted to better understand the current environment of infection control within home healthcare settings. Home-visit nursing stations were interviewed on their respective infection control measures, as well as the overall environment of home healthcare. Of those interviewed, 65.3% responded that they possess a place to consult for infection and infection control measures. Further inquiry revealed that only 53.2% conducted a pre-nursing examination for the presence of MRSA. This survey results reflect that the level of environment infection awareness is inadequate where aspiration and treatment is conducted with a catheter retained in the bladder. In conclusion, the author of this report noted that there is a necessity to establish a system to share information and develop nursing guidelines and procedures to be followed in home care settings, as well as emphasizing the importance of containing MRSA infection, for it was found that information sharing was insufficient among medical institutions, and home-nursing operators. [79]

4. Recommendations for infection prevention in home healthcare

- Establish a policy which enhances the understanding of home healthcare, thus providing the patient and family members with a peace of mind.

- The importance of collaboration with not only healthcare workers, but also related occupations regarding organizational infection control measures in which an integrated community approaches can be established and executed.

- Prepare guidelines for infection control in the home setting. Vaccinations to prevent infection among high-risk patients and those who come in direct contact with high-risk home care patients. Infection control education for the patient, family members and nursing service providers.

- Medical devices for use at home settings, appropriate maintenance and routine inspections should be made to prevent infections. Unlike inspections at a healthcare institution, periodical inspections conducted at a residence represents a significant financial burden, an introduction of a new medical fee can be applied toward this residential medical device inspection.

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※1 PICC の低い感染率（海外）【エビデンスレベル I】;
『血管内留置カテーテルに関連する感染予防のCDCガイドライン』（2002）A）の中で、PICCは従来のCVCと比較してカテーテル関連血流感染（Catheter Related Blood Stream Infection；CR-BSI）の発生率が低いとされており、Crnichら（2002）のメタ・アナリシス（エビデンスレベルI）B）で、カテーテル1,000日留置あたりのCR-BSI発生件数は、非トンネル型CVC（コーティングなし）が2.3であったのに対して、PICCは0.4であり統計学的に有意に低いことが報告されている。

※2 逆流防止機能付きPICCの低い感染率（国内）【エビデンスレベルⅢ】;
森兼ら（2009）C）によると、カテーテル1,000日留置当たりのCRBSI発生件数は、逆流防止機能付きPICCで5.6、非トンネル型CVCで7.0であり逆流防止機能付きPICCの方が低い傾向が見られ、CR-BSIの因子についてロジスティック回帰分析を行ったところ、カテーテルが逆流防止機能付きPICCであることはCR-BSI発生リスクを有意に低下させる（オッズ比0.55、p＝0.019）因子であることが報告されている（100本あたりの感染率に換算するとCVC17.8%、PICC9.8%。である）。

※3 PICCの挿入時の安全性：【エビデンスレベルI～Ⅲ】
McGeeら（2003）によると、鎖骨下、内頚、大腿静脈からCVCを挿入する際、1回の手技につきおよそ10%程度の挿入時合併症（動脈穿刺、血腫、気胸、血胸など）が発生しているとされる（エビデンスレベルI）D）。また英国NHS（2002）によると、気胸が放置されることによってCVC挿入3,000件に1件の死亡が発生するという概算があるE）。これを受けて医療安全全国共同行動企画委員会は「中心静脈カテーテルの穿刺挿入手技に伴う有害事象とこれに起因する死亡を防ぐ」ためのHow to guide (ver.2)（2008） F）の中で、10%もの合併症が解消されるのであれば、安全性の向上だけでなく、合併症に対する医療費の削減、医師－患者信頼関係悪化の回避などの点も含め、総合的な医療の質の向上が期待されるとし、鎖骨下静脈や内頚静脈からの穿刺を極力避け、安全性の高い上腕静脈等からの穿刺を推奨している。PICCでは理論の上では勿論のこと臨床の現場においても挿入時に重篤な合併症はほとんど発生せず極めて安全なカテーテルである。実際、森兼らの多施設共同研究3）においても逆流防止機能付きPICCの挿入時に重篤な合併症は報告されていない。

※4 逆流防止機能付きPICCの低い閉塞率と簡便な管理【エビデンスレベルⅢ】;
Hinson（1996）らのCost Savings Clinical Report（エビデンスレベルⅢ）G）によると、逆流防止機能付きPICCは、一般型PICCと比較してカテーテルの閉塞率が低く、閉塞に伴う薬剤の使用やカテーテルの入れ替えの頻度が少ないことからカテーテルの維持・管理に係る費用を削減することが示されている。また、カテーテル未使用時であってもヘパリ
ンロック不要であることから、逆流防止機能付き PICC は間欠的な薬剤投与が必要な癌化学療法等に適したカテーテルであり、院内だけでなく在宅でも安全に安心して輸液治療が行えるものである。

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