In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: January 27, 2021

* * * * * * * * * * * * * * *	UNPUBLISHED
SABRINA CHAPPELL-STRICKLAND, *	
*	No. 18-396V
Petitioner, *	
v. *	Special Master Gowen
*	
SECRETARY OF HEALTH *	Findings of Fact; Measles-Mumps-Rubella
AND HUMAN SERVICES, *	(MMR); Shoulder Injury Related to Vaccine
*	Administration (SIRVA); Vaccine
*	Administration Method; Subcutaneous
Respondent. *	Versus Intramuscular.
* * * * * * * * * * * * * * *	

Bridget C. McCullough, Muller Brazil, LLP, for petitioner.
Darryl R. Wishard, United States Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT[1]

On March 15, 2018, Sabrina Chappell-Strickland ("petitioner"), filed a petition for compensation in the National Vaccine Injury Compensation Program.[2] Petition (ECF No. 1). Petitioner alleges as a result of a measle-mumps-rubella (MMR) vaccine administered in her right arm on May 23, 2016, she developed pain and limited range of motion which lasted for more than six months and involved surgical intervention. The following findings of fact pertain to the MMR vaccine's administration.[3]

[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the decision will be available to anyone with access to the Internet.** Before the decision is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). "An objecting party must provide the court with a proposed redacted version of the decision." *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] Pursuant to § 300aa-13(a)(1), in order to reach my conclusion, I considered the entire record. This opinion discusses the elements of the record I found most relevant to the outcome.

I. Relevant Procedural History

In March 2018, petitioner filed the petition accompanied by her exhibits (Pet. Exs.) 1-8 (ECF No. 1). This batch of records included Duke Primary Care's immunization history report listing the MMR vaccine at issue at Pet. Ex. 1, Duke Primary Care records at Pet. Ex. 3, and petitioner's initial affidavit at Pet. Ex. 8.

The claim was originally assigned to the Chief Special Master's Special Processing Unit (SPU), which is designed to expedite the processing of claims that have historically been resolved without extensive litigation. On March 19, 2018, the Chief Special Master ordered petitioner to file any outstanding medical records and a statement of completion. *See* SPU Initial Order filed March 19, 2018 (ECF No 5). On March 28, 2018, petitioner filed a motion for extension of time to complete her filings. Pet. Motion (Mot.) (ECF No. 6). Specifically, petitioner's counsel had identified "deficiencies in the immunization record" and had requested a "comprehensive immunization record". *Id.*; *see also* Pet. Mot. to Issue Subpoena filed April 25, 2018 (ECF No. 9). These motions were granted. On May 14, 2018, petitioner filed another record of the MMR vaccination, not from Duke Primary Care but from the North Carolina Immunization Registry (NCIR). Pet. Ex. 9 (ECF No. 13).

A staff attorney acting on behalf of the Chief Special Master held an initial status conference with counsel. *See* Scheduling Order filed May 21, 2018 (ECF No. 14). Petitioner filed a second affidavit. Pet. Ex. 10 filed June 8, 2018 (ECF No. 15); *see also* Statement of Completion filed July 12, 2018 (ECF No. 16).

On November 27, 2018, respondent filed his report pursuant to Vaccine Rule 4(c), in which respondent recommended that compensation be denied for this claim. Respondent's Report (Resp. Rep't) (ECF No. 22). Most relevant to the instant finding of fact, respondent noted that the effective version of the Vaccine Injury Table creates a presumption of causation if a petitioner establishes that after receiving an MMR vaccine, she developed a shoulder injury related to vaccine administration (SIRVA) with the onset of pain within forty-eight (48) hours. *See* Resp. Rep't at 4-5 (referencing 82 Fed. Reg. 6294 (Jan. 19, 2017); 42 C.F.R. § 100.3(c)). However, the Vaccine Injury Table only recognizes SIRVA following "administration of a vaccine intended for *intramuscular* administration in the upper arm". Resp. Rep't at 4-5; *see also* 42 C.F.R. § 100.3(c)(10). Respondent averred that in this case, the medical records provide that petitioner received the MMR vaccine at issue *subcutaneously* in her right arm. Resp. Rep't at 2 (citing Pet. Ex. 3 at 9 (the immunization history form which does not specify a method of administration), Pet. Ex. 9 at 2 (the NCIR record)). Respondent averred that based on these records, petitioner's injury is not consistent with SIRVA as defined on the Vaccine Injury Table and she is limited to alleging causation-in-fact. Resp. Rep't at 4-5.

After reviewing respondent's report, the Chief Special Master determined that the claim was no longer appropriate for the SPU and it was reassigned to my docket. *See* Order Reassigning Case filed November 28, 2018 (ECF No. 23); Scheduling Order filed December 11, 2018 (ECF No. 25).[4]

[4] Initially, petitioner and/or her counsel did not dispute the medical records reflecting that the MMR vaccine was administered subcutaneously. *See, e.g.*, Pet. Exs. 8, 10, 11; Scheduling Order filed December 11, 2018 (ECF No.

Petitioner filed her third affidavit. Pet. Ex. 11 filed January 24, 2019 (ECF No. 29). Petitioner filed selected Facebook posts referring to the May 23, 2016 medical encounter, the vaccinations, and her subsequent shoulder pain, as well as her husband James Strickland's affidavit. Pet. Exs. 17-18 filed May 4, 2020 (ECF No. 47).

During a status conference on August 4, 2020, petitioner's counsel, citing the Facebook posts and the husband's affidavit, expressly raised the argument that the MMR vaccine was administered improperly. Petitioner's counsel referenced a third vaccine administration record. It was agreed that petitioner would file additional evidence and then a fact hearing would be convened. Scheduling Order filed August 7, 2020 (ECF No. 57).

Petitioner then filed comprehensive vaccination records from Duke Primary Care. Pet. Ex. 29 filed August 10, 2020 (ECF No. 58). At respondent's request, petitioner filed *all* of her Facebook posts dating from November 1, 2015 – December 31, 2016. Pet. Ex. 30 filed September 1, 2020 (ECF No. 60). She filed affidavits from Amrit Gill M.D.[5] and two medical assistants (MAs), Tracie Collins and Rachida Guerrab, whose names appeared on the Duke Primary Care records. Pet. Exs. 31-33 filed November 6, 2020 (ECF No. 71); Pet. Ex. 34 filed November 7, 2020 (ECF No. 73).

A fact hearing was held via videoconference on November 13, 2020. The witnesses were petitioner, James Strickland, Dr. Amrit Gill, MA Tracie Collins, and MA Rachida Guerrab.[6] At the end of the hearing, counsel and I agreed to review the transcript and then discuss further proceedings at a future status conference. *See* Transcript (Tr.) filed December 11, 2020 (ECF No. 76). During that status conference on January 22, 2021, the parties did not request oral argument or written briefing. They requested to hear my preliminary findings of fact, which I offered and are finalized herein. Counsel agreed to review these findings of fact with their respective clients and then propose further proceedings.

II. Legal Standard

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration

25); Scheduling Order filed February 26, 2020 (ECF No. 45). Thus, I authorized petitioner to seek expert opinion(s) as to whether a properly administered MMR vaccine can and did cause her injuries. Petitioner obtained supportive reports from an immunologist and from her treating orthopedist, to which respondent responded. While I have reviewed these reports, they do not help to resolve the factual dispute about how petitioner's MMR vaccine was administered.

[5] The medical records reflect that in 2016, the primary care provider's name was Dr. Amrit *Manes*. At the fact hearing in 2020, it was confirmed that her current last name is Gill. This opinion consistently refers to Dr. Amrit Gill.

[6] Colleen Yopp, an ambulatory risk services manager for Duke Primary Care, was also present during the testimony of MA Collins, Dr. Gill, and MA Guerrab. *See* Tr. 2, 105, 147, 191.

as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

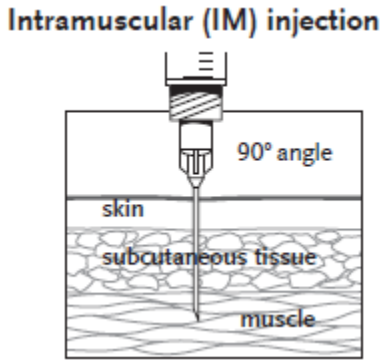
III. Discussion

A. Proper Vaccine Administration

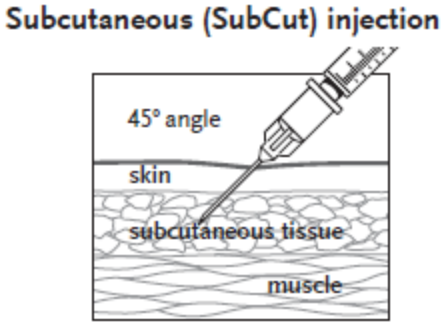
The factual issue to be resolved is whether petitioner's May 23, 2016, MMR vaccination was properly administered subcutaneously.

Respondent filed a fact sheet[7] which addresses proper administration of various vaccines. Resp. Ex. E-29. For example, the method varies for different zoster (shingles) vaccines: Shingrix should be administered intramuscularly while Zostavax should be administered subcutaneously. *Id.* In contrast, tetanus-diphtheria-acellular pertussis (Tdap) vaccines should always be administered intramuscularly. *Id.* MMR vaccines should always be administered subcutaneously. *Id.*

A medical provider administering an *intramuscular* (IM) injection should use a 22 – 25 gauge needle. Resp. Ex. E-29. The proper needle length varies based on the vaccinee's weight. It can be as short as 5/8" for a female or male less than 130 pounds, 1" inch for individuals of more average weights, and up to 1 ½" inches for a female greater than 200 pounds or a male greater than 260 pounds. *Id.* The injection should be made into the deltoid muscle of the arm and should resemble the illustration below:



In contrast, a medical provider administering a *subcutaneous* (SQ) injection should use a 23 – 25 gauge needle. Resp. Ex. E-29. The proper needle length is always 5/8", regardless of the vaccinee's weight or any other factors. *Id.* The injection should be made into the back of the arm, specifically the fatty tissue over the triceps, and should resemble the illustration below:



[7] Immunization Action Coalition, *Dose, Route, Site, and Needle Size*, at www.immunize. org/catg.d/p3085.pdf [Resp. Ex. E-29]. The Centers for Disease Control and Prevention (CDC) "work[s] in concert and provide[s] financial support" to this coalition, which runs several websites. The website cited by respondent is intended as a "non-profit web-based resource" for healthcare professionals. *See* Immunization Action Coalition, *About Us*, at https://www.immunize.org/aboutus/ (last accessed January 25, 2020).

In the Rule 4(c) report, respondent adds that during administration of a subcutaneous vaccine, the medical provider "pinch[es]" the skin to insert the needle. Resp. Rep't at n. 1. I also located the specific MMR vaccine package insert which is consistent with the above explanation. *See* Scheduling Order and Ct. Ex. 1 filed August 7, 2020 (ECF No. 57).

B. Factual Record

I have completed a review of the record to include all medical records, affidavits, testimony, respondent's Rule 4(c) report, and additional evidence filed. I found the following factual evidence to be most relevant to resolution of this issue:

- The medical record which provides that on May 23, 2016, petitioner presented to a Duke Primary Care in Morrisville, North Carolina to establish a new primary care relationship and to receive Tdap and MMR vaccines which were required for her college enrollment. Dr. Amritpal Gill conducted a well-adult examination. Pet. Ex. 3 at 5-9. At 8:37 a.m., Dr. Gill entered orders for Tdap (IM) and MMR (SQ) vaccines. *Id.* at 10. At 9:05 a.m., Dr. Gill entered an order for a pregnancy test on account of "irregular periods". *Id.* at 11. At 9:26 a.m., the result was recorded as negative. *Id.* At 10:00 a.m., medical assistant Tracie Collins (discussed further below) entered another order for "possible pregnancy" which Dr. Gill authorized, then discontinued for being duplicative. *Id.*

- Dr. Gill's initial entry on May 23, 2016, which provides that petitioner would be receiving a Tdap vaccine intramuscularly into the left deltoid, but the status was "incomplete". Pet. Ex. 29 at 7. That same day, MA Tracie Collins added the manufacturer, brand name, lot number, batch number, and expiration date. *Id.* MA Collins also recorded that she administered the Tdap vaccine. *Id.*

- Dr. Gill's initial entry on May 23, 2016, which provides that petitioner would be receiving an MMR vaccine manufactured by Merck & Co. subcutaneously into the left deltoid. Pet. Ex. 29 at 8-9. That same day, MA Rachida Guerrab added the brand name, lot number, batch number, and expiration date. *Id.* at 8. Then, MA Collins changed the site to "right arm" and recorded that she administered the MA vaccine. *Id.*

- The NCIR entry which provides that on May 23, 2016, Dr. Gill ordered and MA Collins administered a MMR vaccine subcutaneously into petitioner's right arm. Pet. Ex. 9 at 2.

- The medical record which provides that on August 15, 2016, petitioner returned to Dr. Gill with a new complaint of right shoulder pain and limited range of motion. Petitioner was concerned that these symptoms were related to the MMR vaccine which was administered in that same arm. Dr. Gill prescribed Tramadol for pain and referred petitioner to orthopedic surgery. Dr. Gill did not address how the vaccine was administered. Pet. Ex. 3 at 40-46.

- The medical record which provides that on October 26, 2016, petitioner presented to an orthopedist, Joseph Wilson, M.D. for a chief complaint of a right shoulder injury

beginning after the MMR vaccine. Dr. Wilson did not address how the vaccine was administered. Pet. Ex. 4 at 12-14.

- The medical record which provides that on November 8, 2016, an MRI of petitioner's right shoulder visualized signal changes that were consistent with tendinosis and a possible partial articular surface interstitial tear. No full-thickness rotator cuff tear was noted, however. The rotator cuff muscle bulk was preserved and the long head of the biceps tendon appeared intact. The MRI also visualized significant subacromial bursitis, arthrofibrosis encompassing the glenohumeral joint, inflammation encompassing the entirety of the bicep tendon, and significant inflammation at the superior labrum with a SLAP tear. Pet. Ex. 4 at 7-11.

- The medical record which provides that on December 7, 2016, Dr. Wilson wrote that the MRI findings were consistent with a partial thickness supraspinatus rotator cuff surface tear less than 50%, a non-displaced type II slap tear, significant subacromial bursitis, and AC joint arthritis. Pet. Ex. 4 at 10-11.

- The operative note which provides that on December 13, 2016, Dr. Wilson performed surgical intervention on petitioner's right shoulder. He recorded that the rotator cuff was completely intact. More significantly, Dr. Wilson noted inflammation of the biceps tendon at its insertion into the superior labrum and that the medial sling of the biceps tendon was torn. He performed a right shoulder arthroscopic lysis of adhesions, subacromial decompression, biceps tenodesis, distal clavicle excision, and manipulation under anesthesia to regain full range of motion. Pet. Ex. 7 at 4-5.

- The medical records which provide that following her surgery, petitioner followed up with Dr. Wilson and participated in physical therapy. Pet. Ex. 4 at 5-6; *see generally* Pet. Ex. 6).

- I have also reviewed petitioner's Facebook posts. Of note, on May 23, 2016, petitioner posted that she had went through "shenanigans" to get her vaccines. She didn't "even know where to begin, but how about the nurse put on her sterile gloves then went on about touching everything in the room before trying to give [petitioner] a shot". Pet. Ex. 30 at 380. Petitioner added that her "arm was killing [her]". *Id.*

- On September 11, 2016, petitioner posted that she was looking for an attorney and learning how the "needle used to administer" a vaccine can cause shoulder injury. Pet. Ex. 30 at 567.

- On October 7, 2016, petitioner posted, in response to a friend's question of how her shoulder was injured, that: "[T]he nurse… put the needle too high in my arm when giving me a vaccine. An hour later, my arm stopped working." Pet. Ex. 30 at 625.

- On December 12, 2016, the day before her shoulder surgery, petitioner wrote a lengthy post recounting what occurred on May 23, 2016, including that "the nurse neglected to ask if [petitioner] might be pregnant", "the nurse" had to be reminded to put on sterile

gloves, and that as "the nurse" was administering a vaccine, a supervisor observed that the needle was "not a subderm needle". Pet. Ex. 30 at 770.

- I have also reviewed petitioner and her husband's later, more detailed recollections of the vaccinations on May 23, 2016. For background, the husband was present for the entire medical appointment. He was sitting in a chair on the right side of the room. Tr. 67. Petitioner was sitting on a table in the center of the examination room. Tr. 8, 66-67.

- Dr. Gill conducted the medical evaluation and left. Then, MA Tracie Collins prepared to administer the Tdap and MMR vaccines. Tr. 7.

- The husband recalled that compared to petitioner who is 5"10' tall (*see* Pet. Ex. 3 at 6) and was sitting on a table, MA Collins was much shorter. *See* Pet. Ex. 18; Tr. 67.

- Petitioner and her husband recalled that when MA Collins was preparing to administer the Tdap vaccine, she briefly left the room. When she came back in, they reminded her to wash her hands and put on sterile gloves. Tr. 8, 66-67.

- Petitioner recalled that MA Collins then administered the Tdap vaccine into the "front side of [petitioner's left] arm, about halfway up the bicep". Tr. 9. She did not pinch the skin of the arm. Tr. 44-45. The husband recalled that because MA Collins was relatively short and petitioner was sitting straight up on the examination table, MA Collins wasn't quite at the level that she needed to be to administer the vaccination at a perpendicular (90 degree) angle. Tr. 68. She seemed to inject the needle "upwards at an angle", "diagonally", rather than going "straight into the arm". Tr. 68. The husband estimated that for both vaccines, the angle was between 30 to 45 degrees; it was "not perpendicular" with the skin. Tr. 98-99.

- Petitioner and her husband recalled that MA Collins started preparing the MMR vaccine, then paused to ask petitioner whether she could be pregnant, which petitioner answered was possible. Petitioner then left the examination room to take a pregnancy test. Petitioner returned to the examination room and to her position on the table. Dr. Gill came back to state that the pregnancy test was negative, then left again. Tr. 10, 69-70.

- Petitioner recalled that MA Collins stood "in front" to administer the MMR vaccine. Tr. 11. The husband recalled that MA Collins was standing at petitioner's front right-hand side of petitioner. The husband was seated slightly beside them both against the wall. MA Collins, petitioner, and the husband formed a triangle. Tr. 71, 94.

- Petitioner recalled that MA Colins then cleaned and sterilized her right arm for the MMR vaccine. Tr. 10. She pinched the skin of the right arm with two fingers. Tr. 11, 44.

- Petitioner recalled that MA Collins administered the MMR vaccine "a little bit higher" than the Tdap vaccine based on where she placed the bandages. Tr. 11-12.

- Petitioner pointed at where the MMR vaccine was administered on her arm, which I observed to be "roughly where the deltoid muscle is" in the "upper middle lateral section of the arm". Tr. 14. On cross-examination, petitioner indicated that compared to the Tdap vaccine, the MMR vaccine was given higher in the arm. The MMR vaccine was also given on the outside of the arm and centrally in the arm. Tr 45-46. I understood petitioner's testimony to be that although MA Collins pinched her skin, MA Collins administered the vaccine high into the deltoid area of the arm and not on the posterior underside of the arm near the triceps.

- The husband recalled that the MMR vaccine was administered at an angle. As noted above, he estimated that the angle was between 30 to 45 degrees; it was "not perpendicular" with the skin. Tr. 98-99.

- Petitioner recalled that as MA Collins was injecting the MMR vaccine, another medical professional looked into the room and remarked that MA Collins was using the wrong needle. Both medical professionals briefly left the room and then MA Collins came back. However, petitioner did not provide a name or any further identification of this person. Tr. 11-12. Her husband provided similar testimony. Tr. 66, 71-72, 77-78.

- Petitioner recalled that upon returning to the examination room, MA Collins advised that it would be normal to expect pain from the MMR vaccine for up to two months. Tr. 12.

- I have also reviewed the testimony of the vaccine administrator Tracie Collins. She obtained an associates degree in health science and completed a program to become a medical assistant in 2015. She became licensed as both a certified medical assistant (CMA) and registered medical assistant (RMA) in early 2016. She was unable to explain the difference, if any, between the two designations. Duke Primary Care hired MA Collins for her first job in that profession in April 2016. She underwent orientation and training throughout the summer of 2016. Tr. 106-08; *see also* Pet. Ex. 34 at ¶¶ 3-5. In December 2019, she transitioned from being partially "on the floor" assisting with patients to working exclusively in the lab at Duke Primary Care. Tr. 106, 111, 131-32.

- MA Collins testified that while the medical records list her name as the administrator of the Tdap and MMR vaccines petitioner received on May 23, 2016, she did not have any independent recollections of those events or having otherwise met petitioner. Tr. 124-25; *see also* Pet. Ex. 34 at ¶¶ 12-15.

- MA Collins testified that she would receive a printout of the patient's information, verify that information by speaking with the patient, and do some dictation and/or entry into the electronic medical record. She would administer the vaccine(s) and then record that it was complete. Tr. 121-23. On cross-examination, respondent's counsel asked, referring to Pet. Ex. 29 at 8, "Now, I know you can't recall this specific case, but in terms of this document is created, is there some type of drop-down menu in the system where you would fill these blanks in regarding date and status?". Tr. 126-27. MA Collins agreed. Tr. 127. She also testified that some of the columns populated on their own once the lot number and the NDC number were entered. Tr. 128-29.

- MA Collins testified that in general, a Tdap vaccine should be administered intramuscularly into the deltoid. She testified that to find the correct spot, she would place a thumb on about the end of the acromion, "and then two fingers and then you would spread between the second and ring finger… and then give the injection in between the second and ring finger." The injection should be at a 90-degree angle. Tr. 112-14; *see also* Pet. Ex. 34 at ¶ 8. MA Collins stated that the proper needle width should be 25-gauge, but she could not state the proper needle length. She seemed to agree that there was a "standard" length. She stated that she would use the same type of needle regardless of the vaccinee's size. Tr. 114-17.

- MA Collins testified that in general, an MMR vaccine should be administered subcutaneously into the "fatty part of the arm, which is more on the back of the arm". MA Collins agreed that as opposed to using the measuring technique she described for the Tdap vaccine, she would "kind of just push up with one hand" to administer the MMR vaccine at a 45-degree angle. Tr. 117-19; *see also* Pet. Ex. 34 at ¶ 9. She stated that for Tdap versus MMR, there was no difference in needle width or length. Tr. 119, 121. She did not administer MMR vaccines to adults very often. Tr. 119-20.

- I have also reviewed the testimony of Rachida Guerrab, who obtained her CMA license in 2013 and was employed at Duke Primary Care from 2014 until October 2018. Pet. Ex. 31 at ¶¶ 2, 4; Tr. 167-69. Since January 2019, MA Guerrab has been employed at a neurology practice, where she does not administer any vaccines. Tr. 167, 188-89.

- As noted above, MA Guerrab entered the brand name, lot number, batch number, and expiration date into the MMR vaccine administration record, before MA Collins actually gave the vaccine. *See* Pet. Ex. 29 at 8. However, MA Guerrab did not recall otherwise assisting with the record or the vaccination itself or otherwise interacting with petitioner on May 23, 2016. Tr. 183-88.

- MA Guerrab testified that at Duke Primary Care, a nurse supervised and trained the medical assistants, including on how to administer vaccines. MA Guerrab did not remember this nurse's name and believed that the nurse had left the practice. Tr. 169-71.

- MA Guerrab testified that in general, a Tdap vaccine should be given intramuscularly at a 90-degree angle. Tr. 173-75. The proper needle length is one inch, regardless of the vaccinee's size. Tr. 175-76; *see also* Pet. Ex. 31 at ¶ 1.

- MA Guerrab testified that for an MMR vaccine, the encouraged "best practice" is subcutaneous administration, but an intramuscular administration would not be "the end of… the world". Tr. 176-77; *see also* Pet. Ex. 31 at ¶¶ 8-10. She stated that a subcutaneous MMR vaccine should be given in the back of the arm, the fatty part, at a 45-degree angle. Tr. 178. She testified that the appropriate needle length is "one and a half inches", which she agreed would be "longer than the needle for the Tdap vaccination." Tr. 179.

- I have also reviewed the testimony of Amrit Gill, M.D., who confirmed that as part of her day-to-day duties at Duke Primary Care, she will enter an order for a patient to receive vaccine(s). Afterwards, Dr. Gill will not participate at all in the vaccinations or the resulting records. She will leave the room and "be done with the patient essentially". She will notify a "nurse" that the patient needs the vaccine(s). The "nurse" will administer the vaccine. Tr. 148-51.

- Dr. Gill confirmed that she established care of petitioner on May 23, 2016. She reviewed petitioner's medical records from that date forward. She did not have any recollections of the encounter with petitioner outside of what was included in the medical records. Tr. 149-66.

C. Findings of Fact

I acknowledge that the medical records memorialize that petitioner's May 23, 2016 MMR vaccine was *intended* for subcutaneous administration. Pet. Ex. 3 at 10; Pet. Ex. 29 at 7; Pet. Ex. 9 at 2.

As noted in the legal standard above, in *LaLonde*, the Court outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe*, 110 Fed. Cl. at 203-04. This case likely presents an additional situation in which medical records may be inaccurate. The records in question do not record events or symptoms that occurred prior to the appointment, but rather, how a medical assistant with less than two months of actual experience actually handled the uncommon administration of an MMR vaccine to an adult. Under these circumstances, I find that petitioner's Facebook posts in 2016 as well as the testimony from the witnesses, particularly petitioner and her husband, should be accorded greater weight than the medical records towards understanding how the MMR vaccine was actually administered.

I specifically find that Dr. Amrit Gill ordered the Tdap and MMR vaccines. Dr. Gill notified either a nurse or a medical assistant that the vaccines needed to be administered. That task was assigned to Tracie Collins, who was licensed as a medical assistant in early 2016, was hired for her first job at Duke Primary Care in April 2016, and was still being trained at the time of petitioner's appointment.

It is more likely than not that MA Collins selected the needle for the Tdap vaccine, since she recorded all of the details and that she was the administrator. She could not state the appropriate needle length but seemed to agree that it was something "standard". Petitioner does not allege that the Tdap vaccine, which was administered in her left arm, caused or contributed to any injury. However, these facts go towards MA Collins's degree of general knowledge about proper vaccine administration.

It is less clear who selected the needle for the MMR vaccine, as the record reflects that MA Guerrab entered many of the details, then MA Collins did the actual administration. *See* Pet. Ex. 29 at 8. However, both individuals were incorrect about the appropriate needle length for an MMR vaccine. MA Guerrab stated that it should be one and a half inches long. Tr. 179. MA Collins testified that it should be the same length as for a Tdap vaccine. Tr. 119, 121. Additionally, petitioner's Facebook posts, as well as petitioner and her husband's credible testimony documented that another unidentified medical provider entered the room and observed, in the moment that MA Collins was administering the MMR vaccine, that she was using an incorrect needle. Thus, regardless of which individual selected the needle for the MMR vaccine, it was more likely than not at least one inch long. This needle length is not appropriate for a subcutaneous vaccine, but rather for an intramuscular vaccine. *See* Resp. Ex. E-29.

The witnesses consistently testified that no medical provider – such as Dr. Gill, the supervising nurse, or MA Guerrab – supervised MA Collins's administration of petitioner's vaccines. A medical assistant does not have the same level of training as a nurse or a doctor and Ms. Collins was early in her career at the time at issue here.

MA Collins started by administering the Tdap vaccine into petitioner's left arm. MA Collins testified that in general, a Tdap vaccine should be administered into the biceps muscle at a ninety-degree angle. She did not specifically remember petitioner's vaccines on May 23, 2016, when she had been working as a medical assistant for less than two months and was still being trained. In contrast, petitioner and her husband testified credibly that MA Collins briefly left the room and when she came back in, she had to be reminded to wash her hands and put on sterile gloves. Tr. 8, 66-67. In addition, MA Collins was relatively shorter than petitioner (at 5"10' and sitting on the table) and she administered the Tdap vaccine upwards at an angle between thirty to forty-five degrees. Tr. 67-68, 98-99. While this is not a dispositive fact, an intramuscular vaccine should actually administered at a ninety-degree angle. *See* Resp. Ex. E-29.

MA Collins then administered the MMR vaccine into petitioner's right arm. MA Collins testified that in general, an MMR vaccine should be administered into the fat on the back of the arm at a 45-degree angle. Tr. 117-19. However, she did not remember administering this specific vaccine to petitioner. In contrast, petitioner and her husband testified credibly that in between administering the Tdap and the MMR vaccines, MA Collins remembered to ask whether petitioner could potentially be pregnant. Petitioner left the examination room to take a pregnancy test. Petitioner then returned to the examination room and to her position on the table. Dr. Gill came into state that the test was negative and then MA Collins resumed with the MMR vaccination. Petitioner and her husband recalled that MA Collins stood in front of petitioner, so that the three of them formed a triangle. Tr. 11, 71, 94. Petitioner testified credibly that MA Collins pinched the skin on her arm to administer the MMR vaccine. Tr. 11. However, MA Collins administered the MMR vaccine a little bit higher on the arm, compared to the Tdap vaccine, based on where she placed the bandage. Tr. 12. Petitioner pointed at where the MMR vaccine was administered on her arm, which I observed to be "roughly where the deltoid muscle is" in the "upper middle lateral section of the arm". Tr. 14. The husband testified credibly that the MA Collins used the same upwards angle of between thirty to forty-five degrees for the MMR vaccine. Tr. 67-68, 98-99. While MA Collins's pinching of the skin and her chosen angle

may have been appropriate for a subcutaneous vaccine, her position standing in front of petitioner and her choice of the upper deltoid muscle area were not. *See* Resp. Ex. E-29.

While it is not surprising that petitioner and her husband had more specific recollections the MMR vaccine's administration and that the medical personnel had no specific recollection of the appointment other than what they could read in the notes, the specific recollections of the appointment and the correlation of the underlying injury with the description of petitioner were consistent, clear, cogent, and compelling. Based on those specific recollections, I conclude that it is more likely than not that MA Collins intended to give the MMR vaccine subcutaneously but she did not, at that early stage of her career, understand where on the arm a subcutaneous vaccine should be administered, the precise angle, or the length of needle that should be used.

Overall, the facts are less consistent with proper subcutaneous administration and more consistent with unintended intramuscular administration of the MMR vaccine.

IV. Conclusion

In addition to the the above findings of fact concerning how the MMR vaccine was administered, during the status conference on January 22, 2021, I noted that petitioner credibly described a stabbing pain upon vaccination and she described significant pain that she had not previously experienced thereafter. The anatomic location of the medial sling of the biceps tendon in the proximal humerus between the greater and lesser tuberosities and the observation that it was torn at the time of surgery, seems most consistent with an injection improperly given at an upward angle in the central part of the proximal humerus. It also seems likely that the adhesive capsulitis described and released under anesthesia by Dr. Wilson likely resulted from pain-protective lack of movement of the right arm in the months following the MMR vaccination.

In accordance with the above, the following is **ORDERED:**

1) Petitioner shall forward a reasonable demand to respondent and file a status report confirming that she has done so **within 30 days, by Friday, February 26, 2021**.

2) Respondent shall file a status report proposing further proceedings **within 30 days thereafter**.

IT IS SO ORDERED.

s/ Thomas L. Gowen
Thomas L. Gowen
Special Master