



The Evolution of IVNT in the UK

Dr Jacques Otto, the head trainer at IntraVita, details the company's development and standards for the training and use of intravenous nutrient therapy

I was introduced to Intravenous Nutrient Therapy (IVNT) in 2009 in the Far East where I noticed the positive health and wellbeing effects of intravenous nutrients.

Teaming up with Vernon Otto, in 2009 we started to manufacture intravenous nutrients (vitamins, amino acids and minerals) under European Good Manufacturing Practice (EU GMP), before establishing IntraVita.

Classification and use

The United Kingdom Medicines and Healthcare Regulatory Agency has advised that there are a number of vitamins and minerals available for intravenous administration in the UK which are labelled as medicinal products and have marketing authorisations. These are for specific medical purposes and often solely by virtue of their mode of administration, default to being prescription-only medicines (POMs). Where products are not intended to be used for a medical purpose and make no medical claims then the MHRA has advised that these may fall outside the definition of a medicine. In such cases, the MHRA advice is that for clinics to ensure that those who administer the products are appropriately qualified. Provided no medicinal claims are made, EU GMP is adhered to and the products are only used for promotion of health and wellbeing. IntraVita's products also fall outside the remit of the Care Quality Commission (CQC) for the same reason. The only POMs used in IntraVita's formulations include 0.9% sodium chloride, sterile water for injection, calcium gluconate and magnesium sulfate. IntraVita's formulations exclude any MAMs for off-license indications and it is company policy that Intravenous Drug Therapy (IVDT) for off-license indications has no place in IVNT. Intravenous nutrition is excluded from clinical education curricula in most countries around the world. Multinational pharmaceutical companies are mostly disinterested in IVNT because a nutrient can't be patented and therefore it can easily be copied. In the light of the MHRA's advice in regard to professional

obligations of those who administer these products IntraVita only supplies clinicians trained and certified (for insurance purposes) by IntraVita, including doctors, dentists, nurses, pharmacists and paramedics. Since 2014 IntraVita has trained more than 1,000 practitioners from the UK and abroad and, for the period 2014 to 2018, has supplied over 60,000 intravenous nutrient formulations to hundreds of clinics.

Formulations

The formulations are preservative free, don't contain traces of animals, so are vegan friendly, and are also free of genetically-modified organisms, hexane and sugar. No serious side effects or complications have been reported during this period, compared to pharmaceutically-manufactured products that contain preservatives to increase product shelf life. This can lead to allergic reactions and, rarely, anaphylaxis. To improve safety and efficacy, over the past three years, our research and development has focused on developing multi-nutrient formulations and, more recently, we introduced ready-mixed multi-nutrient formulations in glass bottles. These formulations enhance ease of infusion preparation, save time, minimise user error and, most importantly, reduce the risk of infusion contamination with microbes.

Insurance and training

IntraVita's products have product liability insurance in the UK and practitioners that have completed our face-to-face or online training can obtain insurance from Cosmetic Insure, Hiscox, Lonsdale and Hamilton Fraser. In the UK, practitioners registered with the General Medical Council (GMC), must undergo appropriate training and have valid insurance in order to practice IVNT. Practitioners that do not use EU GMP intravenous nutrients are urged to contact their insurance company to verify if their insurance is valid and products sourced from jurisdictions outside the EU, for example, the US (FDA approved), India, South Africa

and Canada are advised to check with the MHRA that their products are not regarded as medical products. Efficient training of practitioners has been one of IntraVita's main priorities because IVNT is not taught at medical schools as part of clinical training. Therefore, IntraVita has been very selective in choosing training academy partners. Cosmetic Courses has been our sole partner for the past year and a half, with training being delivered by myself.

Since 2014, the UK IVNT market has evolved rapidly with practitioners offering concierge services to clients in their homes, offices and hotel rooms. Another development includes intravenous infusion services offered to people at festivals where intravenous drugs, e.g. paracetamol and others, are administered. IntraVita disapproves of and distances itself from these new developments and the team draw a clear distinction between IVDT and IVNT. Finally, but most importantly, we are vehemently opposed to beauty therapists administering IVNT. This is because they are not accountable to a regulatory body such as the GMC, General Dental Council, Nursing and Midwifery Council, General Pharmaceutical Council or Health and Care Professions Council, and lack clinical training and experience. Thus, it is our opinion that it is not in the best interest of the public to seek IVNT infusions from beauty therapists. In our opinion, insurance companies that insure beauty therapists demonstrate a lack of insight and disregard of public interest and safety.



Dr Jacques Otto is the head clinical trainer at IntraVita and has postgraduate Master's degrees in pharmacology, general practice and medical law. He was a pharmaceutical physician and scientific affairs manager of Abbott Laboratories in South Africa from 1990 to 1993.



My Experience

Medical director and founder of The IV Clinic and Ghosh Medical Group Dr Arun Ghosh shares his experiences of using and training in the use of IVNT

I have been performing Intravenous Nutritional Therapy (IVNT) exclusively for more than three years and, during this time, I have seen the growth of the industry throughout the UK.

Though we are behind our American counterparts, much can be learnt from their practices and their pitfalls. Our clinic has seen an increase in all demographics for this type of therapy; from the fitness and beauty industry to those worried about their health and nutrition. Personally I have trained on many of the different courses on offer, both here in the UK and abroad. Currently for practitioners, the standards of training differs hugely between companies and organisations. Companies also differ in their goals for IVNT benefits and client base. Clinical standards and guidelines are not the same throughout the different companies and their claims are often not based on any recognised controlled trials. This has led to much criticism in the way IVNT is being offered, from high street shops and home/hotel visits to expensive health clinics, and has contributed to patient complacency and concern regarding the use of IVNT.

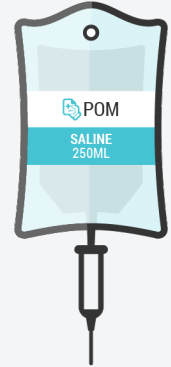
AIMS is the first attempt in the UK to set standards of training and support for practitioners

Standards of care

There are always risks associated with any procedure and I have personally seen reactions and side effects from poor formulas and clinical guidelines, which in hindsight could easily have been avoided if the standards of training were higher and follow-up care was easy to access. The IV Clinic, as a result, tries to be at the forefront of setting these standards in terms of advertising and clinical administration. The IV Clinic has now grown into several clinics in the UK and abroad, and I have taken onboard clinicians across a variety of areas from acute care, oncology and community IV backgrounds. Included in my team are medical, pharmaceutical and nursing directors to create medical standards on par with NHS hospital and CQC levels of care. Currently there is no reason for other clinics to follow suit, but having a level set as high as this means I can reassure all of my clients and staff that their wellbeing is at the forefront of The IV Clinic's ethos.

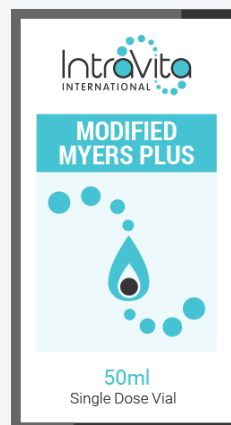
Tailoring treatment

The IV Clinic team has now been well established and gathering feedback from our clinics has been our first aim in tailoring our IVNT menu for maximum benefit. All our practitioners have a good understanding of drip ingredients, osmolarity and infusion rates for safety, so are able to tailor IV drips for individual client's needs, rather than follow set menus. The IV Clinic has blood pathology levels, which are standard for all clients, as they are in many clinics in the US. We feel they are a vital part of the process in order to demonstrate if and when IVNT is indicated, beneficial, and not harmful. The learning has not stopped for me; I continue to train on courses around the world to bring together global data and constantly look to improve our IVNT menu.



Looking forward

We are now aiming to hold trials to provide clear data comparing IVNT with placebo, alternative treatments and how much quicker goals are achieved when IVNT is introduced, whether they be nutritional, beauty or athletic. On a more long-term scale, we also aim to train those who want to bring their IVNT standards up to our level and advance their IVNT training to achieve results safely and gather data from our own collective trials.



Personally, I think that IVNT is very much in its infancy and we will see a huge amount of change in the coming years, for which I hope to be well prepared. If we are willing to learn from the experience of the aesthetics specialty we can correct many issues quickly at this infant stage, prior to it becoming over run and mismanaged by rogue practises. Thus, laying to rest many of the misconceptions that we see printed and, more importantly, reassure the public over the safety of IVNT. The

Association of Intravenous Micro-nutritional Supplementation (AIMS) is the first attempt in the UK to set standards of training and support for practitioners. It offers a chance for companies to try to pull together and set clear standards across the board. Self regulation is the first step in raising the level of IVNT and public reassurance, so I would urge all practitioners looking to offer IVNT to sign up to AIMS.



The Association of Intravenous Micronutrient Supplementation



Director of AIMS Vernon Otto details what member can expect from this association

Development

The Association of Intravenous Micronutrient Supplementation (AIMS) was founded in July 2017 with the aim of raising standards of practitioner education and training, and to inform and educate the public on IVNT. To date, AIMS has 300+ members and is hoping to have more than 600 by December 2019. IVNT has been around for over 30 years in the US, Far East and in some parts of Europe, yet it is fairly new to the UK, especially in the aesthetics specialty. Within aesthetics, two disciplines of nutrient supplementation have emerged; Intravenous Nutrient Therapy (IVNT) and Intravenous Drug Therapy (IVDT). There is a clear distinction between the two and AIMS will ensure that the public and practitioners are aware of the difference.

Policy

IVNT uses intravenous nutritional therapy products for supplementation focusing on vitamins, amino acids and minerals; it does not treat medical conditions nor make medical claims. IVNT, therefore, does not currently fall within the remit of the CQC. IVDT, however, incorporates market authorised prescription-only medicines, such as anti-sickness, painkiller and anti-inflammatory medications. This therefore does come under MRHA and CQC regulations.

AIMS is not in agreement with medicines being used off licence or without correct clinical indication. Our first aim is therefore

to address this type of practice and produce guidelines for practitioners who wish to do this, so they are safe and comply with all regulated guidance.

AIMS is of the view that the infusions should only be administered by doctors, dentists, nurses, pharmacists and paramedics, as the route of administration is intravenous and only suitably-trained medical personal are capable of conducting this after a thorough medical history. We also believe that these are the capable professionals of treating complications such as anaphylaxis. AIMS is strongly opposed to beauticians and non-medically trained personnel administering drips in the UK for these reasons.

Guidance

AIMS will be producing guidelines to support UK IVNT practitioners and encourage all practitioners to follow suit. Particular concerns and issues will be addressed through clinical trials and peer feedback and support; building a pool of knowledge that can be passed on to colleagues to minimise the risk of complications and provide safe protocols for their patients. AIMS will also offer an advice support service for practitioners that need it.

Over the coming months, AIMS will be working closely with insurance companies in the UK and publishing particular guidelines on who can be insured, what products are covered by medical malpractice insurance (usually EU sourced/

Getting Insured

Medical malpractice broker Jacquie Ford outlines how Cosmetic Insure can support IVNT practitioners

Cosmetic Insure is one of the leading brokers for medical malpractice insurance in the UK. It is IntraVita International's broker of choice when it comes to insuring practitioners to administer IVNT in the UK. Cosmetic Insure can arrange insurance for doctors, dentists, nurses, paramedics and pharmacists to administer IVNT treatments in their own clinics or off-site as a concierge service. Only products sourced in the European Union will be covered by medical malpractice insurance policies. To date Cosmetic Insure has had no claims concerning IVNT in the UK, however this does not mean that the treatment is complication or risk free. It merely gives an indication.

manufactured) and what is not covered. AIMS will also be speaking to the CQC and MHRA for any particular concerns they wish to address and guidelines they would like practitioners to follow. In order to protect patients and preserve the procedure in the UK for the foreseeable future, AIMS is encouraging practitioners to join today and follow its guidelines on IVNT administration.

What does the MHRA say?

The United Kingdom Medicines and Healthcare product Regulatory Agency (UK MHRA) has advised that there are a number of vitamins and minerals available for intravenous administration in the UK which are labelled as medicinal products and have marketing authorisations. These are for specific medical purposes and often solely by virtue of their mode of administration, default to being prescription-only medicines (POMs).

Where products are not intended to be used for a medical purpose and make no medical claims then the MHRA has advised that these may fall outside the definition of a medicine. In such cases, the MHRA advice is that for clinics to ensure that those who administer the products are appropriately qualified. **The MHRA has provided advice in respect of the classification of medicinal products in this article.**