

EVALUATING A SAFE, ACCESSIBLE AND HIGHLY EFFECTIVE THERAPY FOR TREATING IRON DEFICIENCY AND IRON DEFICIENCY ANEMIA

MAINLINE WELLNESS QUALITY IMPROVEMENT PROJECT (QIP) FINAL REPORT

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For patients with iron deficiency (ID) and iron deficiency anemia (IDA), IV iron therapy is a well established and extremely effective therapy for those that fail oral iron therapy or for whom oral iron therapy isn't recommended. A significant number of patients deal with chronic ID and IDA, yet access to this safe, effective therapy remains very difficult. In addition to the clinical benefits of IV iron therapy, the cost savings to our health care system of proactive treatment of IDA are significant. For example, anemic patients receiving a single iron infusion can achieve the equivalent benefit of multiple blood transfusions. To better understand this comparison, one should note the fact that, typically, a single unit of blood will raise hemoglobin levels by approximately 10points. As you will see in the Mainline Wellness QIP; anemic patients often saw a hemoglobin level rise of 30 points with a single infusion.

'anemic patients receiving a single iron infusion can achieve the equivalent benefit of multiple blood transfusions'

Summary

Iron deficiency (ID) is the most widespread and common nutritional disorder worldwide and accounts for approximately one-half of anemia cases, with a clear predominance in adolescents and menstruating females. Disorders of iron metabolism are among the most frequently seen in pre-menopausal women, yet thousands of patients still move through Canadian doctors' offices and hospitals each year with chronic iron deficiency conditions that go undiagnosed and untreated. The results of this chronic endemic are devastating; affecting physical, mental, and socioeconomic health.

In the summer of 2022, Mainline Wellness put out a request for volunteers to be part of a Quality Improvement Project examining the health benefits of IV iron as a treatment for ID and IDA. The project also sought to determine the current major barriers for patients seeking to improve their symptoms with IV iron.

The submission form lived on the main page of the Mainline Wellness website and the response rate was astounding with multiple submissions coming in daily. Many of the patients/participants experienced long term suffering from ID and IDA as well as frustration at the difficulties encountered trying to get it addressed. Participants felt that first line treatments had not resulted in sustained positive results and in many cases, no improvement at all. Interestingly, most of these same participants were not offered any further options for treatment when 1st line therapy failed.

Background

As an emergency room physician, Dr. Davidson, the clinical director of Mainline Wellness, has had a front-line view of the health care system and the issues facing both patients and medical professionals. Over the years, he noticed an increase in visits to the emergency room for IV Iron. He found that many patients would come to the ER as a last resort because their symptoms had become so severe, they could no longer wait the weeks or months it took to be seen in an outpatient hospital clinic. For many of these patients, their symptoms could be easily addressed provided they had access to safe and timely IV therapy. Unfortunately, in Vancouver, B.C. and the Lower Mainland, wait times for outpatient hospital IV iron therapy can exceed 6 months.

In addition to long wait-times as a major barrier to therapy, participants in our study revealed that there is still a reticence on the part of physicians to acknowledge the suffering experienced by patients with ID and IDA and to subsequently refer patients for IV treatment. With this report, we hope to encourage the start of a movement towards validating and acknowledging the burden of ID and IDA in the community, to highlight the safety and effectiveness of IV iron therapy, and to increase it's availability to the public under the mandate of universal health care.

The Mainline Wellness QIP included pre and post therapy bloodwork, personal surveys, and an in-person roundtable discussion. A total of 51 participants were included. All patients reported that the side effects of oral iron were uncomfortable and, in the best-case scenario, modestly raised their iron levels despite months to years of use. Whereas, for almost all QIP patients/participants, a single iron infusion was all that was required to normalize blood levels. The average rise in Ferritin for all patients with ID was 104. For IDA patients, a single infusion provided the equivalent benefit of multiple blood transfusions* (*see more detailed description at start of report).

Outcomes

Many patient participants expressed the hope that becoming a part of the study would result in the cost of the IV iron treatment being paid for. This was however not the case. In order to ensure non-bias and consistency across data points, costs and steps were maintained in-line with standard clinic procedures. As a result, some participants were unable to continue with the study due to cost barriers encountered in a private clinic such as Mainline Wellness. This clearly reinforced the **need for equal access to timely, IV Iron therapy for those suffering from ID and IDA in our PUBLIC system**.

The was a remarkable consistency among our Roundtable participants when it came to describing the hurdles they had to overcome when accessing IV iron therapy. Validation and acknowledgment by the medical system of their struggles with ID and IDA was surprisingly rare, despite the fact that their condition presented very real challenges to their quality of life. Participants volunteered their time and energy to further advocate for iron iv treatment because, in their words "it is THE best treatment for alleviating the debilitating effects of iron deficiency and anemia." After their successful treatment they asked: "Why can't this be available and promoted for all?" Under the current system they felt that if you are iron deficient or anemic, prepare yourself for an uphill battle. Many needed to self-advocate by convincing their physician that the oral supplements weren't working, that an iron infusion is a perfectly safe and reasonable solution, and the clinical improvements post IV therapy can be profound. Many felt that since this is an issue that disproportionately affects females, it has not been given the attention it deserves.

"it is the single best treatment to alleviate the debilitating effects of iron deficiency and anemia."

Description of Symptoms felt by Participants

Reporting by participants was varied as to an exact date because symptoms of low iron / anemia became intolerable to day to day function which provoked an investigation into what was fundamentally wrong with their health. **The symptoms of low iron / anemia were the driving factor to the discovery of the condition.** This fact alone should debunk the myth that the physical challenges with low iron are somehow perceived as fabricated by the individual or simply "in their mind". Some participants were able to identify the onset of their condition to puberty and menstruation.

Symptoms of ID and IDA Experienced by Participants

- No energy
- · Racing heart
- · Sleep disturbance
- Lightheaded
- · Shortness of breath
- · Difficulty concentrating
- · Muscle weakness
- Fatigue
- · Joint pain
- Hair loss
- · Restless legs
- · Depression
- Memory issues
- · Numbness in hands and feet
- · Insomnia

Several participants shared that they "felt crazy" speaking up about their health challenges as they seemed to be quickly dismissed by their provider. There is a significant mental health aspect to the process of obtaining a firm diagnosis of ID and IDA: 'When your medical provider minimizes or shrugs off a medical concern, patients are left wondering if they are imagining symptoms or if they aren't doing enough to properly care for themselves: 'that it's somehow their fault'. All participants reported obstacles in trying to advocate for their ability to obtain IV iron. Our conclusion is that physicians generally think that low iron should be something that is tolerated by the individual as opposed to aggressively treated.

Many physicians seem reluctant to refer or consider IV Iron therapy and this leads patients to think that they aren't candidates or don't "deserve" IV therapy. Many physicians seem satisfied to have patients take supplements for months to years despite ineffectiveness and frequent side effects. Several roundtable participants noted that naturopaths seem more aware of the proven success of IV iron and are more open to validating low iron as a true concern.

A sentiment generally shared across all participants was that ID and IDA are viewed as a normal occurrence for females, and if oral therapy was ineffective, patients needed to "grin and bear it." It was common among participants for generations of female relatives to also suffer from ID and IDA. One participant at the roundtable shared that the only solution offered for her mother's chronic anemia was a hysterectomy. This major surgery had also been suggested to another roundtable participant as a solution, instead of IV iron.

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During the Roundtable portion of the QIP, several questions were posed to participants. Below, we have included two of these in order to call out the significant change in overall physical and mental wellness.

Despite the lack of validation, why did you reach out to Mainline Wellness?

- · Needed to feel well
- Last resort
- · Couldn't eat enough red met
- · Work performance suffering
- · Couldn't sleep enough to feel well
- · Needed to stay employed
- · Couldn't do it on my own
- · The side effects of oral iron were horrible

After treatment

- · Higher work function
- · No longer need to sleep during the day
- · Happier
- Less anxiety
- · Participate more fully in life
- · Better mother

Physicians seem quick to attribute the symptoms of low iron as part of a mood disorder or other clinical syndrome. For many women, the symptoms of ID can start shortly after puberty. The hormonal changes and turmoil that can be common in adolescence can distract from a proper diagnosis of ID and it can often go untreated for years. Figure 1 outlines the significant number of years many patients are left without effective treatment. Pregnancy presents another stress on female iron levels and this can often tip women into ID and IDA. There needs to be consistent support and education around ID/IDA and the clinical consequences if untreated. If we want a society that functions at an optimal level, it only makes sense to support screening for ID in woman post-puberty and other susceptible populations. If ID or IDA is present, physicians should initiate oral therapy and be quick to consider IV therapy as an option if oral treatment is ineffective or not tolerated.

Figure 1. Almost all patients had been living with iron for multiple years, with the majority for over 10 years.



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Conclusion

The results of this project clearly outline the need for medical professionals to prioritize focus on ID as having a serious adverse impact on mental and physical health. Clinical effects of ID alone are not routinely taught at medical schools in Canada and may contribute to why patients are not validated when reporting the adverse physical symptoms of low iron. There is a reluctance on the part of physicians to refer patients for IV iron therapy despite an abundance of scientific data showing the successful alleviation of detrimental symptoms. Canadian medical standards outline first line treatments that are simply not effective in many cases. The QIP lab results show clear laboratory improvements and this mirrors the subjective improvements felt clinically by patients. Figure 2. An iron infusion is safe and extremely effective. It needs to be an option readily available to all.

We advocate for routine screening for ID and IDA. Testing is simple and the cost is minimal. ID and IDA are easy to diagnose, can be severely debilitating for patients, and safe, rapid treatment exists. Earlier transition to IV therapy would ultimately unburden the health care system and provide increased quality of life and productivity to a large portion of the population. We must do more to educate physicians and the public.



Has your lifestyle changed at all from before you received IV Iron treatment to after you had IV Iron treatment?

100% Yes

I'm much healthier concentration is better

I have more energy with

I HAVE SO MUCH MORE ENERGY

Mainline Wellness IV Iron OIP 2022

Figure 2. All respondents answers yes to a lifestyle change after having an IV Iron treatment, with all experiencing positive changes in their lives as a direct result of the iron infusion, including increased energy, feeling healthier, better concentration and increased productivity.

Thank you

We would like to thank the 51 participants of this study for generously volunteering their time and publicly sharing their lab results to further advocate for access to IV Iron therapy. Mainline Wellness would like to acknowledge the participants of the Roundtable Discussion. Their candour and participation were impactful.

About Mainline Wellness

The very first iron infusion administered by Dr. Davidson was for a personal friend with severe anemia who couldn't get access to IV iron in hospital. After seeing what a difference this relatively simple treatment made to their overall health and quality of life, the idea of making this service more readily available to others was formed and Mainline Wellness was born. Mainline Wellness is private clinic specializing in IV iron therapy and accepts referrals from health care providers in the Lower Mainland.

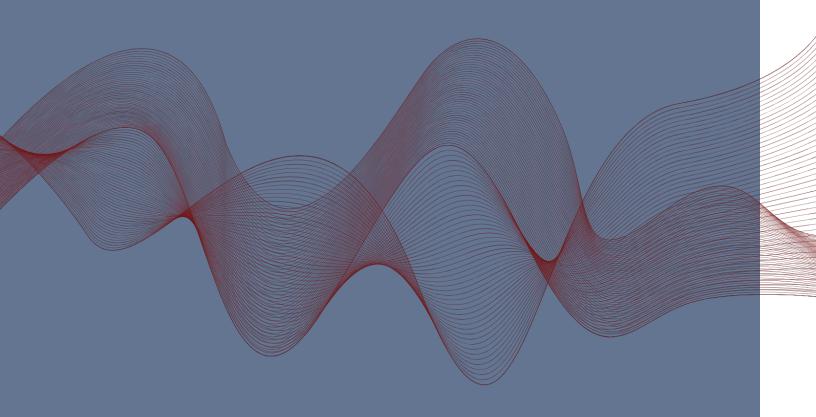
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- 1. Port Moody Health, https://www.portmoodyhealth.com/wp-content/uploads/2019/11/Mainline-Wellness.pdf
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- 3. Mainline Wellness https://mainlinewellness.ca/fags

Conflicts of Interest

A.S., MBA has nothing to declare; K.F. has nothing to declare; A.D., MD, CCFP-EM has received speaking honourariums from Pfizer Canada and is the owner/operator of Mainline Wellness

APPENDICES





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Definitions

Iron Deficiency (ID): insufficient total body iron stores, caused by increased requirements, decreased intake, increased loss, and/or decreased absorption. This results in sub-optimal performance of iron-requiring processes in the body.

Anemia: low hemoglobin level. A hemoglobin value below the local, lab-specific lower reference interval indicates anemia.

Iron deficiency anemia (IDA): anemia due to insufficient body iron stores The following laboratory findings are typical for IDA: microcytic anemia, hypochromia, and decreased ferritin. IDA may be normocytic if anemia is mild or recent.

Signs & Symptoms

Even in the absence of anemia, isolated iron deficiency causes symptoms and warrants investigation and treatment.

Signs and symptoms of ID and IDA in adults:

- Fatique
- Cold intolerance
- Headaches
- Restless leg syndrome
- Irritability/depression
- Nail changes, e.g. koilonychia (spoon nails)
- Angular cheilitis
- Pica/pagophagia (ice craving)
- Decreased aerobic work performance
- Hair loss
- Adverse pregnancy outcome
- Impaired immune function

If you have questions, send them to us at <u>info@mainlinewellness.ca</u> and we'll include answers in our next newsletter. If you think you have low iron and want to know more, contact us at Mainline Wellness. We're happy to help!

Email: info@mainlinewellness.ca Phone: 604-876-2344

References:

https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/bc-guidelines/iron-deficiency, https://mainlinewellness.ca/faq