COLLEGE OF PHYSICIANS AND SURGEONS OF NOVA SCOTIA

DECISION OF INVESTIGATION COMMITTEE "B"

IN THE MATTER OF:

COMPLAINANT: Dr. D.A. (Gus) Grant, Registrar, CPSNS

PHYSICIAN: Dr. William Vitale

PROCESS:

This matter was initiated by information provided by Dr. Robin Taylor, Medical Officer of Health, Capital District Health Authority on December 11, 2013. Dr Taylor advised of information received from a parent of a child who had received an immunization from Dr. Vitale, where the parent observed different practices from what the parent expected. Following a review by Dr. Taylor's team, the matter was reported to the College, and the Registrar, Dr. D.A. Grant, initiated a letter of complaint. A response was received from Dr. Vitale on December 20, 2013.

Investigation Committee "B", formed in accordance with the *Medical Act* of Nova Scotia, 1995-96, was responsible for the investigation of this complaint.

In addition to the complaint and response, the Committee considered all material forwarded to it, including:

- December 12, 2013 memo from Dr. Grant regarding his interview of Dr. Vitale;
- December 11, 2013 letter from Dr. Robin Taylor;
- December 17, 2013 letter forwarding 2005-2006 case files of Dr. Vitale;
- March 15, 2006 letter from Dr. Robert Strang to Dr. Vitale;
- Evidence of Vaccines administered by Dr. Vitale from January 2003- December 13, 2013;
- Practice Audits by Dr. Lesley Whynot and Dr. Elaine DesChenes;
- Certificate of Attendance at the Immunization Competencies Education Program on May 24, 2014.

OVERVIEW AND SUMMARY OF COMPLAINT AND RESPONSE

The Complaint alleges inappropriate immunization practices, specifically, the mixing of vaccines into a single syringe.

Dr. Vitale is an American physician who completed his undergraduate training at McGill and his residency at Dalhousie. He has a certification in paediatrics and practices as a sole practitioner out of an office in Halifax. His practice is split approximately 50/50 between adults and children.

The Complaint

The Complaint by Dr. Grant raises a concern that Dr. Vitale has knowingly administered vaccines in a manner below the standard of care for the profession. Dr. Grant also suggests that that this raises a larger question of whether Dr. Vitale is competent to practice medicine.

The complaint arises in the first instance from a letter dated December 11, 2013 from Dr. Robin Taylor, Medical Officer of Health for the Capital District Health Authority responsible for the Immunization portfolio. Dr. Taylor's letter explains that Public Health was contacted by a concerned parent regarding Dr. Vitale's immunization of her child. Her specific concerns were that two vaccines were mixed together in one syringe and were administered in her child's hip area. Public Health carried out some investigations including an interview of Dr. Vitale in which he confirmed that it was his practice to mix vaccines in a single syringe.

Based on research and investigations of safe and effective immunization practices, Dr. Taylor concluded that the cohort of infants immunized by Dr. Vitale in this manner was at risk for the vaccine-preventable diseases that the NS immunization schedule protects against. Accordingly, Dr. Taylor expressed the opinion that those children would have to be re-immunized.

As summarized in his memo dated December 12, 2013, after receiving Dr. Taylor's letter, Dr. Grant met with Dr. Vitale, together with Dr. Bill Lowe. Dr. Vitale informed them that in 2006 Public Health had advised him to stop his practice of mixing vaccines and had required that he re-immunize a number of patients. Dr. Vitale also reported that he returned to his previous practice of mixing vaccines after a period of time.

Dr. Vitale's Response

Dr. Vitale's response explains that he has come to better appreciate the concerns raised by the complaint.

He explained that his practice was to attempt to minimize mixing of the vaccines by layering them in a 1 ml syringe. Further, he attempted to achieve one inch separation of the entry of the vaccines into the body by angling the syringe in one direction, injecting approximately half of the contents, then angling the syringe in the opposite direction and injecting the remainder. His rationale for this approach was to avoid exposing the infants to the pain of an additional needle stick.

In 2006, after being advised by Public Health to stop the practice of mixing, Dr. Vitale had also been required to test willing patients for antibody levels to determine whether the mixed vaccinations had been effective. He explained that the lab results indicated adequate antibody response for Pertussis, Diphtheria and Tetanus in all but one case. He had relied on this and the fact that he did not know of any significant illness in his patient population, as evidence that the practice of mixing was safe. However, in his response, he acknowledged that this amounted to poor judgment, that there was much more sophisticated testing, that he should not have assumed same syringe effectiveness, and that his method was not proven.

Dr. Vitale undertook to attend an Immunization Competencies Education Program and to refrain from mixing vaccinations in the future.

SUMMARY OF INVESTIGATION AND REVIEW BY COMMITTEE

Interim Suspension

The Committee met on December 13, 2013 and determined that it was in the public interest to impose an interim suspension on Dr. Vitale's licence to practise medicine, given the fact that he had continued an inappropriate vaccination process despite having previously had the matter called to his attention.

On January 22, 2014, following receipt of Dr. Vitale's response and the results of two audits of Dr. Vitale's practice, *[editor's note: the results of the two audits of Dr. Vitale's practice were not available prior to January 22, 2014]* and having been satisfied that there was no public safety risk arising from Dr. Vitale's return to work with restrictions, the College reinstated Dr. Vitale's license subject to the restriction that neither he nor anyone under his authority was to administer vaccines.

Investigation

The Committee requested a complete report of the billings of Dr. Vitale relating to vaccinations from January 2003 to the December, 2013. The Committee met to discuss this case on January 21, 2014, at which point a number of issues were identified:

- Two vaccines were being mixed in one syringe;
- Dr. Vitale was using a ½ inch 25-29 gauge needle which would not reach the appropriate depth for intramuscular injections;
- Vaccinations were being given at the ventrogluteal site, contrary to recommendations for infants;
- Dr. Vitale failed to follow the advice given by Dr. Strang in 2006;
- The measures taken by Dr. Vitale to avoid too much mixing of the individual dosages did not bring his practice in line with provincial guidelines.

In view of the Committee's concern that there could be other deviations from practice standards, it determined that further information was required and it directed that an audit of Dr. Vitale's practice was necessary.

The Committee requested that Dr. Lesley Whynot conduct an audit of the adult portion of Dr. Vitale's practice, and to focus on preventative medicine practices, chronic disease management, appropriateness of referrals and prescribing practices. Dr. Whynot carried out her audit on February 26 and 28, 2014 and reported to the Committee on March 17, 2014.

In addition, the Committee requested that Dr. Elaine DesChenes conduct an audit of the paediatric portion of Dr. Vitale's practice. Dr. DesChenes conducted her audit on June 6 and June 13, 2014 and reported to the Committee on June 20, 2014.

CONCERNS/ALLEGATIONS OF COMPLAINANT

Dr. Grant expressed concerns about Dr. Vitale's practice of administering immunizations. Further, because of the role of vaccination as an integral and core component of primary care medicine and paediatrics, Dr. Grant requested that the Committee consider the larger question of Dr. Vitale's competence to practice medicine.

CONCERNS OF COMMITTEE

As with all complaints, the Investigation Committee is not limited to investigate only the concerns set out in the complaint. The Committee has the responsibility to look into all aspects of a physician's conduct, capacity or fitness to practice medicine that arise in the course of the investigation. In this case, after reviewing all available information, the Committee had concerns about Dr. Vitale's practice generally and determined it was necessary to conduct further investigations.

DISCUSSION

During the investigation carried out by Public Health, the Public Health Immunization Coordinator interviewed Dr. Vitale who she found to be "nonchalant" about his practice. He admitted to knowing that his practice of administering immunizations was not recommended but stated that he had done his own research and was confident the approach was effective. He stated he had been doing vaccinations in this way for five years when immunizing infants at 2, 4 and 12 months of age.

The Committee had serious concerns about Dr. Vitale's practices in relation to vaccination. However, it was equally concerned about the possibility that there could be other areas in which Dr. Vitale did not meet the prevailing standard of care or abide by provincial guidelines.

These concerns arose in large part due to the fact that Dr. Vitale had reverted to a past practice after having received a caution and advice several years earlier from Dr. Robert Strang, Public Health Medical Officer. At that time, Dr. Strang had highlighted the fact that giving the two injections together could result in product interactions which would render the vaccines ineffective. He had stressed that separate syringes were required, although they could be given in the same limb if spaced at least one inch apart.

When discussing his reversion to past practice with Dr. Grant, Dr. Vitale relied on the antibody testing which had been carried out on his patients at the time of Dr. Strang's intervention, referring to it as "a study". He also relied on the fact that using a narrow syringe limited the contact area between the vaccines. It was also his belief that by pointing the syringe in different directions for the first and second halves of the injection he could avoid intermingling of the vaccines.

Dr. Vitale's practice of mixing vaccines demonstrated an unsafe preference for his own judgment and random tests, rather than that of the provincial Public Health Medical Officer and standardized testing protocols. The Committee ordered an audit into Dr. Vitale's practice to determine whether there were other areas where it fell below standard. Separate audits were carried out of the adult and paediatric practices of Dr. Vitale.

The results of the audits were reassuring. Dr. Vitale knows and cares for his patients well. His approach to practice is good. However, both audits indicated concerns respecting his charting. Among various matters observed by the auditors, his charts did not contain cumulative profiles, lacked sufficient patient histories, lacked relevant details regarding physical examinations, and generally fell below acceptable standards.

The Committee noted that while the audits also disclosed room for improvement in areas such as chronic disease management and chronic pain management, and the need to document all prescriptions, these matters did not warrant formal disciplinary action.

As to his practice regarding vaccinations, the Committee was provided with evidence that Dr. Vitale had attended an Immunization Competencies Education Program. He had also undertaken not to revert to the practice of mixing vaccines.

DISPOSITION

The Committee directs the following:

1. Dr. Vitale is ***reprimanded*** for knowingly performing vaccinations improperly, in a manner contrary to the established practices of the profession.

2. The prior restriction on Dr. Vitale's licence with regard to immunizations is lifted.

3. Dr. Vitale's licence is subject to the following ***conditions***:

    a. Dr. Vitale must maintain readily accessible information respecting all patients receiving immunizations, including the names of the patients, the vaccines administered, the method used, and the date. This information will be made available to the auditor conducted to appoint a practice audit of Dr. Vitale's practice as set out in condition (b);

    b. Dr. Vitale is required to submit to a further practice audit, at his expense, to be arranged through the College's Physician Performance Department six months from the date of this decision. The results of the audit will be reviewed by the Physician Performance Department and the Physician Performance Department will determine any further action that may be needed, which action may include a decision that nothing further is required, that remediation is required or that matters necessitate a referral to the Registrar as a new complaint;

    c. Dr. Vitale is required to take the next available offering of the Medical Record Keeping Course offered through the Faculty of Medicine at the University of Toronto, at his expense. In the event that Dr. Vitale does not register for the next offering of this course or successfully complete it, his licence to practice medicine will be suspended pending successful completion of the course.

4. Dr. *Vitale is* ***cautioned*** to improve his medical record keeping in accordance with the Policy on the Content and Maintenance of Medical Records, October 2013.

    A caution is intended to express the dissatisfaction of the Investigation Committee and to forewarn you that if the conduct recurs, more serious disciplinary action may be considered. A caution is more serious than a counsel, but falls short of a reprimand, as the caution is kept in the physician's file but is not disclosed to the public, on Certificates of Standing, or to other licensing authorities without the your consent. The Committee considers a caution to be a notice of a serious nature.

5. Dr. Vitale is ***counselled*** to improve his management of chronic diseases and chronic pain, and is also counselled to ensure that blood pressures are taken during each visit for patients on stimulants. Dr. Vitale is referred to the Physician Performance Department for advice on directing his Continuing Medical Education toward these areas for improvement.

   The College considers a counsel as advice to a physician on how to improve his conduct or practice and it encourages the physician to incorporate this advice into future practices.

6. Dr. Vitale is required to pay costs to the College in the amount of $5,000, as a contribution toward the College's costs in the investigation and resolution of this matter. These costs shall be paid in two equal instalments, with the first instalment due by December 31, 2014, and second instalment due no later than December 31, 2015. Failure to make payment in accordance with this paragraph will result in the immediate suspension of Dr. Vitale's licence to practice medicine.

The Committee believes that the disposition outlined above reflects the serious concerns of the Committee with regard to Dr. Vitale's performance of immunizations, maintenance of practice standards and record keeping, while at the same time recognizing that Dr. Vitale's practice is generally sound and that he knows and cares about his patients.

Dated at Halifax, Nova Scotia this 30th day of October, 2014.

Dr. Keri McAdoo, Chair
Investigation Committee "B"