Santa Barbara County
PUBLIC Health
DEPARTMENT

Disease Control and Prevention

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Inspection Report of Dr. Allen Thomashefsky's Medical Practice

Inspection #1 (Announced)

Performed by:

Paige Batson, RN, PHN

Jaclyn Hagon, RN, PHN

Date: February 23, 2015

A site visit to Dr. Allen Thomashefsky's practice located at 2320 Bath Street, Santa Barbara, California was conducted. The purpose of the visit was to assess infection control practices as part of a recent Acute Hepatitis C investigation. Dr. Thomashefsky informed the Santa Barbara County Public Health Department (PHD) that the only procedures conducted at this practice location were those specifically listed on the website at www.ritdoc.net. A review of the website showed the practice offered medical procedures, including among others, Prolotherapy, Platelet Rich Plasma Therapy (PRP), and Autologous Adipose-Derived Stem Cell Therapy (ADSCT).

The office was composed of:

1) Front area reception desk and waiting area
2) Patient exam room (Room #1)
3) Centrifuge room (Room #2)
4) Kitchen
5) Restroom at end of hall

The office staff was composed of:

1) Dr. Thomashefsky ("physician"), who indicated he was the only person who performed medical procedures in the office.
2) A female, who identified herself as the receptionist and clarified, she had no role in medical procedures other than cleaning the patient exam room. The receptionist was asked a second time if she ever participated in medical procedures and she responded she did not and was the receptionist.

Infection control breaches observed

1) Policies and Procedures
   a) Lack of written infection prevention policies or procedures:
      i) Lack of trained infection preventionist employed by or regularly available to the facility
      ii) Lack of written protocols for managing/ preventing job-related exposures in healthcare personnel
2) Standard Precautions
   a) Supplies necessary for adherence to Standard Precautions were not readily available:
      i) Gloves were not observed in Room #2
      ii) Gloves were not observed in the kitchen
      iii) Box of gloves in Room #1 was in the back of the cupboard, behind other supplies
3) Exposure Events
   a) The facility did not maintain a log of needle sticks, sharps injuries, and other exposure events
4) Clean/ Dirty Area Designations
   a) The following work areas did not have a designation of a clean/ dirty area:
      i) Countertop in Room #1 where physician prepared solutions and materials for patient injections;
      ii) Countertop next to centrifuge in Room #2 where blood and adipose were mixed for Prolotherapy.
   b) The following items were observed to be placed in these areas, with co-mingling of clean/ dirty items:
      i) Multi-dose vials
      ii) Clean syringes and needles
      iii) Dirty syringes and needles
      iv) Clean 4x4 cotton swabs
      v) Dirty 4x4 cotton swabs
   c) The physician was observed handling clean and dirty items interchangeably in these areas.
5) Hand Hygiene
   a) Lack of a sink for hand washing in patient care area (Room #1):
      i) Physician would have to open door, leave exam room, wash hands in kitchen, and return to exam room.
6) Injection Safety
   a) Injections were not prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment:
      i) Centrifuge room: lack of clean/ dirty area, lack of gloves
      ii) Kitchen area next to sink: lack of clean/ dirty area, lack of gloves
      iii) Exam room: lack of clean/ dirty area
   b) The physician was observed re-entering multi-dose vials with the same syringe used to inject the patient. The needle, however, was changed.
      i) When questioned, the physician explained he did not know a new syringe had to be used. The physician further explained he did not believe blood got into the syringe. His response continued with the explanation that he just changed the needle and that was the way he had always done it. When questioned,

the physician explained his regular practice is to re-use syringes between injecting a patient and re-entering multi-dose vials.

c) It was observed that the rubber septum on medication vials was not consistently disinfected with alcohol prior to piercing.
d) Single dose medication vials and an IV bag were observed to be partially full indicating potential use for multiple patients.
e) Multi-dose vials to be used for more than one patient were kept in the immediate patient treatment area (counter top in exam room) instead of a centralized medication area.
f) Failure to discard multi-dose vials
    i) The physician stated that the 100ml multi-dose vials of dextrose and lidocaine solutions were discarded every morning, on a daily basis. The inspector observed multiple opened and partially used vials in the kitchen refrigerator. The physician stated he did not know why the vials were there and thought that the receptionist may have refrigerated them because she sometimes assisted with cleaning the exam room.
g) There was not a log or record of refrigerator temperatures in the kitchen where medications were stored. It was not clear that this refrigerator was designated strictly for medication storage.

7) Environmental Cleaning
    a) Lack of written policies and procedures for routine cleaning and disinfection of environmental surfaces.
    b) The physician and the receptionist confirmed verbally that the receptionist lacked specific training on environmental cleaning; lack of competency validation at hire.
    c) Lack of a written policy or procedures for decontamination of spills of blood or other body fluids.
8) Reusable Medical Device (Centrifuge)
    a) Lack of written policy and procedure to ensure that reusable medical device (centrifuge) is cleaned appropriately on a specified time frame. Lack of records of this cleaning.
9) Labeling
    a) Undated multi-dose vials
        i) Undated multi-dose medication vials in the small kitchen refrigerator included dextrose, lidocaine, glucosamine, and B12.

Plan for Follow-Up

1) The physician was verbally informed at the end of the inspection that the practices below must be immediately corrected:
    a) Stop re-using syringes
    b) Designate clear clean/ dirty areas in Room #1, Room #2, and the kitchen
    c) Wear gloves and change gloves according to aseptic technique
    d) Wash hands between every patient
    e) Label all multi-dose vials with date
    f) Stop using single-dose vials for multi-dose purposes
    g) Maintain a written log of needle sticks and exposure events
    h) Establish Infection Preventionist services to conduct an initial review of clinical practices, develop infection control policies, and infection control training.

The physician was also informed through follow-up phone calls and emails that the above items needed to be corrected immediately.

2) At the end of the inspection, the physician was verbally informed that Public Health would follow-up in approximately two weeks to ensure that the above items were immediately corrected and to also ensure that he had started writing a plan for improvement.
3) In multiple follow-up phone conversations by Paige Batson and Jaclyn Hagon with the receptionist, she repeated each time that she did not participate in medical procedures.
4) In a follow-up phone conversation the physician stated that he does not currently have, nor has ever had, a partner in his medical practice.
    a) A former patient called and reported Dr. Kochan was Dr. Thomashefsky's former partner.
    b) Dr. Dean spoke with Dr. Kochan over the telephone. Dr. Kochan explained that he shared office space and equipment with Dr. Thomashefsky.
    c) Dr. Kochan stated that the receptionist assisted Dr. Thomashefsky with procedures.
    d) According to Dr. Kochan, he (Dr. Kochan) vacated the clinic in December 2014.

Inspection #2 (Unannounced)

Performed by:

Charity Dean, MD, MPH, Health Officer

Paige Batson RN, PHN

Date: March 18, 2015

A site visit to Dr. Allen Thomashefsky's practice located at 2320 Bath Street, Santa Barbara, California was conducted. The purpose of the visit was to ensure that the physician corrected the practices identified in Inspection #1 and had a plan for improvement in place to institute an infection control policy. This inspection was unannounced. Upon arrival, Dr. Thomashefsky agreed to let the inspectors observe a procedure and ask additional questions of the receptionist.

Observations During Prolotherapy Procedure

The physician asked the patient if oral pain medications had been taken prior to the procedure. The patient answered that they had.

1) The physician did not wash his hands before the procedure.
    a) When questioned, the physician stated that the sink was in the kitchen, he didn't want to walk back and forth, and believed his hands were clean.
2) The physician did not wear gloves.

a) When asked to wear gloves, he replied that he has been practicing the same way for over 30 years and has never had a patient report any problems. He noted he has never worn gloves. The physician declined to wear gloves and used bare hands during the procedure.

3) 8 open vials were on the counter top of the exam room. The vials were all dated, but some dates were illegible. The vials contained the following solutions:
   a) 1% Lidocaine, 50cc, dated 3/16, approximately ½ full
   b) Glucosamine, 30 cc, dark bottle, dated 3/14
   c) B12, date illegible
   d) Kenalog, date illegible
   e) 50% Dextrose, 50cc, approximately 1/3 full, date illegible
   f) 8.4% Sodium Bicarbonate, 50cc, approximately ½ full, date illegible
   g) Sterile Water, 30cc, approximately ½ full, date illegible
   h) Mixture of 2.5% / 25% / 25% dated 3/14: when the physician was questioned about the ingredients of the mixture he replied that it was "for prolotherapy"
4) A single IV bag of 5% Dextrose IV dated 3/16 was observed being used
   a) When questioned, the physician explained that the single use IV bag was used as a multi-use bag in order to make dextrose dilutions. The physician estimated one bag was used every three days to treat more than one patient.
5) Process of the procedure
   a) The physician cleaned a small area of the patient's left posterior lumbar region with an alcohol swab
   b) The physician used his bare hands to palpate the injection site.
   c) The physician made approximately 30 repeated injections into the palpated region.
   d) Estimated Blood Loss 1-2 cc.
      i) The blood on the patient's back trickled onto the exam table.
      ii) Without wearing gloves, the physician used a 4x4 cotton swab to wipe the blood.
      iii) The physician then tossed the soiled cotton swab onto the counter.
      iv) The physician wiped his hands on his pants.
   e) After using his bare hands and a swab to wipe the patient's blood, the physician was observed handling multiple vials, the soiled 4x4 swab, and the patient without wearing gloves or washing his hands.
   f) The physician used a new syringe and needle each time he aspirated fluid from a vial.
      i) As he was aspirating from a vial the physician stated that he has stopped using the same syringe, and was not previously aware of this standard of practice to use a new syringe each time.
      ii) The physician expressed he still believed that the blood could not get into the syringe.
      iii) The physician noted, he had always changed needles, just not syringes.
      iv) The physician explained he has always practiced the same way, and felt that PHD's request to use a different syringe each time re-entering a medication being used for multi-dose purposes was overkill.
6) There was no designated clean/ dirty area on the counter during the procedure. The clean/ dirty items were intermingled on the counter.
7) The physician handled the vials immediately after using his bare hands and a swab to wipe the patient's blood.

8) After the patient left the exam room, the physician left the exam room to wash his hands in the kitchen sink and then returned to the exam room.
9) PHD asked the physician to wipe down the exam table. The physician used a Clorox bleach wipe from the supply cabinet to complete the request.
10) The physician was asked to describe the various medications injected during Prolotherapy, PRP, and ADSCT.
    a) He explained that only dextrose and lidocaine are used in Prolotherapy.
    b) He stated that for ADSCT and PRP, all necessary injectable solutions were enclosed in respective sterile kits, which were housed in Room #2 near the centrifuge.

Observations During Facility Inspection (After Procedure) on March 18, 2015

1) Kitchen
    a) Medication refrigerator in kitchen contained:
        i) One unopened glucosamine sulf 100mg / ml Lot 03162015
        ii) Three serostim 6mg "For Reconstitution", unopened
        iii) One serostim 6mg "For Reconstitution", opened and in liquid form, approximately ½ full, about 2cc of liquid, undated.
        iv) The physician stated that the above serostim vials were for his personal use. He also stated that he does administer hormone therapy to patients.
        v) The physician had previously stated that only dextrose and lidocaine are used in Prolotherapy. When questioned about the glucosamine in the kitchen refrigerator, he stated that he sometimes used it for Prolotherapy.
    b) Kitchen Sink
        i) Small with small countertop area
        ii) When the receptionist was questioned she explained that she leaves a white tray of prepared ADSCT injection materials (patient blood and fat) next to the sink so the physician can mix them for the next patient.
        iii) A toothbrush was next to the kitchen sink. The receptionist confirmed this was the physician's personal toothbrush.
        iv) When asked what the receptionist does with the leftover patient plasma and fat, she explained that it is squirted down the kitchen sink.
        v) The receptionist recounted trying to aim for the little holes in the drain so the patient plasma does not splatter as much.
        vi) The receptionist discards emptied syringes in the kitchen trash.
        vii) There was no clean/dirty area designated next to the sink. The clean vials awaiting the next patient were close enough to the sink to feasibly be splattered.
2) Centrifuge Room. According to the receptionist:
    a) There are no protocols for when or how to clean the centrifuge
    b) The centrifuge has never been cleaned
    c) The receptionist completes 100% of patient specimen processing for PRP and ADSCT.
        i) The receptionist's training to operate the Centrifuge consisted of watching a 10 minute video provided by the sales representative.
        ii) It appeared that the receptionist had a significant role in processing all specimens for re-injection. When asked to clarity her previous statement that

she had no role in any medical procedure, she explained that processing specimens was not a medical procedure.

d) The receptionist has no medical training.
e) The receptionist has never had any kind of infection control training.
f) The receptionist has never worn gloves while processing specimens, and did not know this was standard practice. The receptionist appeared confused by the requirement to wear gloves and did not know she was potentially touching blood. The receptionist stated that the physician had never asked her to wear gloves.
g) The receptionist was never offered the Hepatitis B vaccine as part of her employment.
h) Room #2 (centrifuge) has never been used for patient procedures, even though an exam table was present. Only the front exam room is used for patient procedures.
i) For PRP, the physician draws 50cc of the patient's blood in the exam room and hands the syringe to the receptionist, who then carries it to the centrifuge room to process for re-injection into the patient.
j) For ADSCT, the receptionist assists the physician with fat aspiration in the exam room.
    i) The receptionist stated that she hands the physician things and helps out.
    ii) The receptionist then processes the specimen in the centrifuge room. The concentrated fat and concentrated platelet syringes are then placed next to the sink in the kitchen for the physician to mix together. The physician then injects this mixture back into the patient.
k) The receptionist estimates the facility does an average of 1 ADSCT procedure per month.
l) The receptionist disposes the leftover blood and fat (after the concentrate is removed) down the kitchen sink. She referred to this as "oily fat".
m) When asked why the receptionist doesn't use the larger industrial sink in the hallway for disposal, she responded that she didn't want patients watching her squirt their "oily fat" down the sink, so she used the kitchen because the patients couldn't see it.
n) The receptionist has never labeled syringes with patient identifying information, despite multiple PRP and ADSCT procedures being performed on the same day.
    i) The patients arrive in the morning to have specimens drawn and return in the afternoon for re-injection.
    ii) When asked how the receptionist ensures that patient syringes aren't inadvertently switched, she stated that she just keeps them straight.
    iii) When asked to label syringes with patient identifying information, the receptionist didn't understand the need for this but conceded that she could probably use a sharpie pen.
o) Multiple vials were observed to be sitting on the counter next to the centrifuge and stored in the nearby cabinet, not contained within a PRP or ADSCT kit. When asked why the vials were there, since the physician had stated that all vials used for PRP and ADSCT were contained within the kits, the receptionist was unsure. The vials appeared identical to those contained in the kits. They were unopened and unlabeled.

3) Hallway:
    a) There was a sink in the hallway that was not used according to the receptionist and appeared to be a large industrial type sink.

4) Door at end of hallway:
   a) The receptionist stated this was a locked storage room and did not offer to let PHD inside.
5) Vital Sign Monitoring Equipment:
   a) No medical equipment for checking vital signs (blood pressure cuff, oxygen saturation monitor, thermometer) was observed in the medical office.
6) Conversation with the physician:
   a) The physician was asked specifically about pain medications administered prior to and during procedures. He stated that some patients may request oral pain medication to take before a procedure. He did not mention IV sedation.
   b) The physician was asked if he knew of any Hepatitis C positive patients in his practice. He responded that he did not know of any such patients in his practice, and he didn't treat "those types of people".
   c) The physician had previously stated that he did not have, and had never had, a partner in his practice. As discovered at the end of Inspection #1, Dr. Kochan had shared office space with the physician for many years and had vacated the premises in December 2014. When asked about this, the physician stated they had entirely separate medical practices and never assisted each other or shared patients. He stated that they used separate medical supplies and medication vials. Because of this, he did not consider Dr. Kochan a "partner" which is why he previously stated that he did not have, nor had ever had, a partner.

Practices identified in Inspection #1 which had been corrected by Inspection #2

1) Multi-dose vials were all dated (on counter of Room #1)
2) The physician used a new syringe to enter the multi-dose vial.
   a) When acknowledged for making this procedural change, he stated that he still did not believe any blood could get into the syringe. He felt this request was overkill, but agreed to comply.
3) A one-page infection control protocol was in the process of being written.

Continued Infection Control Breaches

1) Lack of designation of clean/ dirty areas in Room #1 (exam room), Room #2 (centrifuge), and kitchen
2) Lack of proper infection control training for the receptionist, including OSHA blood borne pathogen training
3) Lack of vaccination against Hepatitis B for the receptionist

Newly Identified Infection Control Breaches

1) Neither the physician nor the receptionist wore gloves during procedure or handling of patient specimens
2) Potential for contamination of clean medication vials with patient's blood during procedure
3) Potential for contamination of surfaces (countertops, door handles, etc.) with patient's blood during procedure
4) Potential for contamination of clean patient specimens next to sink by "oily fat" being disposed of into the kitchen sink and splattering on patient specimens

5) Lack of labeling of syringes containing patient specimens, despite multiple PRP procedures being performed on the same day
6) Improper disposal of biological hazardous waste
7) Unclear if the receptionist meets the training requirements for performing this procedure and processing of specimens

Inspection #3 (Unannounced)

Performed by:

Charity Dean MD, MPH, Health Officer

Takashi Wada, MD, MPH, Director

Monique Foster MD, MPH, EIS Officer, CDC

Cheri Grigg DVM, MPH, EIS Officer, CDC

Jennifer Yee, MD, EIS Officer, CDC

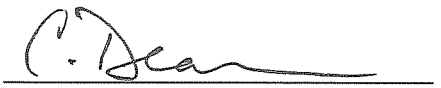
Date: April 9, 2015

Please see attached photos (taken during inspection #3)

The inspectors arrived at the office unannounced. The receptionist stated that she was on her way to see a patient and would not let us into the office. She agreed after being shown the Health Officer Order for inspection. When questioned if she was treating patients outside the office, she clarified that she was on her way to see a client at a hair salon where she was a hairdresser. She denied treating any patients outside of the office setting. When asked why she was at the office on a daily basis since the medical practice had been closed 3 weeks prior, the receptionist told us she was cleaning.

Observations

1) The medical office was clean and did not appear to be currently in use for the purpose of treating patients.
2) A door at the end of the hallway (between the centrifuge room and the restroom) was closed and during inspection #2, the receptionist had stated it was a locked storage room. A team member opened the door and inside the room was a double size bed, hanging clothing, a desk, and personal items. When questioned, the receptionist responded that the room is where the physician lived when he was in Santa Barbara. The physician had previously stated that he lived in Montecito.
3) The kitchen had two large full trash bins. An open, empty cardboard box labeled as midazolam was visible at the top of one of the trash bins.



Charity Dean MD, MPH

Health Officer, Santa Barbara County Public Health Dept.