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BIO-TERRORISM COUNTERACTION USING OZONE AND HYDROGEN PEROXIDE

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Applicant(s): MEDIZONE INTERNAT INC [US] + (MEDIZONE INTERNATIONAL INC)

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Abstract of corresponding document: WO2011085466 (A1)

A process and a system using a disinfecting atmosphere for deactivating Bacillus bacteria and its spores, such as Bacillus anthracis (anthrax) and C Botulinum and its spores, commonly proposed as bioterrorism threats, are described. Said disinfecting atmosphere includes ozone at a concentration of 2-350 ppm by weight and hydrogen peroxide at an amount of 0.2 -10 weight percent at a relative humidity of at least 60%.

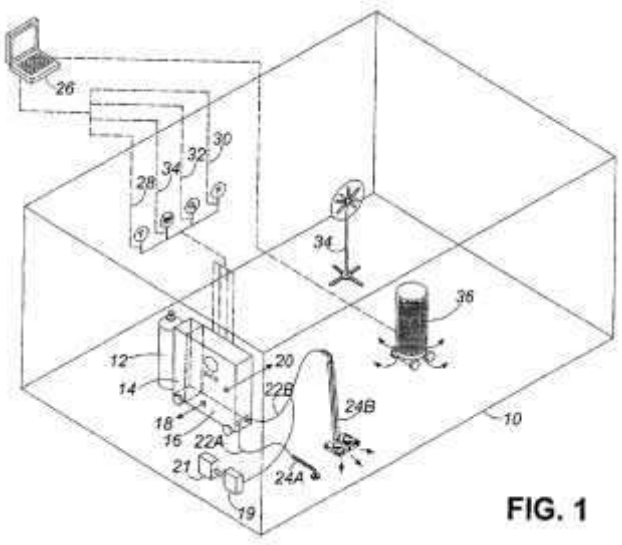

FIG. 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
90607-3	11/14/16

Term of Issuance:
Conditional

Name of Pesticide Product:
AsepticSure™ Oxidative Catalyst

Name and Address of Registrant (include ZIP Code):

Medizone International, Inc.
4000 Bridgeway, Suite 401
Saulsalito, CA 94965

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	**Date:**
Julie Chao, Product Manager 33 Regulatory Management Branch 1, Antimicrobials Division (7510P)	11/14/16

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCI identified below:

    a. Hydrogen Peroxide GDCI-000595-1127

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division.

3. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 90607-3."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/24/2016

If you have any questions, please contact Seiichi Murasaki at (703) 347-0163 or murasaki.seiichi@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Accepted Label

{MASTER LABEL}
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}
{All text in braces {xxx} is administrative communication & will not appear on a printed label.}

AsepticSure™ Oxidative Catalyst

For Industrial and Institutional Use Only - Not for Food Contact or Household Use

AsepticSure™ Oxidative Catalyst is only for use in conjunction with the AsepticSure™ Ozone Generator™ fogging system.

AsepticSure™ Oxidative Catalyst is for use in hospitals, clinics, food industry, sporting venues, and hotels to disinfect hard non-porous surfaces.

Active Ingredients:

Hydrogen Peroxide 6%
Other Ingredients 94%
Total 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See [side] [back] panels for additional precautionary statements]

FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies, call the poison control center 1-800-222-1222. You may also contact Chemtrec at 800-424-9300 for emergency medical treatment information	

EPA Reg. No. 90607- G
EPA Estab. No. 909607-CAN-001
NET CONTENTS: _____ fl oz (_____ L)

ACCEPTED
Nov 14, 2016
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 90607-3

{MASTER LABEL}
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}
{All text in braces {xxx} is administrative communication & will not appear on a printed label.}

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if inhaled. Avoid contact with eyes or clothing. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

[Extended contact with this product may cause a temporary white appearance on the skin of some individuals. Bubbling or foaming may also occur upon contact with dry or damaged skin. These are normal effects from hydrogen peroxide and the white appearance should disappear quickly. To minimize these effects, rinse or wash hands promptly after contact.] [If extended contact with the product results in a temporary white appearance of the skin, or if foaming appears on dry or damaged skin, it is a common reaction to the hydrogen peroxide and will disappear quickly. To minimize the effect, rinse hands after using the product.]

PERSONAL PROTECTIVE EQUIPMENT (PPE):

For early re-entry for the AsepticSure™ Ozone Generator fogging system, the following PPE must be worn:

- Protective eyewear such as goggles, face shield or safety glasses
- R95 Respirator with Activated Charcoal Filter, Powered Air Purifying Respirator or equivalent
- Gloves and a hydrogen peroxide resistant body suit (such as a Tyvek protective suit)

Final selection of additional PPE must be in accordance with hospital site guidelines and take into consideration the product and any infection or exposure hazards related to the environment to be disinfected.

PHYSICAL AND CHEMICAL HAZARDS

This product is incompatible with strong oxidizing and reducing agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labelling. Refer to Users' Manual for complete product use directions.

The surface area to be treated must be cleaned thoroughly prior to treatment

AsepticSure™ Oxidative Catalyst is only to be used in conjunction with the AsepticSure™ system to disinfect hard non-porous surfaces in hospitals, health care facilities, clinics, food industry equipment, sporting venues, and hotels.

Preparation of End-Use Product: AsepticSure™ Oxidative Catalyst is added to the AsepticSure™ fogging system and is combined with ozone produced by the ozone generator. When mixed together, they create an end use vapor containing approximately 80 ppm ozone and 1.4% hydrogen peroxide.

To prepare the AsepticSure™ system, pour 2.7 L of distilled water and 816 mls of AsepticSure™ Oxidative catalyst into the identified reservoir on the AsepticSure™ fogging system. Note that the quantity of hydrogen peroxide added is in excess of the amount typically used in a single treatment. Starting the AsepticSure™ system will automatically facilitate the mixing of the hydrogen peroxide with the ozone. The system will create and dispense the hydrogen peroxide/ozone mixture and upon completion of the treatment will automatically engage the

{MASTER LABEL}
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}
{All text in braces {xxx} is administrative communication & will not appear on a printed label.}
purge cycle to return the room environment to safe ozone levels thereby permitting personnel to re-enter the room.

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

Treatment Overview

Once the AsepticSure™ system has been placed in the room and connected electrically, the room is sealed, the HVAC Systems are shut off to the room, and entry is restricted to authorized personnel only. The AsepticSure™ system is accessed remotely and the disinfection treatment cycle initiated. The duration of the total disinfection process is dependent upon the necessary time to meet the required treatment parameters and can vary with room size ranging from 15 to 90 minutes. The treatment portion of the cycle is standardized at 40 minutes. Upon completion of the cycle, the AsepticSure™ system will draw air from the room through a set of charcoal air purifiers to remove the residual ozone and hydrogen peroxide vapor. Once the ozone level has been reduced to 0.04 ppm the system will indicate the room is safe for re-entry. Allow an additional 10 minutes after ozone levels of 0.04 ppm have been reached before re-entering the treated area.

Re-entry to the treated area is prohibited before hydrogen peroxide levels reach 0.2 ppm.

OSHA guidelines (2015) for ozone in the workplace:

- 0.2 ppm for no more than 2 hours exposure
- 0.1 ppm for 8 hours per day exposure doing light work
- 0.08 ppm for 8 hours per day exposure doing moderate work
- 0.05 ppm for 8 hours per day exposure doing heavy work

In all applications, always use a new solution to ensure effectiveness. Do not reuse solutions and always dispose of product according to local, state or federal law.

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Product should be stored in original container. Never return product to the original container once removed. Store in a dry place no lower in temperature than 50° F or higher than 120° F. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available or puncture and dispose of in a sanitary landfill or by incineration.

{MASTER LABEL}
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}
{All text in braces {xxx} is administrative communication & will not appear on a printed label.}
For more information see Material Safety Data Sheet
AsepticSure™ Oxidative Catalyst is a trademark of Medizone International

Medizone International
401- 4000 Bridgeway
Saulsalito, CA 94965

{MASTER LABEL}
{All text in brackets [xxx] is optional & may or may not be included on a printed label.}
{All text in braces {xxx} is administrative communication & will not appear on a printed label.}
{Small Container Label, if needed}

AsepticSure™ Oxidative Catalyst

For Industrial and Institutional Use Only - Not for Food Contact or Household Use

AsepticSure™ Oxidative Catalyst is only for use in conjunction with the AsepticSure™ Ozone Generator™ fogging system.

AsepticSure™ Oxidative Catalyst is intended for use in hospitals, clinics, food industry, sporting venues, and hotels to disinfect hard non-porous surfaces.

Active Ingredients:

Hydrogen Peroxide	6%
Other Ingredients	94%
Total	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read complete directions and precautions in the accompanying booklet and manual

Medizone International
401- 4000 Bridgeway
Saulsalito, CA 94965

EPA Reg. No. 90607-G
EPA Estab. No. 909607-CAN-001
NET CONTENTS: _____ fl oz (_____ L)

(Device Label)
EPA Reg. # 90607 G

AsepticSure Ozone Generator™ fogging system

For Industrial and Institutional Use Only - Not for Household Use

AsepticSure Ozone Generator™ fogging system is only for use in conjunction with the AsepticSure Oxidative Catalyst.

AsepticSure Ozone Generator™ fogging system is for use in hospitals, clinics, food industry, sporting venues, and hotels to disinfect hard non-porous surfaces.

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read complete directions and precautions in the accompanying booklet and manual

Medizone International, Inc.
4000 Bridgeway, Suite 401
Sausalito, CA 94965

EPA Establishment No.: _____
EPA Reg. # 90607-G

User Manual
Operator Instructions

AsepticSure™ Disinfection System (ADS)

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(International) +1 415-331-0303

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AsepticSure™ is a trademark of Medizone International Inc.

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Chapter

1

Introduction

User Manual Information

This manual describes the safety precautions, function, features and methods of use and care for the AsepticSure™ Disinfection System to be referred to as the AsepticSure™ herein. The AsepticSure™ consists of the Aseptic Sure Primary Station, Remote Station (laptop), and three (3) ozone destructors. Each Disinfection Cycle requires the addition of a consumable Disinfection Catalyst. For additional optional accessories, see **System Description** in **Chapter 2 *Getting Started***.

Please review this manual entirely before using the system.

Note: For accessories for your AsepticSure™ Disinfection System, please contact your sales representative.

The graphics, figures, and images used in this operator manual are examples only. The actual display and design of these may be slightly different on your system.

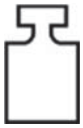
How to use this User Manual

Only trained personnel should operate AsepticSure™ Disinfection System. All personnel should review this manual in its entirety before using the system.

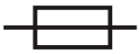
Important notes, warnings, or cautions are *italicized* and segregated from the body of the text. If the warning or caution is safety-related or could result in significant damage if it is not heeded, an additional warning/caution symbol will be displayed in the margin to further alert the reader.

Use of Symbols

Table 1: Packaging and Safety Symbols

Safety Notice	Meaning
 DANGER	A red **DANGER** symbol is used to identify conditions or actions for which a specific hazard is known to exist. These conditions or actions will cause severe personal injury, death or substantial property damage if the instructions are not followed.
 WARNING	An orange **WARNING** symbol is used to identify conditions or actions for which a specific hazard is known to exist. These conditions or actions may cause severe personal injury or substantial property damage if the instructions are not followed.
 CAUTION	A yellow **CAUTION** symbol is used to identify conditions or actions for which a potential hazard may exist. These conditions or actions may cause minor personal injury or property damage if the instructions are not followed.
	Attention: Consult accompanying documents.
	Symbol for Electrostatic Discharge (ESD) sensitivity
	Mass indicates the total weight of the equipment.
	Consult operating instructions before using.

Safety Notice	Meaning
	Indicates the Manufacturer of the device.
	Indicates safety certification.
	Temperature Limitation indicates the range of acceptable temperature conditions for shipping and storage.
	Indicates a potential pinch hazard
	The crossed out wheeled bin symbol is used to mark products that should not be disposed with general household waste, but collected separately for reuse or recycling. No part of the system shall be disposed of in land fill. Return the device to Medizone International Inc. for disposal.
	The batteries and/or battery containing product conform to EU Directive 2006/66/EC. The batteries must be disposed of appropriately and should be separated from the normal municipal waste stream and land fill.
	Single-use only. Do not re-use.

Safety Notice	Meaning
	Non-ionizing electromagnetic radiation
	Service or repair
	Reference number
	Manufactured date
	Serial number
	Fuse rating

Safety

The following are general warning statements pertaining to the user of the AsepticSure™ Disinfection System.

Table 2: General Warnings

Safety Notice	Meaning
 **DANGER**	All personnel using the system must be instructed in the proper set-up and handling of the system and should be familiar with this User Manual.
	Before starting a Disinfection Cycle, the room or environment must be fully sealed. If the room is not sealed, ozone could be exhausted into the ambient environment at levels hazardous to health.
	When conducting a cycle, immediately abort the cycle if ozone can be smelled or otherwise detected.

Safety Notice	Meaning
	If at any time you suspect that there is ozone in the room at levels above acceptable limits when not running a disinfection cycle, use the ozone detector provided to confirm. If the levels are above 0.05 ppm, evacuate immediately and contact the authorized service representative.
	Ensure that prior to performing an AsepticSure™ Disinfection Cycle, the appropriate Primary Stations are selected via the Remote Station. Selecting the wrong Primary Stations could result in injury or damage.
 **WARNING**	Before using the AsepticSure™ Disinfection System, visually inspect it to ensure there is no external damage. Do not operate the AsepticSure™ Disinfection System if there is any visible or suspected damage.
	Do not install any other software on the Remote Station. Do not reconfigure the Remote Station in any way (e.g. enabling the screen saver, sound, brightness, etc.).
	When running an AsepticSure™ Disinfection Cycle, no other applications should be running on the Remote Station
	Ozone can be corrosive. Repeated use of the AsepticSure™ Disinfection System can over time cause minor corrosive damage to ozone-sensitive materials or equipment. Ensure where possible that all such materials are removed from the environment before beginning an AsepticSure™ Disinfection Cycle (see Table 3).
	The AsepticSure™ Disinfection Catalyst contains low concentrations of hydrogen peroxide. As a precaution, ensure that all hydrogen peroxide-sensitive materials or equipment are removed, where possible from the environment before beginning an AsepticSure™ Disinfection Cycle (see Table 4).

Safety Notice	Meaning
	The AsepticSure™ Disinfection Cycle humidifies the room. If necessary, ensure that all humidity-sensitive materials or equipment are removed from the environment before beginning an AsepticSure™ Disinfection Cycle.
	Any modifications made to the system that are not authorized by Medizone International Inc. may void the product warranty and impact the safety of the system.
	Service personnel must have specialized training to ensure the safe operating condition of the AsepticSure™ Disinfection System. To ensure continuing safe and effective functioning of the system, only properly trained and qualified personnel are authorized to service any components of this system.
	If required, suitable Biological Indicators may be used to verify the disinfection cycle. Contact Medizone International or its authorized distributor for the appropriate indicator to use.
 **CAUTION:**	When conducting a cycle, ensure that all vents on the AsepticSure™ Disinfection System are free of obstruction and located with appropriate clearance from walls or other equipment. Obstruction of the vents may significantly impact system performance.
	The AsepticSure™ Primary Station needs to be plugged into a wall outlet. Extension cords not approved for use with the system shall not be used with the AsepticSure™ system.
	No other equipment may be powered on the same circuit as the Primary Station; ensure all other equipment is unplugged or powered off.
	The three (3) ozone destruct stations and dehumidifier (not provided) should be plugged into the appropriate receptacles on the Primary Station. Not plugging in the ozone destruct stations or the dehumidifier into the Primary Station will result in longer-than-expected Disinfection Cycles and may reduce the effectiveness of the Disinfection Cycle.

Safety Notice	Meaning
	Ensure that the wheels of the AsepticSure™ Primary Station and ozone destruct stations are locked before beginning a disinfection cycle or when storing the system
	Ensure that the AsepticSure™ Disinfection Catalyst that is used for the Disinfection Cycle has not surpassed its expiry date. Using expired Disinfection Catalyst may impair the effectiveness of the Disinfection Cycle.
	Do not transport the AsepticSure™ Primary Station with any liquid (such as Disinfection Catalyst) inside. Always empty the unit of all fluids prior to transport.
	In and around the RF operation range of the system (see the **"**Specifications**"** ***section)***, only one (1) AsepticSure™ Remote Station can be running at a time. Failure to do so may cause RF interference when running a disinfection cycle.

Classification

The AsepticSure™ Disinfection System has been evaluated to comply with IEC 61010-1.

Incident Reporting

The operator should contact a service representative immediately to report an incident and/or injury to any individual that occurred as a result of operation of the AsepticSure™ Disinfection System.

If an accident occurs as a result of use of the AsepticSure™, do not operate the equipment until an investigation by authorized personnel has been conducted.

Additional Precautions

The AsepticSure™ Disinfection System should not be stacked on other equipment or AsepticSure™ Disinfection Systems.

Additional Precautions (EMC)

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.

- The AsepticSure™ Disinfection System complies with IEC 61326-1.

Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the AsepticSure™ Disinfection System. Evidence of disruption may include distortion of the display, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption.

To avoid the risk of increased electromagnetic emissions or decreased immunity, use only accessories and peripherals recommended by Medizone International Inc. Connection of accessories and peripherals not recommended by Medizone could result in malfunctioning of the AsepticSure™ Disinfection System or other medical electrical devices in the area.

Contact Medizone or Medizone authorized representative for a list of accessories and peripherals available from or recommended by Medizone.

Additional Precautions (ESD)

Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. Static shock is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to the AsepticSure™ Disinfection System or its accessories.

The following precautions can help reduce ESD:

- anti-static spray on carpets
- anti-static spray on linoleum
- anti-static mats

AsepticSure™ Service

The AsepticSure™ Disinfection System can only be serviced by a trained representative.

If your system has been ordered from Medizone International Inc., please use the following contact information:

Phone: (North America) 1-415-331-0303 or (International) +1 415-331-0303

Email: operations@medizoneint.com

Address: Medizone International Inc.
2330 Marinship Way, Suite 300
Sausalito, CA
94965

Medizone International, Inc.
2330 Marinship Way, Suite 300
Sausalito, CA
94965

Phone: (North America) 1-415-331-0303
(International) +1 415-331-0303

www.medizoneint.com

Chapter

2

Getting Started

Guidelines for Use

The AsepticSure™ Disinfection System is a disinfection system that delivers a proprietary dosage profile of ozone and hydrogen peroxide to a manually-sealed environment. The disinfection takes place via a discrete cycle of approximately 2 hours that is user-initiated and is remotely controlled and monitored in real-time.

DANGER: Before initiating the cycle, the user must ensure that the room is sealed "air-tight". If the room is not sealed, ozone may be exhausted into the ambient environment at levels hazardous to health.

WARNING: Because the gas formula is highly oxidative, care must be taken that the room to be disinfected be appropriate and compatible. Any sensitive equipment that may be adversely affected by ozone or hydrogen peroxide should be removed from the room prior to the start of a disinfection cycle.

WARNING: AsepticSure™ Disinfection System must be continuously monitored by the operator during a cycle.

Prior to each disinfection cycle, the proprietary Disinfection Catalyst must be poured into the system and the ozone destruct stations must be plugged into their appropriate receptacles.

If the humidity level of the room to be disinfected is greater than 40%, a dehumidifier (not provided) must be plugged into its appropriate receptacle.

CAUTION: Failure to pour the Disinfection Catalyst into the system may impair the effectiveness of the Disinfection Cycle.

At the completion of a Disinfection Cycle, the AsepticSure™ monitors the conditions of the environment in order to ensure that the room is safe for re-entry.

Indications for Use/Contraindications

Indications for Use

The AsepticSure™ Disinfection System is intended for the disinfection of exposed surfaces within an enclosed space including whole rooms and facilities. The system has been designed to deliver multiple disinfections as determined necessary by facility management.

DANGER: Do not use AsepticSure™ for anything other than its intended use.

Contraindications and Material Compatibility

WARNING: Ozone can be corrosive and is poisonous in high quantities. Hydrogen peroxide at high concentrations can be corrosive.

Ozone:

The operator should be aware of the following material compatibilities with ozone and hydrogen peroxide and should ensure that equipment that is comprised of incompatible materials is either removed from the environment to be disinfected or appropriately protected. The list in the table below, although extensive, is not exhaustive. If the ozone compatibility properties of a material or equipment are unknown, it is recommended to remove the material or equipment from the room prior to disinfection.

Table 3: Ozone Compatible Materials

Material	Rating*
ABS plastic	B – Good
Acetal (Delrin®)	C – Fair
Aluminum	B – Good
Brass	B – Good
Bronze	B – Good
Buna-N (Nitrile)	D – Severe Effect
Butyl	A – Excellent
Cast iron	C – Fair
Chemraz	A – Excellent
Copper	B – Good

Material	Rating*
CPVC	A – Excellent
Durachlor-51	A – Excellent
Durlon 9000	A – Excellent
EPDM	A – Excellent up to 100°F
EPR	A – Excellent
Epoxy	N/A
Ethylene-Propylene	A – Excellent
Flexelene	A – Excellent
Fluorosilicone	A – Excellent
Galvanized Steel	In water (C – Fair), In Air (A – Excellent)
Glass	A – Excellent
Hastelloy-C®	A – Excellent
HDPE	A – Excellent
Hypalon®	C – Fair
Hytrel®	C – Fair
Inconel	A – Excellent
Kalrez	A – Excellent up to 100°F
Kel-F® (PCTFE)	A – Excellent
LDPE	B – Good
Magnesium	D – Poor
Monel	C – Fair
Natural rubber	D – Severe Effect
Neoprene	C – Fair
NORYL®	N/A
Nylon	D – Severe Effect
PEEK	A – Excellent

Material	Rating*
Polyacrylate	B – Good
Polyamide (PA)	C-D (Not recommended)
Polycarbonate	A – Excellent
Polyethylene	In Water (B-Good), In Air (C-Fair)
Polypropylene	C – Fair
Polysulfide	B – Good
Polyurethane, Millable	A – Excellent
PPS (Ryton®)	N/A
PTFE (Teflon®)	A – Excellent
PVC	B – Good
PVDF (Kynar®)	A – Excellent
Santoprene	A – Excellent
Silicone	A – Excellent
Stainless steel (304)	B – Good/excellent
Stainless steel (316)	A – Excellent
Steel (Mild, HSLA)	D – Poor
Teflon	A – Excellent
Titanium	A – Excellent
Tygon®	B – Good
Vamac	A – Excellent
Viton ®	A – Excellent
Zinc	D – Poor

***Ratings Legend:**
A – Excellent = No effect
B – Good = Minor effect, slight corrosion or discoloration
C – Fair = Moderate effect, not recommended for continuous use. Softening, loss of strength, swelling may occur.
D – Severe Effect = Not recommended for **ANY** use.

Hydrogen Peroxide:
The list in the table below, although extensive, is not exhaustive. If the hydrogen peroxide compatibility properties of a material or equipment are unknown, it is recommended to remove the material or equipment from the room prior to disinfection.

Table 4: Hydrogen Peroxide compatibility

Material	Effects of exposure to Hydrogen Peroxide
Metals:	
Aluminum 5251/H22 (unprotected)	Discoloration and signs of oxidation; avoid use
Aluminum alloy (niploy coated)	No apparent effect
Aluminum bronze	No apparent effect
Anodized aluminum	No apparent effect
Brass	Slight discoloration
Copper	Slight discoloration
Mild Steel	Rusting and shallow pitting; not suitable
Stainless Steel	No apparent effect
Coated/painted metals:	
Brush painted mild steel	Severe blistering of painted surface; not suitable
Epoxy painted mild steel	No apparent effect
Galvanized steel	No apparent effect
Passivated (coated) metal materials	Slight discoloration
Passivated steel	Slight discoloration
Polyester powder coated aluminum	No apparent effect
Stove enamel painted mild steel	Some bubbling or flaking from repeated cycles
Plastics, rubbers, etc.:	
ABS	No apparent effect

Material	Effects of exposure to Hydrogen Peroxide
Acrovyn	No apparent effect
Glass-reinforced Plastic	No apparent effect; recommend careful consideration in application as it is porous
Machinable Nylube	Some color bleaching observed
Natural rubber	Decomposes when exposed to hydrogen peroxide
Neoprene	No apparent effect
Perspex	No apparent effect; some out gassing observed
Polypropylene	No apparent effect; effects of long term exposure unknown
Polythene	No apparent effect, should not be used for long term exposure; readily absorbs hydrogen peroxide
PTFE	No apparent effect
PVC and PVC foam	No apparent effect; out gassing experienced
Silicone rubber (seal)	No apparent effect
Torlon	No apparent effect
Viton	No apparent effect
Component	**Effects of exposure to Hydrogen Peroxide**
Smoke alarm	No apparent effect
Computer system with monitor	Suitable
Linear bearing	Some discoloration of lubricant
Double-glazed window and aluminum frame	No apparent effect
Rubber floor tiles	No apparent effect
Ceramic tiles	No apparent effect
Desmopan (timing drive belt)	Slight discoloration

System Description

The AsepticSure™ Disinfection System can be configured with various accessories, as appropriate for the particular environment and application.

In areas where the environmental humidity is high, an optional dehumidifier (not provided) may be incorporated with the AsepticSure™ by plugging it into the appropriate receptacle on the Primary Station.

CAUTION: Failure to plug the dehumidifier into the appropriate receptacle on the Primary Station may impair the effectiveness of the Disinfection Cycle.

Three (3) ozone destruct stations expedite the removal of ozone from the room after completion of a disinfection cycle. In order to function appropriately, the ozone destruct stations must be plugged into the appropriate receptacles on each AsepticSure™ Primary Station. Also, for larger spaces that have sufficient power available, multiple AsepticSure™ Primary Stations can be connected, controlled by one Remote Station, for increased output. Each Primary Station would have three (3) ozone destruct stations plugged into them.

The AsepticSure™ Disinfection System consists of the following components:

- AsepticSure™ Primary Station
- Three (3) ozone destruct stations
- AsepticSure™ Remote Station (portable laptop)
- Disinfection Catalyst (consumable, new catalyst used for each cycle)
- Ozone detector/Ozone sniffer
- Laptop lock
- Room sealing tape (available from Medizone)
- Warning Sign

Where appropriate, the following accessories may be incorporated into the AsepticSure™ Disinfection System:

- Dehumidifier (plugged into the Primary Station)
- Biological Indicators

General System Function and Components

AsepticSure™ Primary Station

Figure 1 illustrates the AsepticSure™ Disinfection System and components.

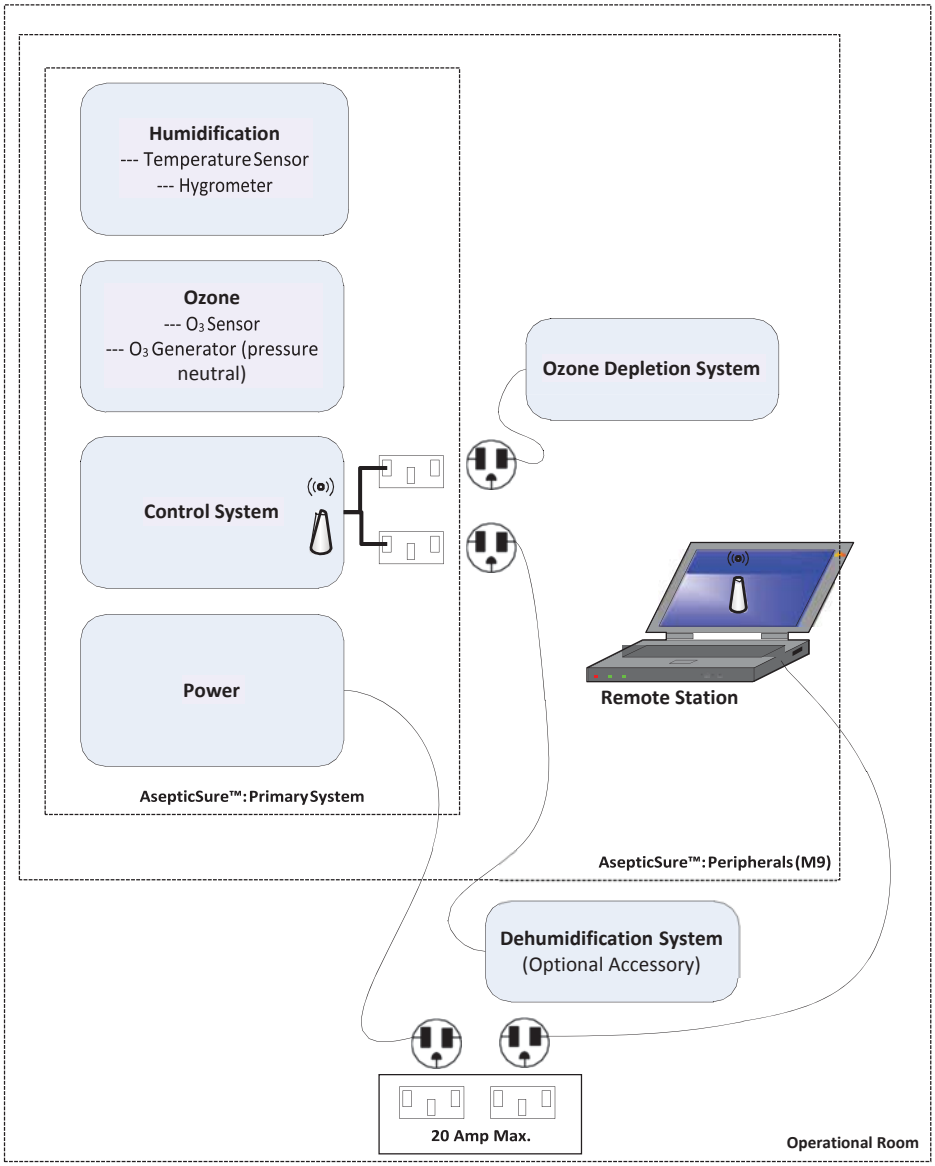


Figure 1: AsepticSure™ Disinfection System and Components

The AsepticSure™ Primary Station delivers the dosage of ozone and Disinfection Catalyst into the environment, controlled and monitored remotely via the Remote Station.

Multiple AsepticSure™ Primary Stations can be used within the same environment, controlled and monitored remotely via Remote Station.

Each AsepticSure™ Primary Station has a unique identifier (to ensure the appropriate control and protection against inappropriate usage).

The AsepticSure™ Primary Station is comprised of ozone generators that use UV to generate the appropriate level of ozone. Intake vents underneath the AsepticSure™ Primary Station chassis provide ambient air into the ozone generators.

The Primary Station also contains a reservoir into which the user pours the AsepticSure™ Disinfection Catalyst. After each disinfection cycle, the reservoir must be emptied. Before starting a Disinfection Cycle, the Primary Station must be refilled with new Disinfection Catalyst. During the Disinfection Cycle, the Primary Station emits the appropriate level of Disinfection Catalyst into the environment.

Primary Station

The Primary Station has four (4) receptacles into which the three (3) ozone destruct stations must be plugged in (in order to be appropriately controlled via the Remote Station). The fourth receptacle is used for the dehumidifier

There is also a Graphical User Interface on the AsepticSure™ Primary Station that is used to place the device into “Standby”, begin an automated self-test diagnostic, place the Station into “Ready” mode, and display any pertinent device information.

Remote Station (portable laptop)

The Remote Station is used to initiate, execute, and, if needed, abort the Disinfection Cycles of the Primary Station(s), in real-time. It is also used to continually monitor the dosage profile to verify that the cycle remains within specification. If the cycle goes outside of specification, the remote station automatically aborts the cycle and begins the Purge stage to bring the ozone level within the room down to safe levels.

At any time, the user can choose to abort the cycle.

If, at any time, the communication between the Remote Station and the Primary Station is lost, cannot occur or is otherwise severed, the cycle will automatically abort.

When the dehumidifier is attached to the Primary Station, it is also controlled by the Remote Station through Primary Station.

Ozone Destruct Stations

Three (3) ozone destruct stations must be plugged into each AsepticSure™ Primary Station in order to facilitate clearing ozone from the environment after the completion of a disinfection cycle or in the event that the cycle is aborted.

Ozone breaks down naturally in the environment, however, the ozone destruct stations significantly reduce the wait time after disinfection to allow reentry into the room.

The location of where the ozone destruct stations are situated will impact the amount of time it takes to reduce the room to safe ozone levels

CAUTION: Do not move the ozone destruct stations to a different location while they are plugged into the Primary Station. Always ensure that they are unplugged before moving.

Dehumidifier (not provided)

A dehumidifier can be attached to the AsepticSure™ system in order to provide pre-conditioning to bring humidity levels to optimal conditions prior to starting the Disinfection Cycle.

The dehumidifier must be plugged into the appropriate outlet on the AsepticSure™ Primary Station in order to be controlled by the Remote Station.

CAUTION: Do not move the dehumidifier to a different location while they are plugged into the Primary Station. Always ensure that they are unplugged before moving.

AsepticSure™ Disinfection Catalyst

The Disinfection Catalyst is single-use only with an expiry date.

If, at the conclusion of a disinfection cycle, there is Disinfection Catalyst remaining in the reservoir, it should be drained and properly disposed.

Before every Disinfection Cycle, the catalyst reservoir must be verified to be empty and then filled with the appropriate amount of Disinfection Catalyst.

The Disinfection Catalyst is a proprietary solution that is required to ensure effective disinfection. Prior to pouring the Disinfection Catalyst into the Catalyst Reservoir of the AsepticSure™ Primary Station, ensure that its expiry date has not been surpassed.

Biological Indicators

Optional Biological Indicators (BI's) may be provided with the AsepticSure™ Disinfection System.

The BI's can be placed within the environment prior to a disinfection cycle and after completion of the cycle, can be used to verify that the disinfection was effective.

Room-Sealing Tape

Room sealing tape is available from Medizone International Inc. Prior to the initiation of a disinfection cycle, the room to be disinfected **must** be sealed to prevent egress of harmful ozone into the ambient environment.

In addition, all Heating Ventilation and Air Conditioning (HVAC) vents and all potential gas leak points must also be sealed off.

Warning Sign

When performing a Disinfection Cycle, the Warning Sign should be prominently displayed on or in front of the door of the room being disinfected. This is to ensure that the room is not inadvertently entered while a Disinfection Cycle is in progress and prevent hazards to health or the environment.

Ozone Detector/Sniffer

Medizone provides an ozone detector to be used to verify that the ozone levels in the vicinity are at a safe level.

For instructions on how to operate the ozone detector, consult the provided manufacturer's instructions.

Using the AsepticSure™ Software

The following describes how to navigate the AsepticSure™ software.

Commands:
To make a selection, drag your mouse pointer over the selection which will highlight it
To advance to the next screen (and accept the selection), click on the Green right arrowhead.
To return to the previous screen, click the Green left arrowhead

A user may abort the cycle at any time (except the Purge stage) during the process by pressing the "Abort" button at the bottom of the screen and following the instructions.

Available AsepticSure™ Software Application Modes

There are three (3) main applications of the Software:

- ***AsepticSure™ Disinfection Cycle**** – this launches the process for disinfecting a room
- ***AsepticSure™ Service**** – this is an application for advanced users where parameters can be customized and real-time parameter values can be graphically displayed in real time for any specific or all Primary Stations.
- ***AsepticSure™ Administration***

AsepticSure™ Disinfection Cycle and Administration are discussed in the next sections. For AsepticSure™ Service, see the *Service Manual*.

* The AsepticSure™ will automatically generate and save a data log for each Disinfection Cycle. There is a default folder location for all generated data logs. However, the user will be prompted at the start of each cycle, if they would like to select (or create) a different folder. The data log is saved via the following filename convention: <*yyyy-mm-dd-***T***hh-mm-ss*.xls> which corresponds to the timestamp at which the Cycle is started (where "**T**" is not variable)

Chapter

3

System Installation

System Installation

AsepticSure™ Primary Station

Unless otherwise indicated, the installation of the device needs to be done by Medizone personnel or a Medizone authorized representative.

Remote Station

The Remote Station will already be provided appropriately configured. Do not alter the configurations in any way or the effectiveness of the AsepticSure™ Disinfection System may be impaired.

For example:

- DO NOT increase the screen brightness
- DO NOT disable screen-saver
- DO NOT configure Remote Station to go into sleep mode
- DO NOT disable the audio capability (as some information is transmitted sonically to the user
- DO NOT install any other applications onto the Remote Station

Chapter

4

AsepticSure™ Disinfection Cycle

Description of Disinfection Cycle

The AsepticSure™ system is designed such that the primary systems are controlled remotely via a Remote Station (laptop) that externally communicates.

Up to four (4) AsepticSure™ primary stations can be controlled simultaneously to disinfect the same environment. The Remote Station monitors the overall environmental conditions (humidity and ozone level) as well as the individual AsepticSure™ Primary Station's performance in order to ensure that an effective and safe disinfection takes place.

Additionally, a dehumidifier can also be attached to the Primary Stations in order to optimize delivery of the oxidative gas formula controlled by the Remote Station.

In order to disinfect a room or environment, the user performs the following steps.

The user first prepares the room for disinfection by removing any items that could be adversely affected by the disinfection cycle, see **Chapter 2 *Getting Started***. The user then positions the desired number of Primary Stations within the room and "readies" them by placing them into "Standby". The user would then turn on the Remote Station, select the stations, verify that appropriate communication can take place with the selected Primary Station(s), and seal the room. Outside of the room, the user will plug in the Remote Station and initiate the Disinfection Cycle from the Remote Station.

Upon completion of the disinfection, the system will automatically begin the clearance of the oxidative gas and notify the user when the room is safe to re-enter (and that the disinfection cycle has been successful).

The disinfection cycle is separated into the following discrete phases:

- Room preparation and set up
- Cycle preparation (configuration of AsepticSure™ system(s))

- Disinfection Cycle
- Purge and Clearance of the room to acceptable ozone levels

Room Preparation & Set Up

The AsepticSure™ Disinfection Cycle consists of delivery of a proprietary oxidative gas formula.

The following table summarizes clinical applications where the AsepticSure™ Disinfection System **should not** be used.

Table 5: Applications where the AsepticSure™ should not be used

Do Not Use the AsepticSure™ for the following applications:
Rooms containing equipment, components, or materials that are not compatible with ozone, hydrogen peroxide, or humidity (which cannot be removed from the room or otherwise protected.)
Rooms containing equipment, components, or materials that are used in high-risk, life support, patient or safety-critical applications where the equipment, components, or materials are not compatible with ozone, hydrogen peroxide, or humidity.
Rooms containing equipment, components, or materials whose compatibility with ozone, hydrogen peroxide, or humidity is not known.

The room to be disinfected should be cleared of all patient-critical, safety-critical, ozone-sensitive, hydrogen peroxide-sensitive or humidity-sensitive equipment, material or components, in accordance with the table above. Surfaces to be treated must be thoroughly cleaned in accordance with the standard institutional cleaning protocol prior to treatment.

Prior to initiation of the Disinfection Cycle, the room must also be fully sealed (including all vents in the Heating Ventilation and Air Conditioning system) in order to ensure that ozone does not exhaust to the environment, resulting in hazards

Minimize the path for ozone gas penetration (e.g. open drawers and closet doors and leave open, etc.) in order to maximize the AsepticSure's™ disinfection effectiveness.

Determine the approximate size of the room to be disinfected.

Determine the number of Primary Stations to be used. To help determine the number of Primary Stations to employ, refer to **"**Specifications**"** ***section***, and take note of the total electrical load required.

Position the Primary Station(s) in the desired location(s) and the locking mechanism on the wheels to prevent inadvertent motion of the Stations. The Primary Station(s) should be placed in the approximate center of the room, away from any potential impediments to both airflow toward the Station intake vent and ozone exhaust from the Station. When more than one Primary Station is used, subdivide the room into approximately equivalent sections and place each Station within the approximate center of each of these subdivisions, ensuring that the airflow both toward and away from each Station will not be impeded.

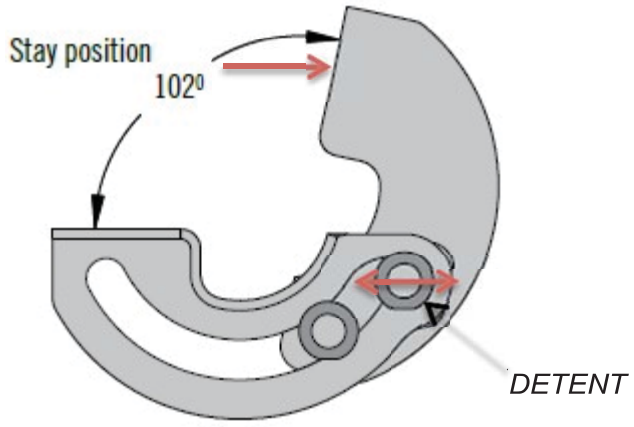
CAUTION: Placing the Primary Station(s) in an inappropriate location (for example, in the corner of the room with the ozone exhaust pointing toward the wall) may result in ineffective disinfection.

WARNING: Failure to lock the wheels could result in potential injury or damage.

Plug in the ozone destruct stations into the appropriate Primary Stations and place them in the appropriate location(s). Lock the wheels on the ozone destruct stations. Subdivide the room into approximately equivalent sections and place each ozone destruct station within the approximate center of each of these subdivisions.

NOTE: Placing the Ozone Destruct Stations in an inappropriate location may cause the reduction of the ozone levels in the room to take longer than expected.

NOTE: Take caution when opening the humidifier filler door. The hinge has a detent that holds the filler door in an open position. To place the door in the open position, open the door fully and then bring it slightly forward. To release the door from the detent, gently push the door in the open direction and then push the door downward to close.



Cycle Preparation (and configuration of AsepticSure™ station(s))

When the AsepticSure™ Primary Station is powered on, it automatically performs a self-test diagnostic. The diagnostic verifies the functionality of:

- The ozone destruct
- The ozone sensor
- The humidity sensor

NOTE: The self-test of ozone sensor also checks for the ozone level of the room. The detection of ozone level too high will also be report as a self-test failure of ozone sensor.

Service and preventive maintenance by trained Medizone service personnel is required. Refer to *Service Manual*.

If maintenance is required, please contact service.

DANGER: In the event that ozone is detected at a level above the safe limit, immediately leave the room and contact service.

When running the diagnostic, the system determines whether a dehumidifier should be incorporated. The effectiveness of the Disinfection Cycle is affected by starting humidity levels above 40%

Cycle Preparation (AsepticSure™ Primary Station)

1. Ensure the catalyst reservoir is empty.
2. Ensure the AsepticSure™ Primary Station passes self-test.
3. Pour in the appropriate amount of Disinfection Catalyst in the catalyst reservoir.

NOTE: Ensure that the expiry date has not been surpassed. If Disinfection Catalyst is used that has surpassed its expiry date, the effectiveness of the Disinfection Cycle may be impaired.

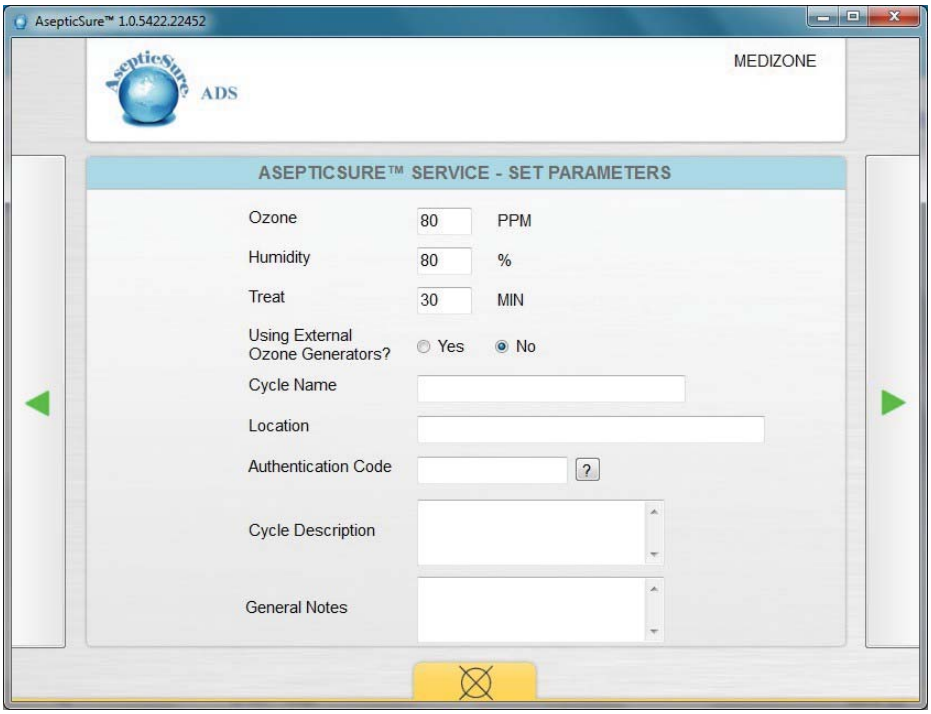
4. Connect to the AsepticSure network on the Remote Station.
5. Turn on the Remote Station and launch the AsepticSure™ application.

Cycle Preparation (Remote Station)

6. At the Splash Screen, enter your ID and password.

7. Select *AsepticSure™ Disinfection Cycle* from the offered available modes to be run.

8. Set parameters and input any pertinent information (eg. Cycle name and location)



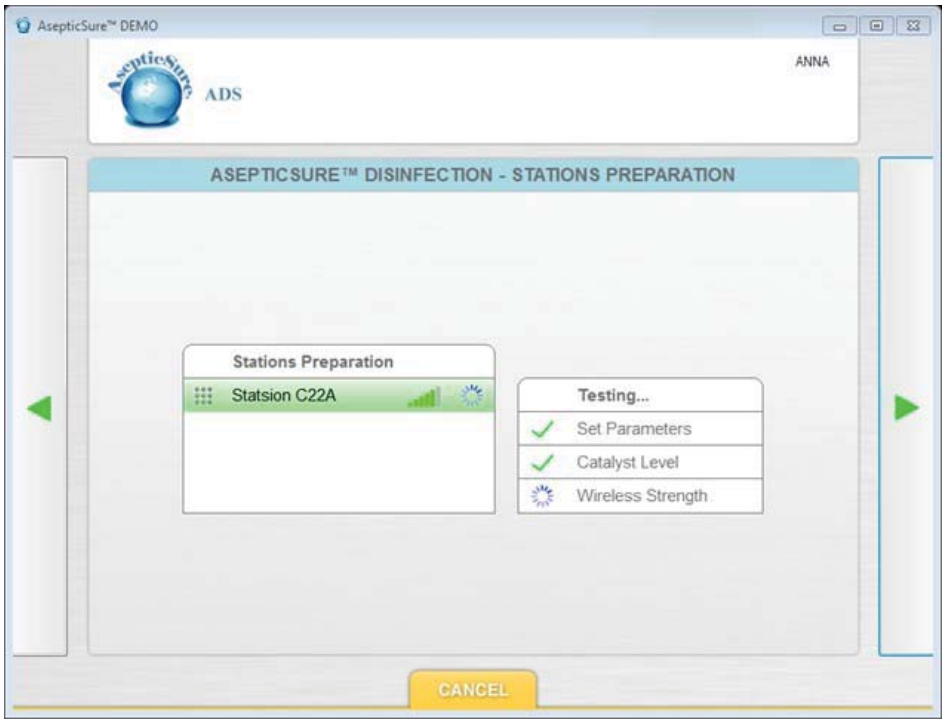
Disinfection Cycle

To prepare the AsepticSure™ system, pour 2.7 L of distilled water and 816 mls of AsepticSure™ Oxidative catalyst into the identified reservoir on the AsepticSure™ fogging system.

9. Place the AsepticSure™ Primary Station into “Waiting for connection” state from the Primary Station GUI. When there are more than one (1) stations, assign the sequence (1-4) of the Primary Stations from “Waiting for connection” screen. Press the refresh “ ” button in the Select Stations screen on the Remote Station and the Remote Station automatically displays the unique ID(s)of all available stations within communication range and in the “Ready” mode.
10. Select the desired Station(s) to be used for the Disinfection Cycle.

WARNING: Ensure that the IDs of the selected stations match the IDs of the stations in the room. If the wrong station is selected, it is possible that a station in a different room may be selected and emit ozone in an environment that is not AsepticSure-ready. It is recommended that the ID of the station be verified by physically viewing the ID on the station (within the room).

11. After the user selects the stations to be used for the cycle, the Remote Station automatically checks the signal strength between the selected AsepticSure™ Stations and the Remote Station.



NOTE: In order to accurately determine the expected signal strength, proceed to where the Remote Station will likely be physically located for the duration of the Disinfection Cycle.

12. The system will automatically check the relative humidity of the room and may suggest to the user to attach the dehumidifier. If applicable, plug the dehumidifier(s) into the Primary Station dehumidifier receptacle and place the dehumidifier(s) in the appropriate location(s) within the room. Turn the dehumidifier and set it to a humidity level less than 40%.
13. Place the dehumidifier in the approximate center of the room. If more than one dehumidifier is used, subdivide the room into approximately equivalent sections and place each dehumidifier within the approximate center of each of these subdivisions.

NOTE: Placing the dehumidifier(s) in an inappropriate location may cause the Pre-Conditioning stage to take longer than expected.

14. If desired, place the optional Biological Indicators at appropriate places within the room.
15. Ensure that the room is **fully sealed**.

DANGER: ozone is poisonous and corrosive, the room, including all HVAC openings, must be fully sealed. Failure to fully seal the room may result in personnel and other environments being exposed to hazardous levels of ozone.

16. The Remote Station will then prompt the User to:
    - Confirm that the Disinfection Catalyst was added.
    - Confirm that the Room is sealed.
    - Confirm that the remote station has been plugged into the wall before starting the Disinfection Cycle.

NOTE: As a safety precaution, if the communication between the Remote Station and any of the Primary Stations is lost for 150 seconds, the cycle will automatically abort (and the ozone destruct will come on to clear the ozone in the room to safe levels). If the laptop is not plugged in, the battery in the Remote Station may fully deplete during the Disinfection Cycle, causing the cycle to abort.

WARNING: If it is not clear whether or not the room is safe for re-entry (e.g the Remote Station is unable to display information about ozone levels in the room), do not enter room and contact the authorized service representative.

17. Launch the Disinfection Cycle on the Remote Station.

18. Prominently display the Warning Sign on or in front of the door.

NOTE: Do not close the Remote Station (laptop) screen during a Disinfection Cycle as this will result in the laptop losing communication with the Primary Stations and aborting the Cycle. A laptop lock is provided to secure the laptop when unsupervised.

19. The Remote Station controls/monitors the cycle, adjusting the quantities of ozone and hydrogen peroxide being emitted based on real-time feedback from the Primary Station(s).

NOTE: It is recommended to periodically use the ozone detector or ozone sniffer to determine if ozone levels outside of the room are at higher-than-expected levels. Consult the manufacturer's instructions for how to appropriately use the ozone detector.

Upon launch of the Disinfection Cycle, the software displays the Cycle Progress screen to communicate to the user what stage of the process the disinfection cycle currently is within.

There are four (4) stages of the Disinfection Cycle that are automatically controlled by the Remote Station once the cycle has been launched by the user:

- Pre-conditioning
- Conditioning
- Treat
- Purge

Both the elapsed time of the cycle and the estimated amount of time until completion of the cycle are displayed on the Remote Station to the user during all phases of the Disinfection Cycle.

20. Periodically monitor the progress of the Disinfection Cycle from the Remote Station.

The **Pre-conditioning** stage takes place when a dehumidifier has been incorporated into the AsepticSure™. If no dehumidifier is installed, the Pre-conditioning stage will be bypassed.

The system will automatically move to the Conditioning stage once the room has been brought to (optional) optimal environmental conditions or it is unable to bring the humidity to optimal within 40 minutes.

The **Conditioning** stage consists of delivering the proprietary oxidative gas formula until the required specification level is reached in the room.

If the Remote Station detects that the specification does not appear to be able to be reached within an expected time (120 minutes maximum), the cycle will automatically abort and inform the user.

The **Treat** stage consists of maintaining the proprietary oxidative gas formula at the appropriate levels for the appropriate duration.

If at any time, the required levels of ozone and humidity cannot be maintained or go below the specifications, the system will automatically abort and the **Purge** stage will automatically be launched.

Table 6: Conditions where Disinfection Cycle will abort (not exhaustive)

Conditions that can initiate an automatic abort (not exhaustive)
Communication is lost between the Remote Station and any AsepticSure™ Primary Stations
Relative Humidity specification cannot be maintained during Treat stage
Ozone specification cannot be maintained during Treat stage
Remote Station loses power during any stage of the Disinfection Cycle
A hardware failure is detected (of the hygrometer, thermometer, ozone sensor, etc.)
User-initiated abort (for example, if ozone is detected)

The **Purge** stage consists of reducing the ozone levels in the room to safe levels. Once safe levels have been reached, the system informs the user that it is now safe to enter. The Remote Station estimates how long it will take to clear the room to safe levels of ozone.

When the room has returned to safe ozone levels, the Remote Station communicates to the user that the Disinfection Cycle has been completed successfully.

21. Remove the sealing tape from the door and enter the room.
22. In the event, that Biological Indicators were used, verify that all of them confirm that the appropriate level of disinfection took place. Dispose of the BI's appropriately.

CAUTION: The BI's must be disposed of as biohazard material.

NOTE: The BI's are single-use only. They must not be re-used.

23. Dispose of any Disinfection Catalyst remaining in the catalyst reservoir by placing the drainage valve below the bottom level of the catalyst reservoir within a receptacle and opening the valve. Ensure that all of the residual catalyst drains out of the reservoir. It is recommended to use the empty container from the original Disinfection Catalyst container as the receptacle.
24. Dispose of the residual catalyst in accordance with the appropriate process.

Chapter

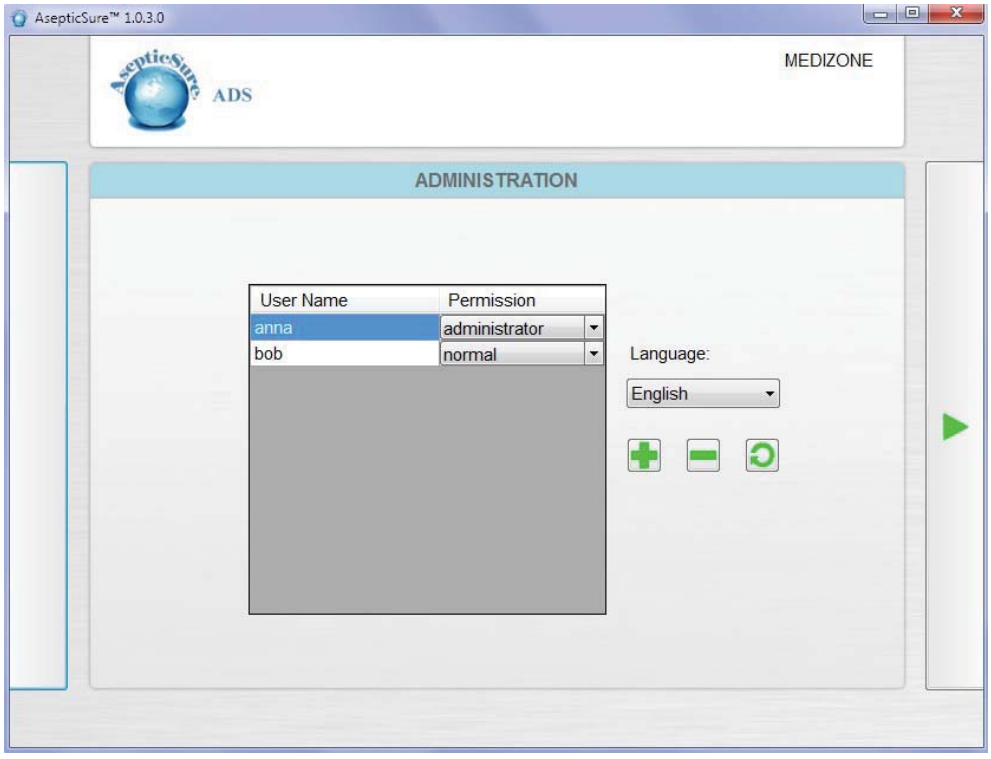
5

AsepticSure™ Administration

Description of the AsepticSure™ Administration function

The AsepticSure™ Administration function is used to

- Add a new user (“+”);
- Delete an existing user (“-”);
- Reset a user password ↻”);
- Change the permission level of a user



Chapter

6

Maintenance / Troubleshooting

Guidelines

In order to operate the AsepticSure™ system, training by Medizone International Inc. personnel is required.

Upon completion of this training, a User ID and password will be provided to the user.

Inspection (every usage)

Prior to every use, The AsepticSure™ systems should be inspected for mechanical damage or breakage.

DO NOT USE THE SYSTEM IF IT HAS OR APPEARS TO HAVE SUSTAINED OR IS SUSPECTED TO HAVE SUSTAINED ANY DAMAGE. Contact your service representative immediately.

Preventive Maintenance

The AsepticSure™ Disinfection System requires preventive maintenance as defined in Service Manual. Please contact your authorized service representative for any additional information.

Special Care Requirements

Cleaning

The cleaning solutions in the following list are recommended for cleaning the Primary Station. Use a cotton cloth to clean the system.

Cleaning solutions not in this list should not be used as they may damage the system. Please contact your service representative if approval of additional cleaning solutions is required.

Table 7: Approved Cleaning Solutions

Solution	Comments
Warm water	Safe for all outer surface areas.
Commercial dishwashing liquid/water combination	Safe for all outer surface areas.

Troubleshooting

This section provides troubleshooting suggestions to solve common problems. If you cannot resolve a problem after trying these solutions, contact your service representative to arrange for service or repairs to the system.

Table 8: Troubleshooting Common Problems

Problem	Possible Solution(s)
Can't find available Primary Station(s)	• Station has not been powered on • Station is not in "Standby" mode • The station is too far away from the Remote Station. • Verify the unique ID of the station. • Station is already being used.
After powering the Primary Station ON, it can't be placed into "Standby"	• Failed self-test diagnostic, identify issue or contact service representative
Can't log into AsepticSure™ application	• Wrong User ID and/or Password
Option to use AsepticSure™ Service or Administration mode not available	• User privileges do not allow access to those modes
Signal strength not high enough	• Move the Remote Station to a different area • If problem persists connect via Ethernet cable.
Disinfection Cycle aborts	• Communication is lost between the Remote Station and a Primary Station. • Battery power of Remote Station has depleted. • System is unable to maintain ozone concentration or humidity within specification

Problem	Possible Solution(s)
	o Dehumidifier might not be plugged into correct receptacle on Primary Station o Ozone destruct station(s) might not be plugged into correct receptacle on Primary Station o Primary Station is located in an inappropriate location o The room is not fully sealed o Not enough Primary Stations were employed for the specific room size. • A component on the Primary Station has failed (e.g. hygrometer, ozone sensor, etc.) • User has initiated an abort
Nothing is displayed on Remote Station screen	• Remote Station has gone into sleep mode • The battery of the Remote Station has fully depleted • Remote Station has been powered off

Chapter

7

Specifications

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

- The AsepticSure™ Disinfection System complies with IEC 61326-1. See Chapter 1 “Additional Precautions (EMC)” for further information.

Operating Conditions

The following tables outline the environmental conditions for which the operation of the AsepticSure™ Disinfection System has been qualified.

Table 9: Operating Conditions

	Minimum	Maximum
Ambient Temperature (°C)	+18	+24
Relative Humidity (non-condensing)	35%	90%

Table 10: Optimal Initial Conditions

	Initial Conditions
Relative Humidity (non-condensing)	≤ 40%

Note that the AsepticSure™ alters the environmental conditions of the room during the Disinfection process.

Storage and Transportation Conditions

The following tables outline the environmental conditions for transporting or storing the AsepticSure™ Disinfection System

Table 11: Transportation and Storage Environment

	Minimum	Maximum
Ambient Temperature (°C)	+5	+45
Relative Humidity (non-condensing)	25%	95%

Specifications

AsepticSure™ System Specifications:

- Voltage Input:
  - 120V,/20A configuration: 120Vac, 20A maximum
  - 120V/15A configuration: 120 Vac, 15A maximum
  - 240V configuration: 230Vac, 12A maximum
- RF: 902 MHz-928 MHz
- Distance of remote station to primary station: ≤90 feet, indoor.

Note that the distance specified to the primary station is under optimal conditions. This will vary depending on the indoor environment (obstructions, materials, etc.)

- Weight: approximately 250 lb

Typical Disinfection Cycle Profile:

For a room up to 64m^3 (or 2260 cu. ft.) and one (1) AsepticSure™ Disinfection System (120V/20A), a typical Disinfection Cycle profile is as follows:

Disinfection Cycle Stage	Duration
Pre-conditioning (if required)	No longer than 40 minutes
Conditioning	50 minutes
Treat	30 minutes
Purge	30 minutes

Chapter

8

Glossary

Definitions and Acronyms

The following are the definitions and acronyms used in this User Manual:

AsepticSure™	A trademark of Medizone International for its disinfection system using its proprietary oxidative gas formula.
The system	For the purpose of this document, “the system” refers to one complete and functional AsepticSure™ device
Requirements	for the purpose of this document, “requirements’ is defined as a set of functions and performances that the device must meet in order to satisfy its intended use, including the needs of the user and patient. Requirements are the design input of the device design.
Disinfection	the process of destroying pathogenic organisms or rendering them inert [note 1].
Disinfection Cycle	For the purpose of this document, disinfection “cycle” is defined as the duration which AsepticSure™ performs its disinfection function. It consists of the **Conditioning** stage, the **Treatment** stage, and the **Purge** stage.
Primary Station	For the purpose of this document, the ‘Primary Station’ is the principal component of the AsepticSure™ Disinfection System that will deliver the proprietary oxidative gas formula.
Peripherals	for the purpose of this document, `Peripherals` are components of the AsepticSure™ system that interact or communicate with the `Primary System`.

	These items are required components of the AsepticSure™ product, but are not integrated in the `Primary System
CISPR	**C**omité **I**nternationale **S**pécial des **P**erturbations **R**adioelectrotechnique (International Special Committee on Radio Interference)
PPM	unit, parts per million
RH	relative humidity
ESD	electrostatic discharge
EMC	electromagnetic compatibility
HVAC	Heating, Ventilation and Air Conditioning

Appendix

A

Forms

Note: Items noted on the forms are only available directly from Medizone International Inc.

Medizone International, Inc.
2330 Marinship Way, Suite 300
Sausalito, CA
94965
Phone: (North America) 1-415-331-0303
(International) +1 415-331-0303

www.medizoneint.com

AsepticSure™ Catalyst Order Form

The following number must appear on all related correspondence, shipping papers, and invoices:

P.O. NUMBER:

Purchaser:
Name:
Company:
Address:
City, State / Province:
Zip / Postal Code:
Phone:

Ship To:
Name:
Company:
Address:
City, State / Province:
Zip / Postal Code:
Phone:

P.O. DATE

QTY	Part Number	DESCRIPTION	UNIT PRICE	TOTAL
			SUBTOTAL	
			SALES TAX (GST in Canada)	
			SHIPPING & HANDLING	
			OTHER	
			TOTAL	

Send all correspondence to:

Authorized by Date

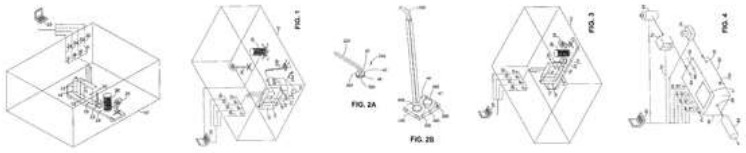
Patents

Food-handling facility disinfection treatment

Abstract

Food handling facilities such as meat packing, plants, dairies, kitchens and the like are disinfected using a disinfecting atmosphere which includes ozone and hydrogen peroxide, at a relative humidity of at least 60%.

Images (5)



Classifications

A61L2/202 Ozone

View 12 more classifications

US9616144B2

United States

Download PDF Find Prior Art Similar

Inventor: Michael Edward Shannon, Dick Eric Zoutman

Current Assignee : Steriliz3 Canada Inc , MEDIZONE INTERNATIONAL Inc

Worldwide applications

2011 US WO ~~CA~~

Application US13/821,483 events

2010-09-08	Priority to US38075810P
2011-09-08	Application filed by MEDIZONE INTERNATIONAL Inc
2013-06-27	Publication of US20130164385A1
2017-04-11	Publication of US9616144B2
2017-04-11	Application granted
Status	Active
2032-03-17	Adjusted expiration

Show all events

Info: Patent citations (24), Non-patent citations (25), Cited by (9), Legal events, Similar documents, Priority and Related Applications

External links: USPTO, USPTO Assignment, Espacenet, Global Dossier, Discuss

Claims (19)

Hide Dependent

What is claimed is:

1. A process of combating human-harmful, food poisoning-causing bacteria and spores thereof in an enclosed space and on surfaces within the space, consisting of:

exposing the bacteria in the space and on surfaces therein to a disinfecting atmosphere which includes ozone at an amount of 2-350 ppm by weight and hydrogen peroxide at an amount of 0.5-10 wt. %, at a relative humidity of at least 60%, and for a period of at least 30 minutes sufficient for an effective kill of the bacteria and spores;

wherein the amount of hydrogen peroxide is derived from a supply solution of 0.2%-10% hydrogen peroxide; and

subsequently removing ozone from the atmosphere, down to 0.04 ppm or less.

2. The process of claim 1 wherein the amount ozone in the disinfecting atmosphere is from 10-350 ppm.

3. The process of claim 2 wherein the amount ozone in the disinfecting atmosphere is from 20-200 ppm.

4. The process of claim 1 wherein the amount ozone in the disinfecting atmosphere is from 20-100 ppm.

5. The process of claim 2 wherein the amount ozone in the disinfecting atmosphere is from 35-100 ppm.

6. The process of claim 1, wherein the hydrogen peroxide amount in the disinfecting atmosphere is from 0.5-7%.

7. The process of claim 6, wherein the hydrogen peroxide amount in the disinfecting atmosphere is from 1-5%.

8. The process of claim 1, wherein the period of exposure is from about 30 minutes to about 120 minutes.

9. The process of claim 8, wherein the period of exposure is from about 60 minutes to about 105 minutes.

10. The process of claim 1, wherein exposing the bacteria in the space occurs while subjecting porous and fibrous surfaces within the space to physical agitation while exposed to the disinfecting atmosphere.

11. The process of claim 10 wherein the physical agitation is conducted with application of bristles.

12. The process of claim 10 wherein the physical agitation is conducted with application of air pressure jets.

13. The process of claim 10 wherein the physical agitation is conducted with application of ultrasonic energy, radio frequency energy or electromagnetic waves, capable of causing physical disruption.

14. The process of claim 1, wherein biofilm carrying surfaces are exposed to a localized stream of the disinfecting atmosphere.

15. The process of claim 14 wherein the localized stream is provided at a pressure of from 14.7 to 100 psi.

16. The process of claim 1, wherein the bacteria is a *Listeria* species.

17. The process of claim 16, wherein the *Listeria* species is *Listeria monocytogenes*.

18. The process of claim 1, wherein the bacteria is a *Salmonella* species.

19. The process of claim 18, wherein the *Salmonella* species is either *Salmonella typhimurium* or *Salmonella typhi*.

Description

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is the national stage under 35 U.S.C. §371 of International Patent Application No. PCT/CA2011/050544, filed Sep. 8, 2011, designating the United States, and published Mar. 15, 2012 as International Publication No. WO/2012/031366, which application claims priority to and the benefit of U.S. Patent Application Ser. No. 61/380,758 filed on Sep. 8, 2010. The disclosures of the above-identified applications are expressly incorporated herein by this reference in their entireties.

FIELD OF THE INVENTION

This invention relates to bacterial disinfection treatments for food handling premises such as food processing rooms, meat packing plants, food packaging rooms, kitchens and the like. More particularly, it relates to processes and systems for methods and systems for disinfecting food handling premises of human-harmful, food poisoning-causing bacteria including *Listeria* species bacteria such as *Listeria monocytogenes* and *Salmonella* species such a *S. typhium*, causative agents of food poisoning in humans and animals.

BACKGROUND OF THE INVENTION

Listeria is a genus of Gram-positive bacteria of the bacilli class. It contains six species, typified by *L. monocytogenes*, the causative agent of listeriosis, an uncommon but potentially lethal food-borne infection. *L. monocytogenes* is one of the most virulent food-borne pathogens. Listeriosis has been reported to be the leading cause of death among food-borne bacterial pathogens, responsible for about 2,500 illnesses and 500 deaths annually in the United States.

L. monocytogenes is commonly found in soil, stream water, sewage, plants and food. Vegetables can become contaminated with *L. monocytogenes* from the soil. Uncooked meats, unpasteurized milk, products made from unpasteurized milk such as certain cheeses, and processed foods commonly contain *Listeria*. Sufficient heating and cooking will kill *Listeria*, but contamination of food products can occur after cooking and before packaging. Meat processing plants, for example, producing ready-to-eat products such as deli meats and hot dogs, follow extensive sanitation policies to guard against *listeria* contamination.

Outbreaks of *Listeria* have reportedly been caused by hot dogs, deli meats, raw milk, soft-ripened cheeses, raw and cooked poultry, raw meats, ice cream, raw vegetables and raw and smoked fish. Pregnant women, the elderly and those with compromised immune systems are the most vulnerable patients. In its early stages *Listeria* infection is effectively treated with antibiotics such as ampicillin, ciprofloxacin and azithromycin, but it is commonly not recognized until a more advanced stage is reached. Prevention of such infections is accordingly of high importance.

Salmonella is a large genus of bacteria, many species of which can cause disease if ingested by humans. *Salmonella* bacteria infections are commonly termed "*Salmonellosis*" and are manifested by diarrhea, vomiting, fever and abdominal cramps (food poisoning). Among the human harmful *Salmonella* species are *S. enteridis* and its sub-species, *S. bongori* and *S. typhi*, the human pathogen of typhoid fever.

BRIEF REFERENCE TO THE PRIOR ART

Effective sanitation of food contact surfaces is necessary to prevent *listeria* or *salmonella* infection. At present, this is done using alcohol as a topical sanitizer. Quaternary ammonium salts are used in combination with alcohol with increased duration Oxidizing agents (chlorine dioxide, peroxides, ethylene oxide, sodium hypochlorite and the like) may be used to clean *Listerium*- or *Salmonella*-contaminated sites, but these are relatively slow-acting. Such clean-up is time-consuming and costly, since the food handling facility must remain out of commission for extended periods of time. Soft and porous fabric surfaces pose a particular problem, since they will harbor live *Listerium* or *Salmonella* bacteria and render them inaccessible to routine liquid or gaseous treatments. It is important that cleaning and sanitizing agents used in food treatment facilities leave no residues which might be harmful if ingested.

Vaporized hydrogen peroxide (VHP) is highly effective as a sanitizing agent when applied to smooth surfaces, but has little or no efficacy on porous materials and is of questionable value against thick biofilms of a nature more characteristic of a food preparation area. Moreover, VHP is very damaging to electronic devices that may be present in the food handling facility.

Once a porous, soft surface such as carpet, drapery, porous material in ceilings and the like becomes impregnated with bacteria, it cannot be effectively disinfected using currently available agents and processes.

Ozone is known to be a powerful anti-bacterial, anti-fungal and anti-viral agent. For over 100 years, it has been used for water purification. It is known to be effective against *Legionella Bacteria, E. coli* and *pseudomonas* populations in such plants.

Canadian Patent 2,491,781 Lynn, issued Jun. 9, 2009, discloses use of a high pressure water stream and a high pressure ozonized water stream for cleaning and sanitizing objects such as surfaces and poultry carcasses.

Canadian Patent 2,473,540 Gibson and Hobbs, issued Dec. 2, 2008, discloses a ventilation system including a duct containing an ultraviolet light source generating ozone in the air stream passing through the duct, the inlet to which is adjacent to a food cooking source, so that purified air is emitted from the cooking environment.

It is an object of the present invention to provide a novel and effective method of treating facilities and objects infected or prone to infection with human-harmful, food poisoning-causing bacteria.

SUMMARY OF THE INVENTION

The present invention provides, from one aspect, a process of combating human-harmful, food poisoning-causing bacteria in an enclosed space and on surfaces therein, which comprises exposing the bacteria in the space to a disinfecting atmosphere which includes ozone at a concentration of 2-350 ppm by weight and hydrogen peroxide at an amount of 0.2-10 wt. %, at a relative humidity of at least 60%, and for a period of at least 30 minutes sufficient for an effective kill of the bacteria; and subsequently removing ozone from the atmosphere, down to 0.04 ppm or less.

Another aspect of the invention provides a portable system for destroying human-harmful, food poisoning-causing bacteria, in rooms and on surfaces and equipment therein, comprising an ozone generator for discharging into the room a gaseous mixture including ozone; an ozone controller adapted to control the amount of discharged ozone; a source of hydrogen peroxide for discharging controlled amounts of hydrogen peroxide into the room; means for discharging the hydrogen peroxide and ozone into the room; humidity adjusting means adapted to increase or decrease the relative humidity of the room during treatment; and an ozone remover adapted to destroy ozone, down to a safe level in the room atmosphere for subsequent human utilization.

BRIEF REFERENCE TO THE DRAWINGS

FIG. 1 of the accompanying drawings is a diagrammatic illustration of an apparatus in accordance with an embodiment of the invention, disposed within a room to be disinfected;

FIGS. 2A and 2B are diagrammatic illustrations of physical agitation systems for use in embodiments of the invention;

FIG. 3 is a diagrammatic illustration of an apparatus according to the invention, in portable, transportation mode;

FIG. 4 is a diagrammatic illustration of a test apparatus used to generate some of the test results reported below;

THE PREFERRED EMBODIMENTS

Preferred ozone amounts for use in the invention are from about 10-350 parts per million in the disinfection atmosphere, more preferably 20-350, or 20-200, or 20-100, or 35-100, or even more preferably 20-90 parts per million in the oxygen/ozone gas mixture, and most preferably 35-80 ppm ozone. Preferred amounts of hydrogen peroxide are the amounts supplied to the disinfecting atmosphere using an aqueous solution containing 0.2-10%, more preferably 0.5-10%, or 0.5-7%, or 0.5-5%, or 1-5%, or 1-3% hydrogen peroxide. In the description below, the peroxide percentages used are sometimes expressed in terms of these solution percentages. The amounts are chosen so that no serious deleterious effects are suffered by other equipment in the treatment room to which the disinfecting atmosphere is supplied. The amount of hydrogen peroxide in the disinfecting atmosphere can be calculated from the volume of aqueous hydrogen peroxide evaporated into the disinfecting atmosphere, the volume of the room being disinfected and the concentration of hydrogen peroxide in the starting solution. Times of exposure of the room and its surface to the disinfecting atmosphere are suitably from 15 minutes to about 120 minutes, preferably from about 60 to about 105 minutes, and most preferably about 90 minutes. These times are constrained to some extent by the need to clear the room of ozone (down to a maximum of 0.04 ppm) following the disinfection phase, and return the room to normal use within a reasonable period of time, with the entire start-to-finish time not exceeding 150 minutes. The ozone removal is an extremely rapid and fully effective process. Both the hydrogen peroxide and the ozone (and any products of interaction between them) should be removed before the room is put back into normal use.

The preferred portable system for destroying human-harmful, food poisoning-causing bacteria according to the present invention includes, as part of its means for discharging the hydrogen peroxide and ozone into the room, a dislodgement system at the outlet end of the discharging means. The dislodgement system allows penetration of carpet, drape and similar porous surfaces in the room, to gain access to concealed/sequestered colonies of the bacteria, and to attack the bacteria protected by a biofilm formed on surfaces in the room and embedding the bacteria and spores therein. The dislodgement system can be manually operated, with operators protected by a hazard suit and mask, or remotely operated or totally automated. It may take the form of one or more outlet jets, with associated manually operable jet pressure controls. It may take the form of a revolving or fixed brush with bristles of appropriate stiffness, alone or in combination with an outlet jet. Any form of dislodgement system effective to disturb the pile of carpet fabrics, upholstery fabrics and the like so as to access the remote parts which might harbor anthrax spores or colonies can be used. This includes non-physical applications such as air jets, ultrasonic energy radio-frequency energy and electromagnetic waves, for example, capable of causing physical disruption and which result in micro-physical movements of fibrous surfaces.

The ozone for use in the present invention can be generated by any known means. In the case of corona or other electrical discharge generation from oxygen, the apparatus of the invention preferably includes a container of medical grade oxygen. The oxygen container can be a standard, pressurized vessel containing medical grade oxygen, of the type commonly found in medical facilities. Oxygen from this container is fed to an ozone generator, where the oxygen is subjected to electrical discharge, normally with high voltage alternating current, to convert small amounts of the oxygen to ozone and produce a gaseous mixture of oxygen and ozone. The quantity of ozone in the mixture is controllable by adjustment of the voltage of the electrical discharge. Suitable ozone generators are known and available commercially. The relative amounts of ozone generated are relatively small, expressed in parts per million (ppm), but such is the power of ozone as a disinfectant, especially in combination with hydrogen peroxide in accordance with this invention, that such small quantities thereof are all that is required.

Alternative forms of ozone generation can be used if preferred. Ultraviolet radiation of appropriate wavelength, incident upon oxygen or air, is one acceptable alternative. In such a system, air from the room itself may be fed into the ozone generating unit to supply the required oxygen for conversion to ozone. Other methods of ozone generation which can be used include photocatalytic reactions, cold plasma, etc.

The relative humidity of the disinfecting atmosphere in the treatment space should be at least 60% and preferably at least 65%, for effective disinfection. To ensure this, one can incorporate a humidifier in the system of the invention, using sterile water from an internal system reservoir to adjust and control the humidity of the issuing gas mixture. In this way, desirable humidity for most effective disinfection is achieved at the point of discharge where dislodgement of a carpet or drapery surface can take place. Since the adjustable humidifier need only increase the humidity of the space to the desirable level, however, it can be placed in any location within the space. In one embodiment, he hydrogen peroxide vapor is applied, in controlled amounts, to the air/water vapor issuing from the humidifier and thus added to the ozone/oxygen containing gas mixture. Alternatively, hydrogen peroxide can be applied to the water used to humidify the target location. Hydrogen peroxide is commercially available as aqueous solutions of standard concentrations of hydrogen peroxide. For use in embodiments of the present invention, a standard solution of known peroxide concentration is suitably diluted down by a fixed volume of distilled water. The peroxide load is standardized based on the known volume of water from the peroxide solution required to raise the relative humidity to the desired extent, e.g. from 40-80%. From this, the amount of hydrogen peroxide in volume % or ppm by volume introduced into the treatment facility can be calculated.

Certain systems according to embodiments of the invention may include a temperature adjuster and controller for the gas mixture. This can be a simple heater/cooler through which either the incident oxygen or the generated oxygen/ozone mixture passes prior to discharge into the room atmosphere. While simple adjustment of the temperature of the room using an external room heating system and thermostat can be effective, it is preferred to adjust the temperature of the issuing gas mixture, for most effective treatment of the carpet and drapery surfaces. The ideal range of temperature for ozone and ozone/hydrogen peroxide decontamination of *Listeria* is 15° C. to 30° C.

The system of the invention also preferably includes an ozone removal unit. Such units are known, and can be purchased commercially for use in the present invention. Depending on the volume of the room atmosphere and the capacity of the ozone removal unit, more than one such unit may be incorporated in the system of the invention. Suitable ozone removal units are those based on activated carbon as the removal medium. These act very quickly, and do not lead to the formation of hazardous reaction products. The inclusion of such units enables the treated facility to be cleared of ozone and returned to normal use rapidly, for economic reasons. Other types include systems based on catalysts such as manganese oxide or other metal oxides, which may be heated to remove moisture, thermal destruction in conjunction with other metals including platinum or palladium.

Human-harmful, food poisoning-causing bacteria to which the present invention is particularly suitable include *Listeria* species such as *Listeria monocytogenes*, and *Salmonella* species such as *S. typhium* and *S. enterides*.

FIG. 1 of the accompanying drawings shows a room **10** such as a room of a food processing facility liable to *Listeria* bacterial contamination and closed ready for disinfection by a process according to an embodiment of the invention. The room is substantially hermetically sealed. Inside the room is a pressurized cylinder **12** of oxygen, feeding oxygen gas into a humidifier **14** and thence to an ozone generator **16**, which includes electrical discharge plates of variable voltage to adjust the quantity of ozone which is generated. A heater and a pressure controller (not shown) may be disposed near the entrance to the ozone generator. Output of oxygen/ozone gas mixture is via room outlets **18**, **20** to the atmosphere of the room **10**, and via wands **22**A and/or **22**B to a dislodgement means in the form of scrubbing brushes **24**A and **24**B mounted on the outlet ends of the respective wands **22**A, **22**B. The heater, the pressure controller, the voltage supplied to the ozone generator **16** and the humidity level supplied by the humidifier **14** are all controlled and adjusted from an external control panel **26** via respective electrical connections **28**, **30**, **32** and **34**. Also disposed within the room is an oscillating fan **34** and an ozone destruct filter unit **36**.

Disposed within the room **10** is a container of aqueous hydrogen peroxide solution **19** and associated air blower **21** which, during operation, blows vaporized hydrogen peroxide in controlled amounts into discharge wand **22**A and **22**B to mix with the output of ozone/oxygen therein. The amount of hydrogen peroxide being supplied is controlled by adjustment of the blower **21** through a connection thereof to the control panel **26**. In an alternative arrangement, hydrogen peroxide can be supplied from generator **19** to the humidifier **14**.

FIGS. 2A and 2B of the accompanying drawings show in more detail forms of dislodgement means **24**A and **24**B for use in the present invention, attached to the outlet, discharge ends of respective wands **22**. The dislodgement means **24**A has a jet outlet nozzle **38**A at its extremity, and a generally circular plate **40** mounted on the wand **22**A near the discharge end. The wand **22**A passes through a central aperture **42** in a plate **40**. The plate **40** has brush bristles **46**A mounted on its lower surface, arranged in two arcs around the jet outlet nozzle **38**A and protruding downwardly to an extent just beyond the extent of outlet from nozzle **38**A. In use, oxygen/ozone gas mixture or oxygen/ozone/hydrogen peroxide gas mixture issues from nozzle **38**A at relatively high pressure, and can be directed by the operator holding the wand to a carpet surface area while at the same time the operator scrubs the carpet surface area with the bristles **46**A.

FIG. 2B shows an alternative but essentially similar arrangement, in which plate **40** is replaced by a wheeled platform **44** carrying two rotary brushes **46**B and three gas jet outlets **38**B for the oxygen/ozone/hydrogen peroxide delivery at pressure, located forwardly of the rotary brushes **46**B.

FIG. 3 of the accompanying drawings illustrates the portability of a system according to the invention. Parts are numbered as in FIG. 1. A 4-wheeled cart **48** is provided, on which all the component parts of the system can be loaded for ease of transportation from one room to another. The instrumentation and control panel can be disconnected for transportation, and re-connected and disposed outside when the apparatus is placed in another room for use as shown in FIG. 1. The cart **48** is removed while the system is in use, but is loaded with the components after use, either for transportation to another room or for storage.

The operation of the system will be readily apparent from the preceding description of its component parts and their inter-connection. The cart **48** carrying the component parts is wheeled into the room **10** to be disinfected, and the parts are distributed around the room and connected together as illustrated in FIG. 1. An operator wearing a hazard suit and other appropriate protective clothing enters the room and holds the wand **22**. The room is sealed. Conditions of treatment are set on the control panel **26**, and the apparatus is switched on so that oxygen/ozone/hydrogen peroxide gas mixture at controlled ozone concentration, hydrogen peroxide concentration, relative humidity, temperature and elevated pressure issues from jet nozzle **38**. The operator applies the jetted gas mixture to the carpet surfaces, drapery surfaces and other absorbent surfaces in the room, scrubbing the surfaces at the same time with the bristles **46**. The room becomes pressurized above atmospheric pressure, due to the introduction of the oxygen/ozone gas mixture. Pressure is continually monitored by the control panel **26** to ensure safe working conditions for the operator, as well as the temperature, humidity and ozone concentration in the room. Smooth surfaces in the room may not need the action of the dislodgement means, but are satisfactorily disinfected by contact with the disinfecting atmosphere in the room. The oscillating fan **34** is operated throughout the procedure, to circulate the oxygen/ozone mixture throughout the room.

After a pre-set time of the procedure, and after all the appropriate, absorbent surfaces have been scrubbed, a time not normally exceeding 90 minutes, the hydrogen peroxide supply, the oxygen supply and ozone generator are switched off. Then the ozone destruct filter **36** is operated, sucking in the ozone-containing gases, destroying the ozone and issuing pure oxygen from it. The room can now be opened, the apparatus disconnected and loaded on the cart **48**, and the room put back to its normal use.

EXPERIMENTAL EXAMPLES

Effective and optimum conditions for use in the present invention were determined using a laboratory apparatus as generally illustrated in FIG. 4 of the accompanying drawings.

A single pure colony of *Listerium monocytogenes* was inoculated to a Columbia agar plate with 5% sheep's blood. They were incubated at 35° C. in room air for 18-24 hours. From the plate, 4-5 isolated colonies were selected, and suspended in tryptic soy broth to achieve a 0.5 McFarland turbidity standard (1.5×10^8 cfu/ml) measured using a spectrophotometer. Inoculum was prepared by performing a series of serial dilutions of 0.9 ml 0.85 NaCl broth with 0.1 ml of original 0.5 McFarland inoculum (6×10 fold) to give solutions of 10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6} and 10^{-7} cfu/mL. Incubation of these serially diluted solutions and subsequent counting of the resulting viable colonies determines the dilution at which growth is eliminated, to be expressed as a log kill. Thus, if growth is eliminated at a three-fold (10^{-3} cfu/ml solution), this is a log **3** kill. This is standard procedure.

Organisms were plated out in triplicate, 0.1 ml of each solution being spread over the surface of Columbia sheep's blood agar plates. Two sets of 12 plates were subjected to ozone/oxygen exposure at preselected concentrations of ozone (ppm), humidity and temperature conditions in the illustrated apparatus. The other sets of 2 were treated as controls, with no ozone exposure, but kept at room temperature.

For ozone exposure, the apparatus generally illustrated in FIG. 4 was used.

The test plates were mounted inside a disinfection chamber **60**, the upstream end **62** of which had an ozone inlet port **64**, a hydrogen peroxide vapor inlet port **65** and a water vapor inlet port **66**. A cylinder **68** of pressurized medical grade oxygen was provided, feeding oxygen to an ozone generator **70**, equipped with alternating current electrical plates to which variable voltage could be supplied via input control **72**. The output of oxygen/ozone mixed gas from the ozone generator **70** was fed to the ozone inlet port **64** of the disinfection chamber **60**. A water vapor humidifier **74** supplied water vapor to inlet port **66**. The disinfection chamber **60** also contained a

heater/cooler (not shown), a temperature sensor **76**, a pressure sensor **78**, a humidity sensor **80** and an ozone sensor **82**, connected electrically via respective lines **84**, **86**, **88** and **90** to a control panel and monitor **92**, connected to feed back to the oxygen cylinder **68** to control flow for pressure adjustment purposes, to the ozone generator **70** to control and adjust the ozone quantity, to the water vapor humidifier **74** to control and adjust relative humidity in the disinfection chamber **60**, and to the heater/cooler to control and adjust the temperature in the chamber. These parameters were all pre-set on the control panel to desired values and automatically re-adjusted themselves to these values as the experiments progressed.

An ozone destruct filter **94** was connected to the downstream end **96** of the disinfection chamber **60** at outlet port **98**, to destroy ozone issuing from the chamber **60** at the end of the experiment. Gases were circulated within the chamber **60**, and expelled therefrom at the termination of the experiment, using a fan **100** mounted therein. After placing the test plates in the chamber **60**, it is sealed until the end of each experiment.

In a similar manner, test plates of *Salmonella typhium* were prepared, with the same serial dilutions, and exposed to ozone and hydrogen peroxide according to the invention

The control plates and the ozone treated plates were placed in an incubator at the same time. The plate counts were read through a microscope, and the numbers of colony forming units on each plate was counted.

Example 1

Table 1 below provides a summary of experiments, whereby combinations of ozone, H_2O_2, humidity and exposure time, at room temperature, were evaluated in terms of the ability to eliminate *Listerium monocytogenesis* and *Salmonella typhium* when artificially applied as a biofilm onto non-porous surfaces namely stainless steel discs. Columns A, B, C and D are the counts at the serial dilutions 10^{-1}, 10^{-2}, 10^{-3} and 10^{-4} respectively.

The steel discs for testing and the agar plates for testing were prepared, exposed and tested as described in the previous Example, in an apparatus generally as illustrated in FIG. 4, with exposure conditions shown in the Table 1 below.

TABLE 1

Run #	Organism	Ozone (PPM)		H202 (%)		EXP (min)		Humidity		Disc	A	B	C	D
Control	*Listeria*	0		0		0		0	1	TNTC	176		12	2
Control	*Listeria*	0		0		0		0	2	TNTC	123		17	1
Control	*Listeria*	0		0		0		0	3	TNTC	189		15	0
1	*Listeria*	80		1.0%		30		80	4	0	0		0	0
1	*Listeria*	80		1.0%		30		80	5	0	0		0	0
1	*Listeria*	80		1.0%		30		80	6	0	0		0	0
2	*Listeria*	80		1.0%		45		80	7	0	0		0	0
2	*Listeria*	80		1.0%		45		80	8	0	0		0	0
2	*Listeria*	80		1.0%		45		80	9	0	0		0	0
3	*Listeria*	80		1.0%		60		80	10	0	0		0	0
3	*Listeria*	80		1.0%		60		80	11	0	0		0	0
3	*Listeria*	80		1.0%		60		80	12	0	0		0	0
4	*Listeria*	80		1.5%		60		80	13	0	0		0	0
4	*Listeria*	80		1.5%		60		80	14	0	0		0	0
4	*Listeria*	80		1.5%		60		80	15	0	0		0	0
Control	*Salmonella*	0		0		0		0	1	TNTC	TNTC		112	26
Control	*Salmonella*	0		0		0		0	2	TNTC	TNTC		63	9
Control	*Salmonella*	0		0		0		0	3	TNTC	TNTC		77	4
1	*Salmonella*	80		1.0%		30		80	4	134	18		1	0
1	*Salmonella*	80		1.0%		30		80	5	161	13		0	0
1	*Salmonella*	80		1.0%		30		80	6	112	15		3	0
1	*Salmonella*	80		1.0%		60		80	4	3	0		0	0
1	*Salmonella*	80		1.0%		60		80	5	5	0		0	1
1	*Salmonella*	80		1.0%		60		80	6	1	0		0	0

Example 2

Another series of experiments was conducted with the same *Listeria monocytogenes* strain at room temperature, but deposited onto fibrous carpet samples instead of steel discs. The *Listeria* carrying carpet samples were suspended in a room as generally depicted in accompanying FIG. 1, and the ozone/hydrogen peroxide/water disinfecting atmosphere was blown at the carpet surface with a fan directed at the carpet, causing physical agitation of the fibrous carpet surface. The agar plates for testing were prepared as previously described. Serial dilutions of 10-fold, 100-fold, 1000-fold and 10,000-fold were effected and incubated. In duplicate runs using 80 ppm ozone, 1% hydrogen peroxide and 80% relative humidity, no viable colonies of *Listeria* were detected, at any of the dilutions, whereas control, unexposed but contaminated carpet samples had colonies too numerous to count.

Similarly, in duplicate runs with the same composition of atmosphere for a duration of 45 minutes, no viable colonies of *Listeria* were detected at any of the dilutions.

Example 3

A further set of experiments was conducted using *Listeria* and *Salmonella*, which produced results which demonstrate efficacy at both 60 ppm and 45 ppm ozone with 1% hydrogen peroxide and an exposure time of 30 minutes at room temperature. In these runs the bacteria were exposed within biofilms on stainless steel discs only. This was done to better mimic the type of material normally found in a government approved food preparation area, i.e. since one normally does not find fabrics in such spaces. Should fabrics be present however, preferentially 80 ppm of ozone for at least 30 minutes (depending on the type of carpet present) should be used to achieve a 100% kill.

TABLE 2

Run #	Organism	Ozone (PPM)	H202 (%)	EXP (min)	Hu-midity	A	B	C	D
Control	Listeria	0	0	0	0	TNTC	176	12	2
Control	Listeria	0	0	0	0	TNTC	123	17	1
Control	Listeria	0	0	0	0	TNTC	189	15	0
Control	Listeria	0	0	0	0	TNTC	135	5	0
Control	Listeria	0	0	0	0	TNTC	186	9	1
1	Listeria	30	1.0%	30	80	0	0	0	0
1	Listeria	30	1.0%	30	80	0	0	0	0
2	Listeria	45	1.0%	30	80	0	0	0	0
2	Listeria	45	1.0%	30	80	0	0	0	0
1	Listeria	45	1.0%	30	80	0	0	0	0
1	Listeria	45	1.0%	30	80	0	0	0	0
2	Listeria	60	1.0%	30	80	0	0	0	0
2	Listeria	60	1.0%	30	80	0	0	0	0
1	Listeria	80	1.0%	30	80	0	0	0	0
1	Listeria	80	1.0%	30	80	0	0	0	0
2	Listeria	80	1.0%	45	80	0	0	0	0
2	Listeria	80	1.0%	45	80	0	0	0	0
2	Listeria	80	1.0%	45	80	0	0	0	0
Control	Salmonella	0	0	0	0	TNTC	187	18	1
Control	Salmonella	0	0	0	0	TNTC	86	6	0
Control	Salmonella	0	0	0	0	TNTC	94	3	1
Control	Salmonella	0	0	0	0	TNTC	193	18	0
Control	Salmonella	0	0	0	0	TNTC	203	16	0
Control	Salmonella	0	0	0	0	TNTC	172	19	2
1	Salmonella	30	1.0%	30	80	0	0	0	0
1	Salmonella	30	1.0%	30	80	0	0	0	0
2	Salmonella	45	1.0%	30	80	0	0	0	0
2	Salmonella	45	1.0%	30	80	0	0	0	0
1	Salmonella	45	1.0%	30	80	0	0	0	0
1	Salmonella	45	1.0%	30	80	0	0	0	0
2	Salmonella	60	1.0%	30	80	0	0	0	0
2	Salmonella	60	1.0%	30	80	0	0	0	0
1	Salmonella	80	1.0%	30	80	0	0	0	0
1	Salmonella	80	1.0%	30	80	0	0	0	0
2	Salmonella	80	1.0%	45	80	0	0	0	0
2	Salmonella	80	1.0%	45	80	0	0	0	0
2	Salmonella	80	1.0%	45	80	0	0	0	0

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Family To Family Citations				

* Cited by examiner, † Cited by third party

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Title
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Family To Family Citations				
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Priority And Related Applications

Priority Applications (3)

Application	Priority date	Filing date	Title
US38075810P	2010-09-08	2010-09-08	*US Provisional Application*
PCT/CA2011/050544	2010-09-08	2011-09-08	Food-handling facility disinfection treatment
US13/821,483	2010-09-08	2011-09-08	Food-handling facility disinfection treatment

Applications Claiming Priority (1)

Application	Filing date	Title
US13/821,483	2011-09-08	Food-handling facility disinfection treatment

Legal Events

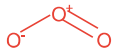
Date	Code	Title	Description
2013-03-07	AS	Assignment	**Owner name**: MEDIZONE INTERNATIONAL INC., CALIFORNIA **Free format text**: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNORS:SHANNON, MICHAEL EDWARD;ZOUTMAN, DICK ERIC;REEL/FRAME:029945/0277 **Effective date**: 20130304
2017-03-22	STCF	Information on status: patent grant	**Free format text**: PATENTED CASE
2020-06-02	AS	Assignment	**Owner name**: ASEPTIC SCIENTIFIC, LLC, CALIFORNIA **Free format text**: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNOR:ESTATE OF MEDIZONE INTERNATIONAL, INC.;REEL/FRAME:052816/0738 **Effective date**: 20180821 **Owner name**: STERILIZ3 CANADA INC., CANADA **Free format text**: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNOR:ASEPTIC SCIENTIFIC

			LLC;REEL/FRAME:052816/0850 **Effective date**: 20200518
2020-06-08	AS	Assignment	**Owner name**: STERILIZ3 CANADA INC., CANADA **Free format text**: CORRECTIVE ASSIGNMENT TO CORRECT THE CONVEYING PARTY NAME PREVIOUSLY RECORDED ON REEL 052816 FRAME 0850. ASSIGNOR(S) HEREBY CONFIRMS THE ASSIGNMENT;ASSIGNOR:ASEPTICSURE SCIENTIFIC, LLC;REEL/FRAME:052873/0209 **Effective date**: 20200518 **Owner name**: ASEPTICSURE SCIENTIFIC, LLC, CALIFORNIA **Free format text**: CORRECTIVE ASSIGNMENT TO CORRECT THE RECEIVING PARTY NAME AND ADDRESS TO: ASEPTICSURE SCIENTIFIC, LLCBOX 742, STINSON BEACH, CA 94970, US PREVIOUSLY RECORDED ON REEL 052816 FRAME 0738. ASSIGNOR(S) HEREBY CONFIRMS THE ASSIGNMENT;ASSIGNOR:ESTATE OF MEDIZONE INTERNATIONAL, INC;REEL/FRAME:052865/0017 **Effective date**: 20180821
2020-06-30	MAFP	Maintenance fee payment	**Free format text**: PAYMENT OF MAINTENANCE FEE, 4TH YR, SMALL ENTITY (ORIGINAL EVENT CODE: M2551); ENTITY STATUS OF PATENT OWNER: SMALL ENTITY **Year of fee payment**: 4

Concepts

machine-extracted

Download Filter table

Name	Image	Sections	Count	Query match
desinfective		title,claims,abstract,description	33	0.000
ozone		claims,abstract,description	86	0.000
hydrogen peroxide		claims,abstract,description	78	0.000
food		claims,abstract,description	22	0.000
Listeria		claims,description	48	0.000
Salmonella		claims,description	39	0.000
method		claims,description	26	0.000
Bacteria		claims,description	20	0.000
Listeria monocytogenes		claims,description	8	0.000
Listeria monocytogenes		claims,description	4	0.000
spores		claims,description	4	0.000
Salmonella enterica subsp. enterica serovar Typhi		claims,description	2	0.000
Salmonella enterica subsp. enterica serovar Typhimurium		claims	1	0.000
meat		abstract,description	6	0.000
dairy products		abstract	1	0.000
hydrogen peroxide		abstract	1	0.000

Show all concepts from the description section

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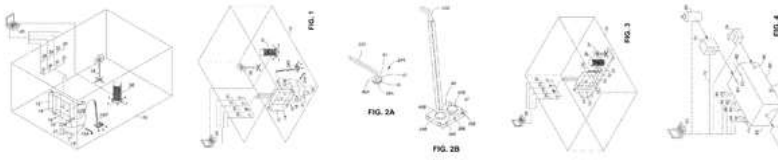
Healthcare facility disinfecting system

Abstract

A system and process for disinfecting rooms such as health care facility rooms with an oxygen/ozone mixture is described, which is effective to combat "superbugs" such as *Clostridium difficile* (*C. difficile*); *E. coli; Pseudomonas aeruginosa*; methicillin-resistant *Staphylococcus aureus* (MRSA); and vancomycin-resistant *Enterococcus* (VRE). In preferred embodiments, hydrogen peroxide is additionally used. The system and process is effective to destroy bacteria deposited on surfaces as biofilm, and, accompanied by physical agitation such as jet nozzle outlets, is effective to disinfect carpet, drapery and similar absorbent and porous surfaces.

Images (6)



Classifications

A61L2/202 Ozone

View 5 more classifications

US8551399B2

United States

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Inventor: Michael Edward Shannon, Dick Eric Zoutman

Current Assignee : Steriliz3 Canada Inc , MEDIZONE INTERNATIONAL Inc

Worldwide applications

2010 *IN* MX WO CA JP *SG* ~~KR~~ CN BR EP 2012 US

Application US13/343,403 events

2009-07-06	Priority to US22321909P
2012-01-04	Application filed by MEDIZONE INTERNATIONAL Inc
2012-04-26	Publication of US20120100037A1
2013-10-08	Publication of US8551399B2
2013-10-08	Application granted
Status	Active
2030-07-05	Anticipated expiration

Show all events

Info: Patent citations (19), Non-patent citations (10), Cited by (27), Legal events, Similar documents, Priority and Related Applications

External links: USPTO, USPTO Assignment, Espacenet, Global Dossier, Discuss

Claims (27)

Hide Dependent

What is claimed is:

1. A process of combating bacteria in an enclosed space within a room and contained in biofilm on surfaces within the room, consisting of:

   creating in the room a disinfecting atmosphere which includes ozone at a concentration of 2-350 ppm by weight and hydrogen peroxide at an amount of 1.0-10 wt. %, at a relative humidity of at least 60%, wherein said amount of hydrogen peroxide is derived from a supply solution of 0.2-10% hydrogen peroxide;

   subjecting the biofilm, including at least biofilm carrying surfaces having live bacteria therein, to said disinfecting atmosphere for a period of time effective to cause substantial kill, by at least a 6 log reduction, of the bacteria in the biofilm, the period of time being at least 30 minutes; and

   subsequently removing ozone from the disinfecting atmosphere, down to 0.04 ppm or less.

2. The process of claim 1 wherein the period of time during which the biofilm is subjected to the disinfecting atmosphere is from about 30 minutes to about 120 minutes.

3. The process of claim 1 wherein the ozone concentration in the disinfecting atmosphere is from 20-350 ppm by weight.

4. The process of claim 1 wherein the ozone concentration in the disinfecting atmosphere is from 20-200 ppm by weight.

5. The process of claim 1 wherein the ozone concentration in the disinfecting atmosphere is from 10-100 ppm by weight.

6. The process of claim 1 wherein the ozone concentration in the disinfecting atmosphere is from 35-100 ppm by weight.

7. The process of claim 1 wherein the ozone concentration in the disinfecting atmosphere is from 20-90 ppm by weight.

8. The process of claim 1 wherein the ozone concentration in the disinfecting atmosphere is from 35-80 ppm by weight.

9. The process of claim 1 wherein the hydrogen peroxide amount in the disinfecting atmosphere is from 1.0-5 wt. %.

10. The process of claim 1 wherein the temperature of the disinfecting atmosphere is 15-30 degrees C.

11. The process of claim 1 wherein the period of time during which the biofilm is subjected to the disinfecting atmosphere is from 60 to 105 minutes.

12. The process of claim 1 wherein the bacteria subjected to the disinfecting atmosphere and substantially killed includes *Clostridium difficile* (*C. difficile*), *E. coli; Pseudomonas aeruginosa*, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus* (VRE), or combinations of two or more of said bacteria.

13. The process of claim 1 wherein the pressure of the disinfecting atmosphere when the biofilm carrying surfaces are exposed thereto is above atmospheric pressure.

14. The process of claim 1 in which the ozone in the disinfecting atmosphere is created using an ozone generator based on electrical discharge generation from oxygen, or on exposure of oxygen or air to ultraviolet radiation.

15. A process or combating spore forming bacteria in an enclosed space within a room and contained in biofilm on surfaces within the room, consisting of:

creating in the room a disinfecting atmosphere which includes ozone at a concentration of 2-350 ppm by weight and hydrogen peroxide at an amount of 1.0-10 wt. % at a relative humidity of at least 60%, wherein said amount of hydrogen peroxide is derived from a supply solution of 0.2-10% hydrogen peroxide;

subjecting the biofilm carrying surfaces having live bacteria therein to said disinfecting atmosphere for a period of time effective to cause substantial kill, by at least a 6 log reduction, of the bacteria in the biofilm, the period of time being at least 30 minutes; and

subsequently removing ozone from the disinfecting atmosphere, down to 0.04 ppm or less.

16. The process of claim 15, wherein the spore forming bacteria is *Clostridium difficile, Bacillus subtilis*, or *Bacillus anthracis.*

17. The process of claim 15 wherein the period of time during which the biofilm is subjected to the disinfecting atmosphere is from about 30 minutes to about 120 minutes.

18. The process of claim 15 wherein the period of time during which the biofilm is subjected to the disinfecting atmosphere is from 60 to 105 minutes.

19. The process of claim 15 wherein the ozone concentration in the disinfecting atmosphere is from 20-350 ppm by weight.

20. The process of claim 15 wherein the ozone concentration in the disinfecting atmosphere is from 20-200 ppm by weight.

21. The process of claim 15 wherein the ozone concentration in the disinfecting atmosphere is from 10-100 ppm by weight.

22. The process of claim 15 wherein the ozone concentration in the disinfecting atmosphere is from 35-100 ppm by weight.

23. The process of claim 15 wherein the ozone concentration in the disinfecting atmosphere is from 20-90 ppm by weight.

24. The process of claim 15 wherein the ozone concentration in the disinfecting atmosphere is from 35-80 ppm by weight.

25. The process of claim 15 wherein the supply solution is 1.0-5% hydrogen peroxide.

26. The process of claim 15 wherein the room a sealed room, and wherein the pressure of the disinfecting atmosphere during exposure of the biofilm carrying surfaces thereto is atmospheric pressure.

27. The process of claim 26 in which creating a disinfecting atmosphere includes using a disinfecting system within the room, the disinfecting system including an ozone generator.

Description

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of, and claims priority to and the benefit of, PCT International Application No. PCT/CA2010/000998 filed Jul. 5, 2010, designating the United States and published Jan. 13, 2011 as International Publication No. WO/2011/003179, which application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/223,219 filed on Jul. 6, 2009, and U.S. Provisional Patent Application No. 61/295,851 filed on Jan. 18, 2010. This application is also related to Canadian Patent No. 2,735,739 issued on Nov. 22, 2011, which Canadian patent also claims priority to and the benefit of PCT International Application No. PCT/CA2010/000998. The disclosures of the above-identified patents and applications are expressly incorporated herein by this reference in their entireties.

FIELD OF THE INVENTION

This invention relates to disinfecting systems for use in healthcare facilities, public health facilities and the like, to eliminate or at least to reduce to acceptable levels, microbial residues which are resistant to conventional disinfectant and sterilization systems.

BACKGROUND OF THE INVENTION

Conventional electronic devices have largely been developed to satisfy a particular need. This is no more apparent than with a traditional telephone. A user would use the telephone specifically to vocally communicate with a person at a remote location. Other devices developed for specific purposes included traditional radios with FM and/or AM tuners, televisions for receiving and displaying broadcast audio-visual programs, and early computers were developed to process and analyze large quantities of data.

Despite intensive preventive efforts over the past several years in hospital and other healthcare facilities, the incidence of life threatening infections caused by a growing array of antibiotic resistant bacteria (sometimes referred to as “superbugs”) has grown significantly and is now posing a serious problem for medical staff worldwide. According to an editorial in the journal “Science” (July 2008), the number of deaths in 2006 attributable to bacterial infections in healthcare facilities in the United States exceeded the U.S. death toll attributed to HIV/AIDS in the same year, and probably result in as many as 70,000 deaths per year in the United States. This is despite the best efforts of healthcare personnel properly to clean their facilities and the equipment contained therein.

The major causative agents (bacteria) for hospital-based infections (nosocomial infections) are *Clostridium difficile* (*C. difficile*); *E. coli; Pseudomonas aeruginosa*; methicillin-resistant *Staphylococcus aureus* (MRSA); and vancomycin-resistant *Enterococcus* (VRE).

Approximately 5% of all acute care hospitalizations in the U.S. develop a nosocomial infection with an incidence rate of five infections per thousand patient days, and an added expenditure in excess of $4.5 billion (Wentzel R, Edmond M D, “The Impact of Hospital Acquired Blood Stream Infections,” *Emerg. Inf. Dis*., March-April

2001:7(174)). When this rate is applied to the 35 million patients admitted to 7,000 acute-care institutions in the U.S., it is estimated that there are more than 2 million cases per year. Nosocomial infections are estimated to double, at least, the mortality and morbidity risks of any admitted patient.

The significant, and growing, incidence of antibiotic resistant bacteria in healthcare facilities has been termed by some as a "Silent Epidemic". On the international scene, a World Health Organization survey of 55 hospitals in 14 countries representing four WHO regions (Europe, Eastern Mediterranean, South-East Asia and Western Pacific) reported that an average of 8.7% of hospital patients had nosocomial infections. The WHO estimates that, at any time, over 1.4 million people worldwide suffer from infection acquired in hospital.

Of particular concern in this context are the bacteria *C. difficile* and MRSA. Until recently, *C. difficile* was relatively uncommon, but has now become epidemic in many regions of the world. Indeed, it is now recognized by a growing number of public health officials as a worldwide epidemic (pandemic) with incalculable financial and health implications. MRSA has been identified by the American Academy of Orthopaedic Surgeons as the single biggest concern for surgical procedures, and concurs with recent journal articles that it constitutes a "silent epidemic." Under current healthcare facility cleaning and sterilizing procedures, both *C. difficile* and MRSA, as well as the aforementioned *E. coli; Pseudomonas aeruginosa*; and vancomycin-resistant *Enterococcus* (VRE), are ineffectively treated and subsequently removed, so that colonies of these pathogens accumulate in healthcare facilities, especially on porous surfaces such as carpets and drapes.

Attempts to combat and kill nosocomial infections caused by bacteria such as *Pseudomonas aeruginosa* and *Staphylococcus aureus* are hampered by the fact that the bacteria grow within biofilms that protect them from adverse environmental factors. A biofilm is an aggregate of microorganisms in which cells adhere to each other and/or to a surface. They are frequently embedded in a self produced matrix of extracellular polymeric substance (EPS), a polymeric conglomeration generally composed of extracellular DNA, proteins and polysaccharides. Biofilms form on surfaces, e.g. in hospital settings, in the presence of water vapor.

Free floating microorganisms in planktonic (single cell) mode attach to a surface, and if not immediately removed, will anchor themselves more permanently to the surface. These first colonists provide more diverse adhesion sites for the arrival of other cells, thus beginning to build a matrix that holds the biofilm together and provides additional anchoring sites for arriving cells. The biofilm grows through a combination of cell division and recruitment. When the biofilm is established, the aggregate cell colonies are apparently increasingly antibiotic resistant. It has also been reported that biofilm bacteria apply chemical weapons to defend themselves against disinfectants and antibiotics (see "Biofilm Bacteria Protect Themselves With Chemical Weapons", Dr. Carsten Matz et. al., Helmholtz Centre for Infection Research, Brauschweig, reported on Inforniac.com, Jul. 23, 2008).

Bacteria living in a biofilm have significantly differently properties from the planktonic form of the same species, as the dense and protected environment of the film allows them to co-operate and interact in various ways. Traditional antibiotic therapy is usually not sufficient to eradicate chronic infections, and one major reason for their persistence seems to be the capability of the bacteria to grow within biofilms that protect them from adverse environmental factors.

Also of growing concern are threatened bioterrorist and warfare attacks using potentially lethal bacteria. Some of the deadliest bacteria, for example anthrax, are highly resistant to conventional sterilization agents and treatments. Contamination of public facilities with such bacteria constitutes a significant threat to human life with residual amounts of such bacteria being almost impossible to remove using current methods.

BRIEF REFERENCE TO THE PRIOR ART

Current procedures for the sanitization of hospitals and other healthcare facilities have become increasingly ineffective, resulting in the accumulation of deadly bacteria throughout the facilities. Rising costs of the provision of healthcare in most if not all countries militate against spending more than the minimum time and effort on cleaning and sterilizing procedures.

Chlorinated solutions with and without ammonia are commonly used, but have shown only limited success. To add to this challenge, such solutions cannot be used on electronic devices commonly installed in wards, recovery rooms, operating theaters, etc.

Vaporized hydrogen peroxide (VHP) is highly effective when applied to smooth surfaces, but has little or no efficacy on porous materials and fabrics. Moreover, VHP is very damaging to electronic devices.

Once a non-medical surface such as carpet, drapery, bedding, porous material in ceilings and the like become impregnated with highly resistant pathogens, especially spore formers such as *C. difficile*, they cannot be effectively disinfected using currently available agents and processes.

Ozone is known to be a powerful anti-bacterial, anti-fungal and anti-viral agent. For over 100 years, it has been used for water purification. It is known to be effective against *Legionella* Bacteria, *E. coli* and pseudomonas populations in such plants.

Ozone use in healthcare facilities is, however, problematic. Solutions containing ozone are explosive on warming. Ozone is medically harmful to those exposed to it, causing irritation of eyes and mucous membranes, pulmonary edema, and chronic respiratory disease if low, safe levels of exposure are exceeded. Moreover, it is widely recognized to be an environmental hazard.

Canadian Patent 2,486,831 (Arts et al.), issued Jul. 12, 2011, discloses the use of a combination of ozone and UV radiation for decontamination of air in a room such as a mobile isolation unit, a hospital room and the like. The air is caused to flow through a portable unit containing a filter exposed to ozone.

U.S. Pat. No. 7,407,624 (Cumberland et al.), issued Aug. 5, 2008, describes methods for abating allergens, pathogens, odors and volatile organic compounds in air, using an atmosphere having specific combinations of ozone concentration, hydrogen peroxide concentrations, temperature and humidity delivered over a specified period of time. The patent contains an experimental account of treating rooms of a residence, effectively treating *cladosporium* mold spores and *penicillium/aspergillus* molds in the room air. No details of the precise conditions used are given. There is no demonstration or disclosure of treatment of contaminated surfaces in a room. The general disclosure of the patent states that selected conditions of ozone concentration, hydrogen peroxide, humidity and temperature are highly effective in killing airborne molds and fungi at ozone concentrations below 6-9 ppm, but the precise conditions used are not disclosed. In general, the patent teaches use in an atmosphere of 2-10 ppm ozone, hydrogen peroxide which is 75%-150% by weight of the atmospheric ozone concentration, at a temperature of 15-27° C. and time 0.5-3 hours. Many other airborne pathogens, including bacteria, are said to be treatable by this method, but no experimental evidence is offered.

There is thus a need for an effective but inexpensive system for disinfecting rooms of healthcare facilities, including all the contents therein. Such a system should drastically reduce (99.999% or greater) the amounts of at least the five aforementioned bacteria in all contaminated spaces to be of clinical and public health value. Furthermore, this level of microbial decontamination must be achieved such that the space is only removed from healthcare use for a minimum period of time, while remaining safe and harmless with respect to electronic and other equipment in the room. Accordingly, the decontamination process should not require that the space in question be emptied of its contents while the system is operated.

SUMMARY OF THE INVENTION

The present invention provides, from one aspect, an ozone-based disinfection system for rooms and their contents within all healthcare facilities, mobile or stationary, and other critical infrastructure such as schools and government buildings. Using such a system, ozone-containing gases are delivered into and applied to the surfaces

and equipment and objects contained within the room. The application can be through simple contact of the gaseous atmosphere with the surfaces, or, in the case of difficult-to-clean surfaces such as drapes, carpets and other fibrous surfaces, it can be by means of a dislodgement system effecting physical agitation of the surface (scrubbing brushes, high pressure jets or the like, sometimes referred to herein as "scrubbing"). The ozone-containing gases are applied at controlled concentrations and, in some cases, elevated pressures which have been found to be effective in destroying critical viral, bacterial and fungal pathogens found in environments, including but not limited to the five especially troublesome bacteria *Clostridium difficile* (*C. difficile*); *E. coli; Pseudomonas aeruginosa*; methicillin-resistant *Staphylococcus aureus* (MRSA); and vancomycin-resistant *Enterococcus* (VRE).

In addition to effectively eliminating aerosolized pathogens within a given space, the system of the invention also allows an operator to apply the ozone-containing gases at predetermined concentrations of ozone directly to problem surfaces in the room, with a physical agitation action and under pressure where appropriate. The system also includes an ozone-destruct unit for removing residual ozone from the room atmosphere. The whole system is portable, so that it can be moved from room to room as required, and is harmless to equipment contained in the room. Once the sterilization process is completed, the room can be back in medical use within 20 minutes, with its residual atmospheric ozone level at an acceptable 0.04 ppm or less.

BRIEF REFERENCE TO THE DRAWINGS

FIG. 1 of the accompanying drawings is a diagrammatic illustration of an apparatus in accordance with an embodiment of the invention, disposed within a room to be disinfected;

FIGS. 2A and 2B are diagrammatic illustrations of physical agitation systems for use in embodiments of the invention;

FIG. 3 is a diagrammatic illustration of an apparatus according to the invention, in portable, transportation mode;

FIG. 4 is a diagrammatic illustration of a test apparatus used to generate some of the test results reported below; and

FIG. 5 is a diagrammatic illustration of the test apparatus used to generate the results reported in Example 10 below.

DETAILED DESCRIPTION

One significant feature of the system according to certain embodiments of the invention is the ability to adjust the pressure of the ozone/oxygen gas mixture being used for disinfection purposes. It has been found that, in many cases, effective disinfection of a room and its contents from bacterial contamination can best be achieved by pressurizing the atmosphere in the room with ozone/oxygen mixture containing from about 10 to about 100 ppm of ozone, to a pressure higher than normal atmospheric pressure, e.g. from about 14.7 psi to about 100 psi. A localized pressurized air jet can also be used, which would obviate the need to raise the overall pressure in the room. Raising the room pressure may require initial sealing of the room prior to the decontamination process. With many rooms where medical procedures are conducted, such as operating theatres, this is a simple process, since such rooms are designed to be substantially sealed when in use for medical procedures. With other rooms, this may require some significant initial preparation.

Another, particularly preferred embodiment of the invention utilizes hydrogen peroxide, as well as ozone, in the disinfecting gaseous atmosphere. When using ozone and hydrogen peroxide, increasing the pressure within the room may not be necessary. The particularly troublesome bacteria which are likely to cause nosocomial infections in a hospital environment, namely *Clostridium difficile* (*C. difficile*); *E. coli; Pseudomonas aeruginosa*; methicillin-resistant *Staphylococcus aureus* (MRSA); vancomycin-resistant *Enterococcus* (VRE), deposit on surfaces in a hospital environment such as stainless steel surfaces, ceramic surfaces and marble surfaces and quickly form a biofilm in which the microorganisms thrive. Treatment with the combination of hydrogen peroxide and ozone, at appropriate humidity, according to this preferred aspect of the invention, destroys the bacteria in the biofilm, either by chemically attacking the biofilm to expose the microorganisms to the biocidal action of the ozone and hydrogen peroxide, or by interference of the bacterial cells' activity in the biofilm by the ozone/hydrogen peroxide combination employed, or by a combination of these, possibly with other, mechanisms.

Thus according to this preferred embodiment of the present invention, from one aspect, there is provided a process of combating bacteria in an enclosed space within a room and contained in biofilm on surfaces within the room, which comprises:

creating in the room a disinfecting atmosphere which includes ozone at a concentration of 2-350 ppm by weight and hydrogen peroxide at an amount of 0.2-10 wt. %, at a relative humidity of at least 60%;
exposing the biofilm carrying surfaces having live bacteria therein to the disinfecting atmosphere for a period of at least 30 minutes sufficient for an effective kill of the bacteria in the microfilm; and
subsequently removing ozone from the atmosphere, down to 0.04 ppm or less.

Preferably the disinfecting atmosphere has a relative humidity of at least 65%.

Another preferred embodiment provides a process for disinfecting a room and surfaces therein to combat at least one of the microorganisms bacteria *Clostridium difficile* (*C. difficile*); *E. coli; Pseudomonas aeruginosa*; methicillin-resistant *Staphylococcus aureus* (MRSA); vancomycin-resistant *Enterococcus* (VRE); *Bacillus subtilis*, and/or anthrax, which comprises exposing the room and surfaces therein to a gaseous atmosphere which includes an effective amount of ozone and an effective amount of hydrogen peroxide, for a period of time which substantially reduces levels of bacteria on the surfaces, and subsequently removing the residual ozone in the room's atmosphere, down to a safe low level.

The process is particularly effective with or without physical agitation, in disinfection of stainless steel surfaces which abound in medical treatment facilities, and on which bacteria are tenacious and difficult to destroy, due at least in part to their generation of a biofilm on such surfaces. The process is also effective in destroying and deactivating anthrax bacteria, as evidenced by its effectiveness against the well-established anthrax surrogate, *Bacillus subtilis*.

According to another aspect of this embodiment, there is also provided a portable system for rapidly disinfecting rooms, surfaces and equipment therein, comprising:

an ozone generator for discharging into the room a gaseous mixture including ozone;
an ozone controller adapted to control the amount of discharged ozone;
a source of hydrogen peroxide for discharging controlled amounts of hydrogen peroxide into the room;
means for discharging the hydrogen peroxide and ozone into the room;
humidity adjusting means adapted to increase or decrease the relative humidity of the room during treatment; and
an ozone remover adapted to destroy ozone, down to a safe level in the room atmosphere for subsequent human utilization.

It is sometimes beneficial, to increase the effectiveness and shorten the duration of the process, to operate at elevated pressure, even when using both ozone and hydrogen peroxide in the disinfecting gas. Thus, according to another aspect of the present invention, there is provided a process for disinfecting a room of a healthcare facility, which comprises:

introducing into the room a gas mixture which includes ozone and hydrogen peroxide in effective amounts;

raising the pressure within the room above atmospheric pressure, or introducing a pressurized gas stream;
physically agitating fibrous and porous surfaces within the room while the surfaces are exposed to the pressurized gas stream of hydrogen peroxide and ozone containing atmosphere of relative humidity at least 60%;
returning the room to atmospheric pressure; and
removing the residual ozone from the room's atmosphere, down to a safe level.

Preferred ozone amounts are from about 20-350 parts per million in the treatment gas atmosphere, more preferably 20-200, even more preferably 20-90 parts per million in the oxygen/ozone gas mixture, and most preferably 35-80 ppm ozone. Preferred amounts of hydrogen peroxide are the amounts supplied to the room treatment atmosphere using an aqueous solution containing 0.2-10%, more preferably 1-5%, hydrogen peroxide. In the description below, the peroxide percentages used are sometimes expressed in terms of these solution percentages. The amounts are chosen so that no serious deleterious effects are suffered by other equipment in the treatment room. The amount of hydrogen peroxide in the disinfecting atmosphere can be calculated from the volume of aqueous hydrogen peroxide evaporated into the disinfecting atmosphere, the volume of the room being disinfected and the concentration of hydrogen peroxide in the starting solution. Times of exposure of the room and its surface to the ozone-containing atmosphere are suitably from 30 minutes to about 120 minutes, preferably from about 60 to about 105 minutes, and most preferably about 90 minutes. These times are constrained to some extent by the need to clear the room of ozone (down to a maximum of 0.04 ppm) following the disinfection phase, and return the room to medical use within a reasonable period of time, with the entire start-to-finish time not exceeding 150 minutes. The ozone removal is an extremely rapid and fully effective process. Both the hydrogen peroxide and the ozone (and any products of interaction between them) should be removed before the room is put back into normal use.

Another significant feature of preferred embodiments of the present invention is the provision of a dislodgement system at the outlet end of the discharge. The dislodgement system allows penetration of carpet, drape and similar surfaces in the room, to gain access to concealed/sequestered spores and/or colonies of bacteria. The dislodgement system can be manually operated, with operators protected by a hazard suit and mask, or remotely operated or totally automated. It may take the form of one or more outlet jets, with associated manually operable jet pressure controls. It may take the form of a revolving or fixed brush with bristles of appropriate stiffness, alone or in combination with an outlet jet. Any form of dislodgement system effective to disturb the pile of carpet fabrics, upholstery fabrics and the like so as to access the remote parts which might harbor bacterial spores or colonies can be used. This includes non-physical applications such as air jets, ultrasonic energy, radio-frequency energy and electromagnetic waves, for example, capable of causing physical disruption and which result in micro-physical movements of fibrous surfaces.

The ozone for use in the present invention can be generated by any known means. In the case of corona or other electrical discharge generation from oxygen, the apparatus of the invention preferably includes a container of medical grade oxygen. The oxygen container can be a standard, pressurized vessel containing medical grade oxygen, of the type commonly found in medical facilities. Oxygen from this container is fed to an ozone generator, where the oxygen is subjected to electrical discharge, normally with high voltage alternating current, to convert small amounts of the oxygen to ozone and produce a gaseous mixture of oxygen and ozone. The quantity of ozone in the mixture is controllable by adjustment of the voltage of the electrical discharge. Suitable ozone generators are known and available commercially. The relative amounts of ozone generated are relatively small, expressed in parts per million (ppm), but such is the power of ozone as a disinfectant, especially in combination with hydrogen peroxide in accordance with this invention, that such small quantities thereof are all that is required.

Alternative forms of ozone generation can be used if preferred. Ultraviolet radiation of appropriate wavelength, incident upon oxygen or air, is one acceptable alternative. In such a system, air from the room itself may be fed into the ozone generating unit to supply the required oxygen for conversion to ozone. Other methods of ozone generation which can be used include photocatalytic reactions, cold plasma, etc.

The relative humidity of the treatment space should be at least 60% and preferably at least 65%, for effective disinfection. To ensure this, it is preferred to incorporate a humidifier in the system of the invention, using sterile water from an internal system reservoir to adjust and control the humidity of the issuing gas mixture. In this way, desirable humidity for most effective disinfection is achieved at the point of discharge where dislodgement of a carpet or drapery surface can take place. The adjustable humidifier need only increase the humidity of the space to the desirable level and can be placed in any location within the space. When using hydrogen peroxide in addition to ozone, the hydrogen peroxide vapor is suitably applied, in controlled amounts, to the air/water vapor issuing from the humidifier and thus added to the ozone/oxygen containing gas mixture. Alternatively, hydrogen peroxide can be applied to the water used to humidify the target location. Hydrogen peroxide is commercially available as aqueous solutions of standard concentrations of hydrogen peroxide. For use in embodiments of the present invention, a standard solution of known peroxide concentration is suitably diluted down by a fixed volume of distilled water. The peroxide load is standardized based on the known volume of water from the peroxide solution required to raise the relative humidity to the desired extent, e.g. from 40-80%. From this, the amount of hydrogen peroxide in volume % or ppm by volume introduced into the treatment facility can be calculated.

Certain systems according to embodiments of the invention may include a temperature adjuster and controller for the gas mixture. This can be a simple heater/cooler through which either the incident oxygen or the generated oxygen/ozone mixture passes prior to discharge into the room atmosphere. While simple adjustment of the temperature of the room using an external room heating system and thermostat can be effective, it is preferred to adjust the temperature of the issuing gas mixture, for most effective treatment of the carpet and drapery surfaces. The ideal range of temperature for ozone and ozone/hydrogen peroxide decontamination of pathogens is 15° C. to 30° C.

The system of the invention also includes an ozone removal unit. Such units are known, and can be purchased commercially for use in the present invention. Depending on the volume of the room atmosphere and the capacity of the ozone removal unit, more than one such unit may be incorporated in the system of the invention. Suitable ozone removal units are those based on activated carbon as the removal medium. These act very quickly, and do not lead to the formation of hazardous reaction products. The inclusion of such units enables the treated facility to be cleared of ozone and returned to normal use rapidly, an important feature where health care facilities are involved. Other types include systems based on catalysts such as manganese oxide or other metal oxides, which may be heated to remove moisture, thermal destruction in conjunction with other metals including platinum or palladium.

FIG. 1 of the accompanying drawings shows a patient room surgical suite **10**, closed ready for disinfection by a process according to an embodiment of the invention. The suite is substantially hermetically sealed. Inside the suite is a pressurized cylinder **12** of oxygen, feeding oxygen gas into a humidifier **14** and thence to an ozone generator **16**, which includes electrical discharge plates of variable voltage to adjust the quantity of ozone which is generated. A heater and a pressure controller (not shown) may be disposed near the entrance to the ozone generator. Output of oxygen/ozone gas mixture is via room outlets **18**, **20** to the atmosphere of the suite **10**, and via wands **22**A and/or **22**B to a dislodgement means in the form of scrubbing brushes **24**A and **24**B mounted on the outlet ends of the respective wands **22**A, **22**B. The heater, the pressure controller, the voltage supplied to the ozone generator **16** and the humidity level supplied by the humidifier **14** are all controlled and adjusted from an external control panel **26** via respective electrical connections **28**, **30**, **32** and **34**. Also disposed within the suite are an oscillating fan **34** and an ozone destruct filter unit **36**.

Disposed within the suite **10** is a container of aqueous hydrogen peroxide solution **19** and associated air blower **21** which, during operation, blows vaporized hydrogen peroxide in controlled amounts into discharge wand **22**A and **22**B to mix with the output of ozone/oxygen therein. The amount of hydrogen peroxide being supplied is controlled by adjustment of the blower **21** through a connection thereof to the control panel **26**. In an alternative arrangement, hydrogen peroxide can be supplied from generator **19** to the humidifier **14**.

FIGS. 2A and 2B of the accompanying drawings show in more detail forms of dislodgement means **24**A and **24**B for use in the present invention, attached to the outlet,

discharge ends of respective wands **22**. The dislodgement means **24**A has a jet outlet nozzle **38**A at its extremity, and a generally circular plate **40** mounted on the wand **22**A near the discharge end. The wand **22**A passes through a central aperture **42** in a plate **40**. The plate **40** has brush bristles **46**A mounted on its lower surface, arranged in two arcs around the jet outlet nozzle **38**A and protruding downwardly to an extent just beyond the extent of outlet from nozzle **38**A. In use, oxygen/ozone gas mixture or oxygen/ozone/hydrogen peroxide gas mixture issues from nozzle **38**A at relatively high pressure, and can be directed by the operator holding the wand to a carpet surface area while at the same time the operator scrubs the carpet surface area with the bristles **46**A.

FIG. 2B shows an alternative but essentially similar arrangement, in which plate **40** is replaced by a wheeled platform **44** carrying two rotary brushes **46**B and three jet outlets **38**B for the oxygen/ozone/hydrogen peroxide delivery at pressure, located forwardly of the rotary brushes **46**B.

FIG. 3 of the accompanying drawings illustrates the portability of a system according to the invention. Parts are numbered as in FIG. 1. A 4-wheeled cart **24** is provided, on which all the component parts of the system can be loaded for ease of transportation from one room to another. The instrumentation and control panel can be disconnected for transportation, and re-connected and disposed outside when the apparatus is placed in another room for use as shown in FIG. 1. The cart **24** is removed while the system is in use, but is loaded with the components after use, either for transportation to another room or for storage.

The operation of the system will be readily apparent from the preceding description of its component parts and their inter-connection. The cart **24** carrying the component parts is wheeled into the room **10** to be disinfected, and the parts are distributed around the room and connected together as illustrated in FIG. 1. An operator wearing a hazard suit and other appropriate protective clothing enters the room and holds the wand **22**. The room is sealed. Conditions of treatment are set on the control panel **26**, and the apparatus is switched on so that oxygen/ozone/hydrogen peroxide gas mixture at controlled ozone concentration, hydrogen peroxide concentration, relative humidity, temperature and elevated pressure issues from jet nozzle **38**. The operator applies the jetted gas mixture to the carpet surfaces, drapery surfaces and other absorbent surfaces in the room, scrubbing the surfaces at the same time with the bristles **46**. The room becomes pressurized above atmospheric pressure, due to the introduction of the oxygen/ozone gas mixture. Pressure is continually monitored by the control panel **26** to ensure safe working conditions for the operator, as well as the temperature, humidity and ozone concentration in the room. Smooth surfaces in the room may not need the action of the dislodgement means, but are satisfactorily disinfected by contact with the atmosphere in the room, especially when hydrogen peroxide and ozone are used in combination. The oscillating fan **34** is operated throughout the procedure, to circulate the oxygen/ozone mixture throughout the room.

After a pre-set time of the procedure, and after all the appropriate, absorbent surfaces have been scrubbed, a time not normally exceeding 90 minutes, the hydrogen peroxide supply (if used), the oxygen supply and ozone generator are switched off. Then the ozone destruct filter is operated, sucking in the ozone-containing gases, destroying the ozone and issuing pure oxygen from it. The room can now be opened, the apparatus disconnected and loaded on the cart **24**, and the room put back to its normal use.

EXPERIMENTAL EXAMPLES

Effective and optimum conditions for use in the present invention were determined using a laboratory apparatus as generally illustrated in FIG. 4 of the accompanying drawings.

A single pure colony of each aerobic test bacteria, namely *E. coli; Pseudomonas aeruginosa*; methicillin-resistant *Staphylococcus aureus* (MRSA); and vancomycin-resistant *Enterococcus* (VRE) was inoculated to a Columbia agar plate with 5% sheep's blood. They were incubated at 35° C. in room air for 18-24 hours. From the plate, 4-5 isolated colonies were selected, and suspended in tryptic soy broth to achieve a 0.5 McFarland turbidity standard (1.5×10^8 cfu/ml) measured using a spectrophotometer. Inoculum was prepared by performing a series of serial dilutions of 0.9 ml 0.85 NaCl broth with 0.1 ml of original 0.5 McFarland inoculum (6×10 fold) to give solutions of 10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6} and 10^{-7} cfu/mL.

Organisms were plated out in triplicate, 0.1 ml of each solution being spread over the surface of Columbia sheep's blood agar plates. Two sets of plates (12 plates per organism) were subjected to ozone/oxygen exposure at preselected concentrations of ozone (ppm), humidity and temperature conditions in the illustrated apparatus. The other sets of 2 were treated as controls, with no ozone exposure, but kept at room temperature.

For ozone exposure, the apparatus generally illustrated in FIG. 4 was used.

The test plates were mounted inside a disinfection chamber **60**, the upstream end **62** of which had an ozone inlet port **64**, a hydrogen peroxide vapor inlet port **65** (which in Examples 1-9 described below was blocked), and a water vapor inlet port **66**. A cylinder **68** of pressurized medical grade oxygen was provided, feeding oxygen to an ozone generator **70**, equipped with alternating current electrical plates to which variable voltage could be supplied via input control **72**. The output of oxygen/ozone mixed gas from the ozone generator **70** was fed to the ozone inlet port **64** of the disinfection chamber **60**. A water vapor humidifier **74** supplied water vapor to inlet port **66**. The disinfection chamber **60** also contained a heater/cooler (not shown), a temperature sensor **76**, a pressure sensor **78**, a humidity sensor **80** and an ozone sensor **82**, connected electrically via respective lines **84**, **86**, **88** and **90** to a control panel and monitor **92**, connected to feed back to the oxygen cylinder **68** to control flow for pressure adjustment purposes, to the ozone generator **70** to control and adjust the ozone quantity, to the water vapor humidifier **74** to control and adjust relative humidity in the disinfection chamber **60**, and to the heater/cooler to control and adjust the temperature in the chamber. These parameters were all pre-set on the control panel to desired values and automatically re-adjusted themselves to these values as the experiments progressed.

An ozone destruct filter **94** was connected to the downstream end **96** of the disinfection chamber **60** at outlet port **98**, to destroy ozone issuing from the chamber **60** at the end of the experiment. Gases were circulated within the chamber **60**, and expelled therefrom at the termination of the experiment, using a fan **100** mounted therein. After placing the test plates in the chamber **60**, it is sealed until the end of each experiment.

The control plates and the ozone treated plates were placed in an incubator at the same time. The plate counts were read through a microscope, and the numbers of colony forming units on each plate was counted. The spores are aerotolerant.

Example 1

A series of tests as described above was conducted on MRSA ATCC 33592. The microorganism-bearing dishes were exposed in the chamber to an oxygen/ozone mixed atmosphere containing 80 ppm ozone, for 90 minutes at 20° C. and 85% relative humidity. Duplicate test plates were run. 10 µL volume aliquots washed off the plates were serially diluted with inoculum, to final dilution factors 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6} and 10^{-7}. Control plates, not subjected to ozone exposure, were prepared, and the plates incubated for 24 hours as described. The surfaces of the agar plates were eluted to remove the bacterial colonies, and the eluates plated out for examination under a microscope.

Counting of the active, reproducing colonies of bacteria in the eluate compositions, under a microscope, revealed that the eluates from control plates at dilutions 10^{-2}, had 19 and 11 cfus (duplicate plates), and no cfus from plates of higher dilution, whereas the experimental, ozone-exposed plates yielded compositions exhibiting no cfus at any of the tested dilutions. A 3.35 log reduction was achieved (8.3 log to 4.9 log).

Example 2

The experiment of example 1 was repeated using the same bacterial strain, but exposing the test plates in the chamber to 50 ppm ozone in oxygen, at 20° C. and 80% relative humidity.

Counting of the active, reproducing colonies of bacteria in the eluate compositions, under a microscope, revealed that the eluates from control plates at dilutions 10^{-2}, had 374, 415, 414 and 423 cfus (quadruplicated plates), 33, 35, 38 and 37 cfus from control plates at dilutions 10^{-3}, had 4, 1, 2 and 2 cfus at dilution 10^{-4} and no cfus at higher dilutions. Those from the eluates of treated plates revealed 27, 11, 42 and 58 active cfus at dilutions 10^{-2}, 3, 1, 3 and 5 cfus at dilution 10^{-3} (quadruplicate plates), and no cfus from plates of higher dilution.

Example 3

The experiment of Example 1 was repeated, except for using as test organism *P. aeruginosa* ATCC 27853. The same conditions of ozone exposure, dilution, incubation and testing were used. On the test plates, active colony counts of 11 and 18 were found at 10^{-2} dilution, and active colony counts of 5 and 27 were found at 10^{-3} dilution. At higher dilutions, there were no detectable colonies. In contrast, the control, non-ozone exposed plates showed colonies too numerous to count, at all dilutions up to and including 10^{-6}. A 2.8 log reduction was achieved (7.9 log to 5.1 log).

Example 4

The experiment of Example 3 was repeated, using the same test organism, but treating the test samples in the chamber with ozone/oxygen gas mixture containing 50 ppm ozone, at 80% humidity, for 90 minutes. By the same recovery and test procedures, it was determined that the control plates had cfus too numerous to count. The test plates, run in duplicate, had cfu counts of 212 and 183 at dilution 10^{-2}; counts of 13 and 50 at dilution 10^{-3}; and no cfus at higher dilutions.

Example 5

The experiment of Example 3 was repeated but using *Enterococcus faecalis* (high level vancomycin resistant) Clinical Strain 80269 as the test organism, with 90 minute exposure to ozone/oxygen mixture of 35 ppm ozone, at 21° C. and 80% relative humidity. The eluates from control plates (duplicated) had cfu counts too numerous to count at dilution 10^{-2}, 10^{-3} and 10^{-4}; cfu counts of 402 and 346 at dilution 10^{-5}; cfu counts of 35 and 25 at dilution 10^{-6}; and cfu counts of 14 and at dilution 10^{-7}. In contrast, the eluates from the test plates (duplicates) gave cfu counts of 78 and 29 at dilution 10^{-2}; cfu counts of 47 and 6 at dilution 10^{-3}; 112 and 50 at dilution 10^{-4}; cfu counts of 0 and 1 at dilution 10^{-5}; cfu counts of 1 and 0 at dilution 10^{-6}; and cfu counts of 0 and 1 at dilution 10^{-7}. A 2.95 log reduction was achieved (7.7 log to 4.7 log).

Example 6

The experiment of Example 5 was repeated using the same VRE Clinical Strain as the test organism, but with 90 minute exposure to ozone/oxygen mixture of 50 ppm ozone, at 20° C. and 80% relative humidity. The eluates from control plates (duplicated) had cfu counts too numerous to count at dilution 10^{-2}, 10^{-3} and 10^{-4}; cfu counts of 369 and 359 at dilution 10^{-5}; cfu counts of 46 and 46 at dilution 10^{-6}; and cfu counts of 9 and 2 at dilution 10^{-7}. In contrast, the eluates from the test plates (duplicates) gave cfu counts of 50 at dilution 10^{-2}; cfu counts of less than 30 at dilution 10^{-3}; and cfu counts of 0 at higher dilutions 10^{-5}.

Example 7

The experiment of Example 3 was repeated but using *E. Coli* Strain ATCC 25922 as the test organism, with 90 minute exposure to ozone/oxygen mixture of 35 ppm ozone, at 21° C. and 80% relative humidity. The eluates from control plates (duplicated) had cfu counts too numerous to count at dilution 10^{-2}, 10^{-3} and 10^{-4}; cfu counts of greater than 300 at dilution 10^{-5}; cfu counts of 95 and 66 at dilution 10^{-6}; and cfu counts of 3 and 10 at dilution 10^{-7}. In contrast, the eluates from the test plates (duplicates) gave cfu counts of 43 and 38 at dilution 10^{-2}; cfu counts of 25 and 1 at dilution 10^{-3}; 6 and 15 at dilution 10^{-4}; cfu counts of 3 and 10 at dilution 10^{-5}; and cfu counts of 0 at higher dilutions.

A 3.22 log reduction (7.8 log to 4.6 log) was achieved.

Example 8

The experiment of Example 7 was repeated was repeated using the same *E. Coli* Strain ATCC 25922 as the test organism, but with a 90 minute exposure to ozone/oxygen mixture of 50 ppm ozone, at 20° C. and 80% relative humidity. The eluates from control plates (duplicated) had cfu counts too numerous to count at dilution 10^{-2}, 10^{-3} and 10^{-4}; cfu counts of 563 and 350 at dilution 10^{-5}; cfu counts of 74 and 87 at dilution 10^{-6}; and cfu counts of 7 and 7 at dilution 10^{-7}. In contrast, the eluates from the test plates (duplicates) gave cfu counts of 13 and 28 at dilution 10^{-2}; cfu counts of 8 and 7 at dilution 10^{-3}; cfu counts of 7 and 5 at dilution 10^{-4}; and 0 at all other, higher dilutions.

Example 9

A strain of *C. difficile* (clinical strain nontoxigenic #135, Queens University Medical School, Kingston, Ontario, Canada) was also used as a test organism, but owing to the well-known difficulties with growing *C. difficile* strains (anaerobic condition requirements, for example), a somewhat different preparatory method was adopted.

The *C. difficile* strain was streaked on 12-20 pre-reduced *Brucella* blood agar plates and incubated anaerobically for 48 hours at 35° C. Each plate was flooded with 5 ml of sterile distilled water and the bacterial colonies gently scraped from the agar surface with a plastic sterile bacteriological loop. The resulting bacterial suspension was mixed and allowed to rest at room temperature in a sealed tube for 20 minutes to permit the osmotic lysis of the vegetative forms of the bacteria. The bacterial suspension was centrifuged at 3,000× gravity for 20 minutes to pellet the spores and remaining bacterial cells. The supernatant was discarded and the pellet re-suspended in 5-7 milliliters of sterile distilled water and mixed vigorously to re-suspend the spores and remaining bacterial cells. The above steps were repeated three times to produce a pellet consisting of *C. difficile* spores. To kill any remaining vegetative bacteria, the final suspension was placed in a heating block at 70° C. for 20 minutes. The spores were stored in 100% ethanol at 4° C. This preparation yielded approximately 1.5×10^5 cfu/ml of spores. Gram stain of the spore preparation confirmed that the suspension consists of spores with very few vegetative cells.

Serial 10 fold dilutions of the spore suspension in sterile 0.85% NaCl were conducted as previously described, and then inoculation was conducted by spreading 0.1 ml of each dilution over the surface of BAK agar plates. The yield of *C. difficile* spores was about 6×10^4-2×10^6 cfu/ml. Some plates were exposed to ozone in the illustrated apparatus as previously described, others were kept as controls.

Test plates were given a 90 minute exposure to ozone/oxygen mixture of 35 ppm ozone, at 21° C. and 80% relative humidity. The subsequent incubation was for 48 hours

under anaerobic conditions. The eluates from control plates (duplicated) had cfu counts of 113 and 50 at dilution 10^{-2} and 10 and 10 at dilution 10^{-3}; whereas the eluates from the test plates showed no cfus at any dilution tested.

A 4 log reduction (4 log to zero) was achieved.

Example 10

Experiments conducted to simulate the problems commonly faced in most modern hospitals related to decontaminating textiles such as carpets and drapes have clearly demonstrated the superior efficacy of direct pressurized air flow over a more static gaseous environment. An apparatus as diagrammatically illustrated in the accompanying FIG. 5 was used. A chamber **100**, closed while the experiments were in progress, contained near one end a frame **102** holding a layer (disc) **104** of fibrous drape material (sterile cotton gauze), impregnated with MRSA and dried so that a biofilm formed. Ozone rich atmosphere is fed into the chamber. An electrical fan **106** with rotary blades **108** was disposed 3 cm from the gauze, so as to blow gases within the chamber through the gauze at high velocity, to cause physical agitation of the gauze. A dish **110** containing an exposed, similarly impregnated gauze **112** was disposed near the other end of the chamber **100**, so that it was exposed to essentially static atmosphere in the chamber. A control gauze, which was similarly impregnated but received no treatment, was also evaluated.

The results are reported in Table 1 below. In Table 1, columns A, B, C and D are the results at 10 fold serial dilutions, obtained by standard procedure. Results measured on gauzes subjected to physical agitation are recorded as “direct”. Those on the gauzes in essentially static atmosphere are recorded as “indirect”.

In all instances, the combination of 80 ppm ozone and 1% H_2O_2 at a relative humidity of 80% with an exposure time of 30 minutes proved superior to all other combinations including 1% H_2O_2 with no ozone and 80 ppm ozone with no H_2O_2. In these experiments the methodology utilized with respect to microbiological procedures was the same as that described above for other experiments. Accordingly it has been concluded that in order to achieve a 6-7 log bacterial kill in hospital environments wherein carpets and other textiles are commonly found, an ozone/H_2O_2 pressure applicator or physical agitator is essential. Based on the experiments provided and other research, the incremental improvement in bacterial kill achievable through a pressure applicator is in the order of 2-3 logs (100-1000× greater).

TABLE 1

Run #	Organism	Ozone (PPM)				H_2O_2 (%)	EXP (min)	Humidity	Disc		A	B	C	D
Control	MRSA	0	0	0	0	Control	TNTC	180	2	0				
1	MRSA	80	1	30	80	1	0	0	0	0	Direct			
2	MRSA	80	1	30	80	2	77	11	2	1	Indirect			
3	MRSA	0	0	60	80	3	TNTC	TNTC	181	12	Direct			
4	MRSA	0	0	60	80	4	TNTC	233	21	3	Indirect			
5	MRSA	0	1	60	80	5	220	34	0	0	Direct			
6	MRSA	0	1	60	80	6	245	112	0	0	Indirect			
7	MRSA	0	1	90	80	7	134	10	2	0	Direct			
8	MRSA	0	1	90	80	8	112	17	3	0	Indirect			
9	MRSA	80	0	30	80	9	43	14	0	0	Direct			
10	MRSA	80	0	30	80	10	112	15	3	0	Indirect			
11	MRSA	0	1	90	80	11	86	12	0	0	Direct			
12	MRSA	0	1	90	80	12	136	54	0	0	Indirect			

Example 11

Test bacteria, namely *Clostridium difficile* (*C. difficile*); *E. coli; Pseudomonas aeruginosa* (PAU); methicillin-resistant *Staphylococcus aureus* (MRSA); vancomycin-resistant *Enterococcus* (VRE); were prepared as described for the previous experiments (see Example 1 for the preparation of the aerobic bacteria, Example 9 for the preparation of *C. difficile*). *Bacillus subtilis* (the surrogate for anthrax) was prepared analogously to the preparation of *C. difficile*, except that the bacteria was grown on Columbia sheep's blood agar plates incubated for 18-24 hours in room air at 35° C. They were separately cultured on plates for 24 hours. From the plate, 4-5 isolated colonies were selected, and suspended in 0.85 NaCl to achieve a 0.5 McFarland turbidity standard (1.5×10^8 cfu/ml) measured using a spectrophotometer. Inoculum was prepared by performing a series of serial dilutions of 0.9 ml 0.85 NaCl broth with 0.1 ml of original 0.5 McFarland inoculum (6×10 fold) to give solutions of 10^{-1}, 10^{-2}, 10^{-3}, 10^{-4}, 10^{-5}, 10^{-6} and 10^{-7} cfu/mL. Organisms were plated out in triplicate, as previously described, 0.1 ml of each solution being spread over the surface of Columbia sheep's blood agar (in respect of the aerobic bacteria) or *Brucella* anaerobic blood agar plates (in respect of *C. difficile* and *B. subtilis*) on plates, or on stainless steel plates. On agar, the bacteria maintain planktonic mode. On steel plates, biofilms containing the bacteria form.

For the experiments on steel plates, 40 microliters of the original inoculum as prepared above was placed onto the surface of a series of 1 cm diameter stainless steel discs. These were allowed to dry in a biological safety cabinet for approximately 45 minutes until the inoculum spots were dry. The steel discs were placed in a sterile Petri dish to facilitate their transfer to the test chamber. Once dry, the lid of the Petri dish was placed over the discs, and they were carefully transferred to the treatment location where they were exposed to the ozone test conditions. Appropriate numbers of control discs are left covered in the biological safety cabinet, and not exposed to the ozone test conditions.

Some of the plates were subjected to ozone/oxygen exposure using ozone 80 ppm, 42-80% humidity and room temperature of about 22° C., for a period of 90 minutes, in the illustrated apparatus, as controls. Additional controls had no ozone or hydrogen peroxide treatment, but were prepared and exposed in the same way.

With reference to FIG. 4, the test plates were mounted inside the disinfection chamber **60**, and treated with ozone and water vapor as previously described, but additionally using hydrogen peroxide supplied as a vapor to the chamber via port **65**. The disinfection chamber **60** also contained the same heater/cooler system and sensors previously described.

Plates treated according to the invention were exposed to 80 ppm ozone and gaseous hydrogen peroxide from a 1% or a 3% aqueous solution, air being blown through the aqueous solution in the illustrated apparatus to create the gaseous hydrogen peroxide. Other conditions and exposure times were kept the same.

Immediately after the exposure to the test conditions, and similarly for the unexposed control discs, the stainless steel discs were vigorously mixed in 10 ml of sterile 0.85% saline using a vortex mixer at high speed for 60 seconds to elute off all surviving viable bacteria or spores. The eluted suspension, containing both living and dead bacteria, is serially diluted 10 fold in sterile 0.85% saline and the diluted bacteria were quantitatively plated onto Columbia sheep's blood agar plates for the aerobic bacteria or *Brucella* anaerobic blood agar plates for *C. difficile*, incubated under appropriate conditions, in triplicate so as to determine the original inoculum concentration. The survivor colony counts were logarithmically transformed and the geometric mean calculated. The difference between the bacterial counts of the unexposed controls and the exposed test discs yielded the logarithmic reduction in bacteria under the test conditions. If this procedure results in no growth, 100% of the bacteria within the biofilm have been killed by exposure to the ozone/hydrogen peroxide.

The agar plates after exposure were cultivated in an incubator for 24 hours. The plates were then stained, examined through a microscope, and the numbers of colony forming units on each plate was counted.

The results are reported in Table 2 below, as 10 fold reductions in live bacteria on the agar plate or the steel plate, in comparison with the starting plate prior to any exposure. Thus a value of 1 means a 10 fold or one log reduction relative to the control samples which is not considered a significant effect. A value of 5 means a 5 log or 99.999% reduction in live bacteria was achieved, enough to be termed “full disinfection”, for practical purposes. A value of 6 means a 6 log or 99.9999% reduction in live bacteria was achieved which is defined internationally (CDC) as “sterilization”. The bacterial strains were as reported in the previous experiments. The *Bacillus subtilis* was ATCC 19659 spores.

TABLE 2

	Ozone	80 ppm	H_2O_2	3%	Ozone 80 ppm + 1% H_2O_2	
Bacteria	Agar	Steel	Agar	Alone Steel	Steel	
C. difficile	4.5	2.5-3.0	1.5	1.00	6.5+	
MRSA	4.5	5.0	1.5	1.5	7.0+	
E. Coli	4.0	3.5	2.0	1.0	7.0	
VRE	4.5	3.5	1.0	1.0	6.5	
PAU	4.0	3.0	2.0	0.5	7.0	
Bacillus Sub			1.0	1.0	7.0+	

Example 12

Tables 3, 4, 5, 6, 7 and 8 below provide a summary of experiments, whereby combinations of ozone, H_2O_2, humidity and exposure time were evaluated in terms of the ability to eliminate the following bacteria when artificially applied as a biofilm onto non-porous surfaces such as stainless steel discs: *E. coli; Pseudomonas aeruginosa* (PAU); *Bacillus subtilis* (the surrogate for anthrax). *Clostridium difficile* (*C. difficile*); vancomycin-resistant *Enterococcus* (VRE); and methicillin-resistant *Staphylococcus aureus* (MRSA), same strains as before.

The steel discs for testing and the agar plates for testing were prepared exposed and tested as described in the previous example, with exposure conditions shown in the Tables below. In some cases, indicated as “chamber”, the tests were conducted as described in Example 10 and with an apparatus generally as illustrated in FIG. 4. In other cases indicated as “room”, the tests were conducted by exposing the disks and plates in a closed room, as generally illustrated in FIG. 1.

The below Tables of results also report a period of post exposure (PEEP), in minutes, which is the time interval between the ozone/peroxide exposure termination and the start of the procedure for determining the results. This simulates real practice in disinfecting hospital rooms and similar environments, where bacteria, after disinfectant treatment, die over a period of time. To allow for this, it is preferred that at least 25 minutes should elapse from the time the ozone/hydrogen peroxide exposure terminates before the disinfected room is put back into normal service.

TABLE 3

Escherichia coli (*E. Coli*) - ATCC

Material	O_3 (PPM)	H_2O_2 %	Humidity %	Exp.	PEEP	Cham./Room	Log10 RED
Steel	80	1	80-85	90	90	Chamber	5.99
Steel	80	1	80-85	60	90	Chamber	5.99
Steel	80	1	80-85	45	90	Chamber	5.99
Steel	80	1	80-85	45	0	Chamber	5.99
Steel	80	1	80-85	60	0	Room	6.02
Steel	80	1	80-85	25	0	Chamber	6.8
Steel	80	1	80-85	35	0	Chamber	6.8
Steel	80	1	80-85	45	0	Chamber	6.8
Steel	80	1	80-85	60	0	Chamber	6.8

TABLE 4

Pseudo

Material	O_3 (PPM)	H_2O_2 %	Humidity %	Exp.	PEEP	Cham./Room	Log10 RED
Steel	80	1	80-85	90	90	Chamber	5.01
Steel	80	1	80-85	90	90	Chamber	5.01
Steel	80	1	80-85	90	90	Chamber	5.01
Steel	80	1	80-85	25	0	Chamber	7.36
Steel	80	1	80-85	35	0	Chamber	7.36
Steel	80	1	80-85	45	0	Chamber	7.36
Steel	80	1	80-85	60	0	Chamber	7.36
Steel	80	1	80-85	45	0	Chamber	6.35

Steel	80	1	80-85	60	0	Chamber	6.35
Steel	80	1	80-85	90	0	Chamber	6.35

TABLE 5

Bacillus subtilis

Material	O_3 (PPM)	H_2O_2 %	Humidity %	Exp.	PEEP	Cham./Room	Log10 RED
Steel	80	0.5	80-85	90	90	Chamber	0.5
Steel	80	1	80-85	90	0	Chamber	0.1
Steel	80	3	80-85	90	0	Chamber	7.23
Steel	0	3	80-85	90	90	Chamber	0
Steel	80	3	80-85	90	90	Chamber	7.23
Steel	80	1	80-85	90	90	Chamber	7.23
Steel	80	1	80-85	90	90	Chamber	4.61
Steel	80	1	80-85	90	90	Chamber	4.61
Steel	80	1	80-85	90	90	Chamber	4.61
Steel	80	1	80-85	90	90	Room	6.6
Steel	80	3	80-85	90	90	Room	6.6
Steel	80	3	80-85	90	0	Room	6.6
Steel	80	1	80-85	90	90	Chamber	6.34
Steel	80	3	80-85	90	90	Chamber	6.34
Steel	80	3	80-85	90	0	Chamber	6.34

TABLE 6

Clostridium Difficile (*C. Diff*) - ATCC

Material	O_3 (PPM)	H_2O_2 %	Humidity %	Exp.	PEEP	Cham./Room	Log10 RED
Steel	>1000	0	87	90	90	Chamber	3.734
Steel	80	0	87	90	90	Chamber	3.135
Steel	180	0	87	45	90	Chamber	3.161
Steel	80	0	87	90	90	Chamber	2.76
Steel	180	0	87	90	90	Chamber	2.96
Steel	80	0	87	90	90	Chamber	1.95
Steel	180	0	87	90	90	Chamber	1.47
Steel	80	1	80-85	90	90	Chamber	UNK
Steel	80	3	80-85	90	90	Chamber	6.23
Steel	80	0.5	80-85	90	0	Chamber	6.23
Steel	50	0.5	80-85	90	90	Chamber	UNK
Steel	50	3	80-85	90	90	Chamber	1.29
Steel	80	0.5	80-85	90	90	Chamber	6.72
Steel	80	1	80-85	90	90	Room	5.75
Steel	80	1	80-85	45	0	Chamber	7.9
Steel	80	1	80-85	60	0	Chamber	7.9
Steel	80	1	80-85	90	0	Chamber	7.9

TABLE 7

Vancomycin Resistant *Enterococcus* (VRE) - ATCC

Material	O_3 (PPM)	H_2O_2 %	Humidity %	Exp.	PEEP	Cham./Room	Log10 RED
Steel	400	0	80	90	90	Chamber	1.19
Steel	80	0	80	90	90	Chamber	0.66
Steel	80	0	65	90	90	Chamber	1.44
Steel	130	0	65	90	90	Chamber	0.22
Steel	130	0	65	90	90	Chamber	1.08
Steel	80	1	80-85	90	90	Chamber	5.74
Steel	80	1	80-85	90	90	Chamber	5.74
Steel	80	1	80-85	90	90	Chamber	5.74
Steel	80	1	80-85	90	90	Room	5.96
Steel	80	1	80-85	60	90	Room	5.96
Steel	80	1	80-85	45	90	Room	5.96
Steel	80	1	80-85	45	0	Room	5.96
Steel	80	1	80-85	60	0	Chamber	6.08
Steel	80	1	80-85	25	0	Chamber	5.8
Steel	80	1	80-85	35	0	Chamber	5.8

Steel	80	1	80-85	45	0	Chamber	5.8
Steel	80	1	80-85	60	0	Chamber	5.8

TABLE 8

MRSA - ATCC 33952

Material	O_3 (PPM)	H_2O_2 %	Humidity %	Exp.	PEEP	Cham./Room	Log10 RED
Steel	400	0	80	90	90	Chamber	1.223
Steel	80	0	80	90	90	Chamber	0.83
Steel	80	0	65	90	90	Chamber	1.44
Steel	130	0	65	90	90	Chamber	0.22
Steel	130	0	65	90	90	Chamber	1.08
Agar	>1000	0	80	90	90	Chamber	5.15
Agar	80	0	80	90	90	Chamber	4.899
Agar	130	0	?	90	90	Chamber	4.695
Steel	80	0	60-70	90	90	Chamber	0.49
Steel	180	0	80	90	90	Chamber	0.66
Steel	500	0	80	90	90	Chamber	6.73
Steel	180	0	80-85	90	0	Chamber	0.99
Steel	180	0	80-85	90	90	Chamber	6.23
Steel	500	0	80-85	90	90	Chamber	6.23
Steel	50	0	80-85	90	0	Chamber	0.97
Steel	50	0	80-85	90	90	Chamber	1.03
Steel	80	0	80-85	90	0	Chamber	1.04
Steel	80	0	80-85	90	90	Chamber	1.52
Steel	120	0	80-85	90	0	Chamber	0.81
Steel	120	0	80-85	90	90	Chamber	0.99
Steel	180	0	80-85	90	0	Chamber	0.62
Steel	180	0	80-85	90	90	Chamber	1.51-6.5 ?
Steel	80	0	80-85	90	90	Chamber	1.32-6.53
Steel	80	3	80-85	90	90	Chamber	6.53
Steel	180	3	80-85	90	90	Chamber	6.53
Steel	80	0	80-85	90	90	Chamber	0.51
Steel	80	1	80-85	90	90	Chamber	6.39
Steel	0	1	80-85	90	90	Chamber	0.13
Steel	30	1	80-85	90	90	Chamber	1.32
Steel	80	0.5	80-85	90	0	Chamber	6.43
Steel	80	1	80-85	90	0	Room	6.43
Steel	80	1	80-85	60	90	Room	6.36
Steel	80	3	80-85	60	90	Room	6.36
Steel	80	3	80-85	45	0	Room	6.36
Steel	80	1	80-85	90	90	Chamber	6.6
Steel	80	3	80-85	90	90	Chamber	6.6
Steel	80	3	80-85	90	0	Chamber	6.6
Steel	80	1	80-85	25	0	Chamber	6.7
Steel	80	1	80-85	35	0	Chamber	6.7
Steel	80	1	80-85	45	0	Chamber	6.7
Steel	80	1	80-85	60	0	Chamber	6.7
Steel	80	1	80-85	45	0	Chamber	8.11
Steel	80	1	80-85	60	0	Chamber	8.11
Steel	80	1	80-85	90	0	Chamber	8.11
Steel	80	0.2	45	30	0	Chamber	0.128
Steel	80	0.2	45	60	0	Chamber	1.169
Steel	80	0.2	45	90	0	Chamber	1.29
Steel	80	0.2	60	30	0	Chamber	0.04
Steel	80	0.2	60	60	0	Chamber	0.987
Steel	80	0.2	60	90	0	Chamber	1.86
Steel	80	0.2	80	30	0	Chamber	1.4
Steel	80	0.2	80	60	0	Chamber	2.4
Steel	80	0.2	80	90	0	Chamber	8.452
Steel	80	1	60	30	0	Chamber	1.049
Steel	80	1	60	60	0	Chamber	2.505
Steel	80	1	60	90	0	Chamber	8.452

Steel	80	1	60	90	0	Chamber	8.452
Steel	80	1	80	30	0	Chamber	7.37
Steel	80	1	80	60	0	Chamber	7.37
Steel	80	1	80	90	0	Chamber	7.37
Steel	80	3	45	30	0	Chamber	0.849
Steel	80	3	45	60	0	Chamber	2.57
Steel	80	3	45	90	0	Chamber	8.086
Steel	80	3	60	30	0	Chamber	1.87
Steel	80	3	60	90	0	Chamber	8.086
Steel	80	3	80	30	0	Chamber	7.37
Steel	80	3	80	60	0	Chamber	7.37
Steel	80	3	80	90	0	Chamber	7.37

The findings with respect to *Bacillus subtilis* clearly indicate that 80 ppm ozone, 1% H_2O_2 at 80% relative humidity produces a 6 log (+) reduction when these aerobic spores are exposed for 90 minutes. Given the uniqueness of this bacteria and the fact that it is routinely used as a surrogate for anthrax, the above combination of treatment parameters renders this device highly effective in a bioterrorism countermeasures scenario.

The findings with respect to *Pseudomonas aeruginosa* show definitely that 80 ppm ozone, 1% H_2O_2 at 80% relative humidity with an exposure time of 25 minutes produces a 100% kill (7+ logs). The same findings were observed when biofilms of *E. coli* samples on stainless steel discs were exposed for 25 minutes to a combination of 80 ppm ozone, 1% H_2O_2 at a relative humidity of 80%.

With respect to *Clostridium difficile* and vancomycin resistant *Enterococcus*, the same combination of 80 ppm ozone, 1% H_2O_2 and 80% relative humidity proved highly effective in achieving 100% elimination of bacteria in biofilms placed on a stainless steel surface and exposed for 45 minutes.

The results summarized in Table 8 above clearly demonstrates that the same combination of 80 ppm ozone, 1% H_2O_2 and 80% relative humidity achieves 100% kill (6+ log reduction) when biofilms of MRSA were exposed for 30 minutes.

Conclusion

The data provided in the above Tables clearly demonstrate that the process according to the invention is capable of completely eliminating bacteria contained within biofilm preparations on a non-porous hardened surface such as stainless steel. Although small adjustments in the time of exposure are necessary for the common pathogens found in hospital settings (25-45 minutes), *Bacillus subtilis* and therefore its cousin anthrax require almost twice the exposure time, but these pathogens are of little concern to hospitals.

Thus one aspect of the invention is a process for disinfecting a room, which comprises introducing into the room an oxygen/ozone gas mixture, raising the pressure within the room above atmospheric pressure, physically agitating fibrous and porous surfaces within the room while the surfaces are exposed to the ozone containing atmosphere of relative humidity at least 65%, returning the room to atmospheric pressure, and removing the residual ozone from the room's atmosphere, down to a maximum level of 0.04 ppm.

Another aspect of the invention is a portable system for disinfecting rooms and surfaces therein with ozone, comprising an oxygen container, an ozone generator fed with medical grade oxygen from the oxygen container and discharging a mixture of oxygen and ozone, an ozone controller adapted to control the proportion of ozone in the mixture of oxygen and ozone, a discharge tube to receive the mixture of oxygen and ozone from the ozone generator, the discharge tube having an outlet end, a physical agitation system at the outlet end of the discharge tube, for physical agitation of surfaces with oxygen/ozone mixture issuing therefrom, pressure adjusting means connected to the ozone generator arranged to adjust the pressure of the oxygen/ozone mixture discharged by the physical agitation system and the oxygen/ozone gas pressure in the room under treatment, temperature adjusting means connected to the ozone generator arranged to adjust the temperature of the oxygen/ozone mixture discharged by the physical agitation system, humidity adjusting means adapted to humidify the treatment location to a relative humidity not less than 65%, and an ozone remover adapted to receive oxygen/ozone mixture from the environment of use of the discharge tube and to remove ozone from the mixture.

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US5316741A *	1991-05-30	1994-05-31	Zontec Inc.	Ozone generator
US6045846A *	1998-12-18	2000-04-04	Dionex Corporation	Produce sterilization
US20030039729A1 *	1993-07-13	2003-02-27	Lynntech, Inc.	Methods of using ozone to degrade organic material
CA2486831A1	2002-05-20	2004-02-05	Theodore A. M. Arts	Air decontamination devices
US20050129571A1 *	2003-12-10	2005-06-16	Steris Inc.	Ozone enhanced vaporized hydrogen peroxide decontamination method and system
US20050226764A1 *	2002-07-02	2005-10-13	Claude Moirandat	Method and system for decontaminating a clean-room
US20060104858A1 *	2003-01-06	2006-05-18	Potember Richard S	Hydroxyl free radical-induced decontamination of airborne spores, viruses and bacteria in a dynamic system
US20070079455A1 *	2005-05-03	2007-04-12	Ultreo, Inc.	Ultrasonic toothbrushes employing an acoustic waveguide
US7217685B2	2003-05-30	2007-05-15	Steris Inc.	Cleaning and decontamination formula for surfaces contaminated with prion-infected material
US7407624B2 *	2002-04-16	2008-08-05	Prompt Care, Inc.	Method for abatement of allergens, pathogens and volatile organic compounds
US20090263499A1 *	2008-04-18	2009-10-22	Ethicon, Inc.	Area decontamination via low-level concentration of germicidal agent

WO2011003179A1	2009-07-06	2011-01-13	Medizone International Inc.	Healthcare facility disinfecting process and system with oxygen/ozone mixture
Family To Family Citations				
JPH0960931A *	1995-08-30	1997-03-04	Takuma Co Ltd	Ultrasonic wave humidifying and sterilizing device
TW343923B *	1996-01-22	1998-11-01	Duskin Co Ltd	Deodorization/odor-removal/disinfection method and deodorization/odor-removal/disinfection apparatus
JP2001129062A *	1999-11-04	2001-05-15	Mitsubishi Electric Corp	Method and apparatus for disinfecting floor surface
JP4954993B2 *	2005-07-07	2012-06-20	ステリス インコーポレイテッド	Indoor decontamination using hydrogen peroxide vapor
US7604780B2 *	2004-11-11	2009-10-20	Agrimond Usa Corporation	Ozone disinfection apparatus
US7304288B2	2005-07-06	2007-12-04	The United States Of America As Represented By The Secretary Of The Navy	Laser pulse counter
US20070119699A1 *	2005-11-30	2007-05-31	Airocare, Inc.	Apparatus and method for sanitizing air and spaces

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Non-Patent Citations (10)

Title
"Ozone effects on bacteria, molds and viruses-ozone and bacteria destruction" published Dec. 24, 2007. http://web.archive.org/web/20071224191320/http://www.ozoneapplications.com/info/ozone-bacteria-mold-viruses.htm. *
"Ozone effects on bacteria, molds and viruses—ozone and bacteria destruction" published Dec. 24, 2007. http://web.archive.org/web/20071224191320/http://www.ozoneapplications.com/info/ozone—bacteria—mold—viruses.htm. *
Amendment Pursuant to Article 19 of the Patent Cooperation Treating for PCT Application No. PCT/CA2010/000998, Dec. 2, 2010, 14 pages, Ottawa, Ontario, Canada.
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Dr. Carsten Matz, et al "Biofilm Bacteria Protect Themselves With Chemical Weapons." Helmholtz Centre for Infection Research, Bauschweig, reported on Inforniac.com, Jul. 23, 2008.
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PCT Notification of the Recording of a Change for PCT Application No. PCT/CA2010/000998 (adding Dick Eric Zoutman as an inventor), Mar. 17. 2011, 1 page, Ottawa, Ontario, Canada.
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Publication number	Priority date	Publication date	Assignee	Title
US20130164172A1 *	2010-09-08	2013-06-27	Medizone International Inc.	Sports equipment and facility disinfection
US20130276357A1 *	2010-09-08	2013-10-24	Medizone International Inc.	Combating insect infestations
US8636951B2	2010-01-18	2014-01-28	Medizone International, Inc.	Bio-terrorism counteraction using ozone and hydrogen peroxide
WO2015168783A1 *	2014-05-05	2015-11-12	Sanuvox Technologies Inc.	Room decontamination system, method and controller
US9410191B2	2014-05-13	2016-08-09	Rasirc, Inc.	Method and system for decontaminating materials
US9616145B2	2009-07-06	2017-04-11	Medizone International, Inc.	Healthcare facility disinfecting system
US9616144B2	2010-09-08	2017-04-11	Medizone International Inc.	Food-handling facility disinfection treatment
WO2018072000A1 *	2016-10-19	2018-04-26	Corsetti Christopher Alexander	Sanitization system
US10071177B1	2016-08-15	2018-09-11	Synergy Med Global Design Solutions, Llc	Hospital and operating room designs and sterilization methods
US10342246B2	2016-09-09	2019-07-09	Quail Systems, Llc	Ozone generator, system, and methods for retrofit of enclosed and air-conditioned environments

USRE47582E1	2009-07-28	2019-08-27	Sterifre Medical, Inc.	Free radical sterilization system and method
US11000613B1	2016-08-15	2021-05-11	Synergy Med Global Design Solutions, Llc	Transportable self-sterilizing clinical environment
Family To Family Citations				
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WO2015048903A1 *	2013-10-04	2015-04-09	Medizone International Inc.	Healthcare facility disinfecting system
WO2012037678A1 *	2010-09-20	2012-03-29	Medizone International Inc.	Process for sterilization of air spaces and surfaces using advanced oxidation stress
EP2696902A4 *	2011-04-15	2015-08-05	Samuel Richard Trapani	Room sterilization method and system
JP2013158701A *	2012-02-03	2013-08-19	Ihi Shibaura Machinery Corp	Oxidation treatment system
JP2013158699A *	2012-02-03	2013-08-19	Ihi Shibaura Machinery Corp	Oxidation treatment method, and oxidation treatment system
JP5839687B2 *	2012-02-03	2016-01-06	株式会社Ｉｈｉシバウラ	Oxidation treatment system
JP6253223B2 *	2012-07-25	2017-12-27	株式会社Ihi	Sterilizer
US9339572B2	2013-03-15	2016-05-17	EP Technologies LLC	Methods and solutions for killing or deactivating spores
JP6501489B2 *	2014-10-27	2019-04-17	学校法人東海大学	Sterilizer
US10897894B2	2015-08-31	2021-01-26	Gojo Industries, Inc.	Methods of and system for generating antimicrobial wipes
CN105880198B *	2016-03-22	2018-08-31	王慧丽	A kind of pediatric nursing cleaning sterilizing device
WO2018089577A1	2016-11-10	2018-05-17	EP Technologies LLC	Methods and systems for generating plasma activated liquid
WO2020050864A1 *	2018-09-09	2020-03-12	SYNERGY MED GLOBAL DESIGN SOLUTIONS, LLC (a Delaware LLC)	Designs and sterilization methods for hospital and operating rooms
WO2020073075A1 *	2018-10-10	2020-04-16	Wellkleen Pty Ltd	Sterilisation device

* Cited by examiner, † Cited by third party, ‡ Family to family citation

Similar Documents

Publication	Publication Date	Title
Scholtz et al.	2015	Nonthermal plasma—A tool for decontamination and disinfection
US10299882B2	2019-05-28	Sterile site apparatus, system, and method of using the same
McKeen	2018	The effect of sterilization on plastics and elastomers
Boyce	2016	Modern technologies for improving cleaning and disinfection of environmental surfaces in hospitals
Rutala et al.	2013	Disinfectants used for environmental disinfection and new room decontamination technology
Nerandzic et al.	2015	Evaluation of a pulsed xenon ultraviolet disinfection system for reduction of healthcare-associated pathogens in hospital rooms
Klämpfl et al.	2012	Cold atmospheric air plasma sterilization against spores and other microorganisms of clinical interest
Daeschlein et al.	2012	Skin decontamination by low-temperature atmospheric pressure plasma jet and dielectric barrier discharge plasma
Kamgang-Youbi et al.	2009	Microbial inactivation using plasma-activated water obtained by gliding electric discharges
Bourke et al.	2017	Microbiological interactions with cold plasma
Joshi et al.	2010	Control of methicillin-resistant Staphylococcus aureus in planktonic form and biofilms: a biocidal efficacy study of nonthermal dielectric-barrier discharge plasma
Lin et al.	2018	Relative survival of Bacillus subtilis spores loaded on filtering facepiece respirators after five decontamination methods
KR101323982B1	2013-10-30	Aqueous disinfectants and sterilants
US8444919B2	2013-05-21	Space disinfection
JP5209831B2	2013-06-12	Disinfection method
Abreu et al.	2013	Current and emergent strategies for disinfection of hospital environments
Sharma et al.	2008	Ozone gas is an effective and practical antibacterial agent

Maillard	2005	Antimicrobial biocides in the healthcare environment: efficacy, usage, policies, and perceived problems
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Rutala et al.	2010	Room decontamination with UV radiation
Moore et al.	2000	Bactericidal properties of ozone and its potential application as a terminal disinfectant
Venezia et al.	2008	Lethal activity of nonthermal plasma sterilization against microorganisms
ES2417139T3	2013-08-06	Use of ultraviolet germicidal radiation in healthcare environments
US9585390B2	2017-03-07	Materials for disinfection produced by non-thermal plasma
US7354551B2	2008-04-08	Room decontamination with hydrogen peroxide vapor

Priority And Related Applications

Parent Applications (1)

Application	Priority date	Filing date	Relation	Title
PCT/CA2010/000998	2009-07-06	2010-07-05	Continuation	Healthcare facility disinfecting process and system with oxygen/ozone mixture

Child Applications (1)

Application	Priority date	Filing date	Relation	Title
US14/046,535	2009-07-06	2013-10-04	Continuation-In-Part	Healthcare facility disinfecting system

Priority Applications (4)

Application	Priority date	Filing date	Title
US22321909P	2009-07-06	2009-07-06	*US Provisional Application*
US29585110P	2010-01-18	2010-01-18	*US Provisional Application*
PCT/CA2010/000998	2009-07-06	2010-07-05	Healthcare facility disinfecting process and system with oxygen/ozone mixture
US13/343,403	2009-07-06	2012-01-04	Healthcare facility disinfecting system

Applications Claiming Priority (2)

Application	Filing date	Title
US13/343,403	2012-01-04	Healthcare facility disinfecting system
US14/046,535	2013-10-04	Healthcare facility disinfecting system

Legal Events

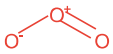
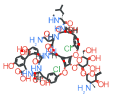
Date	Code	Title	Description
2013-09-18	STCF	Information on status: patent grant	**Free format text**: PATENTED CASE
2013-10-24	AS	Assignment	**Owner name**: MEDIZONE INTERNATIONAL INC., CALIFORNIA **Free format text**: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNORS:SHANNON, MICHAEL EDWARD;ZOUTMAN, DICK ERIC;SIGNING DATES FROM 20130927 TO 20131015;REEL/FRAME:031473/0649
2014-04-01	CC	Certificate of correction	
2017-03-02	FPAY	Fee payment	**Year of fee payment**: 4
2020-06-02	AS	Assignment	**Owner name**: ASEPTIC SCIENTIFIC, LLC, CALIFORNIA **Free format text**: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNOR:ESTATE OF MEDIZONE INTERNATIONAL, INC.;REEL/FRAME:052816/0738 **Effective date**: 20180821 **Owner name**: STERILIZ3 CANADA INC., CANADA

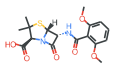
			Free format text: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNOR:ASEPTIC SCIENTIFIC, LLC;REEL/FRAME:052816/0850 **Effective date**: 20200518
2020-06-08	AS	Assignment	**Owner name**: STERILIZ3 CANADA INC., CANADA **Free format text**: CORRECTIVE ASSIGNMENT TO CORRECT THE CONVEYING PARTY NAME PREVIOUSLY RECORDED ON REEL 052816 FRAME 0850. ASSIGNOR(S) HEREBY CONFIRMS THE ASSIGNMENT;ASSIGNOR:ASEPTICSURE SCIENTIFIC, LLC;REEL/FRAME:052873/0209 **Effective date**: 20200518 **Owner name**: ASEPTICSURE SCIENTIFIC, LLC, CALIFORNIA **Free format text**: CORRECTIVE ASSIGNMENT TO CORRECT THE RECEIVING PARTY NAME AND ADDRESS TO: ASEPTICSURE SCIENTIFIC, LLCBOX 742, STINSON BEACH, CA 94970, US PREVIOUSLY RECORDED ON REEL 052816 FRAME 0738. ASSIGNOR(S) HEREBY CONFIRMS THE ASSIGNMENT;ASSIGNOR:ESTATE OF MEDIZONE INTERNATIONAL, INC;REEL/FRAME:052865/0017 **Effective date**: 20180821

Concepts

machine-extracted

Download Filter table

Name	Image	Sections	Count	Query match
desinfective		title,claims,abstract,description	68	0.000
ozone		claims,abstract,description	187	0.000
hydrogen peroxide		claims,abstract,description	132	0.000
Bacteria		claims,abstract,description	57	0.000
method		claims,abstract,description	54	0.000
oxygen		claims,abstract,description	54	0.000
oxygen		claims,abstract,description	53	0.000
oxygen		claims,abstract,description	53	0.000
Clostridioides difficile		claims,abstract,description	31	0.000
Escherichia coli		claims,abstract,description	17	0.000
Pseudomonas aeruginosa		claims,abstract,description	15	0.000
Pseudomonas aeruginosa		claims,abstract,description	14	0.000
VANCOMYCIN		claims,abstract,description	13	0.000
Vancomycin		claims,abstract,description	13	0.000
Vancomycin		claims,abstract,description	13	0.000
Enterococcus		claims,abstract,description	12	0.000
Staphylococcus aureus		claims,abstract,description	10	0.000
Staphylococcus aureus		claims,abstract,description	10	0.000
Methicillin		claims,abstract,description	9	0.000



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spores	claims,description	18	0.000
reducing	claims,description	14	0.000
reduction reaction	claims,description	14	0.000
Bacillus subtilis	claims,description	10	0.000
Bacillus anthracis	claims,description	9	0.000
Bacillus subtilis	claims,description	9	0.000
Bacillus subtilis	claims,description	9	0.000
Bacillus anthracis	claims	1	0.000
mixture	abstract,description	52	0.000
health	abstract,description	4	0.000
absorbent	abstract,description	3	0.000
absorbent	abstract,description	3	0.000

Show all concepts from the description section

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
90607-3	11/14/16

Term of Issuance:
Conditional

Name of Pesticide Product:
AsepticSure™ Oxidative Catalyst

Name and Address of Registrant (include ZIP Code):

Medizone International, Inc.
4000 Bridgeway, Suite 401
Saulsalito, CA 94965

EPA Reg. No. 90607- G
EPA Estab. No. 909607-CAN-001
NET CONTENTS: _____ fl oz (_____ L)

ACCEPTED
Nov 14, 2016
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 90607-3

Medizone International

September 15, 2014

The Honorable Eng. Adel bin Muhammad Faqih
Minister of Health
Riyadh,
Kingdom of Saudi Arabia

and,

Dr. Abdullah Mohammed Saim AlDahr
RAHF Medical Services Company
P.O. Box 50809, Jeddah KSA
Proposed Distributor for KSA

RE: AsepticSure: Viral Testing Results

Dear Sirs,

You will find enclosed herein the results of our extensive viral studies using AsepticSure. These studies were conducted in collaboration with the National Research Council of Canada Viral Testing Laboratory in Montréal, Québec.

During the months of June to August extensive testing was carried out with Human Adenovirus Type 5 and Transmissible Gastroenteritis Coronavirus (TGEV). Adenovirus being a non-enveloped virus demonstrated itself to be resilient to the freeze and thaw cycles inherent in transporting the viral specimens between our laboratory in Kingston and the National Research Council of Canada Laboratory in Montréal. AsepticSure demonstrated the ability to achieve a six log viral kill with 40 minutes of exposure. Given that adenovirus is known to be a very hardy virus and stable in the environment with considerable inherent resistance to disinfection, the ability of AsepticSure to achieve this level of viral kill is an excellent indication of the overall antiviral properties of AsepticSure.

The TGEV coronavirus, being an enveloped virus was more fragile and thus more difficult to achieve the same high concentrations as we did with adenovirus for the test inoculum. The coronavirus was subject to viral titer reductions during the freeze thaw cycles. Nevertheless, AsepticSure demonstrated a 5.11 and 5.45 log viral kill of coronavirus at 60 and 90 minutes of exposure respectively.

These excellent results demonstrate the high level of efficacy of AsepticSure in eradication of pathogenic viruses from non-porous surfaces.

Yours truly

Prof. Dick Zoutman, MD, FRCPC

NATIONAL RESEARCH COUNCIL CANADA

Project Report

Testing AsepticSure™ sterilization system on Adenovirus and Coronavirus

Submitted to

Medizone International Inc

August 19, 2014

National Research Council Canada
Conseil national de recherches Canada

Canada

Written by Name	Department	Signature	Date
Rénald Gilbert	Antibody & Bioprocessing		19/08/2014
Written by Name			
Mehdy Elahi	Antibody & Bioprocessing		
Reviewed by Name			
Dick Zoutman	Medizone International Inc		5/Sept/2014
Reviewed by Name			
Approved by Name			

1. OBJECTIVE

The objective of this project was to evaluate the efficacy of AsepticSure™ ozone-based sterilization system on adenovirus and coronavirus.

2. PROJECT DESCRIPTION

NRC was responsible to prepare and ship to Medizone laboratories the stocks of Adenovirus (human adenovirus Type 5) and Coronavirus (transmissible gastroenteritis virus, TGEV). TGEV was used as a surrogate of Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). After the sterilization procedure was performed by Medizone on steel discs inoculated with the virus, the discs were ship to NRC on dry ice for testing. The tests performed by NRC consisted to verify the presence of infectious virus by infecting permissive cells with medium used to wash the discs. The following controls were used for these tests: discs inoculated with the virus but not treated with AsepticSure (positive control) and mock inoculated disc treated with AsepticSure (negative control).

3. RESULTS AND CONCLUSION

-The results of the tests performed for the adenovirus are presented in Appendix 1.

-The results of the tests performed for TGEV are presented in Appendix 2.

The data show the virus titer obtained by $TCD_{50\%}$ for each disc tested. The efficacy of the sterilization procedure is calculated by dividing the titer of the positive control discs by the titer of the sample discs. The results are expressed as log reduction of virus titer.

In the case of adenovirus, a 6 log (1 million fold) reduction of virus titers after treatment with AsepticSure was demonstrated.

In the case of TGEV, the best reduction of virus titer was 4.9 logs (July 7 experiment). To demonstrate better titer reduction with TGEV, a virus stock with more concentrated virus would most likely be necessary.

4. MATERIAL AND METHODS

4.1 Viruses and cells

Swine testicular (ST) cells (ATCC CRL-1746) and TGEV (Transmissible gastroenteritis virus (ATCC VR-763) and 293A cells were purchased from ATCC. ST cells and 293A cells were cultured in Dulbecco's Modified Eagle Medium supplemented with 5% Fetal Bovine Serum and 2 mM L-Glutamine. The stock of TGEV virus was propagated by infecting ST cells with samples of virus. After incubation for 30 to 48 h at 37°C, the supernatant was harvested, clarified by centrifugation, aliquoted and frozen at -70°C until shipping to Medizone. The wild type adenovirus type 5 [Ad5-PTG3602] (CHARTIER et al., 1996) was amplified on 293A cells as described previously (Hitt et al., 1995). The titer of both viral stocks was measured by a $TCID_{50\%}$ assay as described below.

4.2 Virus titration ($TCID_{50\%}$ assay)

The titer of viruses (adenovirus and TGEV) in exposed and non-exposed samples to AsepticSure was measured using a $TCID_{50\%}$ assay. Briefly, 96- and 24-well plates were seeded with 293A or ST cells one day in advance in order to produce monolayers that are 85% confluent for the titration at the time of infection. Viral samples were serially diluted 10-fold from 10^{-1} to 10^{-8} for non-exposed samples (positive control) and to 10^{-4} for AsepticSure exposed samples and negatives samples. From each dilution, 100 µl was added to six wells of 96-well plates.

In the case of adenovirus, 100 µl of non-diluted adenovirus samples were also added to 4 wells of 96-well plate. For Adenovirus samples, the cell monolayer was examined for cytopathic effect after 7-10 days. The wells were fed with fresh media during this time.

In the case of TGEV, the plates were incubated for 5 days at 37°C. Because some level of toxicity was observed in the wells of 96-well plates infected with non-diluted samples, a second round of amplification was performed in ST cells to confirm the lack of TGEV growth in non-diluted Aseptic exposed samples. This was done by transferring 100 µl of culture from wells previously infected with non-diluted samples for 3-5 days, into new wells of 24-well plates. The new plates were incubated for additional 3-5 days.

For both adenovirus and TGEV, the $TCID_{50\%}$ is calculated by the Spearman & Kärber algorithm as described in Hierholzer & Killington (1996). Log10 reduction was calculated by comparing the virus titer recovered from the control and AsepticSure exposed discs.

LIST of APPENDICES

Appendix 1. Results of the tests performed with adenovirus.

Appendix 2 Results of the tests performed with TGEV

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Appendix 1

Experiment Date: Juin 13, 2014

Virocidal efficacy of AseptiSure ozone-base sterilization system on Adenovirus				
	Log10 reduction in virus titer (TCID50%) and SD after exposure to AseptiSure ozone			
Virus (strain)	Run1		Run2	
	log 10	SD	log10	SD
Human Adenovirus (type 5)	**≥5.96**	0.58	**≥5.66**	0.17

TCID50%: tissue culture infectious dose 50%, SD: Standard deviation
Log10 reduction calculated by comparing the virus titer recovered from the control (samples 4 to 6) and AseptiSure exposed discs.
No virus particules were detected on the AseptiSure exposed discs.

Experiment Date: Juin 13, 2014

Adenovirus-PTG (Run1 40 min exposure)

sample name	TCID50/ml	log10		TCID50/ml	log10		TCID50/ml:	log10
MZ1	≤3.16E+00	≤0.5	**sample +1**	3.98E+05	6.66	(-)1 stock	<3.16E+00	<0.5
MZ2	≤3.16E+00	≤0.5	**sample +2**	3.98E+05	6.66	(-)2 stock	<3.16E+00	<0.5
MZ3	≤3.16E+00	≤0.5	**sample +3**	4.57E+05	6.33			0
MZ4	≤3.16E+00	≤0.5	**sample 1 to 3 did not use in average calculation**					
MZ5	≤3.16E+00	≤0.5						
MZ6	≤3.16E+00	≤0.5	**sample +4**	6.61E+05	5.82			
MZ7	≤3.16E+00	≤0.5	**sample +5**	6.61E+06	6.82			
MZ8	≤3.16E+00	≤0.5	**sample +6**	6.61E+06	6.82			
average	≤3.16E+00	≤0.5		4.62E+06	**6.49**		<3.16E+00	<0.5
stdev		0.00			0.58			0

Experiment Date: Juin 13, 2014

Adenovirus-PTG (Run2 60 min exposure)

sample name	TCID50/ml	log10		TCID50/ml	log10		TCID50/ml:	log10
MZ1	≤3.16E+00	≤0.5	**sample +1**	4.57E+05	6.66	(-)1 stock	<3.16E+00	<0.5
MZ2	≤3.16E+00	≤0.5	**sample +2**	4.57E+05	6.66	(-)2 stock	<3.16E+00	<0.5
MZ3	≤3.16E+00	≤0.5	**sample +3**	3.16E+06	6.5			0
MZ4	≤3.16E+00	≤0.5	**sample 1 to 3 did not use in average calculation**					
MZ5	≤3.16E+00	≤0.5						
MZ6	≤3.16E+00	≤0.5	**sample +4**	1.00E+06	6.00			
MZ7	≤3.16E+00	≤0.5	**sample +5**	1.45E+06	6.16			
MZ8	≤3.16E+00	≤0.5	**sample +6**	2.14E+06	6.33			
average	≤3.16E+00	≤0.5		1.53E+06	**6.16**		<3.16E+00	<0.5
stdev		0.00			0.17			0

Appendix 1

Experiment Date: July13, 2014

Virocidal efficacy of AseptiSure ozone-base sterilization system on Human Adenovirus type 5				
Log10 reduction in virus titer (TCID50%) and (SD) after exposure to AseptiSure ozone				
Virus (strain)	Run#1 (40 min)		Run#2 (20 min)	
	log 10	SD	log10	SD
Human Adenovirus (type 5)	**>6.04**	0	**4.7**	0.39

TCID50%: tissue culture infectious dose 50%, SD: Standard deviation
Log10 reduction calculated by comparing the virus titer recovered from the control (samples 4 to 6) and AseptiSure exposed discs.
No virus particules were detected on the AseptiSure exposed discs at run#1

Experiment Date: July13, 2014

Adenovirus-PTG **(Run 1, 40 minutes)**

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ 1 stock	3.16E+00	<0.5	(+)1 stock	2.15E+06	6.33	(-)1 stock	3.16E+00	<0.5
MZ 2 stock	3.16E+00	<0.5	(+)2 stock	4.64E+06	6.67	(-)2 stock	3.16E+00	<0.5
MZ 3 stock	3.16E+00	<0.5	(+)3 stock	3.16E+06	6.50			
MZ 4 stock	3.16E+00	<0.5	(+)4 stock	3.16E+06	6.50			
MZ 5 stock	3.16E+00	<0.5	(+)5 stock	3.16E+06	6.50			
MZ 6 stock	3.16E+00	<0.5	(+)6 stock	4.64E+06	6.67			
MZ 7 stock	3.16E+00	<0.5						
MZ8 stock	3.16E+00	<0.5						
averge	3.16E+00	**<0.5**		3.49E+06	**6.54**		3.16E+00	**<0.5**
stdev		0			0.13			0

Experiment Date: July13, 2014

Adenovirus-PTG **(Run 2, 20 minutes)**

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ 1 stock	1.47E+02	2.17	(+)1 stock	2.15E+06	6.33	(-)1 stock	3.16E+00	<0.5
MZ 2 stock	1.47E+01	1.17	(+)2 stock	2.15E+06	6.33	(-)2 stock	3.16E+00	<0.5
MZ 3 stock	3.16E+01	1.50	(+)3 stock	3.16E+06	6.50			
MZ 4 stock	1.47E+01	1.17	(+)4 stock	3.16E+06	6.50			
MZ 5 stock	1.47E+02	2.17	(+)5 stock	4.64E+06	6.67			
MZ 6 stock	3.16E+01	1.50	(+)6 stock	2.15E+06	6.33			
MZ 7 stock	3.16E+01	1.50						
MZ8 stock	4.64E+01	1.67						
averge	5.80E+01	**1.76**		2.90E+06	**6.46**		3.16E+00	**<0.5**
stdev		0.39			0.14			0

Appendix 2

Experiment Date: Juin 13, 2014

Virocidal efficacy of AseptiSure ozone-base sterilization system on Transmissible Gastroenteritis Coronavirus (TGEV)								
	Log10 reduction in virus titer (TCID50%) and (SD) after exposure to AseptiSure ozone							
Virus (strain)	Run#1 (1/1)		Run#1 (1/10)		Run#2 (1/1)		Run#2 (1/10)	
	log 10	SD	log 10	SD	log10	SD	log10	SD
TGEV	**2.91**	0.58	**2.41**	0.13	**3.41**	0.35	**2.08**	0.11

TCID50%: tissue culture infectious dose 50%, SD: Standard deviation

Log10 reduction calculated by comparing the virus titer recovered from the control (samples 3 to 4) and AseptiSure exposed discs.

No virus particules were detected on the AseptiSure exposed discs at dilution -1 .

Because of cytotoxicity at non diluted sample in TCID50% assay, limit of detection of test is 31.6 TCID50% per ml.

Experiment Date: Juin 13, 2014

TGEV-Run1 non diluted

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ1	≤3.16E+01	≤1.5	**sample +1**	6.61E+04	4.82	(-)1 stock	<3.16E+01	<1.5
MZ2	≤3.16E+01	≤1.5	**sample +2**	4.57E+04	4.66	(-)2 stock	<3.16E+01	<1.5
MZ3	≤3.16E+01	≤1.5	**sample 1 to 2 did not use in average calculation**					0
MZ4	≤3.16E+01	≤1.5						
MZ5	≤3.16E+01	≤1.5	**sample +3**	1.00E+04	4			
MZ6	≤3.16E+01	≤1.5	**sample +4**	6.61E+04	4.82			
average	≤3.16E+01	≤1.5		3.80E+04	**4.41**		<3.16E+01	<1.5
stdev		0.00			0.58			0

TGEV-Run1 diluted

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ1	≤3.16E+01	≤1.5	**sample +1**	1.41E+04	4.15	(-)1 stock	<3.16E+01	<1.5
MZ2	≤3.16E+01	≤1.5	**sample +2**	1.00E+04	4	(-)2 stock	<3.16E+01	<1.5
MZ3	≤3.16E+01	≤1.5	**sample 1 to 2 did not use in average calculation**					0
MZ4	≤3.16E+01	≤1.5						
MZ5	≤3.16E+01	≤1.5	**sample +3**	6.61E+03	3.82			
MZ6	≤3.16E+01	≤1.5	**sample +4**	1.00E+04	4			
average	≤3.16E+01	≤1.5		8.30E+03	**3.91**		<3.16E+01	<1.5
stdev		0.00			0.13			0

Appendix 2

TGEV-Run2 non diluted

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ1	≤3.16E+01	≤1.5	**sample +1**	1.00E+05	5	(-)1 stock	<3.16E+01	<1.5
MZ2	≤3.16E+01	≤1.5	**sample +2**	6.61E+04	4.82	(-)2 stock	<3.16E+01	<1.5
MZ3	≤3.16E+01	≤1.5	**sample 1 to 2 did not use in average calculation**					0
MZ4	≤3.16E+01	≤1.5						
MZ5	≤3.16E+01	≤1.5	**sample +3**	4.57E+04	4.66			
MZ6	≤3.16E+01	≤1.5	**sample +4**	1.45E+05	5.16			
average	≤3.16E+01	≤1.5		9.51E+04	**4.91**		<3.16E+01	<1.5
stdev		0.00			0.35			0

TGEV-Run2 diluted

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ1	≤3.16E+01	≤1.5	**sample +1**	1.00E+04	4	(-)1 stock	<3.16E+01	<1.5
MZ2	≤3.16E+01	≤1.5	**sample +2**	1.00E+04	4	(-)2 stock	<3.16E+01	<1.5
MZ3	≤3.16E+01	≤1.5	**sample 1 to 2 did not use in average calculation**					0
MZ4	≤3.16E+01	≤1.5						
MZ5	≤3.16E+01	≤1.5	**sample +3**	4.57E+03	3.66			
MZ6	≤3.16E+01	≤1.5	**sample +4**	3.16E+03	3.5			
average	≤3.16E+01	≤1.5		3.87E+03	**3.58**		<3.16E+01	<1.5
stdev		0.00			0.11			0

Appendix 2

Experiment Date: July 7, 2014

Virocidal efficacy of AseptiSure ozone-base sterilization system onTGEV						
	Log10 reduction in virus titer (TCID50%) and (SD) after exposure to AseptiSure ozone					
Virus (strain)	Run#1 (1/10 dilution)		Run#1 (1/1 dilution)		Run#1 (2X)	
	log 10	SD	log 10	SD	log10	SD
TGEV	**2.88**	0.1	**3.35**	0.1	**3.24**	0.1

TCID50%: tissue culture infectious dose 50%, SD: Standard deviation
Log10 reduction calculated by comparing the virus titer recovered from the control and AseptiSure exposed discs.

Experiment Date: July 7, 2014

TGEV-Run1, 40 min

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ 1 1/10	3.16E+01	1.50	(+)1 1/10	2.15E+04	4.33	(-)1 1/10	<3.16E+00	<0.5
MZ 2 1/10	3.16E+01	1.50	(+)2 1/10	3.16E+04	4.50	(-)2 1/10	<3.16E+00	<0.5
MZ 3 1/10	4.64E+01	1.67	(+)3 1/10	3.16E+04	4.50			0
MZ 4 1/10	4.64E+01	1.67						
MZ 5 1/10	3.16E+01	1.50						
average	3.75E+01	**1.57**		2.83E+04	**4.45**		<3.16E+00	<0.5
stdev		0.09			0.10			0
MZ 1 stock	6.81E+01	1.83	(+)1 stock	2.15E+05	5.33	(-)1 stock	<3.16E+00	<0.5
MZ 2 stock	2.15E+02	2.33	(+)2 stock	2.15E+05	5.33	(-)2 stock	<3.16E+00	<0.5
MZ 3 stock	6.81E+01	1.83	(+)3 stock	3.16E+05	5.50			
MZ 4 stock	1.47E+02	2.17						
MZ 5 stock	6.81E+01	1.83						
average	1.13E+02	**2.05**		2.49E+05	**5.40**		<3.16E+00	<0.5
stdev		0.24			0.10			0
MZ 1 x2	4.64E+02	2.67	(+)1 2x	4.64E+05	5.67	(-)1 2x	3.16E+00	<0.5
MZ 2 x2	4.64E+02	2.67	(+)2 2x	6.81E+05	5.83	(-)2 2x	3.16E+00	<0.5
MZ 3 x2	1.47E+02	2.17	(+)3 2x	4.64E+05	5.67			
MZ 4 x2	1.47E+02	2.17						
MZ 5 x2	3.16E+02	2.50						
average	3.08E+02	**2.49**		5.37E+05	**5.73**		<3.16E+00	<0.5
stdev		0.25			0.10			0

Appendix 2

Experiment Date: July 7, 2014

Virocidal efficacy of AseptiSure ozone-base sterilization system on TGEV						
	Log10 reduction in virus titer (TCID50%) and (SD) after exposure to AseptiSure ozone					
Virus (strain)	Run#1 (1/10 dilution)		Run#1 (1/1 dilution)		Run#1 (2X)	
	log 10	SD	log 10	SD	log10	SD
TGEV	**≥3.5**	0	**≥4.62**	0.1	**≥ 4.9**	0.1

TCID50%: tissue culture infectious dose 50%, SD: Standard deviation
Log10 reduction calculated by comparing the virus titer recovered from the control and AseptiSure exposed discs.

Experiment Date: July 7, 2014

TGEV-Run1, 60 min

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ 1 1/10	≤3.16E+00	≤0.5	(+)1 1/10	1.00E+04	4.00	(-)1 1/10	<3.16E+00	<0.5
MZ 2 1/10	≤3.16E+00	≤0.5	(+)2 1/10	1.00E+04	4.00	(-)2 1/10	<3.16E+00	<0.5
MZ 3 1/10	≤3.16E+00	≤0.5	(+)3 1/10	1.00E+04	4.00			0
MZ 4 1/10	≤3.16E+00	≤0.5						
MZ 5 1/10	≤3.16E+00	≤0.5						
average	≤3.16E+00	≤0.5		1.00E+04	**4.00**		<3.16E+00	<0.5
stdev		0.00			0.00			0
MZ 1 stock	≤3.16E+00	≤0.5	(+)1 stock	1.47E+05	5.17	(-)1 stock	<3.16E+00	<0.5
MZ 2 stock	≤3.16E+00	≤0.5	(+)2 stock	1.47E+05	5.17	(-)2 stock	<3.16E+00	<0.5
MZ 3 stock	≤3.16E+00	≤0.5	(+)3 stock	1.00E+05	5.00			
MZ 4 stock	≤3.16E+00	≤0.5						
MZ 5 stock	≤3.16E+00	≤0.5						
average	≤3.16E+00	≤0.5		1.31E+05	**5.12**		<3.16E+00	<0.5
stdev		0.00			0.10			0
MZ 1 x2	≤3.16E+00	≤0.5	(+)1 2x	2.15E+05	5.33	(-)1 2x	3.16E+00	<0.5
MZ 2 x2	≤3.16E+00	≤0.5	(+)2 2x	2.15E+05	5.33	(-)2 2x	3.16E+00	<0.5
MZ 3 x2	≤3.16E+00	≤0.5	(+)3 2x	3.16E+05	5.50			
MZ 4 x2	≤3.16E+00	≤0.5						
MZ 5 x2	≤3.16E+00	≤0.5						
average	≤3.16E+00	≤0.5		2.49E+05	**5.40**		<3.16E+00	<0.5
stdev		0.00			0.10			0

Appendix 2

Experiment Date: July 16 & 25, 2014

Virocidal efficacy of AseptiSure ozone-base sterilization system on TGEV						
	Log10 reduction in virus titer (TCID50%) and (SD) after exposure to AseptiSure ozone					
Virus (strain)	Run#1 (July 16-40min)		Run#1 (July 25-90min)		Run#2 (July 25-60min)	
	log 10	SD	log 10	SD	log10	SD
TGEV	**≥4.4**	0.1	**≥4.64**	0.19	**≥4.81**	0.19

TCID50%: tissue culture infectious dose 50%, SD: Standard deviation
Log10 reduction calculated by comparing the virus titer recovered from the control and AseptiSure exposed discs.

Experiment Date: July 16, 2014

Run 1: 40min exposure

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ 1 stock	≤3.16E+00	≤0.5	(+)1 stock	6.81E+04	4.83	(-)1 stock	<3.16E+00	<0.5
MZ 2 stock	≤3.16E+00	≤0.5	(+)2 stock	6.81E+04	4.83	(-)2 stock	<3.16E+00	<0.5
MZ 3 stock	≤3.16E+00	≤0.5	(+)3 stock	1.00E+05	5.00			
MZ 4 stock	≤3.16E+00	≤0.5						
MZ 5 stock	≤3.16E+00	≤0.5						
MZ 6 stock	≤3.16E+00	≤0.5						
MZ 7 stock	≤3.16E+00	≤0.5						
MZ 8 stock	≤3.16E+00	≤0.5						
average	≤3.16E+00	≤0.5		7.88E+04	**4.90**		<3.16E+00	<0.5
stdev		0.00			0.10			0

Experiment Date: July 25, 2014

Run 1: 90min exposure

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ 1 stock	≤3.16E+00	≤0.5	(+)1 stock	1.00E+05	5.00	(-)1 stock	<3.16E+00	<0.5
MZ 2 stock	≤3.16E+00	≤0.5	(+)2 stock	2.15E+05	5.33	(-)2 stock	<3.16E+00	<0.5
MZ 3 stock	≤3.16E+00	≤0.5	(+)3 stock	1.00E+05	5.00			
MZ 4 stock	≤3.16E+00	≤0.5						
MZ 5 stock	≤3.16E+00	≤0.5						
average	≤3.16E+00	≤0.5		1.38E+05	**5.14**		<3.16E+00	<0.5
stdev		0.00			0.19			0

Experiment Date: July 25, 2014

Run 2: 60min exposure

sample name	TCID50/ml	log10		TCID50/ml:	log10		TCID50/ml:	log10
MZ 1 stock	≤3.16E+00	≤0.5	(+)1 stock	1.47E+05	5.17	(-)1 stock	<3.16E+00	<0.5
MZ 2 stock	≤3.16E+00	≤0.5	(+)2 stock	1.47E+05	5.17	(-)2 stock	<3.16E+00	<0.5
MZ 3 stock	≤3.16E+00	≤0.5	(+)3 stock	3.16E+05	5.50			
MZ 4 stock	≤3.16E+00	≤0.5						
MZ 5 stock	≤3.16E+00	≤0.5						
average	≤3.16E+00	≤0.5		2.03E+05	**5.31**		<3.16E+00	<0.5
stdev		0.00			0.19			0

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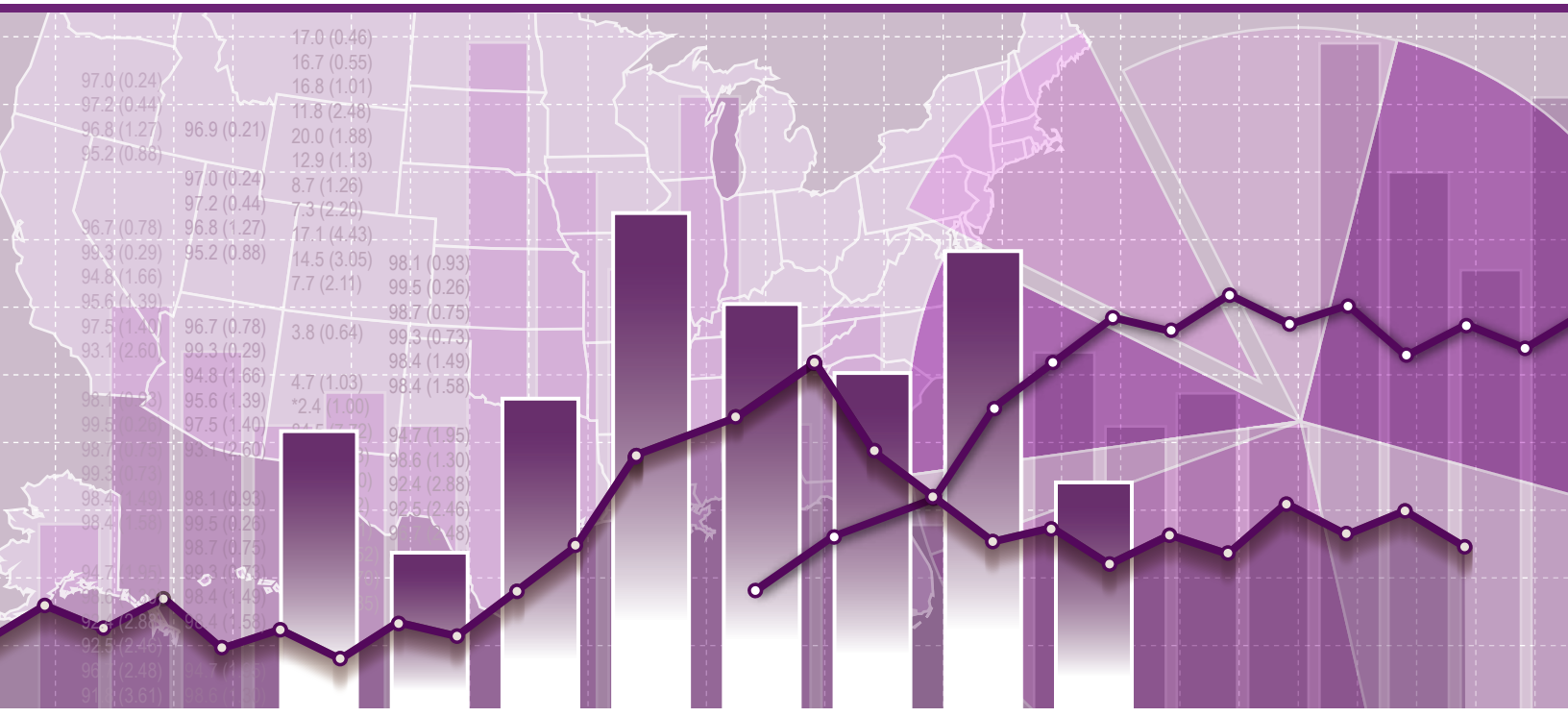

Long-term Care Providers and Services Users in the United States, 2015–2016

Analytical and Epidemiological Studies

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Data from the National Study of Long-Term Care Providers

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Long-term Care Providers and Services Users in the United States, 2015–2016

by Lauren Harris-Kojetin, Ph.D., Manisha Sengupta, Ph.D., Jessica Penn Lendon, Ph.D., Vincent Rome, M.P.H., Roberto Valverde, M.P.H., and Christine Caffrey, Ph.D.

Abstract

Objective

This report presents the most current national results from the National Study of Long-Term Care Providers (NSLTCP) conducted by the National Center for Health Statistics (NCHS) to describe providers and services users in five major sectors of paid, regulated long-term care services in the United States.

Methods

Data sources include NCHS surveys of adult day services centers and residential care communities (covers 2016 data year) and administrative records from the Centers for Medicare & Medicaid Services on home health agencies, hospices, and nursing homes (covers 2015 and 2016 data years).

Results

This report provides information on the supply, organizational characteristics, staffing, and services offered by providers; and the demographic, health, and functional composition, and adverse events among users of these services. Services users include residents of nursing homes and residential care communities, patients of home health agencies and hospices, and participants of adult day services centers. This third edition updates "Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014" (available from: https://www.cdcgov/nchs/data/series/sr_03/sr03_038.pdf). New content in this edition includes an additional service (dietary and nutritional services offered by providers); additional diagnoses (Alzheimer disease, arthritis, asthma, chronic kidney disease, chronic obstructive pulmonary disease, depression, diabetes, heart disease, hypertension, and osteoporosis); overnight hospitalizations among nursing home residents; and estimates by length of stay for selected characteristics (age, sex, race and ethnicity, diagnoses, overnight hospital stays, and falls) for nursing home residents.

Conclusion

In 2016, about 65,600 paid, regulated, long-term care services providers in five major sectors served more than 8.3 million people in the United States. Sectors differed in ownership and chain status, and supply varied by region. Long-term care services users varied by sector in their demographic and health characteristics and functional status.

Companion products will include: "Long-term Care Providers and Services Users in the United States—State Estimates Supplement: National Study of Long-Term Care Providers, 2015–2016" and "Long-term Care Services Use Rates in the United States—U.S. Maps Supplement: National Study of Long-Term Care Providers, 2015–2016." NCHS plans to conduct NSLTCP every 2 years. NSLTCP results and publications are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_products.htm.

Keywords: aging • disability • home- and community-based services • chronic conditions • long-term services and supports • postacute care

Key Findings

In 2016, about 65,600 paid, regulated long-term care services providers in five major sectors served over 8.3 million people in the United States.

- Long-term care services were provided by 4,600 adult day services centers, 12,200 home health agencies, 4,300 hospices, 15,600 nursing homes, and 28,900 assisted living and similar residential care communities (Appendix III, Table V).
- In 2016, there were an estimated 286,300 current participants enrolled in adult day services centers, 1,347,600 current residents in nursing homes, and 811,500 current residents living in residential care communities. In 2015, about 4,455,700 patients were discharged from home health agencies, and 1,426,000 patients received services from hospices (Appendix III, Table VIII).

Sectors differed in ownership and chain status, and supply varied by region.

- The majority of home health agencies, hospices, nursing homes, and residential care communities were for profit, while a minority of adult day services centers were for profit (Figure 4). The majority of nursing homes and residential care communities and a minority of adult day services centers were chain-affiliated (Figure 5).
- The supply of residential care beds per 1,000 persons aged 65 and over was higher in the Midwest and West than in the Northeast and the South, and the capacity of adult day services centers was higher in the West than in the other regions (Figure 3).

Almost 1.5 million nursing employee full-time equivalents (FTEs)—including registered nurses (RNs), licensed practical or vocational nurses (LPNs or LVNs), and aides—and about 35,000 social work employee FTEs worked in the five sectors.

- The relative distribution of nursing and social work employee FTEs varied across sectors; the most common employee FTEs were aides in adult day services centers, nursing homes, and residential care communities, while RNs were the most common employee FTEs in home health agencies and hospices (Figure 9).

Sectors differed in their average staffing levels for nursing, social work, and activities employees.

- Among the three sectors where nursing staff levels (RNs, LPNs or LVNs, and aides) could be examined, the average total nursing staff hours per resident or participant day was higher in nursing homes than in residential care communities and adult day services centers (Figure 11).
- In contrast, the average social work staffing level was higher in adult day services centers than in nursing homes or residential care communities, and the average activities staffing level in adult day services centers was more than twice that of nursing homes and residential care communities.

Daily-use rates among individuals aged 65 and over per 1,000 persons aged 65 and over varied by sector.

- The highest daily-use rate was for nursing home residents, followed by residential care residents, and the lowest daily-use rate was for adult day services center participants.

Long-term care services users varied by sector in their demographic and health characteristics and functional status.

- Adult day services center participants tended to be younger than services users in other sectors (Figure 20). Adult day services center participants were the most racially and ethnically diverse among the five sectors (Figure 22).
- At least one-quarter of services users in each of the five sectors had Alzheimer disease or other dementias, arthritis, heart disease, or hypertension (Figure 24). However, the prevalence of these and six other reported diagnosed chronic conditions varied widely between sectors.
- Fewer adult day services center participants needed assistance with four of six activities of daily living (ADLs; bathing, dressing, toileting, and walking or locomotion) than services users in other sectors (Figure 25).

Adverse events among long-term care services users varied by sector.

- Compared with adult day participants and residential care residents, more home health patients had overnight hospital stays and emergency department visits (Figure 26).
- More residential care residents had falls compared with adult day participants and nursing home residents.

Short- and long-stay current nursing home residents varied on a variety of characteristics.

- Short-stay (less than 100 days) residents differed from long-stay (100 days or more) residents by age and sex, and in the prevalence of numerous diagnosed conditions, overnight hospital stays, and falls (Appendix III, Table IX).

Introduction

Long-term Care Services

Long-term care services include a broad range of health, personal care, and supportive services that meet the needs of frail older people and other adults whose capacity for self-care is limited because of a chronic illness; injury; physical, cognitive, or mental disability; or other health-related conditions (1). Historically, the term "long-term care" has been used to refer to services and supports to help frail older adults and younger persons with disabilities maintain their daily lives. Recently, alternative terms have gained wider use, including "long-term services and supports." The Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) uses the term "long-term services and supports" and defines the term to include certain institutionally based and noninstitutionally based long-term services and

supports [Section 10202(f)(1)]. This report uses "long-term care services" to reflect both the changing vocabulary and the fact that these services can include both health care-related and nonhealth care-related services.

Long-term care services include assistance with activities of daily living (ADLs; dressing, bathing, and toileting), instrumental activities of daily living (IADLs; medication management and housework), and health maintenance tasks. Long-term care services assist people to improve or maintain an optimal level of physical functioning and quality of life, and can include help from other people and special equipment or assistive devices. The need for long-term care services is generally defined based on functional limitations (need for assistance with or supervision in ADLs and IADLs) regardless of cause, age of the person, where the person is receiving assistance, whether the assistance is human or mechanical, and whether the assistance is paid or unpaid.

Individuals may receive long-term care services in a variety of settings (2–5):

- In the community, such as at an adult day services center
- In the home, for example, from a home health agency, hospice, or family and friends
- In institutions, such as in a nursing home or skilled nursing facility
- In other residential settings, for instance, in an assisted living or similar residential care community

Long-term care services provided by paid regulated providers are an important component of personal health care spending in the United States (6). Estimates of expenditures for paid long-term care services vary, depending on what types of providers, populations, and services are included. According to a recent estimate, in 2013 total national spending for paid long-term care services was almost $339 billion, with public spending accounting for about 72% of this amount (7). The cost of long-term care services varies by the type of paid care provided and the type of provider or sector (e.g., adult day services centers, assisted living and similar residential care communities, home health agencies, or hospices) (2,8).

Finding a way to pay for long-term care services is a growing concern for older adults, other persons with disabilities, and their families, and it is a major challenge facing state and federal governments (9–12). People who use paid long-term care services, through home- and community-based services or institutional care, are among the most costly participants in Medicare and Medicaid programs (13). Medicaid finances the largest portion of paid long-term care services, followed by Medicare, out-of-pocket payments by individuals and families, other private sources, private insurance, and other public programs (4,6,14).

Medicaid finances a variety of long-term care services through multiple mechanisms (e.g., Medicaid State Plan, home- and community-based services waiver program, and other options for community-based long-term care services), including an array of home- and community-based services and institutional services (15–17). Medicaid spending on long-term care services totaled $158 billion in 2015, accounting for 30% of total Medicaid expenditures (18). This report does not address all long-term care services financed by Medicaid. For example, intermediate care facilities for people with intellectual or developmental disabilities are excluded.

Experts disagree on whether Medicare expenditures for skilled nursing facilities and home health agencies, since they are postacute services, should be considered long-term care services (14). This report includes Medicare-certified skilled nursing facilities and home health agencies, which are often referred to as postacute care services.

The distribution of the different financing sources described previously varies by long-term care services sector and population. For example, most residents pay out of pocket for assisted living and similar residential care communities (19), with a small percentage using Medicaid to help pay for services (20). In contrast, the largest single payer for long-term nursing home care is Medicaid, whereas Medicare finances hospice costs and a major portion of the costs for short-stay postacute care in skilled nursing facilities for Medicare beneficiaries (21,22).

Although people of all ages may need long-term care services, the risk of needing these services increases with age. The number of Americans over age 65 is projected to shift from 47.8 million in 2015 to over 87.9 million in 2050, representing an increase of 84% and comprising 22% of the population (23). The population aged 85 and over is projected to triple, from 6.3 million in 2015 to over 18.9 million in 2050, and will account for almost 5% of the U.S. population (23). This "oldest old" population tends to have the highest disability rate and highest need for long-term care services, and is also more likely to be widowed and without someone to provide assistance with daily activities (24,25). The number of older people in the United States with significant physical or cognitive disabilities is projected to increase from 6.3 million in 2015 to 15.7 million in 2065 (26).

Decreasing family size and increasing employment rates among women may reduce the traditional pool of family caregivers, further stimulating demand for paid long-term care services (27). Among persons who need long-term care services, adults aged 65 and over are more likely than younger adults to receive paid help (28). Results from the National Health and Aging Trends study show that of the 10.9 million older adults who reported receiving help with daily activities in a given month in 2011, about 3 in 10 received paid help (29). Recent projections using microsimulation modeling estimate that about one-half of Americans reaching age 65 will need long-term care services and will incur, on average, $138,000 in long-term care costs (26). The average projected length of needing long-term

care services is 2 years, including an average length of 1 year of paid long-term care services. However, about one-third of people turning age 65 are projected to need long-term care services for more than 2 years and to incur higher long-term care services costs (26).

In sum, projections estimate that the number of older adults using paid long-term care services will grow considerably in the coming years (30–34). As a substantial share of paid long-term care services is publicly funded through programs such as Medicaid, accurate and timely statistical information can help guide those programs and inform relevant policy decisions. The National Study of Long-Term Care Providers (NSLTCP) is designed to help supply this information.

The National Study of Long-Term Care Providers

The long-term care services delivery system in the United States has changed substantially over the last 30 years. For example, although nursing homes are still a major provider of long-term care services, there has been growing use of skilled nursing facilities for short-term postacute care and rehabilitation (35). Additionally, consumers' desire to stay in their own homes, as well as federal and state policy developments, have led to growth in a variety of home- and community-based alternatives (36–38). Examples of these federal and state policy developments include the Supreme Court's Olmstead decision; introduction of the Medicare Prospective Payment System; and a variety of initiatives to encourage balancing of Medicaid-financed services from institutional to noninstitutional settings, such as Money Follows the Person, Community First Choice Option, and the Balancing Incentives Payment Program (39).

The major sectors of paid long-term care services providers now also include adult day services centers, assisted living and similar residential care communities, home health agencies, and hospices.

In 2011, the National Center for Health Statistics (NCHS) launched the biennial NSLTCP—an integrated strategy for efficiently obtaining and providing statistical information about the major sectors of paid, regulated long-term care services in the United States. NSLTCP is designed to provide reliable, accurate, relevant, and timely statistical information to support and inform long-term care services policy, research, and practice.

The main goals of NSLTCP are to:

1. Estimate the supply, provision, and use of paid, regulated long-term care services
2. Estimate key policy-relevant characteristics and practices
3. Produce national and state estimates, where feasible
4. Compare estimates among sectors
5. Monitor trends over time

NSLTCP replaces NCHS' periodic National Nursing Home Survey and National Home and Hospice Care Survey, as well as the one-time National Survey of Residential Care Facilities. Unlike the previous strategy of surveying major sectors of long-term care services separately and at different times—often several years apart—NSLTCP intends to provide information on five major sectors of providers and services users at a similar point in time, and to provide updated information on all five sectors every 2 years. The NSLTCP core is designed to:

- Broaden NCHS' ongoing coverage of paid, regulated long-term care services providers beyond home health agencies, hospices, and nursing homes to also include adult day services centers and assisted living and similar residential care communities (called "residential care communities" in this report)
- Have the potential over time to add other types of paid, regulated long-term care services providers (e.g., home care agencies)
- Capitalize on existing national administrative data from the Centers for Medicare & Medicaid Services (CMS) on home health agencies, hospices, and nursing homes
- Collect primary data every other year from cross-sectional, nationally representative, establishment-based surveys of adult day services centers and residential care communities, because administrative data do not exist
- Produce state estimates, where feasible
- Compare and monitor trends across the five sectors

In addition to the core content, the NSLTCP data collection system provides the infrastructure on which to build provider-specific surveys, cross-provider topical modules, more in-depth surveys to respond to evolving or emerging policy issues, and sampling and collecting information on individual users (e.g., nursing home residents).

Structure of Report and Other NSLTCP Products

This is the third edition of a descriptive overview report intended to inform policy makers, providers, researchers, consumer advocates, the media, foundations, and others to inform planning for long-term care services. The report includes two sections that present findings. "National Profile of Long-term Care Services Providers" presents findings on providers of long-term care services (i.e., adult day services centers, home health agencies, hospices, nursing homes, and residential care communities). This section includes estimates on provider supply, organizational characteristics, staffing, and services offered. New to this edition, this section presents estimates on dietary and nutritional services offered.

Staffing is especially important to examine because paid long-term care services are provided by a wide array of trained professionals and paraprofessionals, with the largest

share—an estimated 70% to 80%—being direct care workers that include certified nursing assistants and personal care aides and home health aides, generally referred to as aides (40,41). Previous studies have provided evidence that higher nurse staffing levels are associated with higher quality of care outcomes for nursing home residents (42–44); nursing homes are required to meet minimum nurse staffing ratios for participation in Medicare and Medicaid. Less research has been conducted on staffing levels and outcomes in adult day, home health, hospice, and residential care settings (for an exception see reference 45).

In its 2008 report, "Retooling for an Aging America: Building the Health Care Workforce," the Institute of Medicine documented the growing need for gerontological social workers and the lack of interest among social workers in working with older adults (46). According to one study, while about 36,100 to 44,200 professional social workers were employed in long-term care settings in 2002, approximately 110,000 social workers would be needed in these settings by 2050 (47). Projections estimate that social workers and home health and personal care aides are among the long-term care services occupations that will grow the most by 2030 (48). This report contributes to the literature on the long-term care services workforce by using NSLTCP data to provide information by sector on the numbers of nursing, licensed social work, and activities employees, and average hours per service user day.

"National Profile of Long-term Care Services Users" presents findings on users of long-term care services, including participants of adult day services centers, patients of home health agencies and of hospices, and residents of nursing homes and of residential care communities. This section's topics include demographic characteristics; functional status; selected health conditions, including Alzheimer disease and other dementias; and adverse events among services users, including hospitalizations and falls. Alzheimer disease is a common precipitating factor for transition to receiving long-term care services (49). According to the Alzheimer's Association, in 2018 there were about 5.7 million Americans living with Alzheimer dementia; 5.5 million of them were aged 65 and over (50). The number of people with Alzheimer disease or other dementias will continue to increase along with the growth of the older population (49). New to this report, this section presents estimates on 10 diagnoses; estimates on overnight hospitalizations among nursing home residents; and estimates by length of stay for selected characteristics (age, sex, race and ethnicity, diagnoses, overnight hospital stays, and falls) for nursing home residents.

The Technical Notes (Appendix I) describe the data sources used to produce the information on providers and services users in each of the five sectors, outlines the approach used for data analyses, and discusses study limitations. Appendix II defines each variable used for each sector in the study, and Appendix III presents the data tables for the figures in the report.

This report presents national results from the third wave of NSLTCP, using data from surveys about adult day services centers and participants, and residential care communities and residents that were fielded by NCHS between August 2016 and February 2017. The report also uses data from administrative records obtained from CMS on home health agencies and patients, hospices and patients, and nursing homes and residents, which reflect these providers and services users between 2015 and 2016. See the Appendix I Technical Notes for definitions of the five sectors and the corresponding data sources used in this report.

This report also updates previous editions of this report: "Long-Term Care Services in the United States: 2013 Overview"(https://www.cdc.gov/nchs/data/nsltcp/long_term_care_services_2013.pdf), which reported findings from the first NSLTCP wave conducted in 2012 (data years 2011 and 2012); and "Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014 (https://www.cdc.gov/nchs/data/series/sr_03/sr03_038.pdf), which reported findings from the second NSLTCP wave conducted in 2014 (data years 2013 and 2014).

A companion product, "Long-term Care Providers and Services Users in the United States—State Estimates Supplement: National Study of Long-Term Care Providers, 2015–2016," contains tables showing comparable state estimates for the national findings in this report. These state tables update previous editions of this product: "Long-Term Care Services in the United States: 2013 State Web Tables and Maps" (https://www.cdc.gov/nchs/data/nsltcp/State_estimates_for_NCHS_Series_3_37.pdf); and "Long-Term Care Providers and Services Users in the United States—State Estimates Supplement: National Study of Long-Term Care Providers, 2013–2014 (https://www.cdc.gov/nchs/data/nsltcp/2014_nsltcp_state_tables.pdf).

An additional companion product, "Long-term Care Services Use Rates in the United States—U.S. Maps Supplement: National Study of Long-Term Care Providers, 2015–2016," shows rates of use for each sector by state population of adults aged 65 and over and aged 85 and over. These and other NSLTCP results and publications, when published, will be available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_products.htm. NCHS is fielding the fourth wave of NSLTCP surveys between July 2018 and February 2019 and obtaining the fourth wave of administrative data within a similar time frame. NCHS intends to produce future reports to examine trends over time and produce public-use survey data files for the 2018 adult day services center and residential care community surveys. The 2018 surveys are redesigned for the first time to collect data on a scientifically drawn random sample of individual adult day services center participants and residential care residents.

The findings in this report provide the most current national picture of providers and users of five major sectors of paid, regulated long-term care services in the United States.

Findings on differences and similarities in supply, provision, and use; and the characteristics of providers and users of long-term care services offer useful information to policymakers, providers, and researchers as they plan to meet the needs of an aging population.

National Profile of Long-term Care Services Providers

Supply of Long-term Care Services Providers

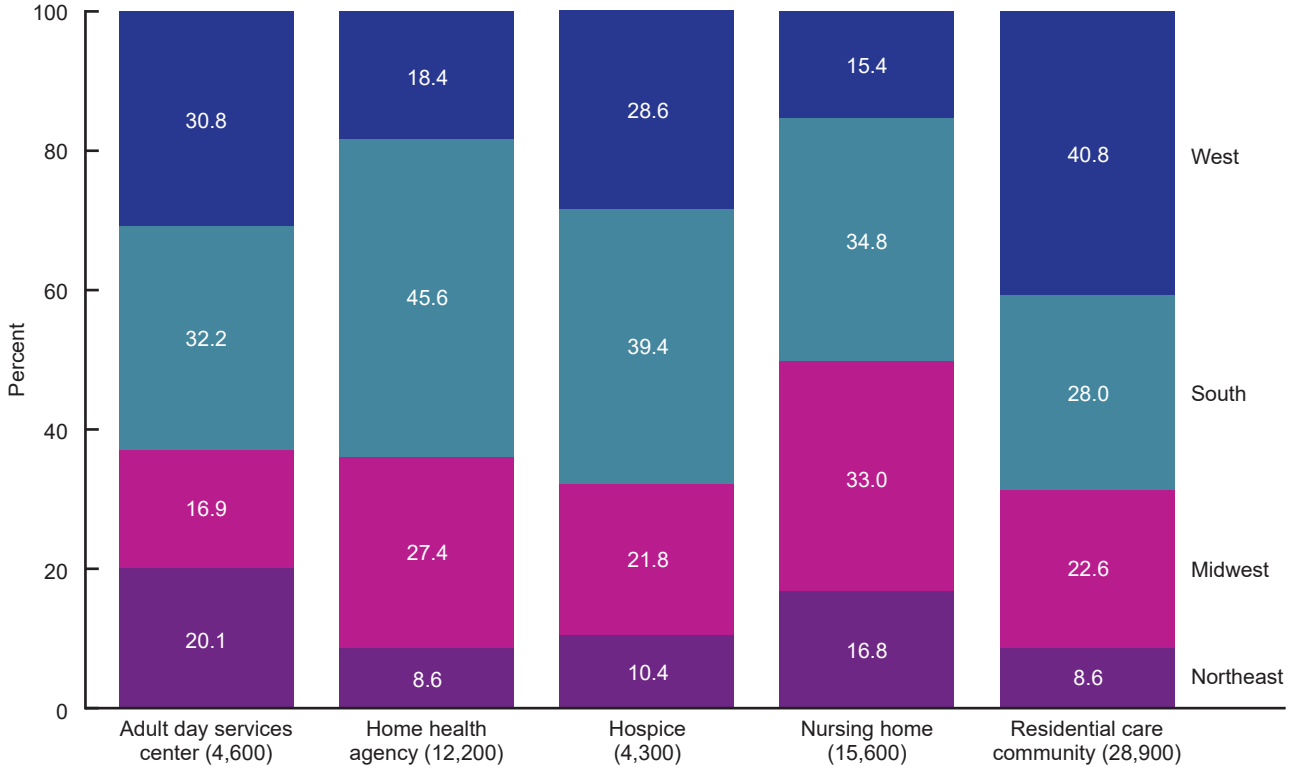
As of 2016 in the United States, there were an estimated 4,600 adult day services centers, 12,200 home health agencies, 4,300 hospices, 15,600 nursing homes, and 28,900 residential care communities. This report includes only providers that are in some way regulated by federal or state government. Adult day services centers and residential care communities were state regulated, home health agencies and nursing homes were Medicare- or Medicaid-certified, and hospices were Medicare-certified. Of these approximately 65,600 paid, regulated long-term care services providers, 7.0% were adult day services centers, 18.6% were home health agencies, 6.6% were hospices, 23.8% were nursing homes, and 44.1% were residential care communities.

This section provides an overview of the supply, organizational characteristics, staffing, and services offered by paid, regulated providers of long-term care services in each of these five sectors. Supply information is provided nationally, by census geographic region, and by metropolitan statistical area (MSA) status. Organizational characteristics include ownership type, chain affiliation, Medicare and Medicaid certification, and number of people served. Staffing measures include number and distribution of nursing and social work employees; percentage of providers employing any nursing, social work, or activities employees; and average hours per resident or participant per day, by staff type. Services include social work, mental health or counseling, therapeutic services, skilled nursing or nursing, pharmacy or pharmacist services, hospice, dietary and nutritional services, and dementia care units.

Geographic distribution

The supply of providers in the five long-term care services sectors varied in their geographic distribution. The largest share of adult day services centers (32.2%), home health agencies (45.6%), hospices (39.4%), and nursing homes (34.8%) was in the South, while the largest share of residential care communities (40.8%) was in the West (Figure 1).

Figure 1. Percent distribution of long-term care services providers, by sector and region: United States, 2016



NOTES: Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table V in Appendix III.

Metropolitan and micropolitan statistical areas are geographic entities defined by the Office of Management and Budget for use by federal statistical agencies in collecting, tabulating, and publishing federal statistics.

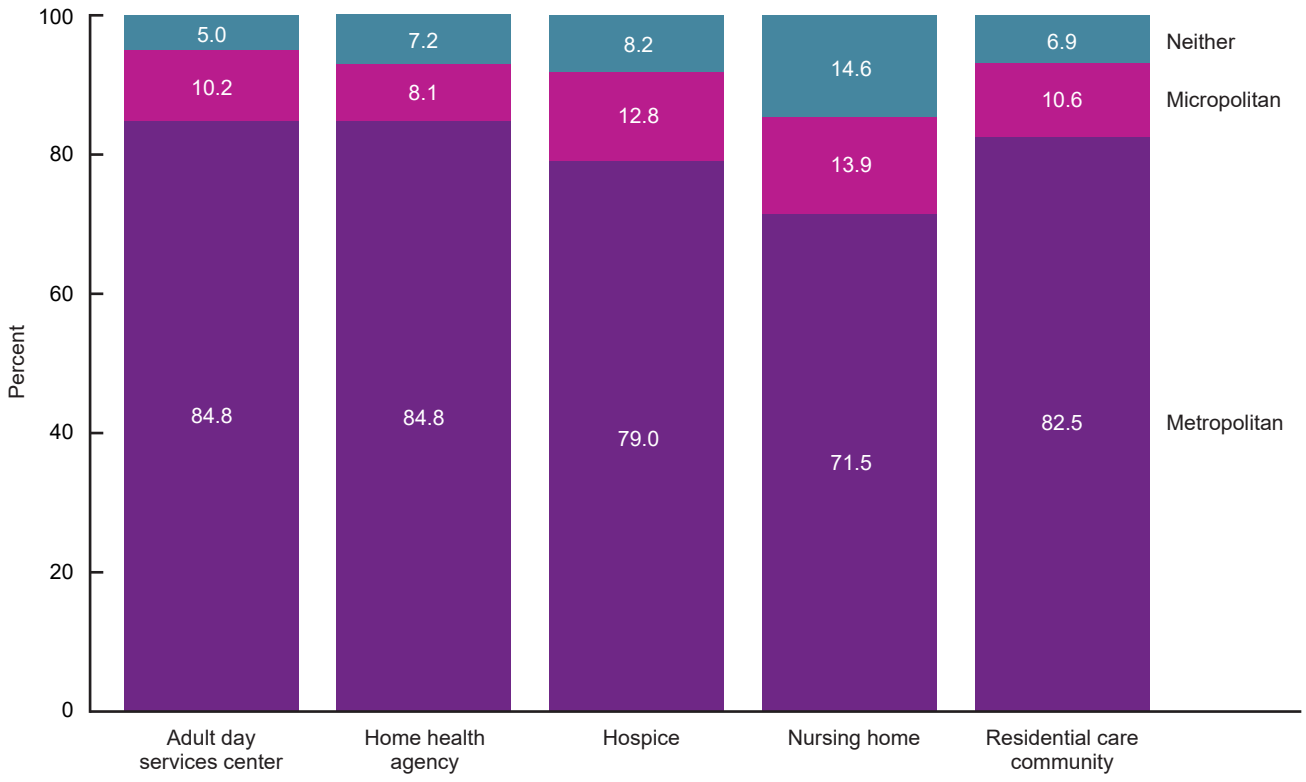
A metropolitan statistical area contains a core urban area of 50,000 or more population, and a micropolitan statistical area contains an urban core of at least 10,000 (but less than 50,000) population. Each metropolitan or micropolitan statistical area consists of one or more counties and includes the counties containing the core urban area, as well as any adjacent counties that have a high degree of social and economic integration (as measured by commuting to work) with the urban core (51). Most providers in all five long-term care services sectors were in MSAs (Figure 2). This distribution reflects the higher population density in these areas. Compared with hospices (79.0%) and nursing homes (71.5%), a greater percentage of adult day services centers (84.8%), home health agencies (84.8%), and residential care communities (82.5%) were located in metropolitan areas.

Capacity

Based on the maximum number of participants allowed, the 4,600 adult day services centers in the country could serve a daily maximum of up to 298,400 participants nationally (Appendix III, Table V). The allowable daily capacity of adult day services centers ranged from 2 to 530, with an average of 66 participants. The 15,600 nursing homes in the country provided a total of 1,660,400 certified beds. Nursing homes ranged in capacity from 2 to 1,389 certified beds, with an average of 106 certified beds. The 28,900 residential care communities in the United States provided 996,100 licensed beds. Residential care communities ranged in capacity from 4 to 518 licensed beds, with an average of 35 licensed beds. Capacity for home health agencies and hospices was not examined because licensed maximum capacity or a similar metric was not available.

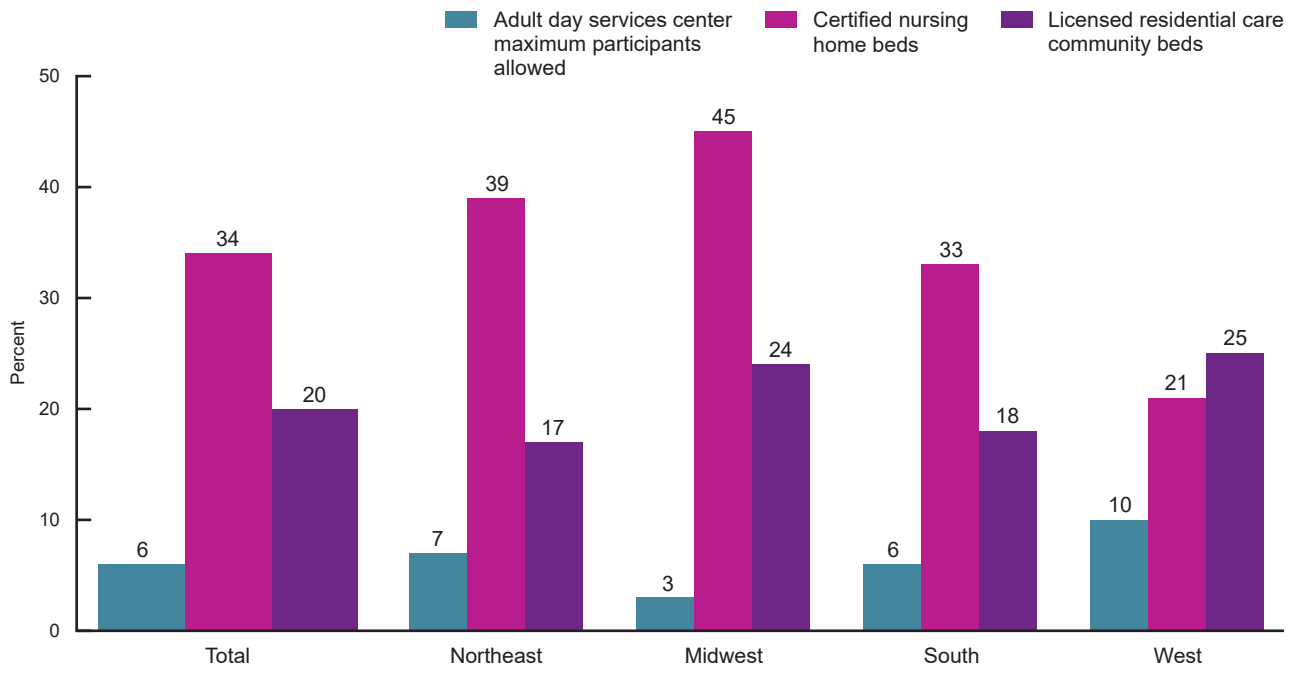
The supply of adult day services center capacity and nursing home and residential care beds varied by region (Figure 3). Compared with other regions, the Midwest had the largest supply of nursing home beds (45) and the smallest supply of adult day services center capacity (3) per 1,000 persons aged 65 and over. The West (25) and Midwest (24) had a

Figure 2. Percent distribution of long-term care services providers, by sector and metropolitan statistical area status: United States, 2016



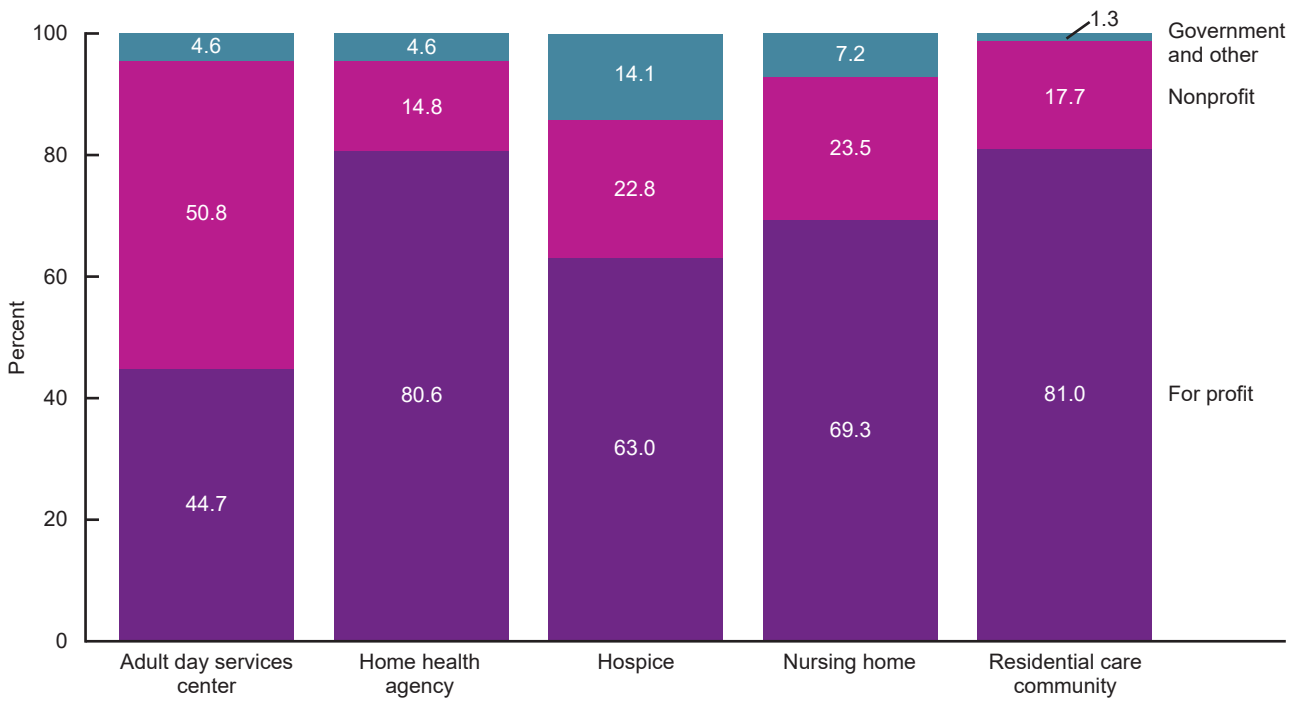
NOTES: Metropolitan statistical areas and micropolitan statistical areas are geographic entities delineated by the Office of Management and Budget for use by federal statistical agencies in collecting, tabulating, and publishing federal statistics. A metropolitan statistical area contains a core urban area of 50,000 or more population, and a micropolitan statistical area contains an urban core of at least 10,000 (but less than 50,000) population. Each metropolitan or micropolitan statistical area consists of one or more counties and includes the counties containing the core urban area, as well as any adjacent counties that have a high degree of social and economic integration (as measured by commuting to work) with the urban core (see reference 51 in report). Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table V in Appendix III.

Figure 3. Long-term care services provider capacity per 1,000 people aged 65 and over, by sector and region: United States, 2015–2016



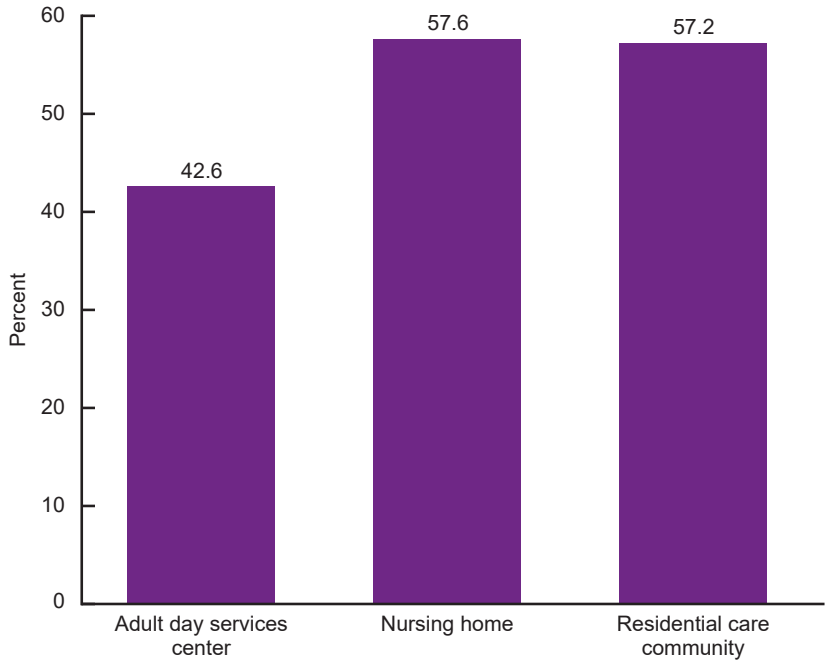
NOTES: Capacity refers to the number of certified nursing home beds, the number of licensed residential care community beds, and the maximum number of adult day services center participants allowed. See Appendix II for definitions of capacity used for each sector. Capacity for home health agencies and hospices was not examined because licensed maximum capacity or a similar metric was not available. Rates are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers.

Figure 4. Percent distribution of long-term care services providers, by sector and ownership: United States, 2016



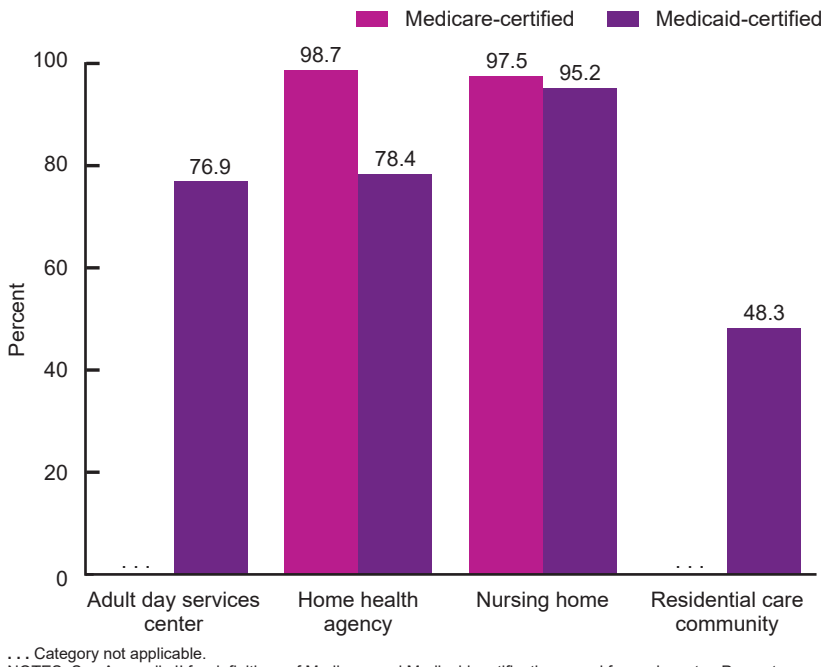
NOTES: See Appendix II for definitions of ownership used for each sector. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table V in Appendix III.

Figure 5. Percentage of long-term care services providers that are chain-affiliated, by sector: United States, 2016



NOTES: See Appendix II for definitions of chain affiliation used for each sector. Chain affiliation for home health agencies and hospices was not examined because this information was not available. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table V in Appendix III.

Figure 6. Percentage of long-term care services providers that are Medicare- and Medicaid-certified, by sector: United States, 2016



. . . Category not applicable.
NOTES: See Appendix II for definitions of Medicare and Medicaid certifications used for each sector. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table V in Appendix III.

aged 65 and over. The West (25) and Midwest (24) had a larger supply of residential care beds per 1,000 persons aged 65 and over compared with the Northeast (17) and the South (18).

In the West, the supply of residential care beds (25) was greater than the supply of nursing home beds (21) per 1,000 persons aged 65 and over, whereas nursing home beds outnumbered residential care beds in all other regions.

Organizational Characteristics of Long-term Care Services Providers

Ownership type

In all sectors except adult day services centers, the majority of long-term care services providers were for profit (Figure 4). Home health agencies (80.6%) and residential care communities (81.0%) had the highest percentages of for-profit ownership, while adult day services centers (44.7%) had the lowest percentage. About one-half of adult day services centers were nonprofit (50.8%).

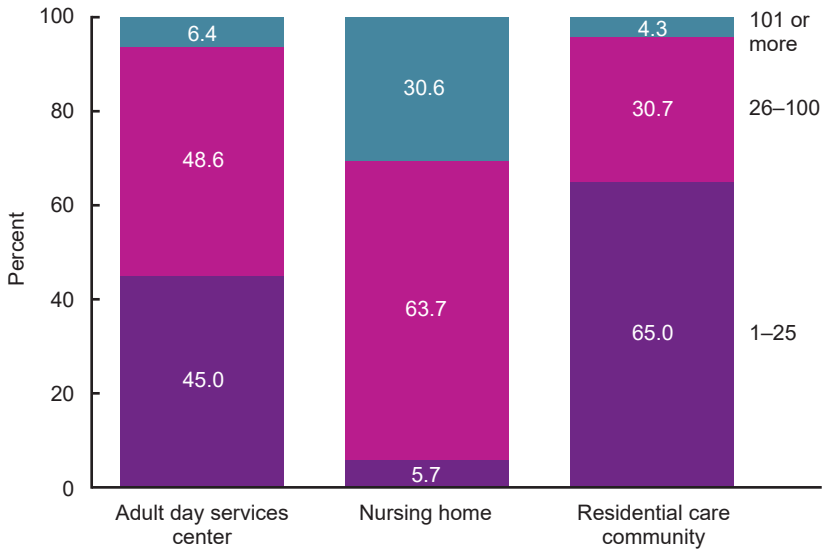
Chain status

The majority of nursing homes (57.6%) and residential care communities (57.2%) were chain-affiliated, while fewer adult day services centers (42.6%) were part of a chain (Figure 5). Chain affiliation for home health agencies and hospices was not examined because this information was not available.

Medicare and Medicaid certification

All data on home health agencies and nursing homes used in this report are only for Medicare- or Medicaid-certified providers, and all data on hospices are only for Medicare-certified hospices. Almost all nursing homes (95.2%), about three-quarters of adult day services centers (76.9%) and home health agencies (78.4%), and almost one-half of residential care communities (48.3%) were

Figure 7. Percent distribution of long-term care services providers, by sector and number of people served daily: United States, 2016



NOTES: Number of people served categorizes the number of current residents (nursing homes and residential care communities) or the average daily attendance of participants in a typical week (adult day services centers) into three categories: 1–25, 26–100, and 101 or more. See Appendix II for definitions of number of people served for each sector. Figure does not include home health agencies or hospices because the data on services users in these sectors that were used for this report are about patients served annually, not daily. Daily use among home health agencies and hospices could not be derived from these data. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table V in Appendix III.

Figure 8. Percent distribution of long-term care services providers, by sector and number of people served annually: United States, 2015

NOTES: Number of people served is derived from the number of home health patients whose episode of care ended at any time in 2015 and the number of hospice patients receiving care at any time in 2015, respectively, and has three categories: 1–100, 101–300, and 301 or more. See Appendix II for definitions of number of people served for each sector. This figure does not include adult day services centers, nursing homes, or residential care communities because the data on services users in these sectors that were used for this report are about services users served daily, not annually. Annual use among adult day services centers, nursing homes, or residential care communities could not be derived from these data. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table V in Appendix III.

authorized or certified to participate in Medicaid (Figure 6). Information was not available on whether any of the Medicare-certified hospices were also certified by Medicaid. Virtually all home health agencies (98.7%), hospices (100.0%; data not shown in figure), and nursing homes (97.5%) were Medicare-certified. In 2016, Medicare did not certify or reimburse for services provided by adult day care services centers or residential care communities; therefore, these providers were not asked about Medicare certification.

Number of people served

See Appendix II for how number of people served was defined for each sector.

In terms of persons served daily per provider, nursing homes served, on average, more than twice the number of people as adult day services centers, and three times the number of people as residential care communities. Nursing homes housed an average of 86 current residents daily, while adult day services centers had a mean weekday daily attendance of 42 participants, and residential care communities served an average of 28 residents daily (Appendix III, Table V).

The majority of nursing homes served between 26 and 100 residents daily (63.7%), while the majority of residential care communities served 25 residents or fewer daily (65.0%) (Figure 7). Nearly one-half of adult day services centers served 26 to 100 participants daily (48.6%); 45.0% served 25 participants or fewer. Figure 7 does not include data for home health agencies or hospices because the data on services users in these sectors that were used for this report are for patients served annually, not daily. Daily use among home health agencies and hospices could not be derived from these data.

The percentage of nursing homes serving more than 100 persons daily (30.6%) was almost five times as large as the percentage of adult day services centers (6.4%) doing so and almost

eight times as large as the percentage of residential care communities (4.3%) doing so (Figure 7).

In terms of persons served annually, a home health agency served an average of 401 patients who were then discharged from the agency in 2015, while a hospice served an average of 353 patients during the year (Appendix III, Table V). About 44.8% of home health agencies discharged 100 patients or fewer annually, while 25.8% discharged 101 to 300, and 29.4% discharged more than 300 (Figure 8). The number of patients served annually per hospice agency was about evenly distributed, with about one-third of agencies each serving 1 to 100 patients (34.2%), 101 to 300 patients (34.0%), and more than 300 patients (31.8%). Figure 8 does not include data for adult day services centers, nursing homes, or residential care communities because the data on services users in these sectors that were used for this report are for services users served daily, not annually. Annual use among adult day services centers, nursing homes, and residential care communities could not be derived from these data.

Staffing: Nursing, Social Work, and Activities Employees

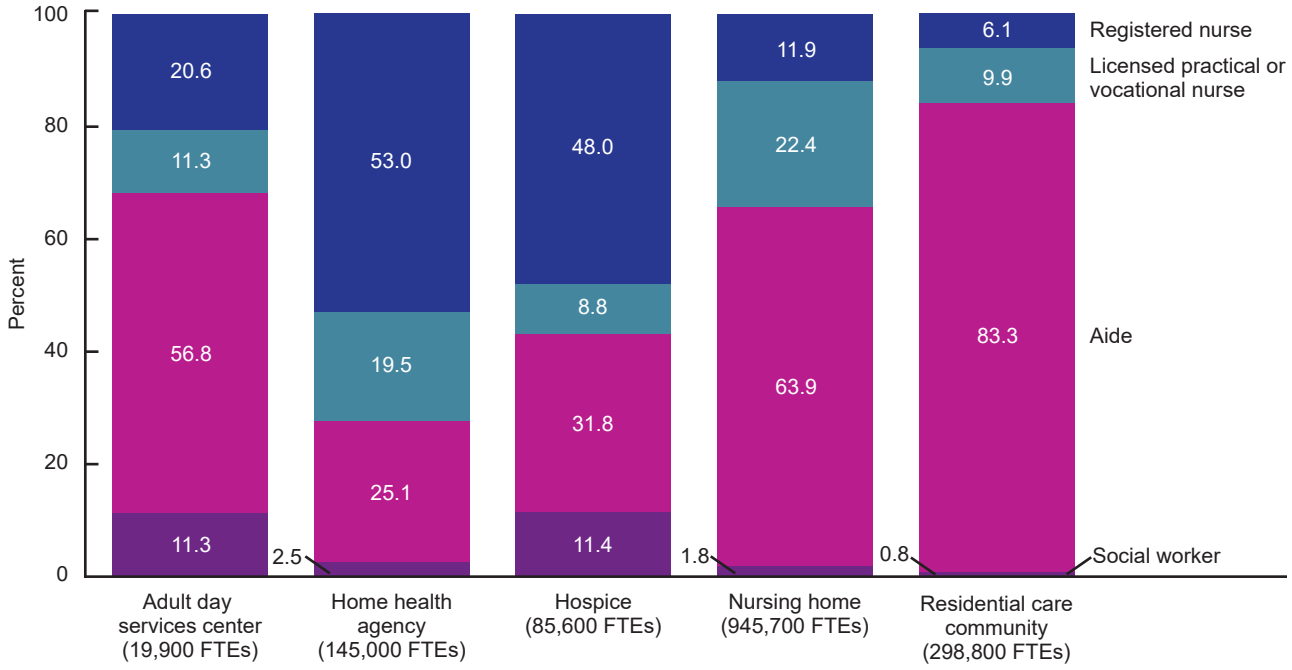
This section focuses on workers employed directly by adult day services centers, home health agencies, hospices, nursing homes, and residential care communities. Information is provided about registered nurses (RNs), licensed practical nurses (LPNs) or licensed vocational nurses (LVNs), aides, social workers, and activities staff. See Appendix II for the definition of full-time equivalent (FTE) and each staff type used for each sector. Contract staff that work for these providers were excluded because comparable information on contract staff was not available for all five sectors.

Nursing and social work employee full-time equivalents

In 2016, about 1,460,400 nursing employee FTEs—including RNs, LPNs or LVNs, and aides—and about 35,000 social work employee FTEs were working in the five sectors (data not shown). Of these nursing and social work employees in the five sectors, 63.3% (945,700 FTEs) worked in nursing homes, 20.0% (298,800 FTEs) were residential care community employees, 9.7% (145,000 FTEs) were employed by home health agencies, 5.7% (85,600 FTEs) were employed by hospices, and 1.3% (19,900 FTEs) were adult day services center employees.

The relative distribution of social work and nursing employee FTEs varied across sectors. In adult day services centers (56.8%), nursing homes (63.9%), and residential care communities (83.3%), the majority of these employee FTEs

Figure 9. Total number and percent distribution of nursing and social work full-time equivalent employees, by sector and staff type: United States, 2016



NOTES: FTEs is full-time equivalent. Only employees are included for all staff types; contract staff are not included. For adult day services centers and residential care communities, aides refer to certified nursing assistants, home health aides, home care aides, personal care aides, personal care assistants, and medication technicians or medication aides. For home health agencies and hospices, aides refer to home health aides. For nursing homes, aides refer to certified nurse aides, medication aides, and medication technicians. Social workers include licensed social workers or persons with a bachelor's or master's degree in social work in adult day services centers and residential care communities; medical social workers in home health agencies and hospices; and qualified social workers in nursing homes. See the Appendix I Technical Notes for information on how outliers were identified and coded. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VI in Appendix III.

were aides (Figure 9). However, in home health agencies (53.0%) and hospices (48.0%), RNs were the most common of these employee FTEs. Social work FTE employees were more common in adult day services centers (11.3%) and hospices (11.4%) than in the other sectors.

The administrative data used in this report for the home health, hospice, and nursing home sectors used less-inclusive wording to capture aides than was used in the questionnaire data for adult day services centers and residential care communities. Consequently, estimates using the administrative data may undercount the number of aides employed by providers in those sectors. See Appendix II for how aide was defined for each sector.

Providers employing any nursing, social work, or activities staff

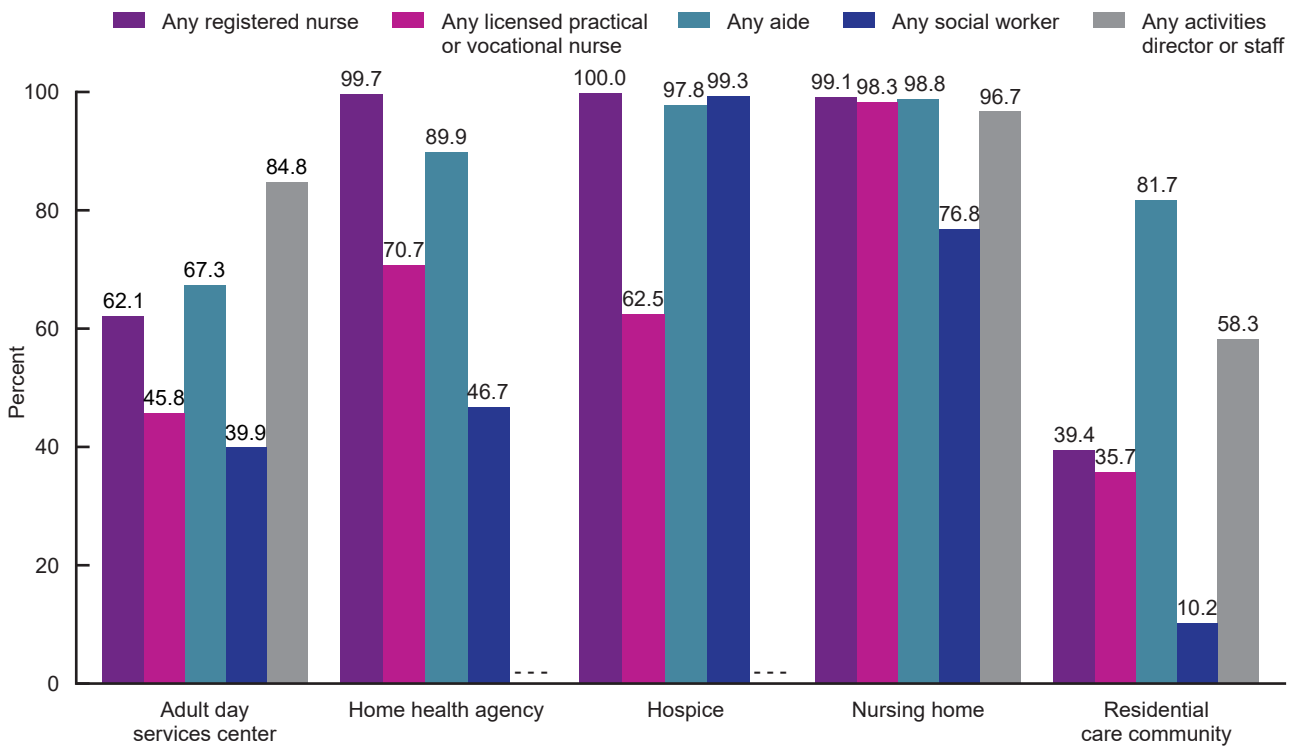
Among the four staff types examined across all five sectors, employing any aides showed the least variation by sector (Figure 10). In all five sectors, the majority of providers employed aides; nursing homes were most likely (98.8%) and adult day services centers were least likely (67.3%) to have any aides on staff.

The majority of providers in all sectors except residential care communities employed licensed nursing staff (either RNs, or LPNs or LVNs). Virtually all home health agencies, hospices, and nursing homes employed at least one RN (99.7%, 100.0%, and 99.1%, respectively). In contrast, 62.1% of adult day services centers and 39.4% of residential care communities directly employed any RNs. The majority of nursing homes (98.3%), home health agencies (70.7%), and hospices (62.5%) employed at least one LPN or LVN, whereas a minority of adult day services centers (45.8%) and residential care communities (35.7%) directly employed any LPNs or LVNs.

Employing any social workers showed the most variation across five sectors. Virtually all hospices employed social workers (99.3%), as did 76.8% of nursing homes. About 46.7% of home health agencies and 39.9% of adult day services centers employed social workers; however, only 10.2% of residential care communities directly employed social workers.

The majority of nursing homes (96.7%), adult day services centers (84.8%), and residential care communities (58.3%) directly employed an activities director or activities staff.

Figure 10. Percentage of long-term care services providers with any full-time equivalent employees, by sector and staff type: United States, 2016



- - - Data not available.
NOTES: Only employees are included for all staff types; contract staff are not included. For adult day services centers and residential care communities, aides refer to certified nursing assistants, home health aides, home care aides, personal care aides, personal care assistants, and medication technicians or medication aides. For home health agencies and hospices, aides refer to home health aides. For nursing homes, aides refer to certified nurse aides, medication aides, and medication technicians. Social workers include licensed social workers or persons with a bachelor's or master's degree in social work in adult day services centers and residential care communities; medical social workers in home health agencies and hospices; and qualified social workers in nursing homes. See the Appendix I Technical Notes for information on how outliers were identified and coded. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VI in Appendix III.

Use of any activities staff was not examined for home health agencies and hospices because this information was not available.

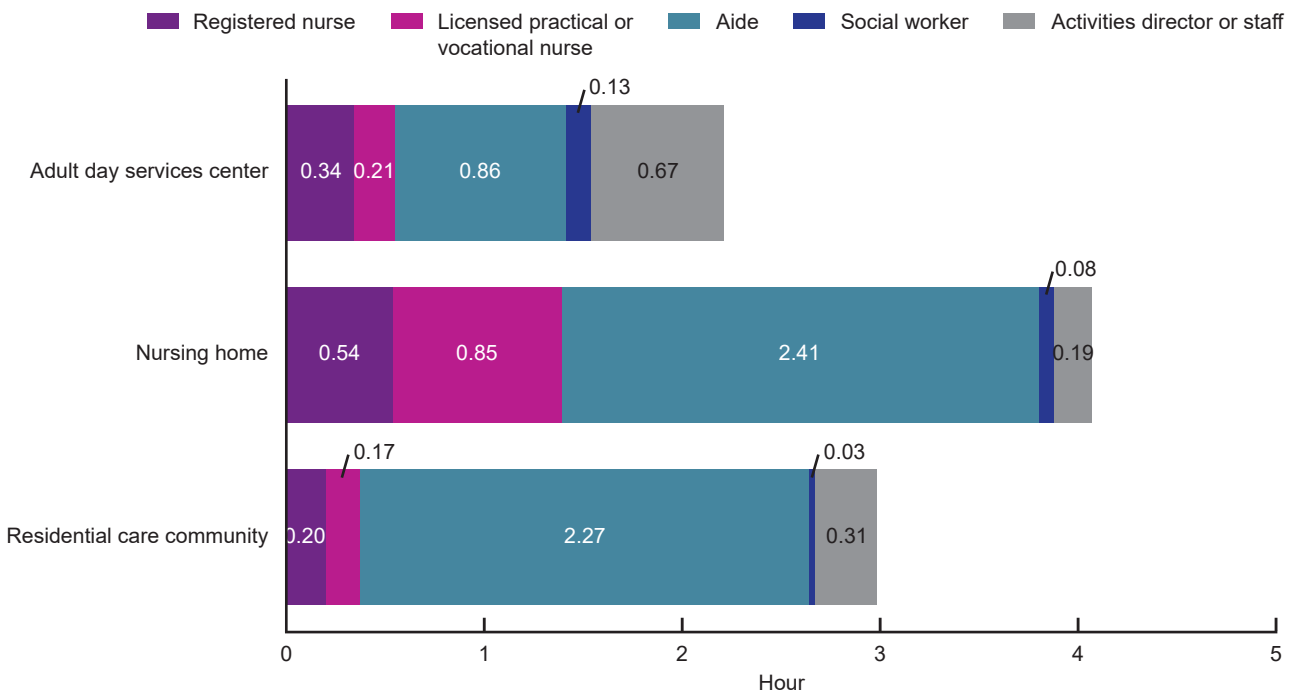
Staffing hours for nursing, social work, and activities staff

Rather than hours per day, which have been used in nursing home and residential care settings, alternative staffing metrics have been reported in the literature for adult day services centers, home health agencies, and hospices, such as average number of visits per 8-hour day (52) and worker-to-participant ratio (53). However, to provide a measure by which to compare staffing levels across sectors, hours per user (resident or participant) per day are provided in this report. See Technical Notes (Appendix I) and Appendix II for details on how hours per resident or participant per day were computed for adult day services centers, nursing homes, and residential care communities. Hours per patient per day could not be provided for home health agencies or hospices, because the administrative data available provided total number of all patients served in a year, not the number served on a given day, which is needed to produce this estimate.

For both licensed nursing staff types examined (i.e., RN, or LPN or LVN), the average staff hours per resident or participant per day was higher in nursing homes than in residential care communities and adult day services centers (Figure 11). In contrast, the average social work staff hours per resident or participant per day was higher in adult day services centers (0.13 hours or 8 minutes) than in nursing homes (0.08 hours or 5 minutes) or residential care communities (0.03 hours or 2 minutes), and the average activities staff hours per resident or participant per day in adult day services centers (0.67 hours or 40 minutes) was more than twice the size of the ratio for residential care communities (0.31 hours or 19 minutes) or nursing homes (0.19 hours or 11 minutes).

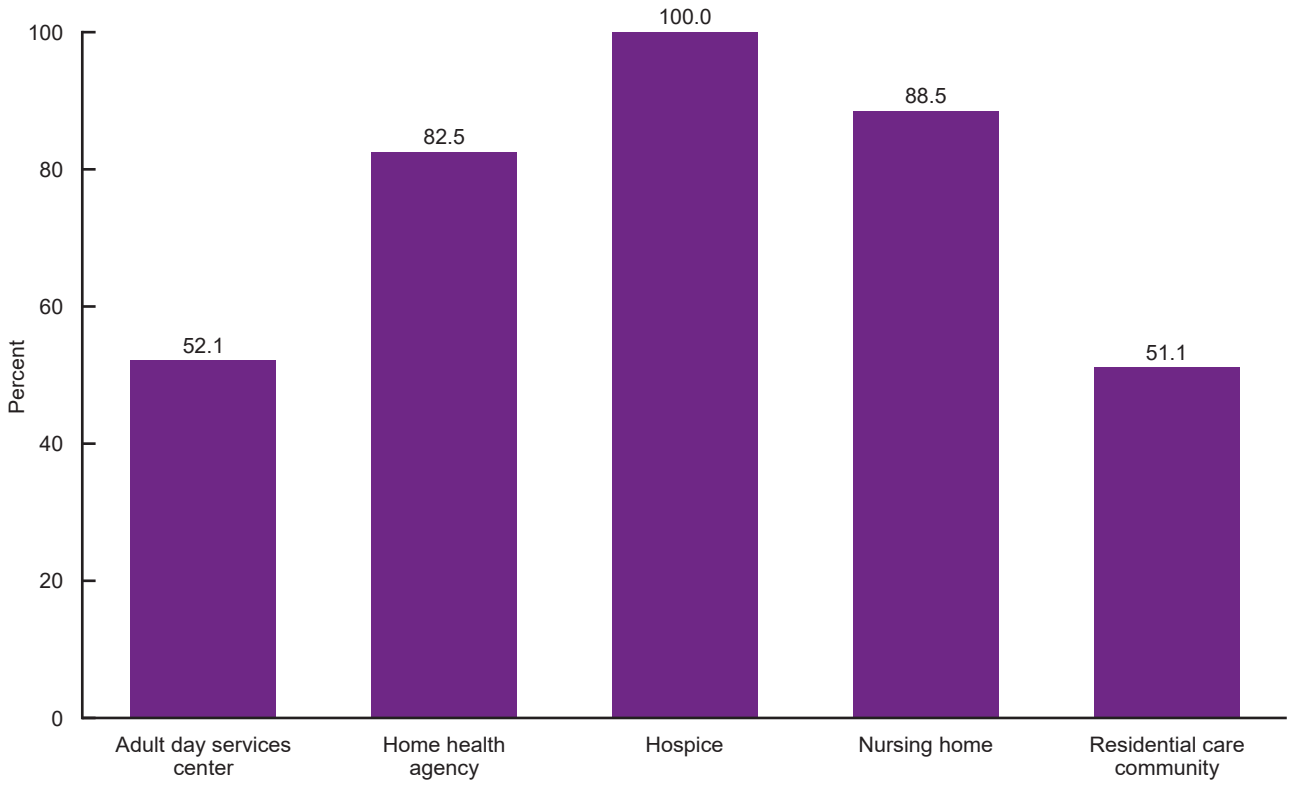
The average total nursing hours (combining RNs, LPNs or LVNs, and aides) per resident or participant per day was 3.80 (3 hours and 48 minutes) for nursing home residents, 2.64 (2 hours and 38 minutes) for residential care residents, and 1.41 (1 hour and 25 minutes) for adult day participants. The average total nursing hours per resident per day in nursing homes was more than twice the size of the ratio for adult day services centers.

Figure 11. Average staff hours per resident or participant per day, by sector and staff type: United States, 2016



NOTES: Only employees are included for all staff types; contract staff are not included. For adult day services centers and residential care communities, aides refer to certified nursing assistants, home health aides, home care aides, personal care aides, personal care assistants, and medication technicians or medication aides. For home health agencies and hospices, aides refer to home health aides. For nursing homes, aides refer to certified nurse aides, medication aides, and medication technicians. Social workers include licensed social workers or persons with a bachelor's or master's degree in social work in adult day services centers and residential care communities; medical social workers in home health agencies and hospices; and qualified social workers in nursing homes. For adult day services centers, average hours per participant per day was computed by multiplying the number of full-time equivalent (FTE) employees for the staff type by 35 hours, and divided by average daily attendance of participants and by 5 days. For nursing homes and residential care communities, average hours per resident per day was computed by multiplying the number of FTE employees for the staff type by 35 hours, and divided by the number of current residents and by 7 days. See the Appendix I Technical Notes for information on how outliers were identified and coded. Hours per patient per day could not be provided for home health agencies or hospices, because the administrative data available provided total number of all patients served in a year, not the number served on a given day, which is needed to produce this estimate. Rates are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VI in Appendix III.

Figure 12. Percentage of long-term care services providers that provide social work services, by sector: United States, 2016



NOTES: Social work services refer to services provided by licensed social workers or persons with a bachelor's or master's degree in social work, and include an array of services such as psychosocial assessment, individual or group counseling, and referral services. See Appendix II for definitions of the provision of social work services for each sector. See the Appendix I Technical Notes for an explanation of differences in how services were measured in 2012, 2014, and 2016. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

The average total licensed nursing hours (combining RNs with LPNs and LVNs) per resident or participant per day was 1.39 (1 hour and 23 minutes) for nursing home residents, 0.55 (33 minutes) for adult day participants, and 0.37 (22 minutes) for residential care residents. The average licensed nursing hours per resident or participant per day in nursing homes was more than twice the size of the corresponding ratios for residential care communities and adult day services centers.

Services Provided

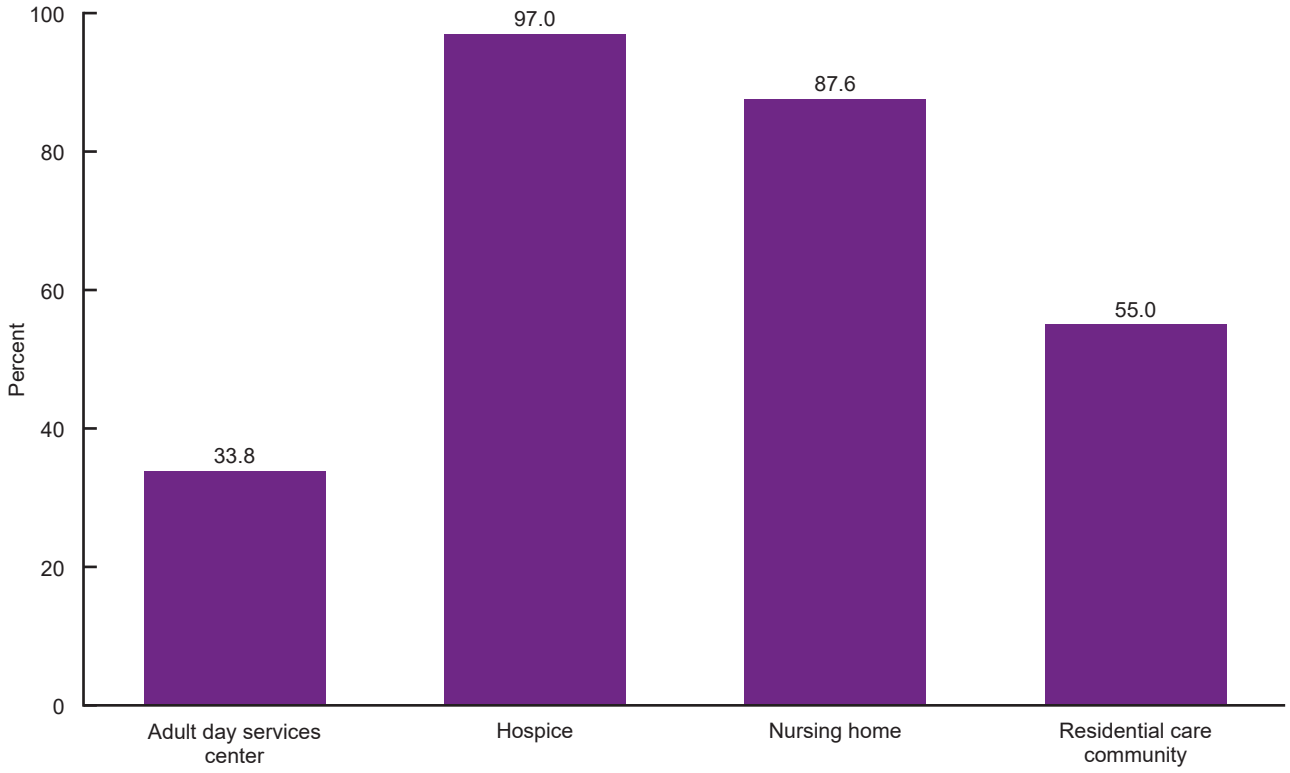
This section provides information on what percentage of providers in each sector (where data were applicable and available) offered each of seven services: social work; mental health or counseling; therapies (physical, occupational, and speech); skilled nursing or nursing; pharmacy or pharmacist; hospice; and dietary and nutrition. Services could be provided directly by the provider or by others through arrangement by the provider. These seven services were chosen because they are commonly provided by Medicare- and Medicaid-certified long-term care services providers, and administrative data were available for most sectors. However, the available administrative data did not have information on whether or not the following sectors provided mental health or counseling services (home health agencies) and pharmacy or pharmacist services (hospices). In addition to the seven services listed, the provision of dementia special care units is also included. See Appendix II for definitions of services included for each sector.

As was done for the 2014 adult day and residential care community questionnaires—but in contrast with the 2012 adult day and residential care community questionnaires—for each service in the 2016 questionnaires, if an adult day services center or residential care community reported offering only referrals to participants or residents, respectively, the provider was considered as not providing the service. See Technical Notes (Appendix I) for more information on differences in how services were measured in 2012 compared with the 2014 and 2016 adult day and residential care community questionnaires.

Social work services

The majority of providers in all sectors offered social work services (Figure 12). All hospices provided social work services (100.0%), as did most nursing homes (88.5%) and home health agencies (82.5%), likely because providing these services is required for Medicare certification.

Figure 13. Percentage of long-term care services providers that provide mental health or counseling services, by sector: United States, 2016



NOTES: Mental health services refer to services that target residents' mental, emotional, psychological, or psychiatric well being, and include diagnosing, describing, evaluating, and treating mental conditions. See Appendix II for definitions of the provision of mental health services for each sector. See the Appendix I Technical Notes for an explanation of differences in how services were measured in 2012, 2014, and 2016. The available administrative data did not have information on whether or not home health agencies provided mental health or counseling services. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

Fewer adult day services centers (52.1%) and residential care communities (51.1%) reported providing social work services.

Mental health or counseling services

Mental health or counseling services were offered by most hospices (97.0%), nursing homes (87.6%), and the majority of residential care communities (55.0%), while about one-third of adult day services centers (33.8%) reported offering these services (Figure 13).

Therapeutic services

Virtually all nursing homes (99.5%), hospices (98.2%), and home health agencies (96.3%) offered therapeutic services, as did more than seven-tenths of residential care communities (71.4%) and almost one-half of adult day services centers (46.7%) (Figure 14).

Skilled nursing or nursing services

All home health agencies, hospices, and nursing homes (100.0%) offered skilled nursing or nursing services, as did the majority of adult day services centers (64.5%) and residential care communities (66.1%) (Figure 15).

Pharmacy or pharmacist services

Nearly all nursing homes (97.2%) and more than four-fifths of residential care communities (83.6%) offered pharmacy or pharmacist services, while fewer adult day services centers (30.0%) and home health agencies (4.9%) provided these services (Figure 16).

Hospice services

About 80.7% of nursing homes offered hospice services, compared with 67.7% of residential care communities, 20.8% of adult day services centers, and 5.7% of home health agencies (Figure 17).

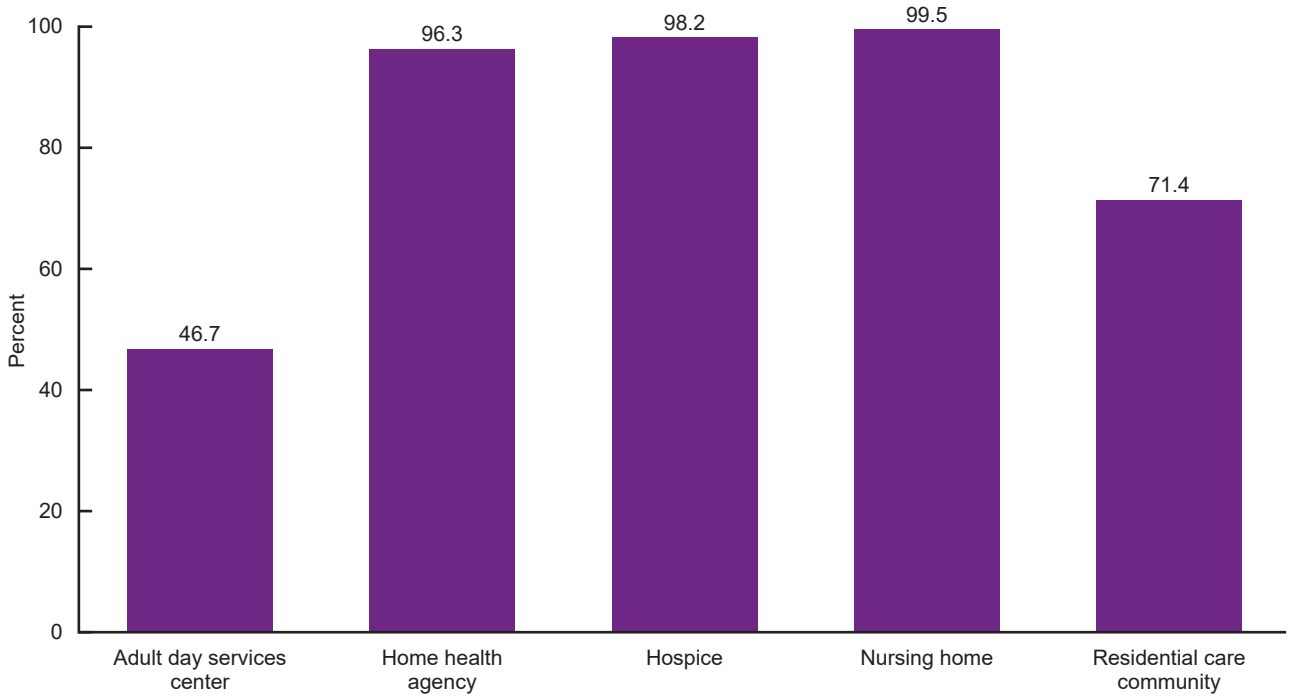
Dietary and nutritional services

All nursing homes (100.0%) and 82.8% of residential care communities offered dietary and nutritional services, while 67.8% of adult day services centers provided these services (Figure 18).

Dementia care units

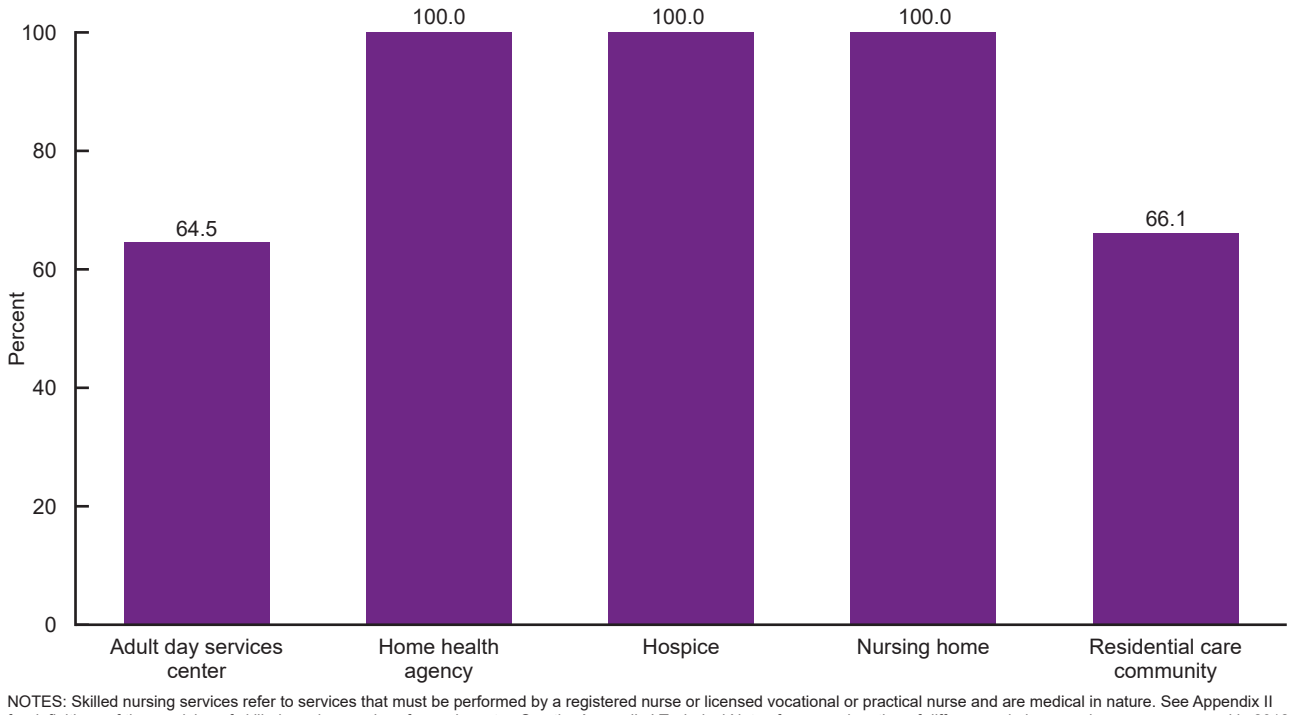
About 14.9% of nursing homes and 14.3% of residential care communities offered a dementia care unit within

Figure 14. Percentage of long-term care services providers that provide any therapeutic services, by sector: United States, 2016



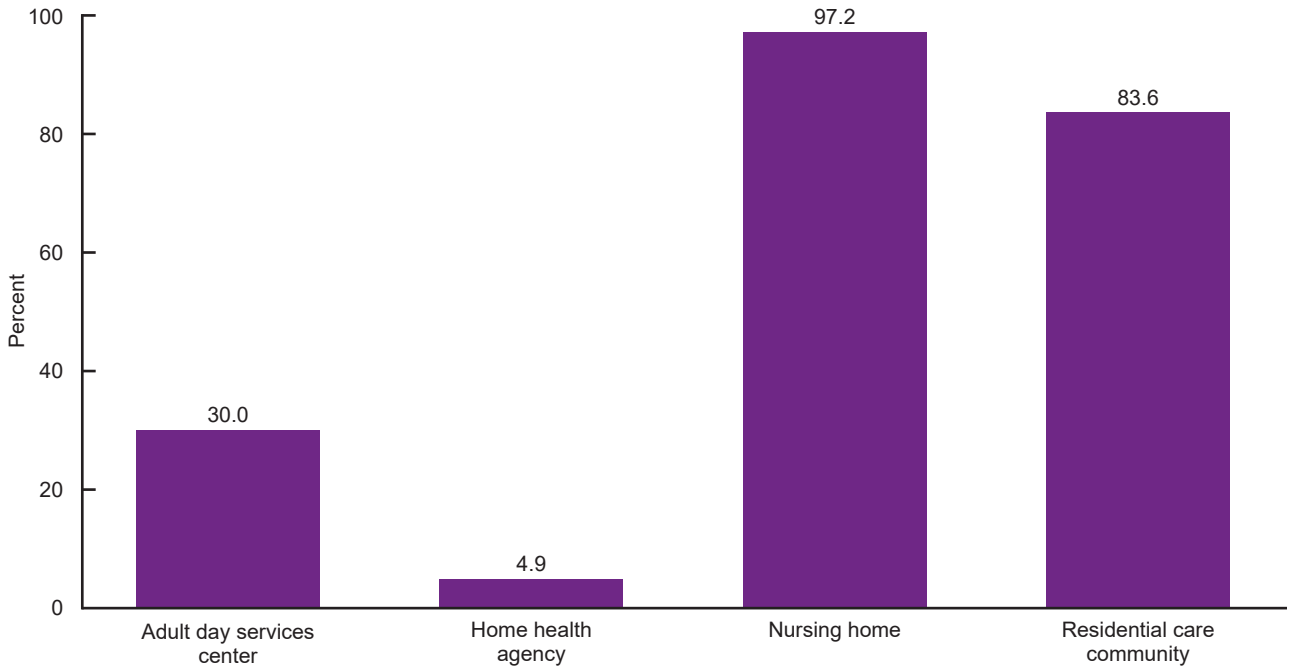
NOTES: Any therapeutic services refer to physical, occupational, or speech therapy services. See Appendix II for definitions of the provision of any therapeutic services for each sector. See the Appendix I Technical Notes for an explanation of differences in how services were measured in 2012, 2014, and 2016. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

Figure 15. Percentage of long-term care services providers that provide skilled nursing or nursing services, by sector: United States, 2016



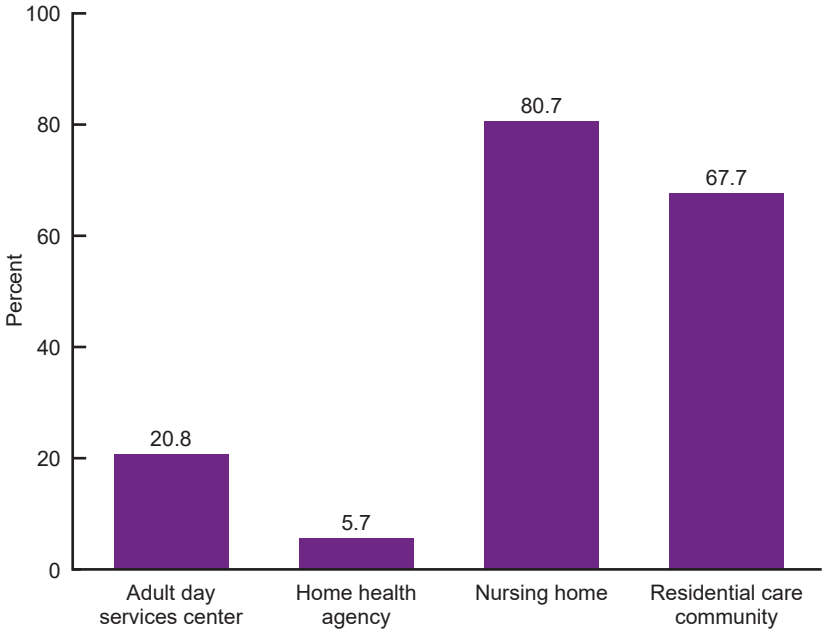
NOTES: Skilled nursing services refer to services that must be performed by a registered nurse or licensed vocational or practical nurse and are medical in nature. See Appendix II for definitions of the provision of skilled nursing services for each sector. See the Appendix I Technical Notes for an explanation of differences in how services were measured in 2012, 2014, and 2016. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

Figure 16. Percentage of long-term care services providers that provide pharmacy or pharmacist services, by sector: United States, 2016



NOTES: Pharmacy services refer to the filling and delivery of prescriptions. See Appendix II for definitions of the provision of pharmacy services for each sector. See the Appendix I Technical Notes for an explanation of differences in how services were measured in 2012, 2014, and 2016. The available administrative data did not have information on whether or not hospices provided pharmacy or pharmacist services. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

Figure 17. Percentage of long-term care services providers that provide hospice services, by sector: United States, 2016



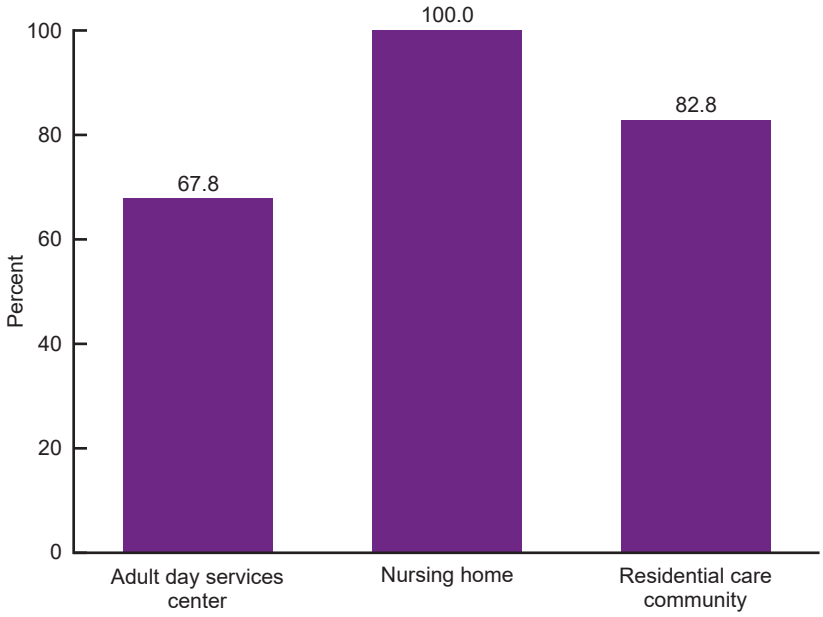
NOTES: See Appendix II for definitions of the provision of hospice services for each sector. See the Appendix I Technical Notes for an explanation of differences in how services were measured in 2012, 2014, and 2016. All hospices were expected to provide hospice services. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

a larger facility or community (Figure 19). While another 8.7% of residential care communities served only residents with dementia, few nursing homes (0.4%) did so. Dementia care units or dementia-only providers were not examined for adult day services centers, home health agencies, or hospices because these topics are more relevant for residential sectors, such as nursing homes and residential care communities.

National Profile of Long-term Care Services Users

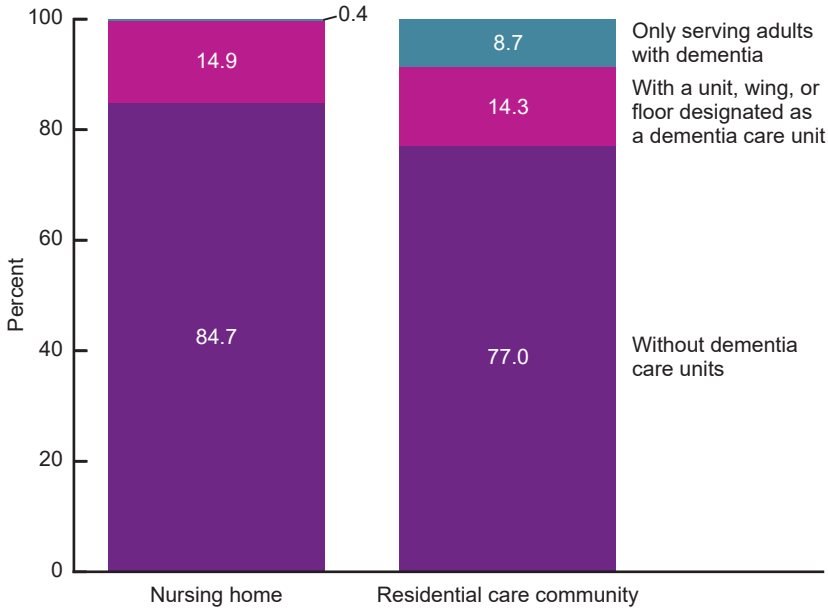
In this report, "current" participants or residents in 2016 refers to those participants enrolled in the adult day services center, or residents living in the nursing home or residential care community, on the day of data collection in 2016, rather than the total number of participants ever enrolled in the center or residents ever living in the nursing home or residential care

Figure 18. Percentage of long-term care services providers that provide dietary and nutritional services, by sector: United States, 2016



NOTES: See Appendix II for definitions of the provision of dietary and nutritional services for each sector. See the Appendix I Technical Notes for an explanation of differences in how services were measured in 2012, 2014, and 2016. The available administrative data did not have information on whether or not home health agencies or hospices provided dietary and nutritional services. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

Figure 19. Percent distribution of long-term care services providers, by sector and dementia care unit: United States, 2016



NOTES: See Appendix II for definitions of dementia care units for each sector. Dementia care units or dementia-only providers were not examined for adult day services centers, home health agencies, or hospices because these topics are more relevant for residential sectors such as nursing homes and residential care communities. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VII in Appendix III.

community at any time throughout the 2016 calendar year.

In 2016, there were an estimated 286,300 current participants enrolled in adult day services centers (of which 193,400 attended on a typical day) and 811,500 current residents living in residential care communities (Appendix III, Table VIII). Of the 1,347,600 current residents in nursing homes in 2016, about 606,800—approximately 43%—had a stay of less than 100 days (short stay), and 794,000—approximately 57%—had a stay of 100 days or longer (long stay) (Appendix III, Table IX). The number of nursing home residents by length of stay (short and long stay) is based on the number of residents in the Minimum Data Set Active Resident Episode Table (MARET) (see the Appendix I Technical Notes), but the total number of nursing home residents is based on Certification and Survey Provider Enhanced Reports (CASPER). After merging MARET and CASPER, some residents from MARET could not be matched with the CASPER file and therefore were not included in the merged data file, resulting in a difference between the estimated total number of residents in nursing homes and the estimated total derived from the sum of short- and long-stay residents. In 2015, about 4,455,700 patients received services and were discharged from home health agencies, and 1,426,000 patients received services from hospices. See the Appendix I Technical Notes for more information on the definitions of services users and data sources used for each sector.

Together these five long-term care services sectors served over 8.3 million (8,327,100) people annually. This estimate is the sum of the estimates of the people served in each of the five sectors, and is a rough approximation. The data used for each sector captured services users in different ways, and the data year used for each sector varied across sectors. The estimated number of adult day services center participants represents current participants in 2016. The estimated number of home

health patients represents patients who ended care in 2015 (i.e., discharges). The estimated number of hospice patients represents patients who received care at any time in 2015. The estimated number of nursing home residents and residential care community residents each represent current residents on any given day in 2016. The same person may be included more than once in the sum of services users in the five sectors, if a person received care in more than one sector in a similar time period (e.g., a residential care resident receiving care from a home health agency). Given that the estimate for the number of current adult day, nursing home, and residential care services users in a given year is likely to be less than the number of all services users in these sectors throughout that year, it is expected that the estimate of all services users in all five sectors as of 2016 is at least nine million, in spite of the possibility of double counting the same person across sectors.

This section provides an overview of the demographic, health, and functional composition of users of long-term care services, and their experience of adverse events, by sector. Demographic measures include age, race and ethnicity, and sex. Medicaid as a payer source is used to measure payment characteristics. Measures of health status include diagnosis of Alzheimer disease and other dementias, arthritis, asthma, chronic kidney disease, chronic obstructive pulmonary disease (COPD), depression, diabetes, heart disease, high blood pressure or hypertension, and osteoporosis. Measures of functional status include needing assistance with selected activities of daily living (ADLs; bathing, dressing, eating, toileting, transferring in and out of a chair or bed, and walking or locomotion). Measures of adverse events include overnight hospital stays, emergency department visits, and falls.

Use of Long-term Care Services

As noted previously, participants in adult day services centers and residents in nursing homes and residential care communities are current users in 2016. Home health patients refer to patients who ended home health care anytime in 2015. Hospice patients refer to patients who received care anytime in 2015. Given the data available, daily-use rates were compared for nursing home residents, residential care residents, and adult day services center participants, while annual-use rates were compared for home health patients and hospice patients. Use of long-term care services by individuals aged 65 and over per 1,000 persons aged 65 and over varied by sector. The daily-use rate was higher for nursing homes (24 per 1,000), compared with residential care communities (15 per 1,000) and adult day services centers (4 per 1,000). The annual-use rate was higher for home health agencies (75 per 1,000) compared with hospices (27 per 1,000).

Demographic Characteristics of Long-term Care Services Users

Long-term care services users by age

The majority of long-term care services users were aged 65 and over: 94.6% of hospice patients, 93.4% of residential care residents, 83.5% of nursing home residents, 81.9% of home health patients, and 62.5% of participants in adult day services centers (Figure 20). Among nursing home residents, 81.4% of short-stay residents and 85.1% of long-stay residents were aged 65 and over (Appendix III, Table IX).

The age composition of services users varied by sector, with residential care communities (52.1%), hospices (47.8%), and nursing homes (38.6%) serving more persons aged 85 and over, and adult day services centers (37.4%) serving more persons under age 65 than other sectors. Among nursing home residents, 32.2% of short-stay residents and 43.5% of long-stay residents were aged 85 and over (Appendix III, Table IX).

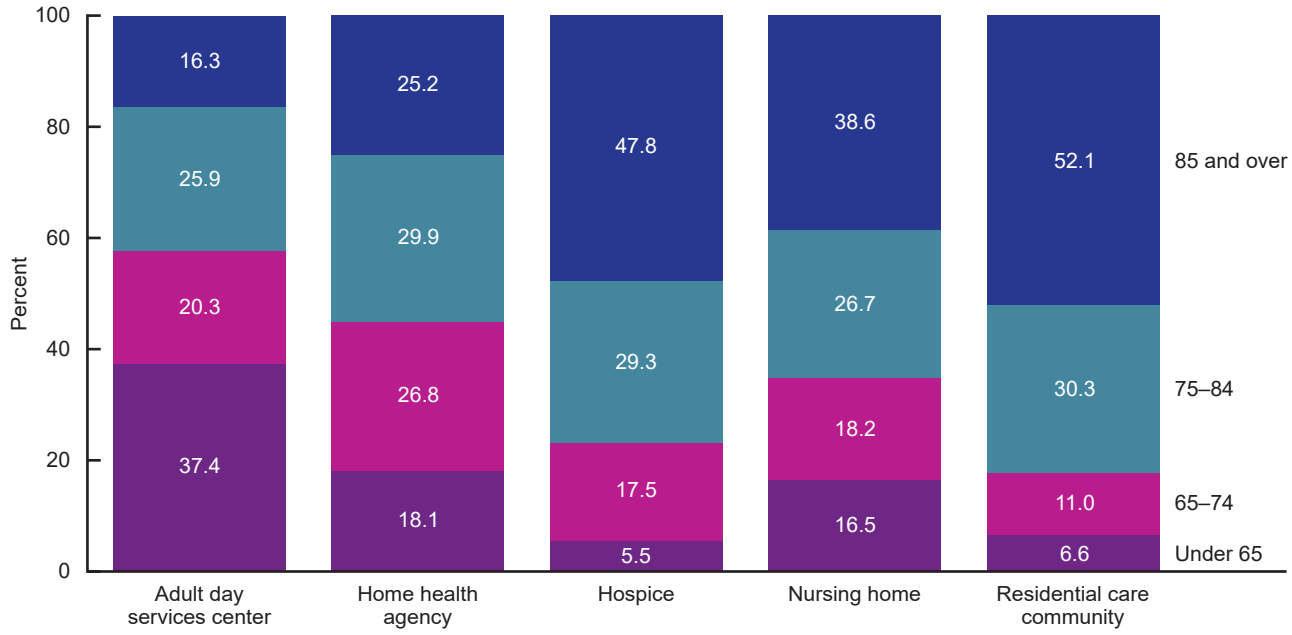
Long-term care services users by sex

In all five sectors, the users of long-term care services were overwhelmingly women, with residential care communities having the highest proportion (70.6%) (Figure 21). Among nursing home residents, 60.3% of short-stay residents and 67.9% of long-stay residents were women (Appendix III, Table IX).

Long-term care services users by race and ethnicity

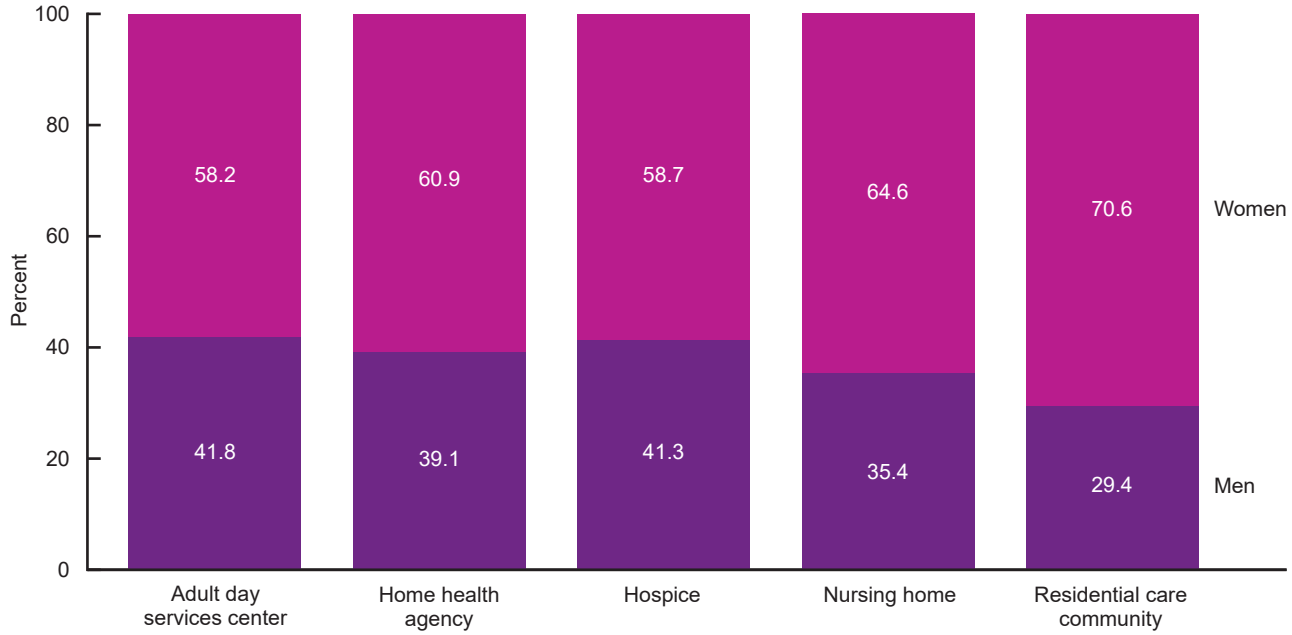
Non-Hispanic white persons accounted for at least three-quarters of users in all long-term care services sectors except adult day services centers (Figure 22). The percentage of non-Hispanic white persons was highest in hospice (83.6%) and residential care communities (81.4%), followed by home health agencies (76.1%) and nursing homes (75.1%). Less than one-half of the participants in adult day services centers were non-Hispanic white (42.0%). Adult day services centers were the most racially and ethnically diverse among the five sectors: 15.4% of center participants were non-Hispanic black and 22.7% were Hispanic. About one-tenth of home health patients (12.9%), nursing home residents (14.3%), and hospice patients (8.2%) were non-Hispanic black, while 4.1% of residential care residents were non-Hispanic black. In nursing homes, 74.6% of short-stay residents and 75.6% of long-stay residents were non-Hispanic white, followed by non-Hispanic black (14.0% and 14.6% among short- and long-stay residents, respectively) (Appendix III, Table IX).

Figure 20. Percent distribution of long-term care services users, by sector and age group: United States, 2015 and 2016



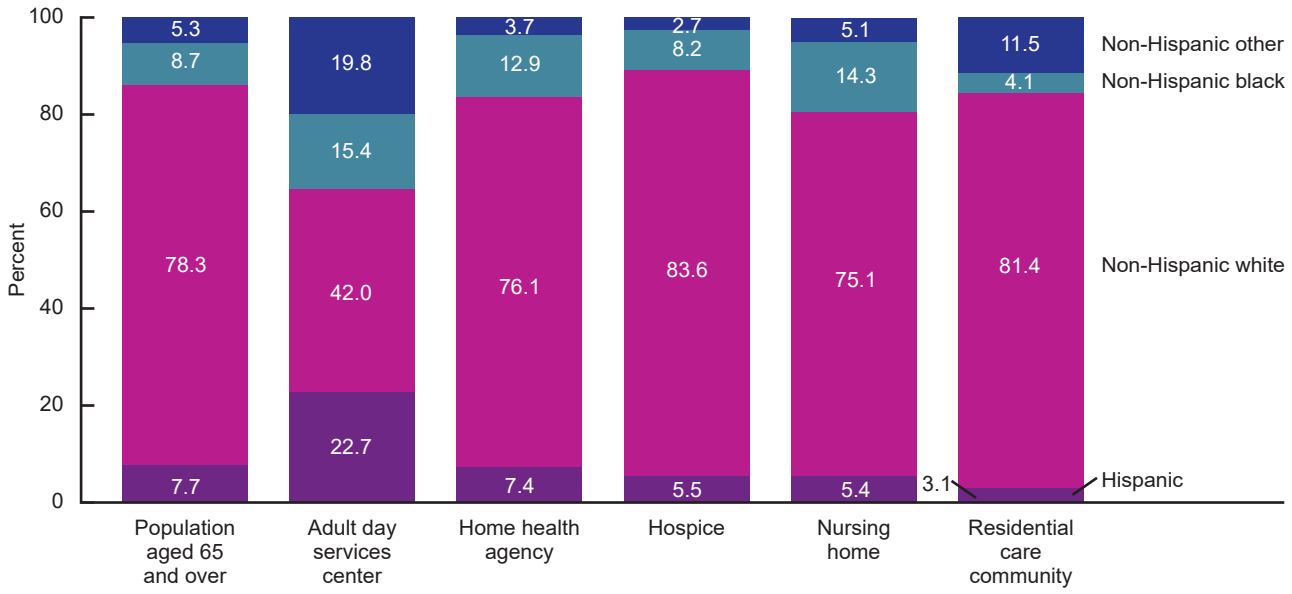
NOTES: Denominators used to calculate percentages for adult day services centers, nursing homes, and residential care communities were the number of participants enrolled in adult day services centers, the number of residents in nursing homes, and the number of residents in residential care communities on a given day in 2016, respectively. Denominators used to calculate percentages for home health agencies and hospices were the number of patients whose episode of care ended at any time in 2015 and the number of patients for whom Medicare-certified hospices submitted a Medicare claim at any time in 2015, respectively. See the Appendix I Technical Notes for more information on the data sources used for each sector. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VIII in Appendix III.

Figure 21. Percent distribution of long-term care services users, by sector and sex: United States, 2015 and 2016



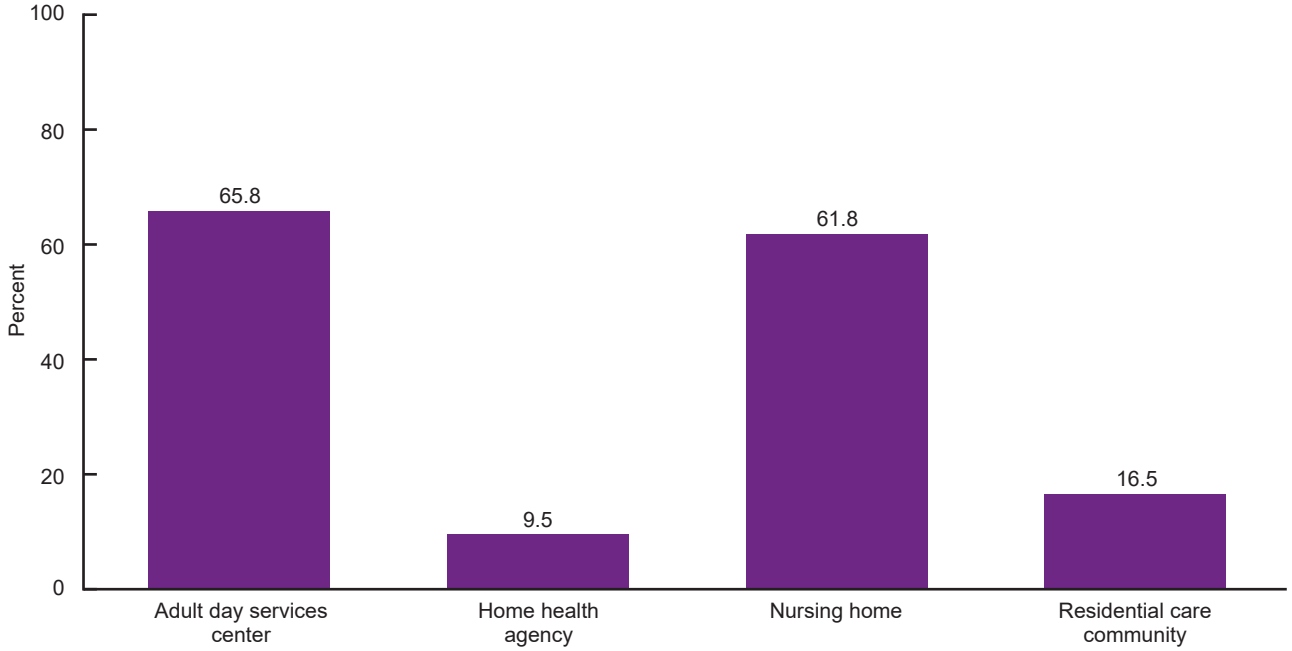
NOTES: Denominators used to calculate percentages for adult day services centers, nursing homes, and residential care communities were the number of participants enrolled in adult day services centers, the number of residents in nursing homes, and the number of residents in residential care communities on a given day in 2016, respectively. Denominators used to calculate percentages for home health agencies and hospices were the number of patients whose episode of care ended at any time in 2015 and the number of patients for whom Medicare-certified hospices submitted a Medicare claim at any time in 2015, respectively. See the Appendix I Technical Notes for more information on the data sources used for each sector. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VIII in Appendix III.

Figure 22. Percent distribution of long-term care services users, by sector and race and Hispanic origin: United States, 2015 and 2016



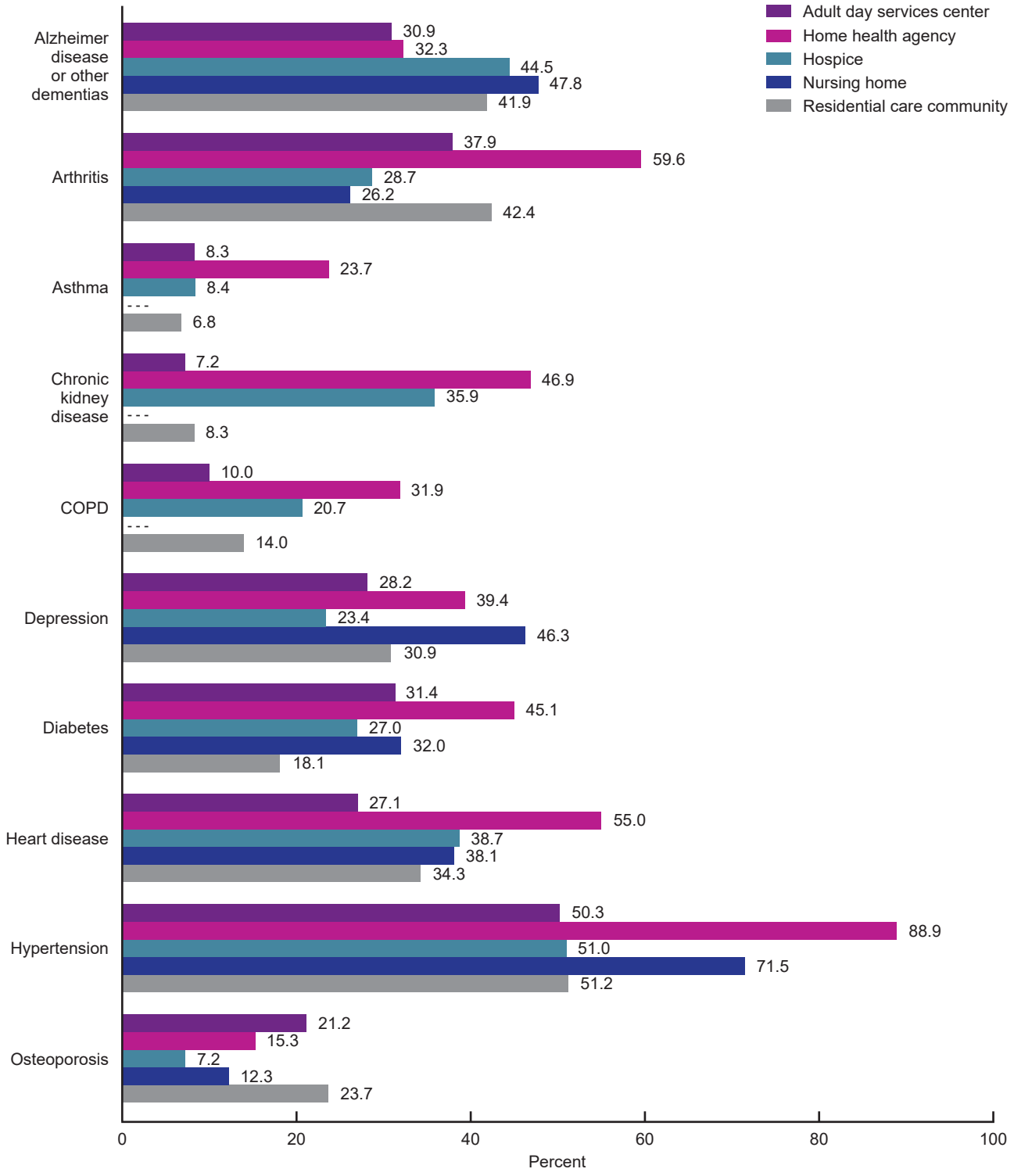
NOTES: Denominators used to calculate percentages for adult day services centers, nursing homes, and residential care communities were the number of participants enrolled in adult day services centers, the number of residents in nursing homes, and the number of residents in residential care communities on a given day in 2016, respectively. Denominators used to calculate percentages for home health agencies and hospices were the number of patients for whom Medicare-certified home health agencies submitted a Medicare claim at any time in 2015 and the number of patients for whom Medicare-certified hospices submitted a Medicare claim at any time in 2015, respectively. For adult day services centers and residential care communities, includes non-Hispanic American Indian or Alaska Native, non-Hispanic Asian, non-Hispanic Native Hawaiian or Other Pacific Islander, non-Hispanic of two or more races, and unknown race and ethnicity. See the Appendix I Technical Notes for more information on the data sources used for each sector. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VIII in Appendix III; and U.S. Census Bureau, Population Division, Population Estimates, July 1, 2016.

Figure 23. Percentage of long-term care services users with Medicaid as payer source, by sector: United States, 2015 and 2016



NOTES: Denominators used to calculate percentages for adult day services centers, nursing homes, and residential care communities were the number of participants enrolled in adult day services centers, the number of residents in nursing homes, and the number of residents in residential care communities on a given day in 2016, respectively. The denominator used to calculate the percentage for home health agencies was the number of patients whose episode of care ended at any time in 2015. Data on Medicaid as payer source were not available for hospice patients. See Appendix II for definitions of Medicaid as payer source for each sector. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VIII in Appendix III.

Figure 24. Percentage of long-term care services users with selected diagnoses, by sector: United States, 2015 and 2016



- - - Data not available.

NOTES: Denominators used to calculate percentages for adult day services centers, nursing homes, and residential care communities were the number of participants enrolled in adult day services centers, the number of residents in nursing homes, and the number of residents in residential care communities on a given day in 2016, respectively. Denominators used to calculate percentages for home health agencies and hospices were the number of patients for whom Medicare-certified home health agencies submitted a Medicare claim at any time in 2015 and the number of patients for whom Medicare-certified hospices submitted a Medicare claim at any time in 2015, respectively. See the Appendix I Technical Notes for more information on the data sources used for each sector. See Appendix II for definitions of conditions used for each sector. Percentages are based on unrounded estimates. Available data for nursing homes could not produce estimates for asthma, chronic kidney disease, and chronic obstructive pulmonary disease (COPD), because asthma and COPD were grouped together (21.2%), and only end-stage renal disease (12.9%) was available, which accounts for only a portion of residents with chronic kidney disease.

SOURCES: NCHS, National Study of Long-Term Care Providers and Table VIII in Appendix III.

Long-term care services users by use of Medicaid as a payer source

The percentage of long-term care services users using Medicaid as a payer source was highest in adult day services centers (65.8%), followed by nursing homes (61.8%) (Figure 23). Among residential care residents, 16.5% used Medicaid as a payer source, followed by 9.5% of home health patients. Data on Medicaid as payer source were not available for hospice patients.

Health and Functional Characteristics of Long-term Care Services Users

Diagnosed chronic conditions among long-term care services users

Alzheimer disease or other dementias were most prevalent among nursing home residents (47.8%) and were least prevalent among adult day services center participants (30.9%) (Figure 24). The percentage of nursing home residents with a diagnosis of Alzheimer disease was higher among long-stay residents (58.9%) than among short-stay residents (36.7%) (Appendix III, Table IX). Arthritis was most prevalent among home health patients (59.6%) and was least prevalent among nursing home residents (26.2% overall; 25.1% among short-stay residents and 29.7% among long-stay residents). The percentage of long-term care services users with a diagnosis of asthma was highest among home health patients (23.7%) and lowest among residential care community residents (6.8%). A diagnosis of chronic kidney disease was most common among home health patients (46.9%), followed by hospice patients (35.9%), and was least common among adult day services center participants (7.2%) and residential care community residents (8.3%). Similarly, COPD was most common among home health patients (31.9%), followed by hospice patients (20.7%), residential care community residents (14.0%), and adult day services center participants (10.0%).

The percentage of long-term care services users with a diagnosis of depression was highest in nursing homes (46.3%) and lowest in hospices (23.4%) (Figure 24). Among nursing home residents, the prevalence of depression was higher among long-stay residents (53.0%) than short-stay residents (42.6%) (Appendix III, Table IX). Diabetes was most prevalent among home health patients (45.1%), followed by nursing home residents (32.0% overall; 37.0% of short-stay residents and 32.2% of long-stay residents) and adult day services center participants (31.4%), but it was least prevalent among residential care community residents (18.1%). A diagnosis of heart disease was most common among home health patients (55.0%). Over one-half of long-term care services users in all five long-term care sectors had a diagnosis of hypertension, with the highest proportion among home health patients (88.9%). The percentage of long-term care services users with a diagnosis of osteoporosis was highest in residential care communities (23.7%), followed by adult day services centers (21.2%), home health agencies (15.3%), nursing homes (12.3% overall; 9.8% of short-stay residents and 15.1% of long-stay residents), and hospices (7.2%).

Need for assistance with ADLs among long-term care services users

This report uses the need for assistance with six ADLs—bathing, dressing, toileting, walking or locomotion, transferring in and out of a chair or bed, and eating—to measure physical and cognitive functioning among residents in nursing homes and residential care communities, home health patients, and adult day services center participants. Data on need for assistance with ADLs were not available for hospice patients.

Overall, functional ability varied by sector. Within each sector except adult day services centers, the need for assistance with bathing was most common. The need for assistance with eating was least common within each of the five sectors (Figure 25). Adult day services centers had fewer participants that needed assistance with four of the six ADLs (bathing, dressing, toileting, and walking or locomotion) than services users in other sectors.

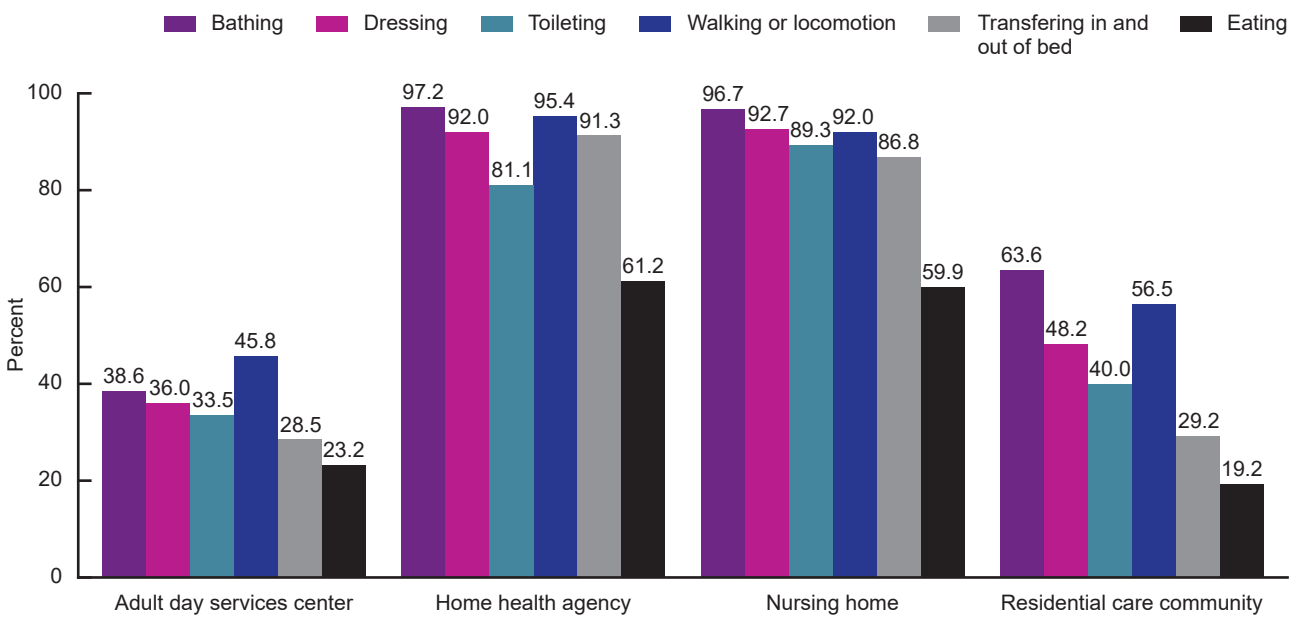
Fewer adult day services center participants needed assistance with ADLs compared with services users in the other four sectors. Among adult day services center participants, the need for assistance with walking or locomotion was most common (45.8%). Therefore, while the prevalence of ADL needs differed by sector, at a minimum, 45.8% of services users across all sectors needed assistance with at least one of the six ADLs.

Adverse events among long-term care services users

This report estimates the prevalence of overnight hospitalizations, emergency department visits, and falls as indicators of adverse, potentially avoidable events. For adult day services centers and residential care communities, adverse events refer to a period of 90 days prior to the survey. For home health agencies, adverse events refer to a period since the last Outcome and Assessment Information Set (OASIS) assessment. For nursing homes, falls refer to the period since admission or since the prior assessment, whichever is more recent. Varying reference periods by sector do not allow for direct comparisons between sectors.

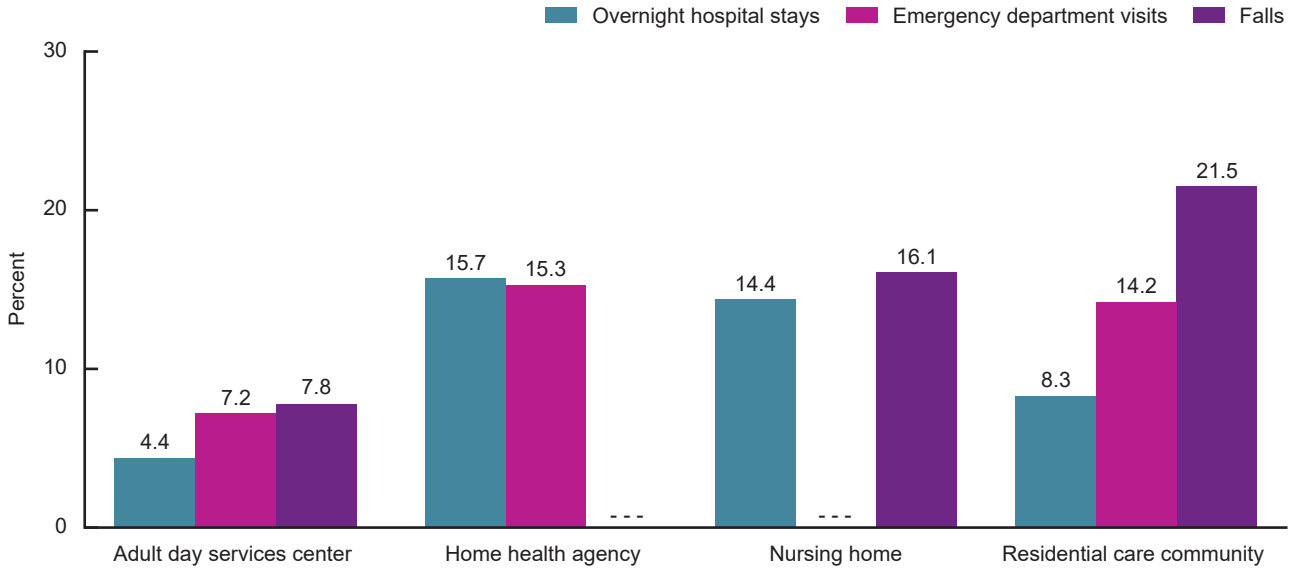
About equal percentages of home health patients had overnight hospital stays (15.7%) and emergency department visits (15.3%) (Figure 26). About 14.4% of nursing home residents had overnight hospital stays; more short-stay residents had overnight hospital stays (23.8%) than long-stay residents (8.7%) (Appendix III, Table IX). About 8.3% of residential care community residents and 4.4% of adult day services center participants had overnight hospital stays. About 7.2% of adult day services center participants

Figure 25. Percentage of long-term care services users needing any assistance with activities of daily living, by sector and activity: United States, 2015 and 2016



NOTES: Denominators used to calculate percentages for adult day services centers, nursing homes, and residential care communities were the number of participants enrolled in adult day services centers, the number of residents in nursing homes, and the number of residents in residential care communities on a given day in 2016, respectively. The denominator used to calculate the percentage for home health agencies was the number of patients whose episode of care ended at any time in 2015. Participants, patients, or residents were considered needing any assistance with a given activity if they needed help or supervision from another person or used assistive devices to perform the activity. See Appendix II for definitions of needing any assistance with activities of daily living used for each sector. Data on needing any assistance with activities of daily living were not available for hospice patients. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VIII in Appendix III.

Figure 26. Percentage of long-term care services users with overnight hospital stays, emergency department visits, and falls, by sector: United States, 2015 and 2016



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NOTES: Denominators used to calculate percentages for adult day services centers, nursing homes, and residential care communities were the number of participants enrolled in adult day services centers, the number of residents in nursing homes, and the number of residents in residential care communities on a given day in 2016, respectively. The denominator used to calculate the percentage for home health agencies was the number of patients whose episode of care ended at any time in 2015. For adult day services centers and residential care communities, adverse events refer to the 90 days prior to the survey. For home health agencies, adverse events refer to a period since the last Outcome and Assessment Information Set. For nursing homes, falls refer to the period since admission or since the prior assessment, whichever is more recent. For hospices, data were not available for overnight hospital stays, emergency department visits, or falls. See the Appendix I Technical Notes for more information on the data sources used for each sector. See Appendix II for definitions of each adverse event used for each sector. Percentages are based on unrounded estimates.
SOURCES: NCHS, National Study of Long-Term Care Providers and Table VIII in Appendix III.

and 14.2% of residential care residents had emergency department visits. About 21.5% of residential care community residents, 16.1% of nursing home residents, and 7.8% of adult day services center participants had falls. Among nursing home residents, more long-stay residents (19.1%) than short-stay residents (13.5%) had falls.

For home health patients, data for falls were not available. For nursing home residents, data for emergency department visits were not available, and data for hospitalizations were not reported because the timing of Medicare claims data did not match the other nursing home data sets used for this report. For hospice patients, data for emergency department visits, overnight hospital stays, and falls were not available.

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Appendix I. Technical Notes

Data Sources

This report uses data from multiple sources, including two main sources: administrative data from the Centers for Medicare & Medicaid Services (CMS) on nursing homes, home health agencies, and hospices; and cross sectional, nationally representative, establishment-based survey data from the National Center for Health Statistics (NCHS) for assisted living and similar residential care communities and for adult day services centers. Data for all five sectors were obtained for comparable time periods, where feasible, for each of the 50 states and the District of Columbia.

Administrative data: Home health agencies, hospices, and nursing homes

Provider-level data

Provider-level data files were from the Certification and Survey Provider Enhanced Reports (CASPER) system. CASPER data are collected to support the survey and certification regulatory functions of CMS; every nursing home, home health agency, and hospice in the United States that is certified to provide services under Medicare, Medicaid, or both is included. The CASPER data used in this report were from the third quarter of 2016. The number of variables in each file and frequency of certification survey data collection varies by sector because different providers are required to report different information during the survey and certification process. This report excluded providers located in American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands.

Home health agency file—Included 12,208 home health agencies coded as active providers located in the United States. About 77.1% were Medicare- and Medicaid-certified, 21.6% were Medicare-certified only, and 1.3% were Medicaid-certified only. About 82.7% of these home health agencies completed a certification survey during the last 3 years (including 55.8% during the last 2 years).

Hospice file—Included 4,348 hospices coded as active providers located in the United States; information on type of certification (Medicare-only, Medicaid-only, or both) was not available. CMS requires certification surveys of Medicare hospices every 6 to 8 years, on average (54). The majority of Medicare hospices (95.5%) completed a certification survey during the last 8 years (including 75.6% during the last 3 years).

Nursing home file—Included 15,638 nursing homes coded as active providers located in the United States. About 92.7% were Medicare- and Medicaid-certified, 4.8% were Medicare-certified only, and 2.5% were Medicaid-certified only. Nearly all of these nursing homes (99.5%) completed a certification survey during the last 18 months (including 80.7% during the last 12 months).

User-level data

User-level assessment and claims data were from different sector-specific CMS data sources. These data were aggregated to the provider level (e.g., the distribution of an agency's patients or a facility's residents by age, race, and sex) using the unique provider identification (ID) number. These user-level data were then merged to the respective provider-specific CASPER data file using the provider ID number.

Home health patients

Outcome-Based Quality Improvement (OBQI) Case Mix Roll-up data (also known as Agency Patient-Related Characteristics Report data) are from the Outcome and Assessment Information Set (OASIS). OBQI data were used as the primary source of information on home health patients whose episode of care ended at any time in calendar year 2015 (i.e., discharges), regardless of payment source. These data included home health patients who received services from Medicare-certified and Medicaid-certified home health providers in states where those agencies were required to meet the Medicare Conditions of Participation. When merged with the CASPER home health agency file by provider ID number, 1,101 of the 12,208 agencies in the CASPER file (9.0%) had no patient information in the OBQI data; 440 of the 11,547 agencies in the OBQI file (3.8%) had no provider information in the CASPER data.

The total number of patients in this merged file (4,455,651) was used as the denominator when calculating percentages of home health patients in different age and sex categories; to calculate percentages of those receiving Medicaid, needing any assistance with activities of daily living (ADLs), having hospitalizations, and having emergency department visits; and to calculate the annual number of users and the annual-use rates of home health care.

Institutional Provider and Beneficiary Summary (IPBS) home health data were used because the OBQI data did not use racial and ethnic categories and information on patients' diagnoses that was comparable to those used in other data sources. The IPBS data file contained information on home health patients for whom Medicare-certified home health agencies submitted a Medicare claim at any time in calendar year 2015. When merged with the CASPER home health agency file, 1,088 of the 12,208 agencies in the CASPER file (8.9%) had no patient information in the IPBS home

health data. The total number of patients in this merged file (4,078,769) was used as the denominator when calculating percentages of home health patients in different racial and ethnic categories, and to calculate percentages of those diagnosed with the selected conditions.

Hospice patients

The **IPBS hospice data** file contained information on hospice patients for whom Medicare-certified hospice agencies submitted a Medicare claim at any time in calendar year 2015. Given that 93.0% of hospice agencies were Medicare-certified in 2007 (based on findings from the 2007 National Home and Hospice Care Survey) and that no other data source was available on hospice patients, IPBS hospice data were assumed to provide current coverage and information on most hospice patients. When merged with the CASPER hospice agency file, 309 of the 4,348 hospices in CASPER (7.1%) had no patient information in the IPBS hospice data. The total number of hospice patients in this merged file (1,426,014) was used for the annual number of users, the annual-use rates, and it was used as the denominator when calculating percentages for all aggregate patient-level measures. Data included demographic characteristics (i.e., age, sex, and racial and ethnic background) and selected diagnosed conditions.

Nursing home residents

Minimum Data Set Active Resident Episode Table (MARET) data contained information on all residents who were residing in a Medicare- or Medicaid-certified nursing home on the last day of the third quarter of 2016, regardless of payment source. Residents whose last assessment during the third quarter of 2016 was a discharge assessment were excluded. Minimum Data Set (MDS) assessment records are provided by nursing homes and maintained by CMS to create a profile of the most recent standard information for each active resident. Within MARET, CMS defines an active resident as "a resident whose most recent assessment transaction is not a discharge and whose most recent transaction has a target date (assessment reference date for an assessment record or entry date for an entry record) less than 150 days old. If a resident has not had a transaction for 150 days, then that resident is assumed to have been discharged."

The resident-level MARET data were aggregated using the provider ID number and merged to the CASPER nursing home file. There were 131 of 15,638 nursing homes in the CASPER file (0.8%) that had no resident information from the MARET data. The number of nursing home residents obtained from MARET and merged to CASPER (1,396,591) was used as the denominator when calculating the percentages of demographic characteristics (i.e., age, sex, race and ethnicity), selected diagnosed conditions, and to calculate the daily-use rates of nursing homes.

The measurement of short-stay (43.3% of residents admitted for fewer than 100 days) and long-stay (56.7% of residents admitted for 100 days or more) nursing home residents was derived from the nursing home admission and assessment dates in MARET. To estimate resident characteristics shown in Appendix III, Table IX by length of stay, MARET was not aggregated to the provider level, but was analyzed at the resident level. Thus, estimates presented in Table IX represent 1,400,810 residents by length of stay.

Medicare Provider Analysis and Review (MedPAR) inpatient claims data from calendar year 2014 were merged with 2014 MARET data using a unique beneficiary ID number to measure overnight hospitalizations among nursing home residents. This method was used because the MARET data exclude residents whose last assessment was a discharge, which contains information on hospitalizations. The time frame, calendar year 2014, is 2 years older than the 2016 MARET data used for the other estimates in this report because of the time lag in processing and releasing MedPAR. The MedPAR file contained 8,445,659 beneficiaries with at least 1, and up to 19 inpatient hospital claims. After merging MedPAR and MARET using the beneficiary ID (included in MedPAR) to the resident ID (included in MARET) crosswalk, there were 1,286,490 individuals in both the nursing home and MedPAR files. Qualifying hospitalizations were measured by having any hospital discharge that occurred after the nursing home admission date.

The **CASPER nursing home file** for the third quarter of 2016 included information on selected measures for 1,347,622 current residents of 15,638 nursing homes; this information was collected using Form CMS-672 (Resident Census and Conditions of Residents). The resident census information was designed to represent the facility at the time of the certification survey. CMS defined current residents as "residents in certified beds regardless of payer source." Because the data were provided at the provider level, file merging was unnecessary, and no nursing home had missing data on resident census items. Resident census information from the CASPER nursing home file was used for the number of current residents and the percentages of residents with ADL limitations.

Survey data: Adult day services centers and residential care communities

NCHS designed and conducted surveys for the adult day services center and residential care community components of the third wave of the National Study of Long-Term Care Providers (NSLTCP) in 2016. The 2016 NSLTCP questionnaires for adult day services centers and residential care communities are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. The NSLTCP questionnaires consist of topics common or comparable across all five sectors ("core topics") and topics that are specific to a particular sector ("sector-specific topics"). To facilitate comparisons across sectors, the core topics for the primary data collection for adult day services centers and residential care communities were designed to be as similar

as possible to the core topics and wording available through the CMS administrative data for home health agencies, hospices, and nursing homes. The adult day services center and residential care community questionnaires included questions that collected information at both the provider and aggregate-user level.

The 2016 NSLTCP surveys of adult day services centers and residential care communities were conducted between August 2016 and February 2017. The survey included mail-, web-, and telephone-administered questionnaires. The survey instruments were designed to assess study eligibility and to collect data on services offered, the staffing profile, center participant or community resident characteristics, and record keeping at adult day services centers or residential care communities. Two sets of questionnaires were used to collect data designed at the state and national level: (1) survey items that were included on both questionnaires and asked of all respondents (designed to provide national- and state-level estimates), and (2) a few selected items included on one version of the questionnaires and designed to provide only national-level estimates. This report only uses items that were included on both questionnaires and can be estimated at the state level, except for the percentages of participants or residents who had a fall.

Adult day services centers

The survey for the adult day services center component of the 2016 NSLTCP was based on a census of U.S. centers. The sampling frame obtained from the National Adult Day Services Association contained adult day services centers that self-identified as adult day care, adult day services, or adult day health services centers that were in operation as of November 2015. After removing duplicates, the final frame consisted of 5,348 adult day services centers that were included in the data collection efforts. The set of eligibility criteria for study participation was determined by self-report in the screener section of the questionnaire. Additionally, adult day services centers had to:

- Be licensed or certified by the state specifically to provide adult day services, or accredited by the Commission on Accreditation of Rehabilitation Facilities; or authorized or otherwise set up to participate in Medicaid (Medicaid state plan, Medicaid waiver, or Medicaid managed care) or part of a Program of All-Inclusive Center for the Elderly.
- Have an average daily attendance of at least one participant based on a typical week.
- Have at least one participant enrolled at the designated center at the time of the survey.

As a result of using these eligibility criteria, all responding eligible centers participated in Medicaid or were in some way regulated by the state. A total of 182 (3.4%) centers were either invalid or out of business. However, 2,041centers (38.2%) could not be contacted; therefore, the final eligibility status of these centers was unknown. Using the eligibility rate, a proportion of these centers of unknown eligibility was estimated to be eligible. Eligibility rate was calculated by the number of known eligible adult day services centers divided by the total number of adult day services centers with known eligibility status. Centers that were invalid or out of business and centers that screened out as ineligible were classified as "known ineligibles." This estimated number and the total number of eligible centers resulting from the screening process were used to estimate the total number of eligible adult day services centers in the United States.

Of the 4,586 eligible and presumed eligible centers, 2,836 completed the questionnaire, for a response rate of 61.8%. Response rates are calculated using standards set by the American Association of Public Opinion Research (AAPOR). AAPOR Response Rate #4 calculations include assumptions of eligibility among potential respondents that are not interviewed. AAPOR Response Rate #4 formula was used to calculate response rates for adult day services centers (completed questionnaires / [completed eligible questionnaires] + [eligibility rate x cases of unknown eligibility]). Response rates by state ranged from 45.5% to 93.8% and are presented in Table I.

Residential care communities

The sampling frame was constructed from lists of licensed residential care communities obtained from the state licensing agencies in each of the 50 states and the District of Columbia. The 2016 NSLTCP used the same definition of residential care community and the same approach to create the sampling frame (55) that was used for the 2010 National Survey of Residential Care Facilities (NSRCF) (56). To be eligible for the study, a residential care community must be licensed, registered, listed, certified, or otherwise regulated by the state to:

- Provide room and board with at least two meals a day and around-the-clock, onsite supervision
- Help with personal care, such as bathing and dressing or health-related services, such as medication management
- Have four or more licensed, certified, or registered beds
- Have at least one resident currently living in the community
- Serve a predominantly adult population

Residential care communities licensed to exclusively serve individuals with severe mental illness, intellectual disability, or developmental disability, and nursing homes were excluded.

The residential care community component used a combination of probability sampling and census taking. Probability samples were selected in the states that had sufficient numbers of residential care communities to enable state-level sample-based estimation. A census was taken of residential care communities in the states that did not have sufficient numbers of residential care communities to enable state-level sample-based estimation. From 42,149 communities in the sampling frame, 11,688 residential care communities were sampled and stratified by state and

Table I. Response rates for adult day services centers, by state, 2016

Area	Rate	Area	Rate
United States	61.8	Missouri	55.3
Alabama	71.4	Montana	72.7
Alaska	71.4	Nebraska	69.6
Arizona	75.0	Nevada	73.7
Arkansas	57.6	New Hampshire	68.8
California	53.0	New Jersey	53.9
Colorado	64.2	New Mexico	45.5
Connecticut	72.5	New York	59.5
Delaware	76.9	North Carolina	85.6
District of Columbia	60.0	North Dakota	61.8
Florida	61.0	Ohio	61.2
Georgia	62.9	Oklahoma	78.4
Hawaii	70.0	Oregon	64.7
Idaho	58.3	Pennsylvania	65.4
Illinois	69.1	Rhode Island	64.0
Indiana	74.5	South Carolina	65.6
Iowa	67.7	South Dakota	82.4
Kansas	60.0	Tennessee	69.5
Kentucky	61.0	Texas	58.9
Louisiana	58.0	Utah	50.0
Maine	51.6	Vermont	93.8
Maryland	71.9	Virginia	72.0
Massachusetts	61.5	Washington	65.5
Michigan	65.6	West Virginia	61.5
Minnesota	74.3	Wisconsin	66.0
Mississippi	63.6	Wyoming	83.3

SOURCE: NCHS, National Study of Long-Term Care Providers, 2016.

Table II. Response rates for residential care communities, by state, 2016

Area	Rate	Area	Rate
United States	50.7	Missouri	55.8
Alabama	48.2	Montana	58.0
Alaska	50.0	Nebraska	65.8
Arizona	47.8	Nevada	51.1
Arkansas	71.8	New Hampshire	56.8
California	43.3	New Jersey	51.7
Colorado	55.0	New Mexico	48.4
Connecticut	63.2	New York	55.1
Delaware	58.3	North Carolina	52.2
District of Columbia	33.3	North Dakota	68.8
Florida	44.3	Ohio	62.3
Georgia	46.4	Oklahoma	55.1
Hawaii	54.1	Oregon	60.1
Idaho	52.9	Pennsylvania	56.1
Illinois	49.3	Rhode Island	50.0
Indiana	52.7	South Carolina	57.0
Iowa	70.9	South Dakota	69.7
Kansas	58.5	Tennessee	59.6
Kentucky	61.0	Texas	46.9
Louisiana	59.3	Utah	60.5
Maine	58.0	Vermont	56.3
Maryland	42.7	Virginia	53.9
Massachusetts	40.4	Washington	51.1
Michigan	49.5	West Virginia	49.1
Minnesota	54.7	Wisconsin	60.3
Mississippi	45.6	Wyoming	86.7

SOURCE: NCHS, National Study of Long-Term Care Providers, 2016.

community bed size. A set of screener items in the questionnaire was used to determine eligibility: 135 (1.2% weighted) communities were invalid or out of business and an additional 1,490 (24.0% weighted) communities in the sample were determined to be ineligible during data collection because they did not meet the set eligibility criteria. However, 5,485 communities (49.3% weighted) could not be contacted by the end of data collection and, therefore, the final eligibility status of these communities was unknown.

Using the eligibility rate, a proportion of the 5,485 communities of unknown eligibility was estimated to be eligible. The eligibility rate was calculated by the number of known eligible residential care communities divided by the total number of residential care communities with known eligibility status. Communities that were invalid or out of business and communities that screened out as ineligible were classified as "known ineligibles." This estimated number and the total number of eligible communities resulting from the screening process were used to estimate the total number of eligible residential care communities in the United States. Of the 8,626 eligible and presumed eligible residential care communities, 4,643 returned the survey questionnaire, however, 65 communities (0.6%) only completed the eligibility screener questions and were coded as nonrespondents.

The number of residential care communities that fully completed the questionnaire was 4,578, with a weighted response rate (for differential probabilities of selection) of 50.7%. Response rates are calculated using standards set by AAPOR. AAPOR Response Rate #4 calculations include assumptions of eligibility among potential respondents that are not interviewed. AAPOR Response Rate #4 formula was used to calculate response rates for residential care communities (completed questionnaires / [completed eligible questionnaires] + [eligibility rate x cases of unknown eligibility]).

Response rates (weighted) by state ranged from 33.3% to 86.7% and are presented in Table II.

Differences in the number of residential care communities estimated in 2010, 2012, 2014, and 2016

Estimates of the number of residential care community providers varied between the 2010 NSRCF and the 2012 NSLTCP. NCHS assessed these differences and concluded that they were largely related to the eligibility differences between the 2010 NSRCF and the 2012 NSLTCP. While both surveys used the same eligibility criteria, overall screener-based eligibility dropped from 81.0% in the 2010 NSRCF to 67.1% in the 2012 NSLTCP (Table III). The screener-based eligibility rate was computed based on residential care communities that completed the screening questions (completed eligible / [completed eligible + completed ineligible]).

This decrease in the screener-based eligibility rate was most pronounced for providers with small bed sizes (4 to 10 beds): a decrease from 63.6% in 2010 to 45.8% estimated in 2012. Given that the 2012 NSLTCP (n = 11,690) had a much larger sample than NSRCF (n = 3,605), and that small bed size providers make up the largest proportion of all residential care communities, the lower eligibility rate in 2012 compared with 2010 among small-sized residential care communities had a large effect on the differences in the eligibility rate for the two surveys.

The discrepancy in eligibility between the 2010 NSRCF and the 2012 NSLTCP was likely due to differences in data collection modes used in 2010 (interviewer-administered computer-assisted telephone interviewing [CATI] screener followed by an in-person interview for eligible communities) and 2012 (primarily respondent self-administered screener and questionnaire completed by mail or web), and the resulting differences in how the respondents who self-administered the questionnaire interpreted the eligibility questions. In the 2012 NSLTCP, the most common eligibility criterion that providers, particularly small-bed size residential care communities, did not meet, was provision of onsite, 24-hour supervision. Some respondents using the self-administered modes (i.e., hard copy questionnaire or web questionnaire) likely did not fully comprehend this question and may have screened themselves out of the study erroneously. For more information, see "Long-Term Care Services in the United States: 2013 Overview" (available from: https://www.cdc.gov/nchs/data/nsltcp/long_term_care_services_2013.pdf) and the 2012 residential care community data file (available from: https://www.cdc.gov/nchs/data/nsltcp/NSLTCP_RCC_Readme_RDC_Release.pdf). Cognitive testing was conducted to assess these eligibility questions, and preliminary findings supported this hypothesis. To address these differences, NCHS revised the NSLTCP eligibility question asking whether the residential care community provided 24-hour supervision. The eligibility question asking whether the residential care community provided 24-hour supervision is question 4 on the 2012 questionnaire (https://www.cdc.gov/nchs/data/nsltcp/2012_NSLTCP_Residential_Care_Communities_Questionnaire.pdf) and question 6 on the 2014 questionnaire (https://www.cdc.gov/nchs/data/nsltcp/2014_NSLTCP_Residential_Care_Communities_Questionnaire.pdf).

Results from the 2014 wave indicated that the overall eligibility rate increased to 80.7%, similar to the 2010 NSRCF rate. However, the 2014 eligibility rates for all bed size categories except small providers (4–10 beds) were slightly lower compared with the 2010 NSRCF (Table III) and may be attributed to mode differences between 2010 and 2014. In 2016, the overall eligibility rate decreased to 73.8%. Decline in eligibility was observed in all bed size categories, but mostly among small and medium categories. The estimated national number of residential care communities ranged from 31,100 in 2010, 22,200 in 2012, and 30,200 in 2014, to 28,900 in 2016. The number of beds were estimated at 971,900 in 2010, 851,400 in 2012, 1,006,300 in 2014, and 996,100 in 2016 (Table IV). NCHS is currently assessing what caused the decline in eligibility between 2014 and 2016.

Population bases for computing rates

Populations used for computing rates of national supply and rates of use by state population were obtained from the U.S. Census Bureau's Population Estimates Program. The program produces estimates of the population for the United States, its states, counties, cities, and towns, and for the Commonwealth of Puerto Rico and its municipalities.

Table III. Eligibility rate among residential care communities, by bed size and survey year

Eligible community	National Study of Long-Term Care Providers			2010 National Survey of Residential Care Facilities
	2016	2014	2012	
Overall (percent)	73.8	80.7	67.1	81.0
Bed size				
Small (4–10 beds)	55.5	65.3	45.8	63.6
Medium (11–25 beds)	74.5	81.0	68.5	82.8
Large (26–100 beds)	86.9	91.7	82.4	94.5
Extra large (more than 100 beds)	91.2	93.8	85.5	95.9

SOURCES: NCHS, National Study of Long-Term Care Providers, 2016, 2014, 2012; and National Survey of Residential Care Facilities, 2010.

Table IV. Weighted number and percent distribution of residential care communities, by bed size and survey year

Characteristic	National Study of Long-Term Care Providers						2010 National Survey of Residential Care Facilities	
	2016		2014		2012			
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Number of residential care communities	28,900	100.0	30,200	100.0	22,200	100.0	31,100	100.0
Small (4–10 beds)	13,200	45.6	14,500	47.9	9,300	41.7	15,400	50.0
Medium (11–25 beds)	4,400	15.3	4,500	14.9	3,700	16.8	4,900	16.0
Large (26–100 beds)	9,100	31.5	9,100	30.1	7,300	32.7	8,700	28.0
Extra large (more than 100 beds)	2,200	7.7	2,100	7.0	1,900	8.7	2,100	7.0
Number of beds	996,100	100.0	1,006,300	100.0	851,400	100.0	971,900	100.0
Small (4–10 beds)	81,800	8.2	89,600	8.9	64,700	7.6	96,700	9.9
Medium (11–25 beds)	76,500	7.7	76,900	7.6	86,900	10.2	86,800	8.9
Large (26–100 beds)	518,300	52.0	522,600	51.9	434,800	51.1	493,800	50.8
Extra large (more than 100 beds)	319,500	32.1	317,200	31.5	265,000	31.1	294,600	30.3

SOURCES: NCHS, National Study of Long-Term Care Providers, 2016, 2014, 2012; and National Survey of Residential Care Facilities, 2010.

Demographic components of population change (births, deaths, and migration) were produced at the national, state, and county levels of geography. Additionally, housing unit estimates were produced for the country, states, and counties. Population estimates for each state and territory were not subject to sampling variation because the sources used in the demographic analysis were complete counts. For a more detailed description of the estimates methodology, see: https://www.census.gov/popest/.

For calculating rates of national supply and rates of use by state for adult day services centers, nursing homes, and residential care communities, estimates of the population aged 65 and over for July 1, 2016, were used (57). For calculating rates for use by state for home health agencies and hospices, estimates of the population aged 65 and over for July 1, 2015, were used to match the time frame of the administrative data for these sectors (57).

Comparing NSLTCP estimates with estimates from other data sources

Administrative data

Home health agencies—Selected estimates from the 2016 merged home health file (which was created by linking the CASPER home health file, IPBS home health file, and OBQI Case Mix Roll-up file by provider ID number) were compared with estimates from different reports and data sources. These benchmark data sources included the Medicare Payment Advisory Commission's "Report to the Congress: Medicare Payment Policy" chapter on home health services (58); *Home Health Chartbook 2017* (59); and 2015 CMS Program Statistics (60). Estimates also were compared with analyses on Medicare- or Medicaid-certified home health agencies that participated in NCHS' 2007 National Home and Hospice Care Survey (NHHCS) and with data used in the 2012 and 2014 NSLTCP. Select provider and user characteristics were comparable with other data sources except certification status, age distribution of patients, and patients diagnosed with select conditions. About 1% of home health agencies in the 2014 and 2016 merged home health file were Medicaid-only certified compared with 14% from NHHCS. About 18% of patients in the 2014 and 2016 merged home health file were under age 65 compared with 31% in NHHCS. These differences in the number and age distribution of patients could be related to the 2016 home health merged file's inclusion of fewer Medicaid-only certified home health agencies, and the fact that the 2016 merged file contained discharged home health patients rather than current home health patients (on whom the 2007 NHHCS collected data).

Hospices—Selected estimates from the 2016 merged hospice file (which was created by linking the CASPER hospice file and IPBS hospice file by provider ID number) were compared with estimates on hospice care services provided in the MedPAC (58) report. Estimates also were compared with analyses on Medicare- or Medicaid-certified hospice agencies that participated in the 2007 NHHCS and with data used in the 2012 and 2014 NSLTCP. Select provider and user characteristics were comparable with other data sources except age distribution of patients; about 6% of hospice patients in the merged file were under age 65 compared with 17% in NHHCS. Estimates for age distribution of patients varied due to differences in the patient population each data source covered. NHHCS collected information on patients (not just Medicare beneficiaries) discharged from hospices in 2007 that were Medicare- or Medicaid-certified, pending certification, or state licensed; the 2016 merged hospice file included Medicare beneficiaries who received hospice services from Medicare-certified hospices in 2015.

Nursing homes—Estimates from the merged 2016 CASPER nursing home and MARET files were compared with estimates on skilled nursing facilities from the MedPAC report (58), the Nursing Home Data Compendium (61), and the LTCFocus 2015 data (62). Provider-related estimates using the 2016 merged nursing home file were comparable with these other data sources.

Survey data

Estimates from the 2016 adult day services center and residential care community components of NSLTCP were compared with the 2010 MetLife National Study of Adult Day Services (53) and findings from the 2010 National Survey of Residential Care Facilities, respectively. Differences between 2010, 2012, 2014, and 2016 estimates for the number of residential care communities, beds, and residents were discussed previously in this appendix. The 2016 estimates for select provider and user characteristics for both adult day services centers and residential care communities were found to be comparable with these other data sources.

Differences between survey waves

The adult day and residential care components of NSLTCP have evolved over the three waves of the study, in terms of new questions, changes in question wording and response categories, as well as data editing. A comparison of the questions used in the three waves lists all the new items added to NSLTCP (https://www.cdc.gov/nchs/data/nsltcp/NSLTCP_2012-2016_crosswalk.pdf). In addition to new questions, the question wording and response categories for several questions were revised in the 2016 wave, as listed below. Some of these differences may have led to differences in data editing methods, as well as differences in estimates between the waves.

- Response categories for the revenue source question in the adult day services center questionnaires (Question 11 in 2012, Question 9 in 2014, and Question 10 in 2016) were revised after each wave. The 2012 and 2014 questions included six response categories: Medicaid, Medicare, other government, out-of-pocket payment by the participant family, private insurance, and other. In 2014, a brief definition was added to the Medicaid response category to specify that this category include Medicaid managed care programs. In 2016, the number of response categories increased to eight, with the "other government" category broken into three separate categories: Older Americans Act, Veterans Administration, and other federal, state, or local government. Also, the Medicaid category definition was revised to include revenue from a Medicaid state plan, Medicaid waiver, Medicaid managed care, or California regional center.
- Response categories for questions on services provided in the adult day services center questionnaires (Questions 19 in 2012, 12 in 2014, and 30 in version A and 27 in version B in 2016) and the residential care community questionnaires (Questions 16 in 2012, 15 in 2014, and 28 in version A and 29 in version B in 2016) were revised after each wave. In 2012, each service item had four response categories indicating that the service was "not provided," "provided only by residential care community/adult day services center employees," "provided only by others through arrangement," or "provided by both residential care community/adult day services center employees and others through arrangement." In 2014, respondents were asked to mark one or more of five categories indicating that the service was provided by "paid residential care community/adult day services center employees," "arranging for and paying outside vendors," "arranging for outside vendors paid by others," "referral," or "none of these apply/not provided." In 2016, the response options were revised to four categories indicating that a residential care community or adult day services center "provides the service by paid residential care community/adult day services center employees," "arranges for the service to be provided by outside services," "refers residents/participants or family to outside service providers," or "does not provide, arrange, or refer for this service."
- Formatting and wording for staffing questions in the adult day services center (Questions 23 in 2012, 14 in 2014, and 31–33 in version A and 28–30 in version B in 2016) and residential care community (Questions 26 in 2012, 17 in 2014, and 29–31 in version A and 30–32 in version B in 2016) questionnaires changed between the three waves. In 2012, respondents had the option of providing either the separate numbers of full-time and part-time staff or the number of full-time equivalent (FTE) staff. In 2014, the response categories only included number of full-time staff and number of part-time staff (not FTEs). In both 2012 and 2014, the staffing questions were formatted as a block to include both employees and contract staff. In 2016, respondents continued to provide the number of full-time and part-time staff (not FTEs), but the questions were formatted into two separate blocks for employees and contract staff. Also in 2016, respondents could skip the contract staff block if they answered "no" to a stem question about having any contract or agency staff.

The differences in formatting in 2016 led to some methodological changes to the staffing data edits in 2016 compared with previous waves. Details about differences in how the staffing data were edited in 2014 and 2016 are provided in the "Data Description and Usage (Readme)" documents for the adult day services center survey (https://www.cdc.gov/nchs/data/nsltcp/NSLTCP_2016_ADSC_Readme_RDC.pdf) and the residential care community survey (https://www.cdc.gov/nchs/data/nsltcp/NSLTCP_2016_RCC_Readme_RDC.pdf).

- The ADL question about walking or locomotion in the adult day services center (Questions 32g in 2012, 19f in 2014, and 16f in 2016) and residential care community (Questions 34g in 2012, 22f in 2014, and 17f in 2016) questionnaires changed. The 2012 and 2016 waves

included a brief description stating that assistance with locomotion or walking included using a cane, walker, wheelchair, or help from another person; this description was not included in the 2014 wave.

- The question on falls in the adult day services center (Questions 22 in 2014 and 25 in version A in 2016) and residential care community (Questions 25 in 2014 and 23 in version A in 2016) questionnaires changed. The 2014 wave asked about the number of falls (any) in the last 90 days and directed respondents to include onsite and offsite falls. The 2016 wave added instructions for respondents to include falls that occurred in the residential care community or adult day services center or offsite, whether or not the resident or participant was injured, and whether or not anyone saw the resident/participant fall or caught them. Respondents also were asked to only count one fall per resident or participant who fell, even if the resident or participant fell more than one time, and to include a resident or participant who had a fall in the last 90 days even if they were currently in a hospital or rehabilitation facility.

Data Analysis

Results describing providers and services users were analyzed at the individual agency or facility level. Findings from administrative data on nursing homes, home health agencies, and hospices were treated as sample based, and population standard errors were calculated to account for some random variability associated with the files. For the survey data for residential care communities and adult day services centers, point estimates and standard errors were calculated using appropriate design and weight variables to account for complex sampling, when applicable.

For survey data, statistical analysis weights were computed as the product of two components: the sampling weight (only for residential care communities in states where they were sampled) and adjustment for unknown eligibility due to nonresponse. Sampling weights were used only for residential care communities where a sample was drawn; sampling weights were not used for adult day services centers or for residential care communities in states where a census was taken. To adjust the adult day services center and residential care community weights for unknown eligibility, the SUDAAN procedure WTADJUST (63) was used; the procedure uses a constrained logistic model to predict known eligibility and to compute the unknown eligibility adjustment factors for the weights. Standard errors for survey data were computed using Taylor series linearization.

Variance estimates

Administrative data: Home health agencies, hospices, and nursing homes

The home health, hospice, and nursing home data files were created using CMS administrative data. The files represented 100% of the CMS population at the specific time that the data set was constructed, and they were not subject to sampling variability. Thus, the standard errors could be seen as being zero. However, there might be some random variability associated with the numbers. For example, if the administrative data were drawn at a different time, the estimates might be different. Also, the data are subject to potential data entry and other reporting errors. To account for these types of variability, the administrative data estimates were treated as a simple random sample, providing conservative standard errors for the random variation that might be associated with the files.

Survey data: Adult day services centers and residential care communities

Although a census of all adult day services centers was attempted, estimates were subject to variability due to the amount of nonresponse. Although the records that comprise the adult day services center file were not sampled, the variability associated with the nonresponse was treated as if it were from a stratified (by state) sample without replacement.

Data from residential care communities included a mix of sampled communities from states that had enough residential care communities to produce reliable state estimates and a census of residential care communities in states that did not have enough communities to produce reliable state estimates. Consequently, the residential care community estimates were subject to sampling variability and nonresponse variability. The variability for the residential care communities estimates was treated as if it were from a stratified (by state and size) sample without replacement.

Statistical significance tests

All statements in this report describing differences in estimates indicate that statistical testing was performed, and the differences between two point estimates were determined to be statistically significant at the 0.05 level. Differences among sectors were evaluated using *t* tests. All statistical significance tests were two sided using $p < 0.05$ as the significance level. Lack of comment regarding the difference between any two statistics does not necessarily mean that the difference was tested and found not to be statistically significant. Data analyses were performed using SAS version 9.3, the SAS-callable SUDAAN version statistical package (63), and STATA/SE 14.0 (64). Individual estimates may not sum to totals because estimates were rounded.

Data editing

Data files were examined for missing values and inconsistencies. To minimize cases with missing values and inconsistencies, residential care community and adult day services center survey instruments were programmed to show critical items with missing values in the CATI and web applications, to inform respondents that an answer

was required, and to include data validations such as asking respondents to check an answer if it was not the expected number. For instance, if responses to items that needed to total the number of residential care community residents or adult day services center participants did not match the total, respondents were reminded to check their responses.

For the adult day services center and residential care community survey data, selected aggregate resident- or participant-level variables were imputed (i.e., age, race, and sex). Although administrative data were also reviewed for missing values and inconsistencies, the files did not go through the same data cleaning and editing as the survey data.

For both survey and administrative data, staffing information was edited in the same manner. Outliers were defined as values two standard deviations above or below the size-specific mean for a given staff type, where size was defined as number of people served. When calculating the size-specific mean for a given staff type, cases were coded as missing if the number of FTE registered nurse employees was greater than 999, if the number of FTE licensed practical or vocational nurse employees was greater than 999, if the number of FTE personal care aide employees was greater than 999, if the number of FTE social work employees was greater than 99, or if the number of FTE activities director or staff employees was greater than 99. Additional edits were made to the staffing variables, some of which were different from earlier waves of NSLTCP. For the definitions and categories of number of people served for each sector, see Appendix II.

Cases with missing data were excluded from analyses on a variable-by-variable basis. For administrative data used to estimate characteristics of nursing home residents and home health patients, individual user-level information was rolled up to provider-level data. If a nursing home or home health agency had missing data on a given variable for 20% or more of its residents or patients, it was considered to not have enough data to provide an estimate representative of that nursing home or home health agency, and was coded as having missing data on the variable. Variables used in this report had a percentage (weighted if survey data, unweighted if administrative data) of cases with missing data ranging between 0.2% and 15.8%. The range of cases with missing data for each sector is as follows:

- Adult day services center: 0.2% (Medicaid participation status) to 15.8% (number of participants diagnosed with osteoporosis).
- Home health agency: 8.9% to 9.1% were missing data on all patient measures (e.g., number of patients aged 65 and over) due to agencies with no patient information available in the IPBS data and the OBQI home health data, respectively. In addition, 10.4% of home health agencies had no information on the number of patients who had utilized a hospital emergency department, including 9.1% of agencies with no patient information available in the OBQI data and 1.3% of agencies with missing data on the variable for 20% or more of its patients.
- Hospice: 7.1% were missing data for all patient measures (e.g., number of patients diagnosed with depression) due to agencies with no patient information available in the IPBS hospice data.
- Nursing home: 0.8% were missing data for all resident demographic information due to nursing homes with no resident information available in the MARET data. In addition, 10.2% of nursing homes had no information on the number of residents who had osteoporosis and arthritis, including 0.8% of nursing homes with no resident information available in the MARET data and 9.4% of nursing homes with missing data on the variable for 20% or more of its residents.
- Residential care community: 1.9% (e.g., Medicaid status) to 15.6% (e.g., number of residents diagnosed with asthma).

Limitations

Differences in question wording among data sources

While every effort was made to match question wording in the NSLTCP surveys to the administrative data available through CMS, some differences remained and may affect comparisons between these two data sources (e.g., capacity and reference periods used for adverse events). When possible (i.e., when available and appropriate), findings were presented on a given topic for all five sectors. However, due to two types of data-related differences, for some topics in the report, information was provided for some but not all five sectors.

The first type of data-related difference was due to the settings served by the five sectors. For example, home health agencies were not residential and, therefore, it was not relevant to discuss the number of beds in this sector, whereas it was relevant for nursing homes and residential care communities. As a result, information on capacity as measured by the number of beds was presented for nursing homes and residential care communities only.

The second difference was attributable to differences among the administrative data sources used for nursing homes, home health agencies, and hospices. For example, the CASPER data did not include information on whether home health agencies offered mental health or counseling services, but they did include this information for nursing homes and hospices. The NSLTCP residential care community and adult day services center surveys included additional content that was not presented in this report because no comparable data existed in the CMS administrative data (e.g., electronic health records and health information exchange). NCHS produced *Data Briefs* and weighted estimates tables that presented additional results on adult day services centers and

residential care communities, using survey data not included in this overview report. These latest reports are available from: http://www.cdc.gov/nchs/nsltcp/nsltcp_products.htm.

Differences in time frames among data sources

Different data sources had different time frames or reference periods. For instance, user-level data used for home health agencies (i.e., OBQI and IPBS home health data) and hospices (i.e., IPBS hospice data) were from patients who received home health or hospice care services at any time in calendar year 2015. In contrast, survey data on residential care community residents and adult day services center participants and CMS data on nursing home residents were from current services users in 2016. In this report, "current" participants or residents in 2016 refers to those participants enrolled in the adult day services center, or residents living in the nursing home or residential care community, on the day of data collection in 2016, rather than the total number of participants ever enrolled in the center or residents ever living in the nursing home or residential care community at any time throughout the 2016 calendar year. In other words, the estimated number of adult day services center participants represents current participants in 2016. The estimated number of home health patients represents patients who ended care in 2015 (i.e., discharges). The estimated number of hospice patients represents patients who received care at any time in 2015. The estimated number of nursing home residents represents current residents in 2016. The estimated number of residential care community residents represents current residents in 2016. Given these differences in denominator, comparisons across all five sectors were not feasible for some variables.

Age of administrative data

The administrative data for home health agencies, hospices, and nursing homes were collected to support the survey and certification function of CMS in these different sectors; both the content and the frequency with which the certification surveys were conducted differ across these three provider sectors. Consistent with the required frequency for the recertification survey, CASPER data on virtually all nursing homes were under 18 months old: 82.7% of CASPER home health agency data were no more than 3 years old, and 95.5% of CASPER hospice data were no more than 8 years old. When these relatively older home health agency and hospice data were linked to user-level data of calendar year 2015, 9.0% of home health agencies and 7.1% of hospices in the CASPER files did not match with provider ID numbers in OBQI and IPBS hospice data, respectively. It is possible that home health agencies and hospices with missing patient-level information might no longer be operational or might have begun operating in 2016, so their patient information was not captured in the user-level data from 2015. Of 888 home health agencies that did not match with provider numbers in OBQI data, about 62% had completed the agency's initial certification survey in 2014.

Appendix II. Crosswalk of Definitions by Sector

Supply of long-term care services providers, by sector

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Number of providers[1]	Number of paid, regulated long-term care services providers	Number of adult day services centers based on 2016 National Survey of Long-Term Care Providers (NSLTCP) survey of adult day services centers	Number of assisted living and similar residential care communities based on 2016 NSLTCP survey of residential care communities	Number of home health agencies certified to provide services under Medicare, Medicaid, or both in the third quarter of 2016	Number of hospices certified to provide services under Medicare, Medicaid, or both in the third quarter of 2016	Number of nursing homes certified to provide services under Medicare, Medicaid, or both in the third quarter of 2016
Region	Grouping of conterminous states into geographic areas corresponding to groups used by the United States Census Bureau. A map showing the states included in each of the four U.S. Census regions is available from: https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf.	Four census regions 1= Northeast 2= Midwest 3= South 4= West	Four census regions 1= Northeast 2= Midwest 3= South 4= West	Derived from: [STATE_CD] 1= Northeast 2= Midwest 3= South 4= West	Derived from: [STATE_CD] 1= Northeast 2= Midwest 3= South 4= West	Derived from: [STATE_CD] 1= Northeast 2= Midwest 3= South 4= West
Metropolitan statistical area (MSA) and micropolitan statistical area[2]	Geographic entities delineated by the Office of Management and Budget (OMB) for use by federal statistical agencies in collecting, tabulating, and publishing federal statistics. A metropolitan area contains a core urban area of 50,000 or more population, and a micropolitan area contains an urban core of at least 10,000 (but less than 50,000) population. Each area consists of one or more counties and includes the counties containing the core urban area, as well as any adjacent counties that have a high degree of social and economic integration (as measured by commuting to work) with the urban core.	Metropolitan statistical area status 1= Metropolitan 2= Micropolitan 3= Neither	Metropolitan statistical area status 1= Metropolitan 2= Micropolitan 3= Neither	Derived from: [ZIP_CD] 1= Metropolitan 2= Micropolitan 3= Neither	Derived from: [ZIP_CD] 1= Metropolitan 2= Micropolitan 3= Neither	Derived from: [ZIP_CD] 1= Metropolitan 2= Micropolitan 3= Neither

See footnotes at end of section.

Supply of long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Capacity[3]	Used to quantify the supply of long-term care services provided in the community (i.e., adult day services center or residential care community) or in an institutional setting (i.e., nursing home).	Q4. What is the maximum number of participants allowed at this adult day services center at this location? This may be called the allowable daily capacity and is usually determined by law or by fire code, but may also be a program decision.	Q2. At this residential care community, what is the number of licensed, registered, or certified residential care beds? Include both occupied and unoccupied beds.	…	…	Derived from: [CRTFD_BED_CNT] Number of beds in Medicare- or Medicaid-certified areas within a facility.

… Category not applicable.
[1]Study-specific eligibility criteria were used to define residential care communities. See the Appendix I Technical Notes for information on eligibility criteria.
[2]All provider types used the 2013 OMB standards for delineating metropolitan and micropolitan statistical areas.
[3]For NH, the number of certified beds was used because current residents in the Certification and Survey Provider Enhanced Reports (CASPER) (CNSUS_RSDNT_CNT) are defined as those in certified beds regardless of payer source.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in National Study of Long-Term Care Providers (NSLTCP) questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is the Centers for Medicare & Medicaid's (CMS') CASPER.

Organizational characteristics of long-term care services providers, by sector

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Ownership	Classified into three categories: for profit, nonprofit, and government and other. Publicly traded company or limited liability company (LLC) was categorized as for profit.	1= For profit 2= Nonprofit 3= Government and other Derived from: [OWNERSHP] Q9. What is the type of ownership of this adult day services center? 1= Private, nonprofit 2= Private, for profit 3= Publicly traded company or limited liability company (LLC) 4= Government—federal, state, county, local If OWNERSHP= 3, code OWN as 2. Else if OWNERSHP= 1, code OWN= 1; Else OWN= 3.	1= For profit 2= Nonprofit 3= Government and other Derived from: [OWNERSHP] Q8. What is the type of ownership of this residential care community? 1= Private, nonprofit 2= Private, for profit 3= Publicly traded company or limited liability company (LLC) 4= Government—federal, state, county, local If OWNERSHP= 3, code OWN as 2. Else if OWNERSHP= 1, code OWN= 1; Else OWN= 3.	1= For profit 2= Nonprofit 3= Government and other Derived from: [GNRL_CNTL_TYPE_CD] 01= Voluntary NP, religious affiliation 02= Voluntary NP, private 03= Voluntary NP, other 04= Proprietary 05= Government, state/county 06= Government, Combination Government and Voluntary 07= Government, local If GNRL_CNTL_TYPE_CD= ’01’, ‘02,’ ‘03’, code HHA as OWN= 2; Else if GNRL_CNTL_TYPE_CD= ’04’, code HHA as OWN= 1; Else OWN= 3;	1= For profit 2= Nonprofit 3= Government and other Derived from: [GNRL_CNTL_TYPE_CD] 01= Nonprofit, church 02= Nonprofit, private 03= Nonprofit, other 04= Proprietary, individual 05= Proprietary, partnership 06= Proprietary, corporation 07= Proprietary, other 08= Government, state 09= Government, county 10= Government, city 11= Government, city/county 12= Combination Government and NP 13= Other If GNRL_CNTL_TYPE_CD= ’01’, ‘02,’ ‘03’, code HOS as OWN= 2; Else if GNRL_CNTL_TYPE_CD= ’04’,’05’, ‘06’, ‘07’, code HOS as OWN= 1; Else OWN= 3;	1= For profit 2= Nonprofit 3= Government and other Derived from: [GNRL_CNTL_TYPE_CD] 01= For profit, individual 02= For profit, partnership 03= For profit, corporation 04= Nonprofit, church related 05= Nonprofit, corporation 06= Nonprofit, other 07= Government, state 08= Government, county 09= Government, city 10= Government, city/county 11= Government, hospital district 12= Government, federal 13= Limited Liability Company If GNRL_CNTL_TYPE_CD= ’01’, ‘02,’ ‘03’,’13’, OWN= 1; Else if GNRL_CNTL_TYPE_CD= ’04’,‘05’, ‘06’, OWN= 2; Else OWN= 3;

See footnotes at end of section.

Organizational characteristics of long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Number of people served	Categorizes providers into three categories based on the number of current participants or residents (adult day services centers, nursing homes, and residential care communities), the number of patients receiving care at any time in calendar year 2015 (hospices), or the number of patients who ended an episode of care at any time in calendar year 2015 (home health agencies).	1= 1–25 2= 26–100 3= 101 or more Derived from: [AVGPART] Q2. Based on a typical week, what is the approximate average daily attendance at this adult day services center at this location?	1= 1–25 2= 26–100 3= 101 or more Derived from: [TOTRES] Q5. What is the total number of residents currently living at this residential care community? Please include residents for whom a bed is being held while in the hospital. If you have respite care residents, please include them.	1= 1–100 2= 101–300 3= 301 or more Derived from: [TOTPAT from Outcome-Based Quality Improvement (OBQI) Case Mix Roll-up data] Number of home health patients whose episode of care ended at any time in calendar year 2015 (i.e., discharges), regardless of payment source.	1= 1–100 2= 101–300 3= 301 or more Derived from: [BENE_CNT in Institutional Provider and Beneficiary Summary (IPBS) hospice data] Number of hospice care patients for whom Medicare-certified hospice care agencies submitted a Medicare claim at any time in calendar year 2015.	1= 1–25 2= 26–100 3= 101 or more Derived from: [CNSUS_RSDNT_CNT] Number of current residents reported in CASPER, defined as those in certified beds regardless of payer source.
Medicare certification	Refers to Medicare certification status of home health agencies, hospices, and nursing homes	...	...	1= Certified 2= Not certified Derived from: [PGM_PRTCPTN_CD] Indicates if the provider participates in Medicare, Medicaid, or both programs. 1= MEDICARE ONLY 2= MEDICAID ONLY 3= MEDICARE AND MEDICAID	1= Certified 2= Not certified All hospices included in CASPER are assumed to be Medicare-certified.	1= Certified 2= Not certified Derived from: [PGM_PRTCPTN_CD] Indicates if the provider participates in Medicare, Medicaid, or both programs. 1= MEDICARE ONLY 2= MEDICAID ONLY 3= MEDICARE AND MEDICAID

See footnotes at end of section.

Organizational characteristics of long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Medicaid certification	Refers to Medicaid certification or participation status	1= Certified 2= Not certified Derived from: [MEDICAID] Q1_b. Is this adult day services center authorized or otherwise set up to participate in Medicaid (Medicaid state plan, Medicaid waiver, or Medicaid managed care) or part of a Program of All-Inclusive Care for the Elderly (PACE)?	1= Certified 2= Not certified Derived from: [MEDICAID] Q9. Is this residential care community authorized or otherwise set up to participate in Medicaid?	1= Certified 2= Not certified Derived from: [PGM_PRTCPTN_CD] Indicates if the provider participates in Medicare, Medicaid, or both programs. 1= MEDICARE ONLY 2= MEDICAID ONLY 3= MEDICARE AND MEDICAID	- - -	1= Certified 2= Not certified Derived from: [PGM_PRTCPTN_CD] Indicates if the provider participates in Medicare, Medicaid, or both programs. 1= MEDICARE ONLY 2= MEDICAID ONLY 3= MEDICARE AND MEDICAID
Chain affiliation	Refers to chain affiliation status of adult day services centers, residential care communities, and nursing homes	Q5. Is this center owned by a person, group, or organization that owns or manages two or more adult day services centers? This may include a corporate chain.	Q13. Is this residential care community owned by a person, group, or organization that owns or manages two or more residential care communities? This may include a corporate chain.	- - -	- - -	Derived from: [MLT_OWND_FAC_ORG_SW] Owned or leased by multifacility organization Check “yes” if the facility is owned or leased by a multifacility organization, otherwise check “no.” A Multifacility organization is an organization that owns two or more long-term care facilities. The owner may be an individual or a corporation. Leasing of facilities by corporate chains is included in this definition.

... Category not applicable.
- - - Data not available.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in NSL TCP questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is CMS' CASPER.

Staffing: Nursing, social work, and activities employees, by sector

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Registered nurse[1]	Number of full-time equivalent (FTE) registered nurse (RN) employees (based on a 35-hour work week)	Derived RNFTE1 from: [RNFT1, RNPT1] Q31a/Q28a. RNs: Number of full-time employees; Number of part-time employees.	Derived RNFTE1 from: [RNFT1, RNPT1] Q29a/Q30a. RNs: Number of full-time employees; Number of part-time employees.	Derived RNFTE1 from: [RN_CNT] Number of FTE registered professional nurses employed by a provider.	Derived RNFTE1 from: [RN_CNT] Number of FTE registered professional nurses employed by a provider.	Derived RNFTE1 from: [RN_FLTM_CNT, RN_PRTM_CNT] Number of FTE registered nurses employed by a facility on a full-time basis; Number of FTE registered nurses employed by a facility on a part-time basis.
Licensed practical nurse (LPN) or licensed vocational nurse (LVN)[1]	Number of FTE licensed practical nurse or licensed vocational nurse (LPN/LVN) employees (based on a 35-hour work week)	Derived LPNFTE1 from: [LPNFT1, LPNPT1] Q31b/Q28b. LPNs/LVNs: Number of full-time employees; Number of part-time employees.	Derived LPNFTE1 from: [LPNFT1, LPNPT1] Q29b/Q30b. LPNs/LVNs: Number of full-time employees; Number of part-time employees.	Derived LPNFTE1 from: [LPN_LVN_CNT] Number of FTE licensed practical or vocational nurses employed by a provider.	Derived LPNFTE1 from: [LPN_LVN_CNT] Number of FTE licensed practical or vocational nurses employed by a provider.	Derived LPNFTE1 from: [LPN_LVN_FLTM_CNT, LPN_LVN_PRTM_CNT] Number of FTE licensed practical or vocational nurses employed by a facility on a full-time basis; Number of FTE licensed practical or vocational nurses employed by a facility on a part-time basis.

See footnotes at end of section.

Staffing: Nursing, social work, and activities employees, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Aide[1]	Number of FTE aide employees (based on a 35-hour work week) Aides refer to paid staff providing direct care and assistance to residents, participants, or patients with a broad range of activities. Different terms are used to describe aides in different data sources. For adult day services centers and residential care communities, aides include certified nursing assistants, home health aides, home care aides, personal care aides, personal care assistants, and medication technicians or medication aides who are employees of a community or center. For home health agencies and hospices, aides refer to home health aides employed by the agency. For nursing homes, aides refer to certified nurse aides, and medication aides or technicians who are facility employees.	Derived AIDEFTE1 from: [AIDEFT1, AIDEPT1] Q31c/Q28c Certified nursing assistants, nursing assistants, home health aides, home care aides, personal care aides, personal care assistants, and medication technicians or medication aides: Number of full-time employees; Number of part-time employees.	Derived AIDEFTE1 from: [AIDEFT1, AIDEPT1] Q29c/Q30c Certified nursing assistants, nursing assistants, home health aides, home care aides, personal care aides, personal care assistants, and medication technicians or medication aides: Number of full-time employees; Number of part-time employees.	Derived AIDEFTE1 from: [HH_AIDE_CNT] Number of FTE home health aides employed by a provider.	Derived AIDEFTE1 from: [HH_AIDE_EMPLEE_CNT] Number of FTE home health aides employed by a provider.	Derived AIDFTE1 from: [NRS_AIDE_FLTM_CNT, NRS_AIDE_PRTM_CNT, MDCTN_AIDE_FLTM_CNT, MDCTN_AIDE_PRTM_CNT] Number of FTE certified nurse aides employed by a facility on a full-time basis; Number of FTE certified nurse aides employed by a facility on a part-time basis; Number of FTE medication aides or technicians employed by a facility on a full-time basis; Number of FTE medication aides or technicians employed by a facility on a part-time basis.

See footnotes at end of section.

Staffing: Nursing, social work, and activities employees, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Social worker[1]	Number of FTE social worker employees (based on a 35-hour work week)	Derived SOCWFTE1 from: [SOCWFT1, SOCWPT1] Q31d/Q28d Social workers—licensed social workers or persons with a bachelor's or master's degree in social work: Number of full-time employees; Number of part-time employees.	Derived SOCWFTE1 from: [SOCWFT1, SOCWPT1] Q29d/Q30d. Social workers—licensed social workers or persons with a bachelor's or master's degree in social work: Number of full-time employees; Number of part-time employees.	Derived SOCWFTE1 from: [SCL_WORKR_CNT] Number of FTE social workers employed by a provider.	Derived SOCWFTE1 from: [MDCL_SCL_WORKR_ CNT] Number of FTE medical social workers employed by a provider.	Derived SOCWFTE1 from: [SCL_WORKR_FLTM_CNT, SCL_WORKR_PRTM_CNT] Number of FTE social workers employed by a facility on a full-time basis; Number of FTE social workers employed by a facility on a part-time basis.
Activities directors or activities staff[1]	Number of FTE activities directors or activities staff employees (based on a 35-hour work week)	Derived ACTFTE1 from: [ACTFT1, ACTPT1] Q31e/Q28e. Activities directors or activities staff: Number of full-time employees; Number of part-time employees.	Derived ACTFTE1 from: [ACTFT1, ACTPT1] Q29e/Q30e. Activities directors or activities staff: Number of full-time employees; Number of part-time employees.	- - -	- - -	Derived ACTFTE1 from: [ACTVTY_PROFNL_FLTM_ CNT, ACTVTY_PROFNL_ PRTM_CNT, ACTVTY_ STF_OTHR_FLTM_CNT, ACTVTY_STF_OTHR_PRTM_ CNT) Number of FTE activity professionals employed full time by a facility; Number of FTE activity professionals employed part time by a facility; Number of FTE other activities staff providing therapeutic services employed full time by a facility; Number of FTE other activities staff providing therapeutic services employed part time by a facility.

See footnotes at end of section.

Staffing: Nursing, social work, and activities employees, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Hours per resident or participant per day (HPPD)[2]	Refers to the number of hours providing care for one resident or participant per day for a given staff type. For adult day services centers, HPPD for a given staff type was computed by multiplying the number of FTEs for the staff type by 35 hours, and dividing the total number of hours for the staff type by average daily attendance of participants and by 5 days. For nursing homes and residential care communities, the number of FTEs for a given staff was converted into hours by multiplying by 35 hours for the staff type, and dividing the total number of hours for the staff type by the number of current residents in the facility, and by 7 days, to calculate the HPPD.	Derived from: [RNFTE1, LPNFTE1, AIDEFTE1, SOCWFTE1, ACTFTE1/ AVGPART] RNHPPD1= (RNFTE1*35)/ AVGPART/5 days; LPNHPPD1= (LPNFTE1*35)/ AVGPART/5 days; AIDEHPPD1= (AIDEFTE1 *35)/AVGPART/5 days; SOCWHPPD1= (SOCWFTE1*35)/ AVGPART/5 days; ACTHPPD1= (ACTFTE1*35)/ AVGPART/5 days	Derived from: [RNFTE1, LPNFTE1, AIDEFTE1, SOCWFTE1, ACTFTE1/ TOTRES] RNHPPD1= (RNFTE1*35)/ TOTRES/7 days; LPNHPPD1= (LPNFTE1*35)/ TOTRES/7 days; AIDEHPPD1= (AIDEFTE1*35)/ TOTRES/7 days; SOCWHPPD1= (SOCWFTE1*35)/ TOTRES/7 days; ACTHPPD1= (ACTFTE1*35)/ TOTRES/7 days	- - -	- - -	Derived from: [RNFTE, LPNFTE, AIDEFTE, SOCWFTE/ CNSUS_ RSDNT_ CNT] RNHPPD1= (RNFTE1*35)/ CNSUS_ RSDNT_CNT/7 days; LPNHPPD1= (LPNFTE1*35)/ CNSUS_ RSDNT_CNT/7 days; AIDEHPPD1= AIDEFTE1*35)/ CNSUS_ RSDNT_CNT/7 days; SOCWHPPD1= (SOCWFTE1 *35)/ CNSUS_ RSDNT_CNT/7 days; ACTHPPD1= (ACTFTE1*35)/ CNSUS_ RSDNT_CNT/7 days

- - - Data not available.

[1]For ADSC and RCC, the number of full-time and part-time employees for a given staff type were converted into FTEs with an assumption that full time is 1.0 FTE and part time is 0.5 FTE. For HHA and HOS, the number of FTE employees by staff type is provided in data. For NH, data report the number of hours for a given staff type during the 2 weeks prior to their annual survey. CMS converts the number of hours into FTEs (based on a 35-hour work week). For all provider types, outliers are defined as cases with FTEs that are two standard deviations above or below the mean for a given size category, and recoded as the size-specific mean of FTE for the given staff type. See the Appendix I Technical Notes for more information on editing of the staffing data.

[2]Residential settings (i.e., nursing homes and residential care communities) and adult day services centers operate and staff differently to serve the needs of their residents or participants; these differences between provider types are reflected in using average daily attendance and 5 days (as opposed to number of current residents and 7 days) when computing HPPD for staff working at adult day services centers.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in NSLTCP questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is CMS' CASPER.

Services provided by long-term care services providers, by sector

Characteristic	Definition	Survey data: Adult day services center (ADSC)	Survey data: Residential care community (RCC)	Administrative data: Home health agency (HHA)	Administrative data: Hospice (HOS)	Administrative data: Nursing home (NH)
Social work services[1]	In survey data, refers to services provided by licensed social workers or persons with a bachelor's or master's degree in social work, and may include an array of services such as psychosocial assessment, individual or group counseling, and referral services. In administrative data, refers to qualified social workers services in nursing homes, and medical social services in home health agencies and hospices.	1= Provided 2= Not provided (includes referral only) Derived from: [SERVSOCW1, SERVSOCW2, SERVSOCW3, SERVSOCW4] Q30_b/Q27_b. Social work services—provided by licensed social workers or persons with a bachelor's or master's degree in social work, and may include an array of services such as psychosocial assessment, individual or group counseling, and referral services 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided (includes referral only) Derived from: [SERVSOCW1, SERVSOCW2, SERVSOCW3, SERVSOCW4] Q28_b/Q29_b. Social work services—provided by licensed social workers or persons with a bachelor's or master's degree in social work, and may include an array of services such as psychosocial assessment, individual or group counseling, and referral services 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided Derived from: [MDCL_SCL_SRVC_CD] Indicates how medical social services are provided. 0= NOT PROVIDED 1= PROVIDED BY STAFF 2= PROVIDED UNDER ARRANGEMENT 3= COMBINATION If MCDL_SCL_SRVC_CD= 0, SERVSOCW= 2; else if MDCL_SCL_SRVC_CD>0, SERVSOCW= 1;	1= Provided 2= Not provided Derived from: [MDCL_SCL_SRVC_CD] Indicates how medical social services are provided. 0= NOT PROVIDED 1= PROVIDED BY STAFF 2= PROVIDED UNDER ARRANGEMENT 3= COMBINATION If MCDL_SCL_SRVC_CD= 0, SERVSOCW= 2; else if MDCL_SCL_SRVC_CD>0, SERVSOCW= 1;	1= Provided 2= Not provided Derived from: [SCL_WORK_SRVC_ONST_RSDNT_SW, SCL_WORK_SRVC_ONST_NRSDNT_SW, SCL_WORK_SRVC_OFSITE_RSDNT_SW] Qualified social workers services 1) Services provided onsite to residents, either by employees or contractors; 2) Services provided onsite to nonresidents; 3) Services provided to residents offsite/or not routinely provided onsite If "No" to 1), 2), and 3), SERVSOCW= 2; Else SERVSOCW= 1;

See footnotes at end of section.

Services provided by long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Mental health or counseling services[1]	Mental health services in survey data refer to services that target a person's mental, emotional, psychological, or psychiatric well-being, and may include diagnosing, describing, evaluating, and treating mental conditions. For hospices, counseling services are provided to the patient and family to assist them in "minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process" (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf).	1= Provided 2= Not provided (includes referral only) Derived from: [SERVMH1, SERVMH2, SERVMH3, SERVMH4] Q30_c/Q27_c. Mental health services—target participants' mental, emotional, psychological, or psychiatric well-being and may include diagnosing, describing, evaluating, and treating mental conditions 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided (includes referral only) Derived from: [SERVMH1, SERVMH2, SERVMH3, SERVMH4] Q28_c/Q29_c. Mental health services—target residents' mental, emotional, psychological, or psychiatric well-being and may include diagnosing, describing, evaluating, and treating mental conditions 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	- - -	1= Provided 2= Not provided Derived from: [CNSLNG_SRVC_CD] Counseling services 0= Not provided 1= Provided by agency staff 2= Provided under arrangement 3= Combination If CNSLNG_SRVC_CD= 0, SERVMH= 2; else if CNSLNG_SRVC_CD>0, SERVMH= 1;	1= Provided 2= Not provided Derived from: [MENTL_HLTH_ ONST_RSDNT_SW, MENTL_ HLTH_ONST_NRSDNT_SW, MENTL_HLTH_OFSITE_RSDNT_ SW] Mental health services 1) Services provided onsite to residents, either by employees or contractors; 2) Services provided onsite to nonresidents; 3) Services provided to residents offsite/or not routinely provided onsite If "No" to 1), 2), and 3), SERVMH= 2; Else SERVMH= 1;

See footnotes at end of section.

Services provided by long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Therapeutic services[1]	Refers to providing any of the three therapeutic services: physical therapy, occupational therapy, or speech therapy or pathology.	1= Provided 2= Not provided (includes referral only) Derived from: [SERVTX1, SERVTX2, SERVTX3, SERVTX4] Q30_d/Q27_d. Any therapeutic services—physical, occupational, or speech 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided (includes referral only) Derived from: [SERVTX1, SERVTX2, SERVTX3, SERVTX4] Q28_d/Q29_d. Any therapeutic services—physical, occupational, or speech 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided Derived from: [PT_SRVC_CD, OT_ SRVC_CD, SPCH_ THRPY_ SRVC_CD] Physical therapy, occupational therapy, or speech therapy 0= Not provided 1= Provided by agency staff 2= Provided under arrangement 3= Combination If PT_SRVC_CD= 0 AND OT_SRVC_CD= 0 AND SPCH_THRPY_SRVC_CD= 0, SERVTX= 2; Else SERVTX= 1;	1= Provided 2= Not provided Derived from: [PT_SRVC_CD, OT_SRVC_CD, SPCH_ PTHLGY_SRVC_CD] Physical therapy, occupational therapy, or speech pathology 0= Not provided 1= Provided by agency staff 2= Provided under arrangement 3= Combination If PT_SRVC_CD= 0 AND OT_SRVC_CD= 0 AND SPCH_PTHLGY_SRVC_CD= 0, SERVTX= 2; Else SERVTX= 1;	1= Provided 2= Not provided Derived from: [PT_ONST_ RSDNT_SW, PT_ONST_ NRSDNT_SW, PT_OFSITE_ RSDNT_SW, OT_SRVC_ ONST_RSDNT_SW, OT_ SRVC_ONST_NRSDNT_SW, OT_SRVC_OFSITE_RSDNT_ SW, SPCH_PTHLGY_ ONST_RSDNT_SW, SPCH_PTHLGY_ONST_ NRSDNT_SW, SPCH_ PTHLGY_OFSITE_RSDNT_ SW] Physical therapist services, occupational therapist services, or speech or language pathologists 1) Services provided onsite to residents, either by employees or contractors; 2) Services provided onsite to non-residents; 3) Services provided to residents offsite/ or not routinely provided onsite If “No” to all 9 variables, SERVTX= 2; Else SERVTX= 1;

See footnotes at end of section.

Services provided by long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Pharmacy services[1]	Includes filling of or delivery of prescriptions.	1= Provided 2= Not provided (includes referral only) Derived from: [SERVRX1, SERVRX2, SERVRX3, SERVRX4] Q30_e/Q27_e. Pharmacy services—including filling of or delivery of prescriptions 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided (includes referral only) Derived from: [SERVRX1, SERVRX2, SERVRX3, SERVRX4] Q28_e/Q29_e. Pharmacy services—including filling of or delivery of prescriptions 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided Derived from: [PHRMCY_ SRVC_CD] Pharmaceutical services 0= Not provided 1= Provided by agency staff 2= Provided under arrangement 3= Combination If PHRMCY_SRVC_CD= 0, SERVRX_RC= 2; else if PHRMCY_SRVC_CD>0, SERVRX= 1;	- - -	1= Provided 2= Not provided Derived from: [PHRMCY_ SRVC_ONST_RSDNT_SW, PHRMCY_SRVC_ONST_ NRSDNT_SW, PHRMCY_ SRVC_ OFSITE_RSDNT_SW] Pharmacist services 1) Services provided onsite to residents, either by employees or contractors; 2) Services provided onsite to non-residents; 3) Services provided to residents offsite/or not routinely provided onsite If “No” to 1), 2), and 3), SERVRX= 2; Else SERVRX= 1;

See footnotes at end of section.

Services provided by long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Skilled nursing services[1]	In survey data, refers to services that must be performed by an RN or LPN and are medical in nature. For home health agencies, the definition for nursing services is not provided in CMS' "State Operations Manual." For hospices, nursing services are "routinely available on a 24-hour basis, 7 days a week," and hospices must "provide nursing care and services by or under the supervision of a registered nurse" (available from: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_m_hospice.pdf). Nursing services in nursing homes refer to "coordination, implementation, monitoring and management of resident care plans. Includes provision of personal care services, monitoring resident responsiveness to environment, range-of-motion exercises, application of sterile dressings, skin care, naso-gastric tubes, intravenous fluids, catheterization, administration of medications, etc." (CMS form 671).	1= Provided 2= Not provided (includes referral only) Derived from: [SERVNURS1, SERVNURS2, SERVNURS3, SERVNURS4] Q30_g/Q27_g. Skilled nursing services—must be performed by an RN or LPN and are medical in nature 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided (includes referral only) Derived from: [SERVNURS1, SERVNURS2, SERVNURS3, SERVNURS4] Q28_g/Q29_g. Skilled nursing services—must be performed by an RN or LPN and are medical in nature 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided Derived from: [NRSNG_SRVC_CD] Nursing care 0= Not provided 1= Provided by agency staff 2= Provided under arrangement 3= Combination If NURSNG_SRVC_CD= 0, SERVNURS= 2; Else if NURSNG_SRVC_CD>0, SERVNURS= 1;	1= Provided 2= Not provided Derived from: [NRSNG_SRVC_CD] Nursing services 0= Not provided 1= Provided by agency staff 2= Provided under arrangement 3= Combination If NURSNG_SRVC_CD= 0, SERVNURS= 2; Else if NURSNG_SRVC_CD>0, SERVNURS= 1;	1= Provided 2= Not provided Derived from: [NRSNG_SRVC_ ONST_RSDNT_SW, NRSNG_ SRVC_ONST_NRSDNT_SW, NRSNG_SRVC_OFSITE_RSDNT_ SW] Nursing services 1) Services provided onsite to residents, either by employees or contractors; 2) Services provided onsite to non-residents; 3) Services provided to residents offsite/or not routinely provided onsite If "No" to 1), 2), and 3), SERVNURS= 2; Else SERVNURS= 1;

See footnotes at end of section.

Services provided by long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency HHA)	Hospice (HOS)	Nursing home (NH)
Hospice services[1]	For home health agencies, the agency was coded as providing hospice services if the agency also participates in the Medicare program as a hospice. If nursing homes have at least one bed identified and dedicated for residents needing hospice services or have one or more residents receiving hospice care benefits, they were coded as providing hospice services.	1= Provided 2= Not provided (includes referral only) Derived from: [SERVHOS1, SERVHOS2, SERVHOS3, SERVHOS4] Q30_a/Q27_a. Hospice services 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided (includes referral only) Derived from: [SERVHOS1, SERVHOS2, SERVHOS3, SERVHOS4] Q28_a/Q29_a. Hospice services 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided Derived from: [MDCR_ HOSPC_SW] Indicates if the agency also participates in the Medicare program as a hospice provider. If MDCR_HOSPC_SW= 'Y', SERVHOS= 1; Else if MDCR_HOSPC_SW= 'N', SERVHOS= 2;	…	1= Provided 2= Not provided Derived from: [HOSPC_BED_CNT, CNSUS_HOSPC_CARE_CNT] 1) Number of beds in a unit identified and dedicated by a facility for residents needing hospice services; 2) Number of residents receiving hospice care benefit If HOSPC_BED_CNT>0 or CNSUS_HOSPC_CARE_ CNT>0, SERVHOS= 1; Else if HOSPC_BED_CNT= 0 AND CNSUS_HOSPC_CARE_ CNT= 0, SERVHOS= 2;
Dietary and nutritional services[1]	Refers to dietary and nutritional services	1= Provided 2= Not provided (includes referral only) Derived from: [SERVDIET1, SERVDIET2, SERVDIET3, SERVDIET4] Q30_f /Q27_f. Dietary and nutritional services 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	1= Provided 2= Not provided (includes referral only) Derived from: [SERVDIET1, SERVDIET2, SERVDIET3, SERVDIET4] Q28_f/Q29_f. Dietary and nutritional services 1= Provides the service by paid center employees 2= Arranges for the service to be provided by outside service providers 3= Refers participants or family to outside service providers 4= Does not provide, arrange, or refer for this service	- - -	- - -	1= Provided 2= Not provided Derived from: [DTRY_ ONST_RSDNT_SW, DTRY_ONST_NRSDNT_SW, DTRY_OFSITE_RSDNT_SW] Dietary services 1) Services provided onsite to residents, either by employees or contractors; 2) Services provided onsite to non-residents; 3) Services provided to residents offsite/or not routinely provided onsite If "No" to 1), 2), and 3), SERVDIET= 2; Else SERVDIET= 1.

See footnotes at end of section.

Services provided by long-term care services providers, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Dementia care units	Refers to the provision of dementia care units	…	1= Serves only residents with dementia 2= Provides dementia care units within larger community Derived from: [ONLYDEM, DEMWING] [Questions only in Version B] Q27. Does this residential care community only serve adults with dementia or Alzheimer's disease? Q28. [If no to Q27] Does this residential care community have a distinct unit, wing, or floor that is designated as a dementia or Alzheimer's care unit?	…	…	1= Serves only residents with dementia 2= Provides dementia care units within larger facility Derived from: [CRTFD_BED_CNT, ALZHMR_BED_CNT] Number of certified beds; Number of beds in a unit identified and dedicated by the facility for residents with Alzheimer's disease if CRTFD_BED_CNT= ALZHMR_BED_CNT then DSU= 1; else if ALZHMR_BED_CNT>0 then DSU= 2; else DSU= 0;

- - - Data not available.
… Category not applicable.
[1]For ADSC and RCC, the 2016 questionnaires used "mark all that apply" questions to ask about different services provided. Respondents indicated as many as three different ways that the ADSC or RCC provided a given service. For each service, four binary variables were created: three separate variables corresponding to three different ways that ADSCs or RCCs provide the service (i.e., by paid employees, by arranging for service to be provided by outside providers, or by referral); one variable indicating whether the ADSC or RCC provides the service in any of these ways or does not provide the service. For this report, a derived variable with two mutually exclusive categories was used: 1) Provided by paid employees, or arranging for service to be provided by outside providers, in addition to referral; 2) Not provided or provide only by referral.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in NSLTCP questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is CMS' CASPER.

Use of long-term care services, by sector

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Number of services users	Number of users of services provided by paid, regulated long-term care services providers	Q3. What is the total number of participants currently enrolled at this adult day services center at this location? Average daily attendance of participants (AVGPART) was used to create SIZE variable (number of people served), while this data item (TOTPART) was used to estimate the number of adult day services center participants in the United States; TOTPART was used as the denominator when computing percentages for all aggregate, participant-level measures.	Q5. What is the total number of residents currently living at this residential care community? Please include residents for whom a bed is being held while in the hospital. If you have respite care residents, please include them. This data item (TOTRES) was used to create SIZE variable (number of people served) and to estimate the number of residents in residential care communities in the United States; TOTRES was used as the denominator when computing percentages for all aggregate, resident-level measures.	Derived from: [patient ID from OBQI Case Mix Roll-up data] Number of home health patients whose episode of care ended at any time in CY (calendar year) 2015 (i.e., discharges), regardless of payment source; 1,101 agencies (9.1%) with missing OBQI Case Mix Roll-up data; This data item (TOTPAT) was used to create SIZE variable (number of people served) and to obtain the number of home health patients in the United States; TOTPAT was used as the denominator when computing percentages for selected aggregate, patient-level measures (i.e., age, sex, and patients needing any assistance with activities of daily living).	Derived from: [BENE_CNT from IPBS hospice data] Number of hospice patients for whom Medicare-certified hospice submitted a Medicare claim at any time in CY 2015; 309 agencies (7.1%)with missing IPBS hospice data; This data item (BENE_CNT) was used to create SIZE variable (number of people served) and to obtain the number of hospice patients in the United States; BENE_CNT was used as the denominator when computing percentages for all aggregate patient-level measures.	Number of current residents in certified beds in CASPER nursing home data. This data item (CNSUS_RSDNT_CNT) was used to create SIZE variable and to obtain the number of current nursing home residents in the United States; CNSUS_RSDNT_CNT was used when computing percentages for selected aggregate, resident-level measures (i.e., residents needing any assistance with activities of daily living).

See footnotes at end of section.

Use of long-term care services, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Number of services users—Con.	Additional data on home health patients and nursing home residents were available; these data contain information on a smaller number of home health patients (who are Medicare beneficiaries receiving services from Medicare-certified home health agencies) and current nursing home residents (who were residing in a Medicare- or Medicaid-certified nursing home on the last day of the third quarter of 2016, regardless of payment source. Residents whose last Minimum Data Set [MDS] assessment was a discharge assessment were excluded).	…	…	Derived [from: [BENE_CNT from IPBS home health data] Number of home health patients for whom Medicare-certified home health care agencies submitted a Medicare claim at any time in CY 2015; 1,088 agencies (8.9%) with missing IPBS home health data. This data item (BENE_CNT) was used as the denominator when computing percentages for selected aggregate, patient-level measures (i.e., race and ethnicity, diagnosed with chronic conditions).	…	Derived from: [resident ID from Minimum Data Set Active Resident Episode Table (MARET) data] Number of active nursing home residents; 131 nursing homes (0.8%) in CASPER was missing MARET data. This data item (NUMRES) was used as the denominator when computing percentages for selected aggregate, resident-level measures (i.e., age, sex, race and ethnicity, diagnosed with chronic conditions).

… Category not applicable.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in NSL TCP questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is CMS' CASPER.

Demographic characteristics of long-term care services users, by sector

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Age[1]	Number of long-term care services users under age 65	Derived from: [AG17LESSRC, AG18TO44RC, AG45TO54RC, AG55TO64RC] Q15. Of the participants currently enrolled at this center, what is the age breakdown? a. 17 years or younger? b. 18–44 years? c. 45–54 years? d. 55–64 years?	Derived from: [AG17LESSRC, AG18TO44RC, AG45TO54RC, AG55TO64RC] Q16. Of the residents currently living in this residential care community, what is the age breakdown? a. 17 years or younger? b. 18–44 years? c. 45–54 years? d. 55–64 years?	Derived from: [MSR_201_ VAL/ TOTPAT from OBQI Case Mix Roll-up data] Calculated age at the time of episode of care.	Derived from: [AGE_ LESS_65/ BENE_CNT from IPBS hospice data] Number of beneficiaries under age 65 utilizing the provider.	Derived from: [C_RSDNT_ AGE_NUM from MARET data] Calculated age at the time of nursing home assessment.
	Number of long-term care services users between ages 65 and 74	Q15. Of the participants currently enrolled at this center, what is the age breakdown?: e. 65–74 years?	Q16. Of the residents currently living in this residential care community, what is the age breakdown? e. 65–74 years?	Derived from: [MSR_201_ VAL/ TOTPAT from OBQI Case Mix Roll-up data] Calculated age at the time of episode of care.	Derived from: [AGE_65_69, AGE_70_74/ BENE_CNT from IPBS hospice data] Number of beneficiaries between ages 65 and 69 utilizing the provider; Number of beneficiaries between ages 70 and 74 utilizing the provider.	Derived from: [C_RSDNT_ AGE_NUM from MARET data] Calculated age at the time of nursing home assessment.
	Number of long-term care services users between ages 75 and 84	Q15. Of the participants currently enrolled at this center, what is the age breakdown? f. 75–84 years?	Q16. Of the residents currently living in this residential care community, what is the age breakdown? f. 75–84 years?	Derived from: [MSR_201_ VAL/ TOTPAT from OBQI Case Mix Roll-up data] Calculated age at the time of episode of care.	Derived from: [AGE_75_79, AGE_80_84/ BENE_CNT from IPBS hospice data] Number of beneficiaries between ages 75 and 79 utilizing the provider; Number of beneficiaries between ages 80 and 84 utilizing the provider.	Derived from: [C_RSDNT_ AGE_NUM from MARET data] Calculated age at the time of nursing home assessment.
	Number of long-term care services users aged 85 and over	Q15. Of the participants currently enrolled at this center, what is the age breakdown? g. 85 years and older?	Q16. Of the residents currently living in this residential care community, what is the age breakdown? g. 85 years and older?	Derived from: [MSR_201_ VAL/ TOTPAT from OBQI Case Mix Roll-up data] Calculated age at the time of episode of care.	Derived from: [AGE_ OVER_84/ BENE_CNT from IPBS hospice data] Number of beneficiaries over age 84 utilizing the provider.	Derived from: [C_RSDNT_ AGE_NUM from MARET data] Calculated age at the time of nursing home assessment.

See footnotes at end of section.

Demographic characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Race and ethnicity[2]	Number of long-term care services users of Hispanic or Latino origin	Q13. Of the participants currently enrolled at this center, what is the racial-ethnic breakdown? a. Hispanic or Latino, of any race?	Q14. Of the residents currently living in this residential care community, what is the racial-ethnic breakdown? a. Hispanic or Latino, of any race?	Derived from: [RACE_ HISPN/ BENE_CNT from IPBS home health data] Number of Hispanic beneficiaries utilizing the provider.	Derived from: [RACE_ HISPN/ BENE_CNT from IPBS hospice data] Number of Hispanic beneficiaries utilizing the provider.	Derived from: [A1000D_ HSPNC_CD/ TOTRES from MARET data] Number of Hispanic residents. Coded so that indicator includes all Hispanic, regardless of race indicator.
	Number of long-term care services users who are non-Hispanic white	Q13. Of the participants currently enrolled at this center, what is the racial-ethnic breakdown? f. White, not Hispanic or Latino?	Q14. Of the residents currently living in this residential care community, what is the racial-ethnic breakdown? f. White, not Hispanic or Latino?	Derived from: [RACE_ WHITE/ BENE_CNT from IPBS home health data] Number of non-Hispanic white beneficiaries utilizing the provider.	Derived from: [RACE_ WHITE/ BENE_CNT from IPBS hospice data] Number of non-Hispanic white beneficiaries utilizing the provider.	Derived from: [A1000F_ WHT_CD/ TOTRES from MARET data] Number of white residents. Coded so that indicator includes only non-Hispanic white.
	Number of long-term care services users who are non-Hispanic black	Q13. Of the participants currently enrolled at this center, what is the racial-ethnic breakdown? d. Black, not Hispanic or Latino?	Q14. Of the residents currently living in this residential care community, what is the racial-ethnic breakdown? d. Black, not Hispanic or Latino?	Derived from: [RACE_ BLACK/ BENE_CNT from IPBS home health data] Number of non-Hispanic black beneficiaries utilizing the provider.	Derived from: [RACE_ BLACK/ BENE_CNT from IPBS hospice data] Number of non-Hispanic black beneficiaries utilizing the provider.	Derived from: [A1000C_ AFRCN_AMRCN_CD/ TOTRES from MARET data] Number of African-American residents. Coded so that indicator includes only non-Hispanic African American.

See footnotes at end of section.

Demographic characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Race and ethnicity[2]—Con.	Number of long-term care services users who are of a race other than white or black	Derived from: [AIANRC, ASIANRC, NHOPIRC, MULTIRACERC, OTHERRC, UNKNOWNRC] Q13. Of the participants currently enrolled at this center, what is the racial-ethnic breakdown? b. American Indian or Alaska Native, not Hispanic or Latino? c. Asian, not Hispanic or Latino? e. Native Hawaiian or Other Pacific Islander, not Hispanic or Latino? g. Two or more races, not Hispanic or Latino? h. Some other category reported in this center's system? i. Not reported (race and ethnicity unknown)?	Derived from: [AIANRC, ASIANRC, NHOPIRC, MULTIRACERC, OTHERRC, UNKNOWNRC] Q14. Of the residents currently living in this residential care community, what is the racial-ethnic breakdown? b. American Indian or Alaska Native, not Hispanic or Latino? c. Asian, not Hispanic or Latino? e. Native Hawaiian or Other Pacific Islander, not Hispanic or Latino? g. Two or more races, not Hispanic or Latino? h. Some other category reported in this residential care community's system? i. Not reported (race and ethnicity unknown)?	Derived from: [RACE_ NATIND, RACE_ API, RACE_ OTHER/ BENE_CNT from IPBS home health] Number of American Indian or Alaska Native, Asian Pacific Islander, and other beneficiaries not elsewhere classified utilizing the provider.	Derived from: [RACE_ NATIND, RACE_ API, RACE_ OTHER/ BENE_CNT from IPBS hospice data] Number of American Indian or Alaska Native, Asian Pacific Islander, and other beneficiaries not elsewhere classified utilizing the provider.	Derived from: [A1000A_ AMRCN_INDN_AK_NTV_CD, A1000B_ASN_CD, A1000E_ NTV_HI_PCFC_ISLNDR_CD/ TOTRES from MARET data] Number of American Indian or Alaska Native, Asian, and Native Hawaiian or Pacific Islander residents. Coded so that indicator includes only non-Hispanic "other" races.

See footnotes at end of section.

Demographic characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Sex[1]	Number of long-term care services users who are male	Q14. Of the participants currently enrolled at this center, what is the sex breakdown? a. Male?	Q15. Of the residents currently living in this residential care community, what is the sex breakdown? a. Male?	Derived from: [MSR_202_VAL/TOTPAT from OBQI Case Mix Roll-up data] "Patient History, Demographics, Gender: Male".	Derived from: [MALE/BENE_CNT from IPBS hospice data] Number of male beneficiaries utilizing the provider.	Derived from: [A0800_GNDR_CD/ TOTRES from MARET data] Identifies the resident's sex: 1= Male
	Number of long-term care services users who are female	Q14. Of the participants currently enrolled at this center, what is the sex breakdown? b. Female?	Q15. Of the residents currently living in this residential care community, what is the sex breakdown? b. Female?	Derived from: [MSR_202_VAL/TOTPAT from OBQI Case Mix Roll-up data] "Patient History, Demographics, Gender: Female".	Derived from: [FEMALE/BENE_CNT from IPBS hospice data] Number of female beneficiaries utilizing the provider.	Derived from: [A0800_GNDR_CD/ TOTRES from MARET data] Identifies the resident's sex: 1= Female
Medicaid as payer source[3]	Number of long-term care users with Medicaid paying for some or all long-term care services received	Q18. During the last 30 days, for how many of the participants currently enrolled at this adult day services center did Medicaid pay for some or all of their services received at this center? Please include any participants that received funding from a Medicaid state plan, Medicaid waiver, Medicaid managed care, or California regional center.	Q10. During the last 30 days, for how many of the residents currently living in this residential care community, did Medicaid pay for some or all of their services received at this center? If none, enter "0."	Derived from: [MSR_207_VAL/TOTPAT from OBQI Case Mix Roll-up data] Number of patients coded as having Medicaid as payer source if they had any Medicaid as traditional fee-for-service or HMO (health maintenance organization) or managed care as current payment sources for home care at start of care or resumption of care.	- - -	Derived from: [CNSUS_MDCD_CNT/ TOTRES] Number of residents whose primary payer source is Medicaid.

- - - Data not available.

[1]For ADSC and RCC, cases with missing data were imputed. For HHA and NH, MARET data are individual resident-level data, and OBQI Case Mix Roll-up data are also individual patient-level data. When rolling up individual user-level data to provider ID number, facilities or agencies with 20.0% or more of their resident or patient information missing for a given data item were coded as missing. Other than cases with missing data due to nonmatching (HHA–9.1%; NH–0.8%), no facilities or agencies had missing data. For HOS, the IPBS–Hospice file contains hospice patient information at the provider-level; other than cases with missing data due to nonmatching (7.1%), no agencies had missing data.

[2]For ADSC and RCC, cases with missing data were imputed. For NH, MARET data are individual resident-level data; when rolling up individual user-level data to provider ID number, facilities with 20.0% or more of their resident information missing for a given data item were coded as missing. About 0.9% of facilities, including facilities with missing data due to nonmatching (NH–0.8%), had missing data. For HHA and HOS, IPBS home health data were used; race and ethnicity data in OBQI Case Mix Roll-up do not match race and ethnicity categories used in other data sources. IPBS home health data and IPBS hospice data contain information on home health patients and hospice patients at the provider level, respectively; other than cases with missing data due to nonmatching (HHA–8.9%; HOS–7.1%), no agencies had missing data.

[3]For HHA, OBQI Case Mix Roll-up data are individual patient-level data; when rolling up individual user-level data to provider ID, agencies with 20.0% or more of their patient information missing for a given data item were coded as missing. Other than 9.1% of cases missing due to nonmatching, no agencies had missing data.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in NSLTCP questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is CMS' CASPER.

Health and functional characteristics of long-term care services users, by sector

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Diagnosed with Alzheimer disease or dementia[1]	Number of long-term care services users diagnosed with Alzheimer disease or dementia	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? a. Alzheimer's disease or other dementias	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? a. Alzheimer's disease or other dementias	Derived from: [ALZRDSD_ BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for Alzheimer's broad classification, including dementia and utilizing the provider (Alzheimer's disease and related disorders or senile dementia).	Derived from: [ALZRDSD_ BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for Alzheimer's broad classification, including dementia and utilizing the provider (Alzheimer's disease and related disorders or senile dementia).	Derived from: [I4200_ ALZHMR_CD, I4800_ DMNT_CD/ TOTRES from MARET data] Indicates whether the resident had an active diagnosis of Alzheimer's disease in the last 7 days or indicates whether the resident had an active diagnosis of non-Alzheimer's dementia such as vascular or multi-infarct dementia; mixed dementia; or frontotemporal dementia such as Pick's disease and dementia related to stroke, Parkinson's disease, or Creutzfeldt-Jakob disease in the last 7 days.
Diagnosed with depression[1]	Number of long-term care services users diagnosed with depression	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? g. Depression	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? g. Depression	Derived from: [DEPR_BENE_ CNT / BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for depression utilizing the provider.	Derived from: [DEPR_BENE_ CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for depression utilizing the provider.	Derived from: [I5800_ DPRSN_CD/ TOTRES from MARET data] Indicates if the resident had an active diagnosis of depression (other than bipolar) in the last 7 days.
Diagnosed with diabetes[1]	Number of long-term care services users diagnosed with diabetes	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? h. Diabetes	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? h. Diabetes	Derived from: [DIAB_BENE_ CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for diabetes utilizing the provider.	Derived from: [DIAB_BENE_ CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for diabetes utilizing the provider.	Derived from: [I2900_DM_ CD/ TOTRES from MARET data] Indicates whether the resident had an active diagnosis of diabetes mellitus (diabetic retinopathy or neuropathy) in the last 7 days.

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Diagnosed with arthritis[1]	Number of long-term care services users diagnosed with arthritis	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? b. arthritis	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? b. arthritis	Derived from: [RAOA_BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for rheumatoid or osteoarthritis and utilizing the provider.	Derived from: [RAOA_BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for rheumatoid or osteoarthritis and utilizing the provider.	Derived from: [I3700_ARTHTS_CD/ TOTRES from MARET data] Indicates whether the resident had an active diagnosis of arthritis in the last 7 days.
Diagnosed with asthma[1]	Number of long-term care services users diagnosed with asthma	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? c. asthma	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? c. asthma	Derived from: [ASTHMA_BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for asthma and utilizing the provider.	Derived from: [ASTHMA_BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for asthma and utilizing the provider.	---
Diagnosed with chronic kidney disease[1]	Number of long-term care services users diagnosed with chronic kidney disease	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? e. chronic kidney disease	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? e. chronic kidney disease	Derived from: [CKD_BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for chronic kidney disease and utilizing the provider.	Derived from: [CKD_BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for chronic kidney disease and utilizing the provider.	---
Diagnosed with chronic obstructive pulmonary disease (COPD)[1]	Number of long-term care services users diagnosed with COPD	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? f. COPD (chronic bronchitis or emphysema)	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? f. COPD (chronic bronchitis or emphysema)	Derived from: [COPD_BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for COPD and utilizing the provider.	Derived from: [COPD_BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for COPD and utilizing the provider.	---

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Diagnosed with heart disease[1]	Number of long-term care services users diagnosed with heart disease	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? i. heart disease (for example, congestive heart failure, coronary or ischemic heart disease, heart attack, stroke)	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? i. heart disease (for example, congestive heart failure, coronary or ischemic heart disease, heart attack, stroke)	Derived from: [IHD_BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for ischemic heart disease and utilizing the provider.	Derived from: [IHD_BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for ischemic heart disease and utilizing the provider.	Derived from: [I0400_CAD_CD, I0600_HRT_FAILR_CD, I4500_STRK_CD/ TOTRES from MARET data] Indicates whether the resident had an active diagnosis of coronary artery disease, congestive heart failure, or stroke (CVA or TIA or Stroke) in the last 7 days.
Diagnosed with high blood pressure or hypertension[1]	Number of long-term care services users diagnosed with high blood pressure or hypertension	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? j. high blood pressure or hypertension	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? j. high blood pressure or hypertension	Derived from: [HYPERT_BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for hypertension and utilizing the provider.	Derived from: [HYPERT_BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for hypertension and utilizing the provider.	Derived from: [I0700_HYPRTNSN_CD/ TOTRES from MARET data] Indicates whether the resident had an active diagnosis of hypertension in the last 7 days.
Diagnosed with osteoporosis[1]	Number of long-term care services users diagnosed with osteoporosis	Q17. Of the participants currently enrolled at this center, about how many have been diagnosed with each of the following conditions? o. osteoporosis	Q18. Of the residents currently living in this residential care community, about how many have been diagnosed with each of the following conditions? o. osteoporosis	Derived from: [OST_BENE_CNT/ BENE_CNT from IPBS home health data] Number of beneficiaries meeting the chronic condition algorithm for osteoporosis and utilizing the provider.	Derived from: [OST_BENE_CNT/ BENE_CNT from IPBS hospice data] Number of beneficiaries meeting the chronic condition algorithm for osteoporosis and utilizing the provider.	Derived from: [I3800_OSTPRS_CD/ TOTRES from MARET data] Indicates whether the resident had an active diagnosis of osteoporosis in the last 7 days.

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Assistance with eating[2]	Number of long-term care services users needing any assistance with eating. Assistance refers to needing any help or supervision from another person or use of assistive devices.	Q16. Of the participants currently enrolled at this center, about how many need any assistance at their usual residence or this center in each of the following activities? b. With eating, like cutting up food	Q17. Of the residents currently living in this residential care community, about how many need any assistance in each of the following activities? b. With eating, like cutting up food	Derived from: [MSR_342_ VAL/ TOTPAT from OBQI Case Mix Roll-up data] Number of patients coded as needing any assistance with eating if they: are able to feed self independently but require meal setup or intermittent assistance or supervision from another person; require a liquid, pureed, or ground meat diet; are unable to feed self and must be assisted or supervised throughout the meal or snack; are able to take in nutrients orally and receive supplemental nutrients through a nasogastric tube or gastrostomy; are unable to take in nutrients orally and are fed nutrients through a nasogastric tube or gastrostomy; or are unable to take in nutrients orally or by tube feeding.	- - -	Derived from: [CNSUS_ EATG_ ASTD_CNT, CNSUS_ EATG_ DPNDNT_CNT/ CNSUS_RSDNT_CNT] Number of residents coded as needing any assistance with eating if they require supervision, limited or extensive assistance from staff, or full staff performance every time during entire 7-day period. If the facility routinely provides “setup” activities (e.g., opening containers, buttering bread, and organizing the tray) and if this is the extent of assistance provided for the resident, the resident was coded as not needing any assistance with eating.

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Assistance with dressing[2]	Number of long-term care services users needing any assistance with dressing. Assistance refers to needing any help or supervision from another person or use of assistive devices.	Q16. Of the participants currently enrolled at this center, about how many need any assistance at their usual residence or this center in each of the following activities? c. With dressing	Q17. Of the residents currently living in this residential care community, about how many need any assistance in each of the following activities? c. With dressing	Derived from: [MSR_335_VAL & MSR_336_VAL/ TOTPAT from OBQI Case Mix Roll-up data] Number of patients coded as needing any assistance with dressing if: they are able to dress upper and lower body without assistance, if clothing and shoes are laid out or handed to the patient; someone must help the patient put on upper body clothing or undergarments, slacks, socks or nylons, and shoes; or patient depends entirely upon another person to dress the upper and lower body.	- - -	Derived from: [CNSUS_DRS_ASTD_CNT; CNSUS_DRS_DPNDNT_CNT/ CNSUS_RSDNT_CNT] Number of residents coded as needing any assistance with dressing if they require supervision, limited or extensive assistance from staff, or full staff performance every time during entire 7-day period. If the facility routinely set out clothes for all residents, and this is the only assistance the resident receives, the resident was coded as not needing any assistance with dressing.

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Assistance with toileting[2]	Number of long-term care services users needing any assistance with using bathroom. Assistance refers to needing any help or supervision from another person or use of assistive devices.	Q16. Of the participants currently enrolled at this center, about how many need any assistance at their usual residence or this center in each of the following activities? e. With using the bathroom (toileting)	Q17. Of the residents currently living in this residential care community, about how many need any assistance in each of the following activities? e. With using the bathroom (toileting)	Derived from: [MSR_339_ VAL/ TOTPAT from OBQI Case Mix Roll-up data] Number of patients coded as needing any assistance with toileting if: the patient is able to manage toileting hygiene and clothing management without assistance if supplies or implements are laid out for the patient; someone must help the patient to maintain toileting hygiene or adjust clothing; or the patient depends entirely upon another person to maintain toileting hygiene. Toileting hygiene refers to the patient's current ability to maintain perineal hygiene safely, or adjust clothes or incontinence pads before and after using toilet, commode, bedpan, and urinal. If managing ostomy, it includes cleaning area around stoma, but not managing equipment.	- - -	Derived from: [CNSUS_ TOILT_ ASTD_CNT, CNSUS_ TOILT_ DPNDNT_CNT/ CNSUS_RSDNT_CNT] Number of residents coded as needing any assistance with toileting if they require supervision, limited or extensive assistance from staff, or full staff performance every time during entire 7-day period. If all that is done for the resident is to open a package (e.g., a clean sanitary pad), the resident was coded as not needing any assistance with toileting.

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Assistance with bathing[2]	Number of long-term care services users needing any assistance with bathing or showering. Assistance refers to needing any help or supervision from another person or use of assistive devices.	Q16. Of the participants currently enrolled at this center, about how many need any assistance at their usual residence or this center in each of the following activities? d. With bathing or showering	Q17. Of the residents currently living in this residential care community, about how many need any assistance in each of the following activities? d. With bathing or showering	Derived from: [MSR_337_VAL from OBQI Case Mix Roll-up data] Number of patients coded as needing any assistance with bathing if the patient is: with the use of devices, able to bathe self in shower or tub independently, including getting in and out of the tub or shower; able to bathe in shower or tub with the intermittent assistance of another person; able to participate in bathing self in shower or tub, but requires presence of another person throughout the bath for assistance or supervision; unable to use the shower or tub, but able to bathe self independently with or without the use of devices at the sink, in chair, or on commode; unable to use the shower or tub, but able to participate in bathing self in bed, at the sink, in bedside chair, or on commode, with the assistance or supervision of another person throughout the bath; or unable to participate effectively in bathing and is bathed totally by another person.	- - -	Derived from: [CNSUS_BATHG_ASTD_CNT, CNSUS_BATHG_DPNDNT_CNT/CNSUS_RSDNT_CNT] Number of residents coded as needing any assistance with bathing if they require supervision, physical help limited to transfer only or in part of bathing activity, or full staff performance every time during entire 7-day period. If the facility provides setup assistance to all residents, such as drawing water for a tub bath or laying out bathing materials, and the resident requires no other assistance, the resident was coded as not needing any assistance with bathing.

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Assistance with walking or locomotion[2]	Number of long-term care services users needing any assistance with walking or locomotion. Assistance refers to needing any help or supervision from another person or use of assistive devices.	Q16. Of the participants currently enrolled at this center, about how many now need any assistance at their usual residence or this center in each of the following activities? f. With locomotion or walking—this includes using a cane, walker, or wheelchair, or help from another person	Q17. Of the residents currently living in this residential care community, about how many need any assistance in each of the following activities? f. With locomotion or walking—this includes using a cane, walker, or wheelchair, or help from another person	Derived from: [MSR_341_VAL from OBQI Case Mix Roll-up data] Number of patients coded as needing any assistance with ambulation or locomotion if they are: able to independently walk on even and uneven surfaces and negotiate stairs with or without railings without use of an assistive device, with the use of a one-handed assistive device, or with the use of a two-handed device; able to walk only with the assistance of another person at all times; chairfast, unable to ambulate but are able to wheel self independently; chairfast, unable to ambulate and unable to wheel self; or bedfast, unable to ambulate or be up in a chair.	- - -	Derived from: [CNSUS_INDPNDNT_MBLTY_CNT, CNSUS_RSDNT_CNT] Number of residents who require no help or oversight; or help or oversight was provided only one or two times during the past 7 days. Do not include residents who use a cane, walker, or crutch. Subtracted from CNSUS_RSDNT_CNT.

See footnotes at end of section.

Health and functional characteristics of long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Assistance with transferring[2]	Number of long-term care services users needing any assistance with transferring. Assistance refers to needing any help or supervision from another person or use of assistive devices.	Q16. Of the participants currently enrolled at this center, about how many now need any assistance at their usual residence or this center in each of the following activities? a. With transferring in and out of a chair	Q17. Of the residents currently living in this residential care community, about how many need any assistance in each of the following activities? a. With transferring in and out of a bed or chair	Derived from: [MSR_340_ VAL from OBQI Case Mix Roll-up data] Number of patients coded as needing any assistance with transferring if they are: able to transfer with minimal human assistance or with use of an assistive device; able to bear weight and pivot during the transfer process but unable to transfer self; unable to transfer self and are unable to bear weight or pivot when transferred by another person; bedfast, unable to transfer but are able to turn and position self in bed; bedfast, unable to transfer and are unable to turn and position self.	- - -	Derived from: [CNSUS_ TRNSFR_ASTD_CNT, CNSUS_ TRNSFR_DPNDNT_ CNT/ CNSUS_RSDNT_CNT] Number of residents who require help moving between surfaces, including, to or from bed, chair, wheelchair, or standing positions. Excludes transfers to or from the bath or toilet. If the facility routinely provides "setup" assistance to all residents, such as handing the equipment (e.g., sliding board) to the resident, and this is the only assistance required, the resident was coded as not needing assistance with transferring.

- - - Data not available.

[1]For NH, MARET data are individual resident-level data; when rolling up individual user-level data to provider ID number, facilities with 20.0% or more of their resident information missing for a given data item were coded as missing. From 8.6% (for diabetes) to 10.2% (for osteoporosis and arthritis) of facilities (including 0.8% of missing data due to nonmatching) had missing data. For HHA and HOS, IPBS home health data and IPBS hospice data contain information on home health patients and hospice patients at the provider level, respectively; other than cases with missing data due to nonmatching (HHA–8.9%, HOS–7.1%), no agencies had missing data.

[2]For HHA, OBQI Case Mix Roll-up data are individual patient-level data; when rolling up individual user-level data to provider ID number, agencies with 20.0% or more of their patient information missing for a given data item were coded as missing. Other than cases with missing data due to nonmatching, (HHA–9.1%), no agencies had missing data.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in NSLTCP questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is CMS' CASPER.

Adverse events among long-term care services users, by sector

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Overnight hospital stay[1]	Number of long-term care users who were discharged from an overnight hospital stay	Q20. Of the participants currently enrolled at this center, about how many were discharged from an overnight hospital stay in the last 90 days? Exclude trips to the hospital emergency department that did not result in an overnight hospital stay.	Q20. Of the residents currently living in this residential care community, about how many were discharged from an overnight hospital stay in the last 90 days? Exclude trips to the hospital emergency department that did not result in an overnight hospital stay.	Derived from: [MSR_447_VAL from OBQI Case Mix Roll-up data] To which inpatient facility has the patient been admitted? 1= Hospital	- - -	Derived from: [PRVDRNUM hospital codes and DSCHRGDT from 2014 Medicare Provider Analysis and Review (MedPAR) inpatient claims data merged to MARET] Overnight hospital stay defined as residents with at least one inpatient hospitalization claim discharged after the nursing home admission date within the 2014 calendar year.
Emergency department visits[2]	Number of long-term care users who had emergency department visits	Q19. Of the participants currently enrolled at this center, about how many were treated in a hospital emergency department in the last 90 days?	Q19. Of the residents currently living in this residential care community, about how many were treated in a hospital emergency department in the last 90 days?	Derived from: [MSR_426_VAL from OBQI Case Mix Roll-up data] Since the last time Outcome and Assessment Information Set data were collected, has the patient utilized a hospital emergency department (includes holding or observation)?	- - -	- - -

See footnotes at end of section.

Adverse events among long-term care services users, by sector—Con.

Characteristic	Definition	Survey data		Administrative data		
		Adult day services center (ADSC)	Residential care community (RCC)	Home health agency (HHA)	Hospice (HOS)	Nursing home (NH)
Falls[3]	Number of long-term care users who had falls	Q25. As best you know, about how many of your current participants had a fall in the last 90 days? Please include falls that occurred in your center or off-site, whether or not the participant was injured, and whether or not anyone saw the participant fall or caught them. Please just count one fall per participant who fell, even if the participant fell more than one time. If one of your participants fell during the last 90 days, but is currently in the hospital or rehabilitation facility, please include that person in your count. [Question only in Version A]	Q23. As best you know, about how many of your current residents had a fall in the last 90 days? [Question only in Version A]	- - -	- - -	Derived from: [J1800_FALL_LAST_ASMT_CD/ TOTRES from MARET data] Has the resident had any falls since admission or the prior assessment, whichever is more recent?
Length of stay[4]	Short-stay residents had been admitted less than 100 days from assessment date and long-stay residents had been admitted for 100 days or more	- - -	- - -	- - -	- - -	Derived from: [LAST_TRGT_DT and A1600_ENTRY_DT from MARET data] if LOS<= 100 then SHORTSTAY_100= 1; else if LOS>100 then SHORTSTAY_100= 0;

- - - Data not available.
[1]For HHA, OBQI Case Mix Roll-up data are individual patient-level data; when rolling up individual user-level data to provider ID, facilities or agencies with 20.0% or more of their patient information missing for a given data item were coded as missing. About 9.5% of agencies (including 9.1% of missing data due to nonmatching) had missing data.
[2]For HHA, OBQI Case Mix Roll-up data are individual patient-level data; when rolling up individual user-level data to provider ID, facilities or agencies with 20.0% or more of their patient information missing for a given data item were coded as missing. About 10.4% of agencies (including 9.1% of missing data due to nonmatching) had missing data.
[3]For NH, MARET data are individual resident-level data; when rolling up individual user-level data to provider ID number, facilities with 20.0% or more of their resident information missing for a given data item were coded as missing. About 8.6% of facilities (including 0.8% of missing data due to nonmatching) had missing data.
[4]For NH, MARET data are individual resident-level data that were not rolled up to the user-level data. This variable was used to compare short- and long-stay nursing home residents on various user characteristics.

NOTES: For survey data, (ADSC and RCC), question numbers refer to the order in NSLTCP questionnaires. Questionnaires and detailed documentation on survey variables are available from: https://www.cdc.gov/nchs/nsltcp/nsltcp_questionnaires.htm. For administrative data (HHA, HOS, and NH), when the data source is not specified, the source is CMS' CASPER.

SOURCE: NCHS, National Study of Long-Term Care Providers, 2015–2016.

Appendix III. Detailed Tables

Table V. Long-term care services providers, by geographical and organizational characteristics and sector: United States, 2015–2016

Characteristic	Adult day services center	Standard error	Home health agency	Standard error	Hospice	Standard error	Nursing home	Standard error	Residential care community	Standard error
					Number					
Number of providers[1]	4,600	3	12,200	. . .	4,300	. . .	15,600	. . .	28,900	68
Number of beds or licensed maximum capacity[1]	298,400	2,883	. . .	. . .	. . .	. . .	1,660,400	. . .	996,100	8,787
Average number of beds or licensed maximum capacity[2,3]	66.0	0.6	- - -	- - -	- - -	- - -	106.0	0.5	35.0	0.3
Average number of people served[3,4]										
Daily	42.0	0.4	. . .	. . .	. . .	. . .	86.0	0.4	28.0	0.3
Annually	. . .	. . .	401.0	9.8	353.0	10.7	. . .	. . .	. . .	. . .
Region					Percent distribution					
Northeast	20.1	0.0	8.6	0.3	10.4	0.5	16.8	0.3	8.6	0.1
Midwest	16.9	0.0	27.4	0.4	21.8	0.6	33.0	0.4	22.6	0.1
South	32.2	0.0	45.6	0.5	39.4	0.7	34.8	0.4	28.0	0.1
West	30.8	0.0	18.4	0.4	28.6	0.7	15.4	0.3	40.8	0.1
Metropolitan statistical area status										
Metropolitan	84.8	0.4	84.8	0.3	79.0	0.6	71.5	0.4	82.5	0.6
Micropolitan	10.2	0.3	8.1	0.3	12.8	0.5	13.9	0.3	10.6	0.5
Neither	5.0	0.2	7.2	0.2	8.2	0.4	14.6	0.3	6.9	0.4
Ownership										
For profit	44.7	0.6	80.6	0.4	63.0	0.7	69.3	0.4	81.0	0.7
Nonprofit	50.8	0.6	14.8	0.3	22.8	0.6	23.5	0.3	17.7	0.7
Government and other	4.6	0.2	4.6	0.2	14.1	0.5	7.2	0.2	1.3	0.2
People served[5]					Number					
Category 1	45.0	0.5	44.8	0.5	34.2	0.8	5.7	0.2	65.0	0.3
Category 2	48.6	0.6	25.8	0.4	34.0	0.8	63.7	0.4	30.7	0.4
Category 3	6.4	0.3	29.4	0.4	31.8	0.7	30.6	0.4	4.3	0.2
Certification					Percent					
Medicare-certified	. . .	. . .	98.7	0.1	- - -	- - -	97.5	0.1	. . .	. . .
Medicaid-certified	76.9	0.5	78.4	0.4	- - -	- - -	95.2	0.2	48.3	0.8
Chain-affiliated	42.6	0.6	- - -	- - -	- - -	- - -	57.6	0.4	57.2	1.0

. . . Category not applicable.
- - - Data not available.
0.0 Quantity more than zero but less than 0.05.
[1]Estimates are rounded as whole numbers to the nearest hundred.
[2]For adult day services centers, capacity is based on licensed maximum capacity. For nursing homes and residential care communities, capacity is based on number of licensed or certified beds.
[3]Averages are based on unrounded numbers.
[4]The estimated number of adult day services center participants represents current participants in 2016.The estimated number of home health patients represents patients who ended care in 2015 (i.e., discharges). The estimated number of hospice patients represents patients who received care at any time in 2015. The estimated number of nursing home residents represents current residents in 2016. The estimated number of residential care community residents represents current residents in 2016.
[5]For adult day services centers, nursing homes, and residential care communities, number of people served is based on current users on any given day in 2016, and the categories are 1–25, 26–100, and 101 or more. For home health agencies and hospices, number of people served is based on number of patients in 2015, and categories are 1–100, 101–300, and 301 or more. Home health patients are patients who received and ended care anytime in 2015. Hospice patients are patients who received care anytime in 2015.

NOTES: Percent distributions may not add to 100 because of rounding. Percentages are based on unrounded estimates.

SOURCE: NCHS, National Study of Long-Term Care Providers, 2015–2016.

Table VI. Staffing characteristics of long-term care services providers, by staff type and sector: United States, 2016

Characteristic	Adult day services center	Standard error	Home health agency	Standard error	Hospice	Standard error	Nursing home	Standard error	Residential care community	Standard error
					Number					
Total number of nursing and social work employee FTEs	19,900	228	145,000	1,572	85,600	1,521	945,700	4,158	298,800	3,969
Total nursing and social work employee FTEs					Percent distribution					
Registered nurse	20.6	0.3	53.0	0.4	48.0	0.3	11.9	0.1	6.1	0.2
Licensed practical nurse or licensed vocational nurse	11.3	0.2	19.5	0.3	8.8	0.2	22.4	0.1	9.9	0.2
Aide	56.8	0.4	25.1	0.4	31.8	0.3	63.9	0.1	83.3	0.3
Social worker	11.3	0.2	2.5	0.0	11.4	0.1	1.8	0.0	0.8	0.0
Providers with one or more employee FTEs					Percent					
Registered nurse	62.1	0.6	99.7	0.1	100.0	0.0	99.1	0.1	39.4	0.8
Licensed practical nurse or licensed vocational nurse	45.8	0.6	70.7	0.4	62.5	0.7	98.3	0.1	35.7	0.7
Aide	67.3	0.6	89.9	0.3	97.8	0.2	98.8	0.1	81.7	0.9
Social worker	39.9	0.6	46.7	0.5	99.3	0.1	76.8	0.3	10.2	0.5
Activities director or staff	84.8	0.5	---	---	---	---	96.7	0.1	58.3	0.9
Employee hours per resident or participant per day					Mean					
Registered nurse	0.34	0.01	---	---	---	---	0.54	0.01	0.20	0.01
Licensed practical nurse or licensed vocational nurse	0.21	0.01	---	---	---	---	0.85	0.01	0.17	0.01
Aide	0.86	0.02	---	---	---	---	2.41	0.01	2.27	0.10
Social worker	0.13	0.00	---	---	---	---	0.08	0.00	0.03	0.00
Activities director or staff	0.67	0.01	---	---	---	---	0.19	0.00	0.31	0.02

0.0 or 0.00 Quantity more than zero but less than 0.05.
- - - Data not available.

NOTES: FTE is full-time equivalent. Percent distributions may not add to 100 because of rounding. Percentages are based on unrounded estimates.

SOURCE: NCHS, National Study of Long-Term Care Providers, 2015–2016.

Table VII. Provision of services by long-term care services providers, by type of service and sector: United States, 2016

Service provided	Adult day services center	Standard error	Home health agency	Standard error	Hospice	Standard error	Nursing home	Standard error	Residential care community	Standard error
					Percent					
Social work	52.1	0.6	82.5	0.3	100.0	—	88.5	0.3	51.1	1.1
Mental health or counseling	33.8	0.6	- - -	- - -	97.0	0.3	87.6	0.3	55.0	1.1
Therapeutic	46.7	0.6	96.3	0.2	98.2	0.2	99.5	0.1	71.4	1.0
Skilled nursing or nursing	64.5	0.6	100.0	—	100.0	—	100.0	—	66.1	1.0
Pharmacy or pharmacist	30.0	0.6	4.9	0.2	- - -	- - -	97.2	0.1	83.6	0.8
Hospice	20.8	0.5	5.7	0.2	. . .	. . .	80.7	0.3	67.7	1.0
Dietary and nutritional	67.8	0.6	- - -	- - -	- - -	- - -	100.0	—	82.8	0.9
Dementia-specific units										
Only serve residents with dementia	. . .	. . .	. . .	. . .	. . .	. . .	0.4	0.1	8.7	0.8
Have a distinct unit, wing, or floor designated for dementia special care	. . .	. . .	. . .	. . .	. . .	. . .	14.9	0.3	14.3	0.8

— Quantity zero.
- - - Data not available.
. . . Category not applicable.

NOTES: Percent distributions may not add to 100 because of rounding. Percentages are based on unrounded estimates.

SOURCE: NCHS, National Study of Long-Term Care Providers, 2015–2016.

Table VIII. Long-term care services users, by selected characteristics and sector: United States, 2015–2016

Characteristic[1]	Adult day services center	Standard error	Home health agency	Standard error	Hospice	Standard error	Nursing home	Standard error	Residential care community	Standard error
					Number					
Users[2]	286,300	3,180	4,455,700	109,617	1,426,000	43,639	1,347,600	6,769	811,500	8,343
Age					Percent					
Under 65	37.4	0.6	18.1	0.2	5.5	0.1	16.5	0.1	6.6	0.3
65 and over	62.5	0.6	81.9	0.2	94.6	0.1	83.5	0.1	93.4	0.3
65–74	20.3	0.2	26.8	0.1	17.5	0.1	18.2	0.1	11.0	0.3
75–84	25.9	0.4	29.9	0.1	29.3	0.1	26.7	0.1	30.3	0.5
85 and over	16.3	0.3	25.2	0.2	47.8	0.2	38.6	0.2	52.1	0.7
Sex					Percent distribution					
Men	41.8	0.2	39.1	0.1	41.3	0.1	35.4	0.1	29.4	0.3
Women	58.2	0.2	60.9	0.1	58.7	0.1	64.6	0.1	70.6	0.3
Race and ethnicity										
Hispanic	22.7	0.5	7.4	0.2	5.5	0.4	5.4	0.1	3.1	0.2
Non-Hispanic white	42.0	0.6	76.1	0.3	83.6	0.5	75.1	0.3	81.4	0.8
Non-Hispanic black	15.4	0.3	12.9	0.2	8.2	0.2	14.3	0.2	4.1	0.2
Other[3]	18.1	0.6	3.7	0.1	2.7	0.1	5.1	0.1	3.7	0.3
Diagnosis[4]					Percent					
Alzheimer disease or other dementias	30.9	0.5	32.3	0.2	44.5	0.3	47.8	0.1	41.9	0.7
Arthritis	37.9	0.7	59.6	0.2	28.7	0.2	26.2	0.1	42.4	0.8
Asthma	8.3	0.2	23.7	0.1	8.4	0.1	---	---	6.8	0.2
Chronic kidney disease	7.2	0.2	46.9	0.1	35.9	0.2	---	---	8.3	0.3
COPD	10.0	0.3	31.9	0.2	20.7	0.2	---	---	14.0	0.4
Depression	28.2	0.5	39.4	0.1	23.4	0.2	46.3	0.1	30.9	0.6
Diabetes	31.4	0.4	45.1	0.2	27.0	0.2	32.0	0.1	18.1	0.3
Disease[5]	27.1	0.5	55.0	0.2	38.7	0.3	38.1	0.1	34.3	0.6
High blood pressure or hypertension	50.3	0.6	88.9	0.1	51.0	0.3	71.5	0.1	51.2	0.7
Osteoporosis	21.2	0.6	15.3	0.1	7.2	0.1	12.3	0.1	23.7	0.6
Need assistance in physical functioning										
Eating	23.2	0.5	61.2	0.4	---	---	59.9	0.3	19.2	0.5
Bathing	38.6	0.7	97.2	0.1	---	---	96.7	0.1	63.6	0.8
Dressing	36.0	0.6	92.0	0.2	---	---	92.7	0.1	48.2	0.7
Toileting	33.5	0.6	81.1	0.4	---	---	89.3	0.1	40.0	0.7
Walking or locomotion	45.8	0.6	95.4	0.1	---	---	92.0	0.1	56.5	0.8
Transferring in and out of a chair or bed	28.5	0.6	91.3	0.2	---	---	86.8	0.1	29.2	0.7

See footnotes at end of table.

Table VIII. Long-term care services users, by selected characteristics and sector: United States, 2015–2016—Con.

Characteristic[1]	Adult day services center	Standard error	Home health agency	Standard error	Hospice	Standard error	Nursing home	Standard error	Residential care community	Standard error
					Percent					
Medicaid as payer source	65.8	0.7	9.5	0.3	---	---	61.8	0.2	16.5	0.6
Adverse event										
Overnight hospital stay[6]	4.4	0.1	15.7	0.1	---	---	14.4	0.0	8.3	0.2
Emergency department visit	7.2	0.1	15.3	0.1	---	---	---	---	14.2	0.3
Fall	7.8	0.4	---	---	---	---	16.1	0.1	21.5	0.7

- - - Data not available.
0.0 Quantity more than zero but less than 0.05.
[1]All cases with missing data were removed from the denominator when calculating percentages. For variables that had missing data for more than 10% of all cases, the percentage missing is reported in a footnote.
[2]Estimates are rounded as whole numbers to the nearest hundred. The estimated number of adult day services center participants represents current participants in 2016. The estimated number of home health patients represents patients who ended care in 2015 (i.e., discharges). The estimated number of hospice patients represents patients who received care at any time in 2015. The estimated number of nursing home residents represents current residents in 2016. The estimated number of residential care community residents represents current residents in 2016.
[3]For adult day services centers and residential care communities, includes non-Hispanic American Indian or Alaska Native, non-Hispanic Asian, non-Hispanic Native Hawaiian or Other Pacific Islander, non-Hispanic of two or more races, and unknown race and ethnicity.
[4]For adult day services centers, the percentage of missing data was 11.2% for Alzheimer disease, 14.3% for arthritis, 14.8% for asthma, 15.0% for chronic kidney disease, 15.3% for chronic obstructive pulmonary disease (COPD), 13.1% for depression, 11.8% for diabetes, 14.1% for heart disease, 13.1% for hypertension, and 15.8% for osteoporosis. For residential care communities, the percentage of missing was 14.1% for arthritis, 15.6% for asthma, 15.3% for chronic kidney disease, 13.6% for COPD, 12.6% for depression, 12.5% for diabetes, 13.0% for heart disease, 11.5% for hypertension, and 15.0% for osteoporosis.
[5]For adult day services center participants and residential care community residents, heart disease includes congestive heart failure, coronary or ischemic heart disease, heart attack, and stroke. For home health and hospice patients, heart disease refers to ischemic heart disease. For nursing home residents, heart disease refers to coronary artery disease, congestive heart failure, and stroke.
[6]For nursing home residents, overnight hospital stay is defined as any resident in the 2014 Minimum Data Set Active Resident Episode Table 3rd quarter file having any inpatient hospital stay as determined in the 2014 Medicare Provider Analysis and Review data file.

NOTES: Percent distributions may not add to 100 because of rounding. Percentages are based on unrounded estimates.

SOURCE: NCHS, National Study of Long-Term Care Providers, 2015–2016.

Table IX. Nursing home residents, by selected characteristics and length of stay: United States, 2016

Characteristic	Short stay (less than 100 days)[1]	Standard error	Long stay (100 days or more)[1]	Standard error
		Number		
Users[2]	606,800	586	794,000	586
Age		Percent		
Under 65	18.6	0.1	14.9	0.0
65 and over	81.4	0.1	85.1	0.0
65–74	20.8	0.1	16.1	0.0
75–84	28.4	0.1	25.5	0.1
85 and over	32.2	0.1	43.5	0.1
Sex		Percent distribution		
Men	39.7	0.1	32.1	0.1
Women	60.3	0.1	67.9	0.1
Race and ethnicity				
Hispanic	5.4	0.0	5.4	0.0
Non-Hispanic white	74.6	0.1	75.6	0.1
Non-Hispanic black	14.0	0.0	14.6	0.0
Other	6.0	0.0	4.5	0.0
Diagnosis		Percent		
Alzheimer disease or other dementias	36.7	0.1	58.9	0.1
Arthritis	25.1	0.1	29.7	0.1
Depression	42.6	0.1	53.0	0.1
Diabetes	37.0	0.1	32.2	0.1
Heart disease[3]	35.8	0.1	38.8	0.1
High blood pressure or hypertension	76.8	0.1	75.8	0.1
Osteoporosis	9.8	0.0	15.1	0.0
Need assistance in physical functioning				
Eating	---	---	---	---
Bathing	---	---	---	---
Dressing	---	---	---	---
Toileting	---	---	---	---
Walking or locomotion	---	---	---	---
Transferring in and out of a chair or bed	---	---	---	---
Medicaid as payer source	---	---	---	---
Adverse event				
Overnight hospital stay[4]	23.8	0.1	8.7	0.0
Emergency department visit	---	---	---	---
Fall	13.5	0.1	19.1	0.0

0.0 Quantity more than zero but less than 0.05.
- - - Data not available.
[1]Average length of stay among all residents is 485 days; 43% of residents are short-stay and 57% are long-stay.
[2]Estimates are rounded as whole numbers to the nearest hundred. The estimated number of nursing home residents represents current residents in 2016.
[3]Heart disease refers to coronary artery disease, congestive heart failure, and stroke.
[4]Overnight hospital stay is defined as any resident in the 2014 Minimum Data Set Active Resident Episode Table 3rd quarter file having any inpatient hospital stay as determined in the 2014 Medicare Provider Analysis and Review data file.

NOTES: Percent distributions may not add to 100 because of rounding. Percentages are based on unrounded estimates.

SOURCE: NCHS, National Study of Long-Term Care Providers, 2015–2016.

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2	110 Volt	20 Amps
3	220 Volt	10 Amps

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Height	40"
Width	23"
Depth	36"
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Ozone Destruct Unit

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Height	15"

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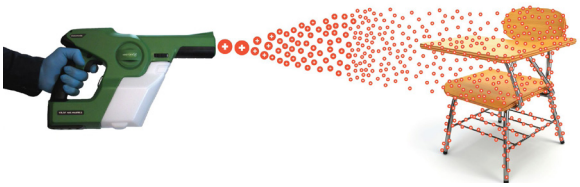

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- Vancomycin-resistant Enterococcus (VRE)
- Salmonella
- Listeria
- Bacillus spp.
- Mycobacterium terrae
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- Klebsiella pneumoniae
- Adenovirus PTG 3602
- Coronavirus, TGEV (ATCC VR-763)
- Fungi, Mold, Bed bugs, Lice, Fleas, and more...

REVISED Version 141109

DRAFT Clinical Evaluation Protocol for AsepticSure in an Acute Hospital

By Dick Zoutman, MD, FRCPC and Michael Shannon, MD, MSc, MA

Confidential and Privileged

Introduction

Surfaces in the hospital environment can easily become contaminated with disease-causing, or pathogenic, microorganisms. These microorganisms can come from patients, healthcare workers, visitors, or from external sources. In turn, pathogens that contaminate environmental surfaces can then be spread to patients through direct contact with the surface or indirectly, typically on the hands of healthcare workers, potentially leading to the development of healthcare-associated infections (HAIs).

The role of contaminated environmental surfaces in causing HAIs is unclear, largely because most HAIs are either caused by endogenous organisms (those that a patient carries on or in their body prior to infection) or transmitted from person to person. Human behavior, such as hand hygiene compliance, can influence whether or not an organism contaminating an environmental surface is transmitted to a patient. The proportion of HAIs attributed to environmental surfaces has been estimated at 20% (Weinstein, 1991), but the actual proportion is unknown and depends on the setting, patient population, pathogen, and type of HAI. At the hospital level, it is important to have a comprehensive infection prevention program that tracks HAIs and major nosocomial pathogens to assess for temporal or geographic patterns that might suggest an environment source of transmission. For example, a clustering of cases of *C. difficile* diarrhea by hospital ward might lead to enhanced environmental cleaning. Unfortunately, recent experience throughout the healthcare sector in all countries clearly demonstrate that conventional cleaning practices fall far short of stopping the spread of many pathogens and this deficiency constitutes, universally, a serious health risk for patients.

The purpose of this protocol is to evaluate a novel approach to hospital disinfection which based on recent experience in Canada offers an effective solution to the world wide and ever growing problem of hospital acquired infections.

Overview

There are four components to a clinical evaluation of AsepticSure in an Acute Hospital setting divided into two phases as follows:

Phase 1:

i. Feasibility and time motion analysis of AsepticSure in the clinical environment and cost comparison to standard manual cleaning methods;
ii. *In vivo* testing of microbial removal from actual in room surfaces with quantitative touch plates (RODAK plates).

Phase 2:

i. Clinical efficacy for reduction of selected HAI's in the healthcare environment.
ii. *In vivo* testing of microbial removal from actual in room surfaces with quantitative surface swabs;
iii. *In vitro* testing with discs in the treated patient rooms.

Study Design

Overall, a before-after design is contemplated to facilitate multi centre participation. Most hospitals that would participate would have historical data on numbers of cases of MRSA, VRE, C. difficile and Acinetobacter species, ESBL/CRE for many years prior to the study period. Having high quality data is essential to being a participating hospital.

A standard AsepticSure disinfection protocol will be used for all ICU isolation units in a Hospital selected by designated authorities within the MOH of the Kingdom of Saudi Arabia.

Phase 1 of the evaluation protocol will involve all ICU isolation rooms as well as ward rooms identified within the same hospital as being contaminated with bacterial pathogens. All rooms will undergo comprehensive pre and post microbiological testing as described herein (see below).

For the initial **phase 1** protocol as defined above the surface culturing will be of a simpler nature using touch plates (RODAK plates) with quantification of total viable vegetative bacterial count.

In the Phase 1 protocol each selected room will be terminally cleaned with the cleaner and disinfectant product(s) using the standard protocol of the study facility.

10-20 surfaces of each room will be cultured using touch contact plates (RODAK Plates) before and after the cleaning. The touch plates will be incubates at 37°C in room air over night and bacterial colonies counted. The mean count will be expressed as CFU/25 cm^2.

Touch contact plates (25 cm^2) to be used are from Remel (part of Thermo Fisher Scientific). Tryptic soy agar catalogue number R111083.

Phase 2 Protocol

Each room so selected will be randomly assigned to either an AsepticSure group (Treated) or a Control group. Each "Treated" room will undergo AsepticSure disinfection following the discharge or move of each patient and PRIOR to the admission of new patients. Each "Control" room will undergo standard room cleaning in accordance with the conduct of practice for the hospital.

The protocol will be in place for a period of 30 calendar days. During this period, financial and operational impact analyses will also be conducted to assess the cost-benefit of the AsepticSure intervention as well as the extent of ward disruption. The primary endpoint for this phase of the study will be the microbiological assessment of total viable bacteria counts (TVBC) before and after AsepticSure disinfection. In addition to the "within treatment" before and after comparisons, results for the "treated" rooms will be compared against similar before and after assessments for equivalent "control" rooms.

With respect to viral testing, eg MERS-CoV or any other virus, one must proceed with caution as such testing is far more complex in that there are no standardized methods to reliably test for these viruses on surfaces. Any attempt to include direct before and after viral measures in this protocol, therefore, will require more careful consideration at a later date. This being said however, AsepticSure has been recently been demonstrated to reliably achieve high level kill of both non-enveloped and enveloped viruses (Adenovirus and Coronavirus) in controlled laboratory settings using the exact protocol proven to be efficacious (>6 $\log_{10}$ kill) against all hospital based bacterial pathogens including spore formers such as C. difficile, and Bacillus subtilis. Accordingly, if bacteria and bacterial spores are shown to be killed to a high level using a standard AsepticSure disinfection protocol, direct proof of viral elimination in any given clinical space is not strictly necessary. Thus, if non pathogenic bacillus spores (>6 $\log_{10}$ concentrations) are

placed in each contaminated room prior to AsepticSure disinfection and all such spores preparations are found to be 100% killed, one can safely conclude that any viral contaminant present will also have been killed.

Phase 2 of the evaluation will assess the impact of AsepticSure disinfection on the incidence of Hospital Acquired Infections (HAI) within one or more selected hospitals in the Kingdom of Saudi Arabia. Options for design reflect considerations of sample size calculations and assumptions regarding the incidence of HAI within a hospital or hospital service. If average incidence is employed as a basis for sample size calculations, an appropriate number of patients required for a power of 80% will be chosen. If however, sample size calculations are based of the incidence of HAI for "contaminated rooms" only, the numbers may be reduced significantly with the overall duration likely reduced to 4 to 6 months (see statistical calculations below). Unfortunately, more precise numbers will be required from the MOH of the Kingdom of Saudi Arabia in order to complete such calculations with any degree of accuracy,

Phase 2 Protocol Statistical Considerations:

Sample Size

The number of cases to seek to have included in the study depends on the following factors;

1) Expected infection rate among control patients:
    a. ~13/1,000 admissions or 1.3% based upon current surveillance methods. Does vary considerably by facility however.
    b. although about 35% of rooms in isolation as any point in time according to Passaretti's paper in CID in Canadian hospitals is lower about 15-20% or so but is quite variable.

2) Minimum room disinfection efficacy which is desired to be detectable
    a. Passaretti in CID noted 61.3% reduction in ARO acquisition between cases in prior isolation rooms cleaned with HPV vs standard methods (10.6% reduced to 4.1%). Most of this was due to VRE reduction. 78% reduction in VRE acquisition (Stat sig), 67% reduction in MRSA (Not Sig), 33% reduction in MDR gram negs (Not Sig), 66% reduction in C. difficile (Not Sig).
    b. Our experience with AsepticSure is higher than this with no new

MRSA cases on an in patient unit one year after using AsepticSure for MRSA outbreak (Zoutman et al Infection Prevention & Control Canada (IPAC) National Scientific Meeting, Halifax NS, June 2014).

3) Level of statistical significance desired:
    a. alpha 5%

4) 4Level of power desired
    a. 80%

Unlike traditional hypothesis testing, where the working presumption is that the null hypothesis is true, for sample size (and power) calculations in an infectious disease prevention trial, the assumption is that the null hypothesis is NOT true and that a particular alternative hypothesis is true. The alternative hypothesis in this case depends directly on the magnitude of the effect being studied, ie the minimum room disinfection efficacy which is considered to be worth detecting. This will depend on a number of factors, the smaller the minimum room disinfection efficacy we wish to be able to detect, the larger the sample size required.

Room disinfection efficacy is defined as the proportion of the expected infections prevented by room disinfection. This is given by the equation:

$$Room\ Disinfection\ Efficacy = \frac{Pc - Pr}{Pc}$$

where

Pc = Proportion of patients in the control arm who become infected

Pr = Proportion of patients in the room disinfection arm who become infected

In terms of the specific hypotheses, these can be expressed as:

Null Hypothesis (H_0) - *no difference in infection rates between room disinfection and control arms, i.e. Room Disinfection Efficacy = 0*

Alternative Hypothesis (H_1) - *difference in infection rates between room disinfection and control arms, i.e. Room Disinfection Efficacy >0/=?*

The following equation details the numbers of patients which must be included in **EACH** of the room disinfection and control groups in order to fulfill the specifications/estimates given [**NOTE**: the underlying assumption is that ONE patient is observed for each disinfected and control room]:

$$n\,(each\ group) = \frac{\big(Pc * (1 - Pc) + Pr * (1 - Pr)\big) * (Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{(Pc - Pr)^2}$$

where

Pc = Proportion of patients in the control arm who become infected

Pr = Proportion of patients in the room disinfection arm who become infected

$Z_{1-\alpha/2}$ = value of standard normal distribution for a significance level of α

$Z_{1-\beta}$ = value of standard normal distribution for a power level of 1-β

In the situation where α=0.05 and β=0.20 we can illustrate the calculated values of n for a range of expected control infection proportions and minimum detectable room disinfection efficacies.

This is a relatively simplistic set of calculations which make a number of simplifying assumptions:

- One patient = one room
- All patients drawn from one hospital and/or underlying infection rate in control arms will be the same across participating hospitals
- Analysis is based at patient-level, i.e. patients become infected or not as a dichotomous outcome rather than a time-to-event (/survival) analysis.

Therefore for:

$\alpha = 0.05$

$\beta = 0.80$

Incidence of infection in control group = 0.02 (2%)

Predicted efficacy of AsepticSure to prevent infection = 0.60 (highly conservative estimate)

Sample size is 1,500 in AsepticSure treatment arm and the same in the control group.

Thus 6-7 treatments per day during week days. Thus need several busy wards likely from multiple hospitals. However each separate hospital must have nearly identical pre-AsepticSure data collection and room cleaning procedures.

If there are ~35 isolated patients per month on a busy 25 bed in patient unit yielding about 100 terminal cleans per month the study would take up to 18 months to achieve statistical significance. THIS STATISTIC NEEDS TO BE VERIFIED BUT IS NOT LIKELY VERY FAR OFF.

If predicted efficacy of AsepticSure to prevent infection in patients is 0.7 then sample size is reduced to 1,024 cases needed. If efficacy is 0.5 then sample size is 2,315.

Statistical Considerations For Microbiology Measurements as End Points

The level of hospital room contamination as measured by surface cultures for Clostridium difficile is variable. Rates of detection of C. difficile spores on surfaces range between 7 and 57% in recent studies of patient rooms of persons with C. difficile infection.

If one assumes the C. difficile contamination rate is a conservative value of 7% and the efficacy of AsepticSure is only 80% to remove the contamination, a highly conservative assumption, then the number of room treatments needed to be studied is approximately 200 in treatment arm and 200 in the control arm (ie 400 rooms). If we assume the efficacy of AsepticSure is 100% then 110 room treatments are needed in each arm of the study approximately. These calculations assume an alpha of 0.05 and a power of 80%.

Outcome measurements for the Phase 2 Protocol:

Patients with VRE/MRA/CRE and/or Acinetobacter colonization:
- At start of period
- At admission to MICU

MICU admission rate for patients with VRE/MRSA/CRE and/or Acinetobacter colonization, admissions per day

Patients with VRE/MRSA/CRE and/or Acinetobacter acquisition after admission to MICU

No. of patient-days at risk for VRE/MRSA/CRE and/or Acinetobacter

Rate of VRE/MRSA/CRE and/or Acinetobacter acquisition, acquisitions per 1000 patient-days

Days until VRE/MRSA/CRE and/or Acinetobacter acquisition
- Mean ±SD
- Median

Daily colonization pressure, mean value ± SD

The focus is on the terminal cleaning (aka “discharge isolation cleaning”) of rooms that were occupied by a patient with one or more of the following HAIs: MRSA, VRE, ESBL/CRE/Acinetobacter or C. difficile.

Comparison of time, paid hours, reagents/supplies to terminally clean one isolation room.

Component	**Manual Clean Protocol**	**AsepticSure Protocol**	**Comments**
Cycle time	90 mins	60 min-90 min	90 min for C difficile
HR Costs	$45	$15-22.50	@$30/hr. Cleaner does “hotel clean” and sets up AsepticSure then moves to next room to be cleaned while AsepticSure runs
Supplies and materials	Sporocidal cleaner 300 ml =$2.60 + Microfiber cloths + gloves + respirator & goggles + gown Total=$5.00	Quat cleaner 300 ml = $0.10 +std cloths + gloves +gown Total=$1.00 + AsepticSure ?????????	
Level of Achieved Disinfection	1-2 log (Low level)	6-7 log (High level)	
Opportunity for bacterial regrowth	6 hours	0	
Patient Safety	+	++++	
Annualized cleaning costs based on 6-7 terminal cleans per day on average (10% of	$140,000 (very conservative assumptions)	$44,736 + costs of AsepticSure	Does not take into account cost savings from avoiding infection or outbreaks that cost in the millions

cases in isolation with 1 discharge and 2 transfers per admission)			per year.

***In vivo* testing of microbial removal from actual in room surfaces with quantitative surface swabs**

In order to evaluate the impact of AsepticSure vs standard cleaning on pathogenic microbiome of the patient rooms would plan to do swabs of the isolation rooms before cleaning after patient is discharged in all of the rooms as a base line for the first 20-30 discharges prior to implementing AsepticSure as this technique will likely leave the rooms with a very low residual microbiome for many weeks regardless of who occupies the room. Particularly want to culture the same rooms repeatedly after several patients have been isolated in the rooms to evaluate the stability of the room microbiome. Do cultures before cleaning and after cleaning to measure effectiveness of standard manual cleaning.

Upon commencing the use of AsepticSure would swab the room before cleaned and after AsepticSure protocol completed.

This swabbing does not need to be done before and after each clean. A 10% sample drawn at random of 150 room treatments is adequate (< 1 room per day).

Swabbing Method for Phase 2 of the Protocol
We will use Flocked swabs by Copan.

The tip of a swab is immersed into Letheen broth, and then pressed against the wall of the tube to remove excess solution. The swab is rotated and rubbed in a zigzag pattern over the whole surface and this process was repeated at an angle of 90° to the first rub. The swab is then put in a tube with 1 mL Letheen broth, pressed against the wall of the tube and shaken to dislodge bacteria. Thereafter an initially dry swab which is moistened during sampling by the solution that remains on the surface after completion of the first swab. The second swab is gently applied to the surface to absorb as much solution as possible, and then

put into the same tube with sampling solution as the first swab. The swabs are left in the tube for 5 min and then, after vortexing the tube, discarded.

Serial 10-fold dilutions of the sampling solution is prepared in PBS, and 100 mL from each dilution was inoculated on to blood agar plates. After incubation at 36°C for 24 h the numbers of cfu on each plate were counted. Counts in the range 15-300 cfu will be used for computation.
If suitable counts were obtained from two adjacent dilution steps, the weighted arithmetic mean of both was calculated.

Choices of neutralizing buffer or media:

1. Neutralizing Buffer (Solar Biologicals Cat # BS-10NB) Neutralizing buffer assists in the recovery of microorganisms in samples taken from surfaces exposed to sanitizing agents. Neutralizing buffer has the ability to inactivate the bactericidal and bacteriostatic effects of sanitizing agents containing chlorine, iodine, and quaternary ammonium compounds (Difco Manual).

2. Dey-Engley (DE) Neutralizing Broth (Solar Biologicals Cat # BS-10DE) DE Neutralizing Broth assists in the recovery of microorganisms in samples taken from surfaces exposed to sanitizing agents. It has the ability to neutralize the bactericidal and bacteriostatic effects of sanitizing agents such as chlorine, quaternary ammonium compounds, iodine, phenolics, mercurials, formaldehyde, and glutaraldehyde (Difco Manual). The medium also contains nutritive agents that aid in the recovery and promote the growth of microorganisms.

3. Buffered Peptone Water (BPW) (Solar Biologicals Cat # BS-10BPW) Buffered Peptone Water is a useful pre-enrichment medium in the isolation of Salmonella from foods. During many food processes, Salmonella and other species can suffer sublethal injury from processes involving heat, desiccation, preservatives, pH changes or osmotic pressure shifts. The use of a pre-enrichment media such as BPW before selective media has been shown to facilitate the resuscitation of injured cells and provides superior results compared to a direct selection method[2].

4. Butterfield's Phosphate Buffer (BPB) (Solar Biologicals Cat # BS-10BPB) Butterfield's Phosphate Buffered Water is the buffer of choice recommended by the United States Federal Department of Agriculture for use in Mega-reg/HACCP programs, as well as by the Federal Drug Administration and Bacteriological Analytical Manual as a general laboratory diluent.

5. Letheen Broth (LB) (Cat # BS-10LB) Letheen broth is a highly nutritional medium that contains lecithin and Tween 80. It is therefore used for testing efficacy of sanitizing protocols as lecithin neutralizes quaternary ammonium compounds while Tween 80 neutralizes phenols, hexachlorophene, and formalin.

Summary Table of Culture Methods

Pathogen	Sampling Method	Enrichment Broth	Plate	Identification
MRSA	Two flocked swabs	mannitol salt with 6 mg/l oxacillin	MRSA Chromogenic media	as per Chromogenic media
VRE	Two flocked swabs	Enterococcosel broth	Enterococcosel agar or VRE Chromogenic media	as per Chromogenic media
C. difficile	Two flocked swabs	CCF broth containing 0.1% taurocholic acid x 48 hr	cycloserine-cefoxitin-fructose agar containing 0.1% taurocholic acid (CCFA-TA)	Pro Disc by Key Scientific
Coliforms/ Pseudomonas	Two flocked swabs	TSB with 1 mg/l ceftazidime or cefotaxime Or for optimal sensitivity of susceptible strains as well use simply nutrient broth and plate to Chromagar	ESBL Chromogenic media	as per Chromogenic media
Acinteobacter species	Two flocked	Nutrient agar	Acinetobacter Chromogenic	as per Chromogenic

	swabs		agar	media

In vitro testing with discs in the treated patient rooms

In the rooms where we do microbiology sampling we would also do testing for sporocidal killing with B. subtilis spores on steel discs in 4 locations in the room in duplicate (8 discs). Analysis is per Medizone standard methods. This also serves as a quality control of the AsepticSure system itself.

Clinical efficacy for reduction of selected HAI's in the healthcare environment

In addition to the statistical considerations above other considerations for a clinical protocol such as this is:

1. requirement for human ethics board approvals. May not be needed if the view taken is that a licensed method (in Canada, Australia and New Zealand) is used to clean the hospitals property after the patient vacates the room.
2. It would be best to increase microbial surveillance of patients during the study period. This improves pick up of cases of MRSA, VRE, Acinetobacter, and ESBL/CRE. Weekly in house swabs and swabs upon discharge would be ideal. These incur some costs and do require Human Ethics Board approvals and patient consent.
3. Time frame for application of the AsepticSure system in the selected ICU or other units, Monday to Friday 8 am to 4 pm or 24/7?
4. Patients in rooms next to AsepticSure treated rooms may need to be notified and consented. This has never been a problem so far.