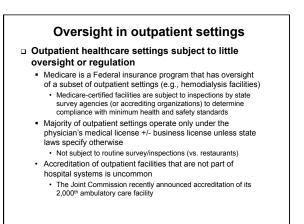
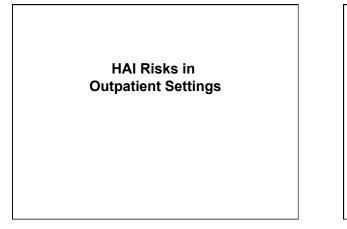


Outpatient settings

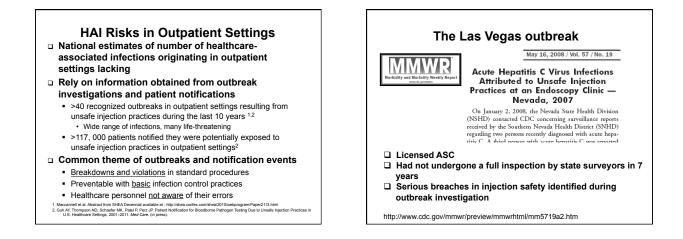
Provide similar services as hospitals

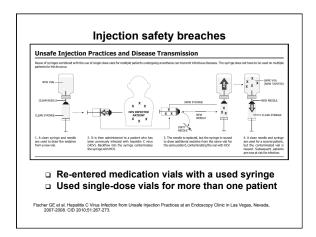
- Surgery, injections, infusions (chemotherapy, antimicrobials, contrast)
- Increasingly vulnerable patient populations
 - Age extremes
 - Immunocompromised
- Expansion of services without proportionally expanded infection control infrastructure and oversight

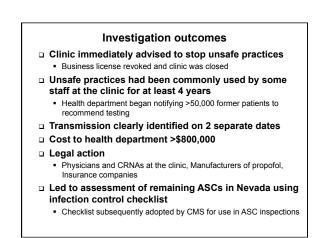




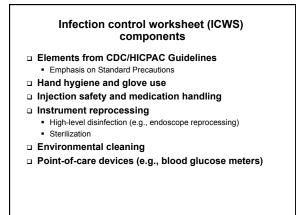
The following table occurring in a varie ambulatory surgica health fairs. This is consequences that infection control. Si thousands of patie licensing boards fo	ety of outpatien of centers, pain ot an exhaus can result wh uch consequen ents of possible	t settings includi remediation clini stive list but it se en healthcare pe ices include: infe exposure to blo	ng primary care cli cs, imaging facilitie rves as a reminder rsonnel fail to follo ction transmission odborne pathoger	nics, pediatric of s, oncology clin of the serious w the basic pr to patients, no s, referral of p	offices, nics, and inciples of vification of
These events are p are urged to review	w the <u>Guide to .</u>	Infection Preventi	on for Outpatient S		
Expectations for Sai policies and procee are in accordance	dures in their fa	acility as well as t		Checklist to as practices to as	ssess the
policies and proced	dures in their fa	acility as well as t	heir own personal	Checklist to as practices to as	Infection Breaches
policies and proced are in accordance	dures in their fa with evidence-l Year	acility as well as t based guidelines	heir own personal and to prevent pa	Checklist to as practices to a tient harm. Patient notification performed (# notified) Yes (101)	ssess the ssure they Infection Control Breaches





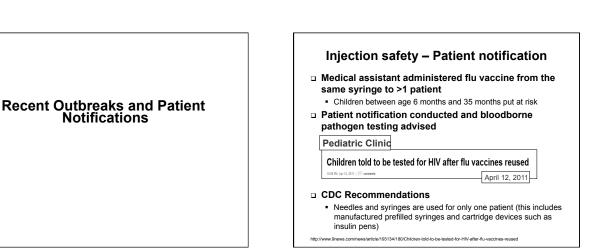


Inspection of CMS-ce	ertified ASCs
 Prior to 2009, inspections did n observations of procedures or assessment of infection contro After 2009 	standardized
 Case-tracer methodology Follow at least 1 patient throughout t 	
while observing practices (e.g., docu Use of standardized checklist	mentation, mection control)
 Systematic assessment of infection provide the systematic assessment of the systematic ass	
 www.omc.gov/monuals/downloads/s 	om107_exhibit_351.pdf
 www.cms.gov/manuals/downloads/s 	
Exhibit 351 Exhibit 351 Intellativy Strayford Center INFECTION CONTROL SURVEYORY (Rev. 68 Issued: 11-24-10, Effective 11-24-10, Intellation)	
Exhibit 351 Ambilatory Storgical Center INFECTION CONTROL SURVEYOR V	other infusates) other infusates) dminister medications and perform res anesthetists, nurses).
Exhibit 351 INFECTION CONTROL 0000 (Rev. of Standt 1124-10, Fung (Rev. of Standt 1124-10,	other infusates) dminister medications and perform
Eshibit 351 mainteney Surgerd Source FUTECTION Control (1997) (Rev. 48) Instead 11-32-10, Effective 11-32-10, Effective 11-32-10, Effective 11-32-	other infusates) dminister medications and perform cse anesthetists, nurses). Was Practice Manner of

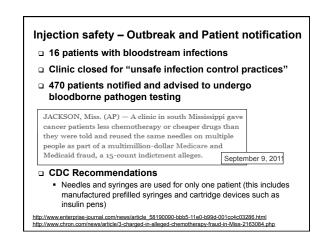


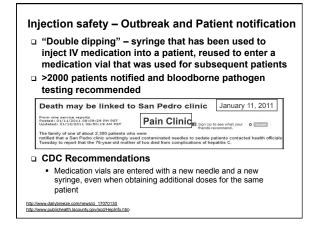
Melissa K. Schaefer, MD Michael Jhung, MD, MPH Marilyn Dahl, MA Sarah Schillie, MD, MPH, MBA	Context More than 5000 ambulatory surgical centers (ASCs) in the United State participate in the Medicare program. Little is known about infection control practice in ASCs. The Centers for Medicare & Medical Bervices (CMS) piloted an infection control audit tool in a sample of ASC inspections to assess facility adherence to rec ommended practices.	
Crystal Simpson, MD, MHS Eloisa Llata, MD, MPH Ruth Link-Gelles. MPH	Objective To describe infection control practices in a sample of ASCs. Design, Setting, and Participants All State Survey Agencies were invited to participate. Source states would report. Sweets whete the based on generativity disper-	
Priti Patel, MD, MPH Elizabeth Bolyard, RN, Lynne Sehulster, PhD Arjun Srinivasan, MD	of ASCs had at least 1 lapse in infection control had lapses identified in 3 or more of the 5 iories.	
Joseph F. Perz, BrHH, Ma Construction of the second second second results, health care delivery in the further start SWEAR De- ticular has been an area of immense growth. Ambulatory surgical centers (ASCa) are defined by the Contents for Medicare & Medical Services (CMS) as facilities that overate evolusively to non-	Ging of blood plucose montoming equipment. Main Outcome Measures Proportion of Skillstis with lapses in each infection con- trol category. Results Overall, 46 of 64 ACSC (67.6%) 59%, confidence interval [CI], 55.9%, 77.9%) had a least 1 lapse in infection control, 12 of 64 ACSC (77.6%, 59% (2).9%). 23.1%) had lapses in Healthen 13 or more and the 5 interction control categories. Com- mon lapse included using single-dose medication via between thema 1 patient (16). regarding reprosecting of equipment (1976, 28.4%, 59% (2). A4%-59.6%). JAAK-59.0%). JAAK-50.0%). JA	

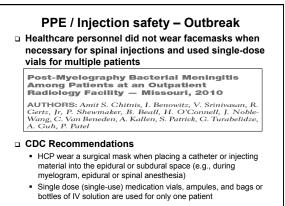
Overall results of 3-state pilot infection control assessments				
Infection Control Category Assessed	Number of Facilities with Lapses Identified			
Hand Hygiene and Use of Gloves	12/62	(19%)		
Injection Safety and Medication Handling	19/67	(28%)		
Equipment Reprocessing	19/67	(28%)		
Environmental Cleaning	12/64	(19%)		
Handling of Blood Glucose Monitoring Equipment	25/54	(46%)		
Schaefer et al. JAMA 2010	;303:2273-2279			



Injection safety – Patient notification Diabetes educator used insulin demonstration pens for >1 patient 2,345 patients notified and recommended to undergo bloodborne pathogen testing Outpatient Clinic Thousands of Wisconsin clinic patients possibly exposed to HIV (August 30, 2011) CDC Recommendations Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)



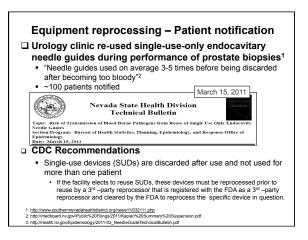




tp://www.cdc.gov/eis/downloads/2011.EIS.Conference.pdf

Injection safety recommendations

- Use aseptic technique when preparing and administering medications
- Never administer medications from the same syringe to multiple patients
- Do not reuse a syringe to enter a medication vial or solution
- Do not administer medications from a single-dose vials or intravenous solution bags to more than one patient
- □ Limit the use of multi-dose vials and dedicate them to a single patient whenever possible
- Wear a surgical mask for when placing a catheter or injecting material into the epidural or subdural space http://www.cdc.gov/hicpac/pdf/isolation/lsolation2007.pdf



How often are lapses in reprocessing occurring?

- January 1, 2007-May 11, 2010 FDA identified¹:
 - 80 reports of inadequate reprocessing filed with the Agency
 - 28 reports of infection that may have occurred from inadequate reprocessing
- ASC 3-state pilot²
 - 28% with lapse in reprocessing of medical equipment
 - 5.8% inappropriately reprocessed single-use devices
 6.7% failed to adequately pre-clean instruments
 - 6.7% failed to adequately pre-clean instruments
 16.7% did not prepare, test, or replace high-level disinfectant
 - appropriately
- December 2002-December 2006 17 healthcare facilities requested assistance from California Dept Health Services regarding inadequately reprocessed endoscopes³

>9000 patients notified of potential exposure to bloodborne pathogens

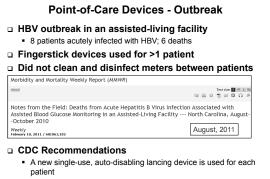
 Stelement of Anthony D. Watson to the House Committee on Veteraris Affairs available at: http://veterans.house.gov/prepared-state prepared statement-anthony - watson-bars m-thad-affaired-on/kinion aneatiesiology
 Schaefer et al. Infection Control Assessment of Ambulatory Surgical Centers. JAMA 2010;33(22):2273-2279.
 Rosenberg et al. Indexplant Reprocessing of Endoscopes: The California Experience.2002.2007. ALIC 2007;55(5):E85-86.

Equipment reprocessing recommendations

- Facilities should ensure that reusable medical equipment (e.g., point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient
- Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer's instructions
 - If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use
 - Not all equipment is reusable (it must be FDA-approved as such)
 In ASC pilot, 6% of facilities inappropriately reprocessed/reused single-use devices

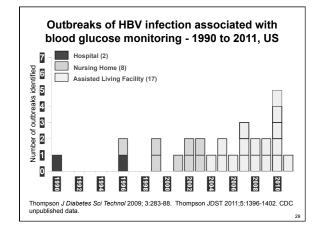
Equipment reprocessing recommendations Point-of-Care Assign responsibilities for reprocessing of medical equipment to HCP with appropriate training HBV outbreak in an as Maintain copies of the manufacturer's instructions of locations where reprocessing of equipment in use at the facility; post instructions at locations where reprocessing is performed Fingerstick devices us Observe procedures to document competencies of HCP Morbidity and Mortality Weekly Report (MMM)

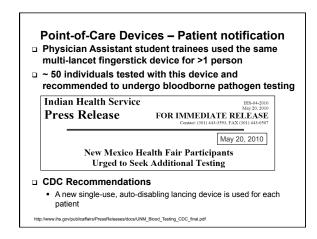
- responsible for equipment reprocessing upon assignment of those duties, whenever new equipment is introduced, and on an ongoing periodic basis (e.g., quarterly)
- Assure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment



The glucose meter is cleaned and disinfected after every use

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6006a5.htm





Point-of-Care Devices

3-state pilot:

- 46% of ASCs at some type of lapse in handling of blood glucose monitoring equipment
 - 32% (17/53) of ASCs failed to clean and disinfect the blood glucose meter between patients
 - 21% (11/53) used the same fingerstick device for >1 patient

Point-of-Care Device Recommendations New single-use, auto-disabling lancing device is used for each patient Lancet holder devices are not suitable for multi-patient use If used for >1 patient, the point-of-care testing meter is cleaned and disinfected after every use according to manufacturer's instructions If the manufacturer does not provide instructions for cleaning and disinfections, then the testing meter should not be used for >1 patient

Infection prevention resources for outpatient surgical settings

http://www.cdc.gov/HAI/settings/outpatient/ outpatient-settings.html Outpatient Guide Outpatient Checklist · List of outbreaks and patient notification events Centers for Disease Control and Prevention Az Index A B C D E E G H I J K L H N D E D R S I U Y W X Healthcare-associated Infections (HAIs) Healthcare-associated Health Outpatient Settings The transition of healthcare delive ambulatory care settings, along w notification events, have demonst Activities elines and mmendations Top CDC Recommendations to Prevent MATE Infection Prevention Guide Guide to Infection Prevention for use Expectations for Safe Care This summary guide of infection prev-Long-Ten Settings Infection Prevention Checklist The Infection Prevention Checklist for Outpatient is a companion to the Guide to Infection Prevention for Safe Care. The checklist should be used for tw Outpatient Car Outpatient Car Checklist

Outpatient Settings

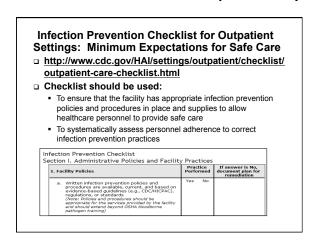
CDC Guide to Infection Prevention in Outpatient Settings

- These recommendations are not new
 Summary of existing evidence-based guidelines produced by the CDC and the Healthcare Infection Control Practices
 - Advisory Committee
 Based primarily upon elements of Standard Precautions
 - Infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting where healthcare is delivered
 - Users should consult the full guidelines for more detailed information and recommendations concerning specialized infection prevention issues (e.g., multi-drug resistant organisms)
 - Does not replace existing detailed guidance for hemodialysis centers or dental practices
- Represent minimum infection prevention expectations for safe care in ambulatory care settings http://www.cdc.gov/HAl/settings/outpatient/outpatient-care-guidelines.html

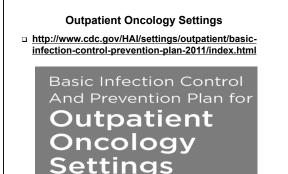
CDC Guide to Infection Prevention in Outpatient Settings

Administrative Measures

- Assure at least one individual with training in infection prevention is employed by or regularly available to the facility
- Educate and Train Healthcare Personnel
- Monitor and Report Healthcare-associated Infections
- Adhere to Standard Precautions
 - Hand Hygiene
 - Personal Protective Equipment
 - Injection Safety
 - Environmental Cleaning
 - Medical Equipment
 - Respiratory Hygiene/Cough Etiquette



<u>http://www.cms.gov/manuals/downloads/</u> <u>som107_exhibit_351.pdf</u> I. Injection Practices (injectable medications, saline, other infusates)					
Observations are to be made of staff who prepare ar injections (e.g., anesthesiologists, certified registered	nd administer medication		perform		
Practices to be Assessed	Was Practice Perforn		Manner of Confirmation		
	O Yes	0	Observation		
A. Needles are used for only one patient	O No	0	Interview		
	O N/A	0	Both		
			Observation		
	O Yes	0	Observation		
B. Syringes are used for only one patient	O Yes O No	· ·			



Hemodialysis Facilities

- http://www.cdc.gov/dialysis/collaborative/toolresources/index.html
- Audit tools and protocols for prevention of bloodstream infections

CDC Evidence-based Guidelines

http://www.cdc.gov/HAI/prevent/prevent_pubs.html

□ These include the following:

- Guideline for Disinfection and Sterilization
- Guidelines for Environmental Infection Control
- Guidelines for Hand Hygiene
- Guideline for Isolation Precautions
 - Standard Precautions
 - Injection Safety

Injection Safety Resources

- http://www.cdc.gov/injectionsafety/
 - Guidelines
 - Links to freely accessible publications
 - FAQs
 - Medscape video Free CME
- http://www.oneandonlycampaign.org/
- Injection safety campaign led by CDC
 - Injection safety training video for healthcare personnel

Point-of-Care Device resources

- <u>http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html</u>
 - Infection prevention recommendations
 - Clinical alerts
 - Fingerstick devices
 - Insulin pens
 - FAQs including
 - "How can Hepatitis B virus be transmitted through the meter?"
 "What products are acceptable for cleaning and disinfection of blood glucose meters?"

HHS Action Plan for ASCs

- <u>http://www.hhs.gov/ash/initiatives/hai/</u> tier2_ambulatory.html
 Summarizes HAI prevention issues specific to ASCs and
 - presents key actions needed to assure safe care in these settings
- http://www.hhs.gov/ash/initiatives/hai/resources/ index.html
 - Infection prevention training for ASCs Free CME

Summary

 Significant portion of healthcare in the United States provided in outpatient settings

- Variable oversight
- Outbreaks and patient notification events continue to identify infection prevention concerns/ opportunities in outpatient settings
 - · Highlight lapses in basic infection control
- Multiple ongoing activities and resources available to facilities



