

Immunogenic Issues in Diabetes, Implications for Covid-19

Beatty DC^{1*} and Yap CG²

¹University of Edinburgh, Scotland, UK

²Monash University, Malaysia

*Corresponding author:

Derek C Beatty,
University of Edinburgh, Scotland, UK,
E-mail: derek.beatty@schillmedical.com

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1. Abstract

This research is written by a person with Type 1 Diabetes diagnosed 44 years ago, treated with insulin 43 years, and with a 50-year career in healthcare. The journey has included experience in Diagnostic Laboratory Pathology Clinical Medicine; Radiology in CT and MRI; Respiratory Inhaled Therapy; Diabetes; Thyroid Disorders including Addison's Disease. The investigations into insulin therapy in diabetes commenced 28 years ago after experience of a life-threatening Hypoglycemia and Neuroglycopenia event in 1994 caused by alleged medical and professional negligence in public office then legal discovery of, on the balance of probability and beyond reasonable doubt, serious near fatal errors in case patient care and subsequent factual misinterpretation and understanding. Sadly, in some cases tragic loss of life has occurred with difficulties in identifying exact cause of Hypoglycemia. Such cases leave on occasion coroner reports in certain cases somewhat hollow when more precise cause may help better understanding for families and loved ones to overcome tragic loss. The research identified a selection of historical cases identifying Hypoglycemia and Neuroglycopenia in clinical areas where insulin normoglycemia is dramatically affected by medication such as antibiotic treatment; infection exposure; exercise; poor diet; vitamin deficiency; electrolyte imbalance; stress; suspected Covid-19 exposure leading to Hypoglycemia and Hyperglycemia spikes which may lead to blood clots, ophthalmic retinopathy trauma; vascular blood flow disruption exposure to heart and limbs along with brain cognitive

effect. This complex combination external patient exposure can cause temporary cognitive interference with mental effects often

associated to behavioral issues requiring Red Alert fast track witness support to correct temporary mental health impairment. Such events must be acted on immediately to prevent coma and death if prompt action is not taken along with possibility of affecting longer term cognitive issues.

2. Introduction

The World's first Diabetic Hypoglycemic Event occurred in Toronto in 1922 when clinical administration of insulin from the first batches produced by Banting, Best and Macleod were injected into Dr Jim Gilchrist. Later in the evening he suffered a Diabetes Hypoglycemic event with convulsions and seizure with Neuroglycopenia which when attended by Toronto Police, and with Clinical attendance, was correctly diagnosed as a Hypoglycemia Clinical Event and certainly not drunkenness as Hypoglycemia is often inferred when no alcohol is involved. 100 years later in 2022 ignorance and failure to understand the forensic aspects of hypoglycemia unawareness has led to tragedy for many patients and families.

Described in 1982 by Michael Bliss in 'The Discovery of Insulin' Banting and Best had described 'Hypoglycemia as a Mysterious Something'. In 1994 at the Banting Memorial Lecture presented by Prof Vincent Marks, University of Surrey, 'Hypoglycemia – Real and Unreal, Lawful and Unlawful' identifies investigations undertaken in case study reports in Diabetes and Hypoglycemia in Addison's Disease with Addisonian or Adrenalin Crisis, low blood glucose, convulsions and seizure, and links Munchausen Syndrome by Proxy with Child Abuse and Murder. The Mental Health link to Diabetes and Addison's Disease, discovered Thomas Addison 1860, has resulted over the years in serious stigma and

diabetes discrimination against clinical patient victims trying their daily best to self-manage and treat a lifelong serious health condition requiring daily insulin injections or hydrocortisone treatment when no cure exists at present. The daily challenge is enhanced in 2022 with attempts to live a sensible lifestyle with diet and exercise post Covid Pandemic 2020.

Publication of 'Forensic Aspects of Hypoglycemia' V Marks 2019; 'Insulin A Voice for Choice' A Teuscher 2007; and identification of potential clinical links between insulin and infection exposure has led to renewed review of published clinical studies and the possible Immunological link to Covid-19 infection exposure leaving many sad deaths of patients with long term diabetes and other health disorders when overcome by Covid-19 Infection.

The introduction of a Covid Vaccination program in the UK following AZ Vaccine discovery with fast track MHRA approval in the UK, followed by two further Covid Vaccine product introduction swiftly followed, has saved many lives but a degree of concern and fear remains. Sadly, some vaccinated patients have suffered side effects, usually minimal for just a few days, but sadly a few have experienced tragic fatal blood clots and other complications leaving concern.

Forensic review of case studies from events pre 2019 and other references led Derek Beatty to successfully have his work presented at World Diabetes 2020, January 2020, Sydney, Australia, on his behalf, and to Diabetes UK, St Albans Voluntary Support Group in early 2020. This and more recent update presentations in 2022 to European Public Health Covid-19 webinar included Diabetes; The 30th Endocrinology and Diabetes Conference, Barcelona; and Global Thyroid webcam has attracted global interest in this unique research and many inquiry links and disclosure requests.

Disapproval by some persons in Hertfordshire, England, at present subject to investigation to correct legal statute lacuna law, and suspected miscarriages of justice within the Judicial System in England since 1994, is ongoing in preparation for Judicial Review of Public Concern and to assist the UK Covid-19 Public Inquiry with submissions gratefully received.

It is noted that findings reviewed in 2020 and disclosed to the Scottish Parliament and independently by the Global Research Community has helped clinical science leading to the introduction of the First Covid-19 vaccination program commenced early 2021 after MHRA Clinical Trials to produce a vaccine to prevent Covid-19 and now an objective to find a cure to treat those affected including Long Covid and extended to other health conditions with immunological risk exposure.

3. Covid-19: Timeline of Events, Economic Effect Summary, Social Issues

16 March 2020: UK Public asked to limit all non-essential contact and travel by UK Government.

17 March 2020: UK Government announce mortgage payment

holiday for homeowners.

23 March 2020: First National Lockdown enforced in the UK.

31 March 2020: Scottish Government advises all house moves should be delayed.

28 May 2020: Phase One of Scottish Government Roadmap out of lockdown commences to open housing market.

29 June 2020: Scotland's First Minister confirms restrictions on house moves will be relaxed.

July 2020: Rise in demand in property market.

5 January 2021: Second National Lockdown Imposed. Moving home is allowed but advice is to postpone.

31 March - 8 April 2021: Mouse move holiday and funding offers changed and closes due to high demand.

9 August 2021: Scotland moves Beyond Level 0 restrictions.

16 December 2021: Open house viewings permitted in Scotland for first time since March 2020.

21 March 2022: Scottish Government confirms removal of all Covid-19 Legal Requirements except face coverings.

18 April 2022: Remaining Covid-19 restrictions are lifted. (Courtesy ESPC, Edinburgh)

February 2014: Start of Ukraine War

February 2022: Russia invades Ukraine. Major food, oil, gas, supply disruption to Global Economy. War trauma. Insulin supply to Diabetes Patients in Ukraine leads to fast-track charity support to assist and arrange emergency Insulin supplies to Ukraine to save lives.

4. Immunogenic Introduction, Research Elaboration and Findings

- 1) Investigation of published evidence from December 1993 into Immunological Issues associated with Insulin and Diabetes is relevant to the fact that in England and Scotland in 2020 an estimated 25-30% of Covid-19 patient deaths were patients with diabetes as disclosed by NHS England and NHS Scotland and in the public domain. On 28 October 2020 a report was submitted to the Scottish Parliament, to Edinburgh University, and others interested with identification of need for further research.
- 2) Events in respect of this matter and comparison identifying lack of knowledge transparency and understanding within Justice Systems and Healthcare Providers are similar in some ways to the Factor 8 Haemophilia Medical Issue leading to ongoing Public Inquiry but with results delayed due to Covid-19 Pandemic, now recognised from findings of fact. The ITV documentary 'In Cold Blood' screened on TV in 2020 provides helpful summary of patient and family experiences leading to the HIV pandemic. In many respects the human insulin debacle is similar

with the GM medical treatment being the first use of GM technology to produce commercially GM Human Insulin following UK research into DNA and RNA by Watson and Crick and commercial link between Genetec and Eli Lilly and Novo Nordisk. BHI was granted MCA Medicines Control Agency approval 26 August 1982 followed closely after by European and FDA approval in the USA.

- 3) The Covid-19 Pandemic in the UK and Worldwide 16 March 2020 has led to global tragedy and a challenge to global healthcare providers and researchers to work together and share knowledge and public health awareness so that future generations can be protected and educated for future tragic infection events were such to arise.

5. Immunogenic Issues Reviewed 1994

- 1) Studies about human insulin were limited before 1980 as significant amounts of human insulin could not be obtained. Research understanding of DNA and RNA by Watson and Crick led to a flurry of research used to produce genetically engineered human insulin. Drug company clinical trials approval was granted by licencing authorities in August 1982 to launch Human Insulin in the UK to treat diabetes patients and subsequently in October 1982 in Germany and the USA. Today Genetically Engineered GM Human Insulin with many combinations is prescribed every day throughout the world to treat diabetes. The pharmaceutical industry successfully purified human and animal insulin with safety advice available to prescribing clinicians and licensing bodies and accepted by prescribing clinicians worldwide.
- 2) In 2020 it is estimated that around 25 - 30% of the sad Covid-19 deaths are people who have an underlying health condition, often diabetes. NHS England statistics appear to endorse this. Today in 2022 immunological questions remain as to why patients with diabetes are more at risk of contracting Covid-19 often with tragic results. In 1988 presented in Edinburgh by G Schernthaner (Austria) was: Is Human insulin better than Animal Insulin in the Treatment of Insulin-Dependent Diabetes Mellitus?
- 3) Is the Diabetes Covid-19 link immunological? Scientific published information reviewed many years ago now suggests there may be a link between type of insulin and why some very ill Covid-19 patients treated with insulin for diabetes may be at more risk and those with obesity.
- 4) In the mid 1990's published content was reviewed by a UK barrister (Abelson deceased) who was involved with the 'Legal Opinion about Human Insulin', Forrest & Evans, 26 January 1993. This advice reviewed a sample of 900 diabetes patient experiences with legal opinion addressing issues raised from the Low Task Force Draft Report, Posner, December 1992 from an estimated sample of 3,000 letters sent to the BDA. The Human Insulin Solicitors Group had been set up with a steering committee elected at a Law Society Meeting in London of over 200 firms who had been contacted by over 1,000 diabetic patients considering legal action against the drug companies by diabetic patients who believed they had suffered damage as a result of their insulin prescription having been changed to Human Insulin. The evidence was collated up to and including the summer of 1992 funded by the Legal Aid Board, England.
- 5) The Chairman of the Steering Group wrote to Derek Beatty on 9 October 1997 in detail. He advised counsel were unable to consider individual medical negligence cases and advice was to the Legal Aid Board. To prove that any GP could have been negligent in their prescribing by change of insulin from animal to human insulin it would be necessary to prove that the medication itself could in fact cause harm.
- 6) A key advisor Professor Tattersall was very clearly of the view that human insulin, while having benefits for those who had never been treated with animal insulin, did have potential side effects in those diabetics who had previously been used to animal insulin to successfully treat T1 Diabetes.
- 7) It had already been established that in multi-party cases involving medication the Department of Health was an inappropriate defendant. The choice was available between animal and human insulin. All the marketing suggested that human insulin was best, which was logical, however the insulin was not from human beings but a genetically engineered version of porcine insulin (Novo) or yeast (Lilly). Human insulin was the nearest one could get without taking insulin cadavers. The pharmaceutical industry had decided that the future of the insulin market was in Human insulin, invested in the opportunity, and achieved global licence safety and marketing approval.
- 8) Side Effects: The steering committee trawled around 800 articles produced under the headings of diabetes, hypoglycaemia, and insulin, in the 10 years prior to when the investigation started.

Side Effects: 2 classes were identified:

 - a) Neurological – Tremor and Confusion
 - b) Physical – Sweating and Shaking. 1994 Banting Memorial Lecture–Hypoglycaemia–Real and Unreal, Lawful and Unlawful: V Marks.
 - a. Charities in the UK, the British Diabetic Association, now Diabetes UK, and the IDDT, Insulin Dependent Diabetes Trust, now the InDependent Diabetes Trust, became concerned by many T1D Diabetes patients disclosing frightening experiences of low blood glucose levels with no warnings of impending hypoglycaemia unawareness and many

including the author were not listened to at the time and often prescribing general practitioners took an old fashioned approach from Victorian times in the UK that the 'Doctor is always Right'. In the treatment of Diabetes patients when they may have experienced immunogenic issues associated with insulin prescription incorrectly aligned to ensure quality of life was maintained by patients loss of warning signs of hypoglycaemia caused many tragedies; unnecessary loss of life; unexplained patient falls; car and vehicle crashes; unexplained deaths which left coroners often unable to offer exact specific explanations to loss of life; incidents of aggressive and occasionally violent patient behaviour when Red Alert Ambulance Paramedic was denied due to ignorance and patient carer, family member, not being informed of exactly how to treat a severe hypoglycaemic event often when no alcohol had been involved and the need for emergency fast acting glucose raising sweet food, glucose tablets, and on occasion when in diabetic coma a glucagon injection. This was the state the writer found himself on 23.2.1994 with witness explanation that diabetes is not an illness and later description by an ignorant insurance broker in court that Diabetes is Nonsense, Hypoglycaemia is a Joke and Domestic Violence. This attitude to Hypoglycaemia and Mental Health possibly stems from the discovery of Addison's Disease 1860 with Thyroid implications associated with Hypopituitarism and Hyperpituitarism. Hydrocortisone treatment following T3 and T4 assay became available in the 1950's and more recently in certain patients Iodine treatment or surgery when cancer is diagnosed in Thyroid patients.

- b. Investigations came to a head in May 1994 when the author, on advice from the IDDT InDependent Diabetes Trust, demanded at Watford General Hospital prescribed insulin be switched back to Porcine Insulin from Human Insulin and within a few days warning signs of impending Hypoglycaemia had returned and Unawareness disappeared, as did muscle cramps and many other side effect experience of wrong Insulin and Dose for 9 years promptly disappeared and health improved. BBC2 Newsnight Team had decided to interview Diabetes Patients including the author and members of IDDT and the Director of Research at the BDA. Public interest dramatically increased with Diabetes Charities and the author being contacted to explain their personal and family experiences leading to greater recognition Globally of the issue. The pharmaceutical industry took on board the need for further research to improve newer insulins and attempt to prevent hypoglycaemia unawareness so that patients can experience improved lifestyle despite the daily challenge of living with a serious healthcare condition.
- c. The effect of Covid-19 from March 2020 before vaccina-

tions were discovered in late 2020 has had a devastating effect on patients with diabetes, obesity, and other health disorders. The time has come to dramatically change the attitude of many to be aware of the Clinical Health Condition of Hypoglycaemia affecting patients with Diabetes and Addisonian Adrenalin Crisis which can be life threatening. It is no longer a social stigma from history but a daily welfare challenge for all patients with Diabetes and other similar health conditions.

- 9) Forensic case law in hypoglycaemia unawareness beyond reasonable doubt identifies alleged violence complaints and abnormal aggressive behaviour when treatment of acute hypoglycaemia and neuroglycopenia is deliberately denied of the diabetes patient as was the writer's personal experience 23.2.1994, when witnesses and on call GP deliberately failed to summon ambulatory/paramedic help.
- 10) The difference between human and animal insulin was not the actual side effects but the order in which they came. Animal insulin caused the physical effects which enabled the brain to react while the general view was that with human insulin the neurological effects happened first and prevented the brain to act in a way which did not allow the diabetic patient to recognise the physical causes leading to loss of warnings of hypoglycaemia. At the time this was not backed up by any of the published studies but subsequently detailed by Teuscher in his published papers, and in his book 'Insulin, A Voice for Choice' published October 2007, Karger. The diabetic community around the world at the time tried to rubbish Professor Teuscher. The author personally witnessed this embarrassment at an International Diabetes Conference in Helsinki, 1997.
- 11) It had been hoped a further large randomised statistical clinical trial would be implemented. The pharmaceutical industry at the time had no reason to financially support such research as human insulin clinical approval and safety had been successfully achieved worldwide.
- 12) Res ipsa loquitur applies in medical negligence but in human insulin the scientific evidence was not there.
- 13) Plaintiffs must set out their grievances in detail for a court to consider and Defendants obliged to answer.
- 14) Peter Stott, Solicitor, remained convinced that one day there will be evidence which will prove that human insulin has a detrimental effect on those previously on animal insulin.
- 15) The key question now arises from the reported statistical facts that in patients who have died from Covid-19 in England 25-30% have been identified as having a previous health condition of diabetes, probably both Type 1 and Type 2, and on the balance of probability this suggests the need

- in any Covid-19 Public Inquiry to address the diabetes link in detail with further research in the immunological issues involved.
- 16) The American Diabetes Association, 3 December 1993 published in *Diabetes Care*, Supplement 3, 'Human Insulin – A Decade of Experience and Future Developments'. This includes Human Insulin after 10 years, J S Skyler. This suggested along with G Scherthaner that human insulin has favourable immunogenicity and should be used to treat diabetes patients. Hypoglycaemia unawareness is referred to along with the hypothesis could human insulin prevent T2 diabetes? Can the immunogenicity mediate β cell damage? Does human insulin metabolically cause dawn regulation of anti β cell immune response?
 - 17) The History of Insulin – M Bliss, In 1889 insulin was named by Minkowski and Mering in reference to Pancreatectomy. In diabetes insulin was described as a mysterious substance responsible for metabolic control. Research in animals by Banting and Best, Collip and Macleod identified a dog experiencing a hypoglycaemic attack which later died. On 11 January 1922 in Toronto Leonard Thompson, aged 14, was injected with insulin from pig extract produced by Collip and treated by Banting and Best. On 23 January 1922 success was announced. Eli Lilly started to manufacture insulin in the USA and in 1923 Novo took to Denmark and the wife of Krogh was treated.
 - 18) Gestational Diabetes GDM – DR Coustan stated 25% of GDM patients need insulin and 20 years later 40% of GDM women develop overt diabetes.
 - 19) New Directions – Mixtures, Analogues, Modelling- JA Gal- loway. Focus was to reduce complications of diabetes. Peak effects of insulin occur 3-4 hours after injection and up to 8 hours. Remaining insulin after injection can remain in the body up to 24 hours and often up to 36 hours and further injections can lead to a build-up of insulin action hence the need for glucose stabilisation in conjunction with daily life-style. GM human insulin has a changed molecule on the alanine chain at Lys (β 28) Pro (β 29). C-peptide can be normal or elevated in NIDDM but deficient in IDDM. In 1993 this was regarded as of no consequence in respect of quality-of-life issues. Could this be relevant to immunogenicity in Covid-19?
 - 20) Insulin Regimes and strategies for IDDM – B Zinman. Insulin injection can cause death, ambient temperature, exercise, food intake, intra subject variation is considerable. Human insulin peak action leads to hypo risk especially during sleep. In 1993 55% long term patients on beef slow acting insulin, switch to porcine or human insulin could cause problems. In 2020 variations occur in hospitalised patients, insulin time, dose change. In forensic analysis of Covid-19 diabetes patient deaths what are the treatment regimes in place before hospital transfer and at home?
 - 21) Insulin therapy in T2 diabetes – VA Koivisto. Insulin therapy can have an anti-atherogenic effects on serum lipid profile. It stimulates glucose uptake and enhances glucose oxidation and storage in muscle tissue leading to T1 mortality to macrovascular complications up to 2-4 times normal. Data on T2 hypo insulin event was scant. Infection risk?
 - 22) Hypoglycaemia Unawareness in IDDM – PE Cryer. Patients suffered 1-2 hypo events per week reducing symptoms and defences against hypo unawareness. Potential infection risk? Life goes on but insulin reactions change over time and circumstance. Infection risk?
 - 23) Hyperinsulinemia – how innocent a bystander? PZ Zimmet, Caulfield, Australia. Nauajo Indians, Prima Indians, Asian Indians, Chinese, weight gain issues. Insulin resistance. Insulin is a survival hormone. Papua New Guinea. Cardiovascular studies plus NIDDM lifestyle leading to T2 diabetes. A powerful moral dilemma faces public health workers while molecular biologists and clinical research scientists attempt to understand the role of hyperinsulinemia in the etiology in these noncommunicable diseases.
 - 24) Nocturnal Blood Glucose Control in Pregnancy – Bolli et al, Italy. Somogyi Phenomenon 1938, Hypo and hyper popular in 1950's during sleep. Human insulin absorbed faster. One amino acid molecule different on the alanine chain. Daily dose of insulin reduced 10 – 25% when switching from animal to human insulin.
 - 25) Sweet Success with Diabetes – Pregnancy- JL Kitzmiller -Insulin therapy for glycaemic control – USA special diabetes and pregnancy clinics to reduce high levels of mortality, diagnosis, surveillance, nocturnal hypoglycaemia for balance and near normoglycaemia as outpatient. Tight glycaemic control prevents foetal macrosomia, birth trauma, respiratory distress, congenital malformation. Dietary therapy is crucial to success, oestrogen protects uterus arteries. Insulin resistance in pregnancy, more insulin is needed for glycaemic control therefore more hypos. Pump therapy, Farquar, 1969, Edinburgh, reviewed 210 children of T1D mothers.
 - 26) Further developments – Insulin Delivery. CD Saudek. DCCT improved BG reduces diabetes complications. Insulin absorption, injection site, depth of skin, infusion pumps, implanted pumps, nasal therapy, 1935 and 1993.
 - 27) R & D Safety of Biosynthetic Insulin-Chance, Frank. R- DNA origin and insulin first genetically engineered treatment. Yeast used by Lilly, porcine used by Novo. Humalin 1982, RNA and DNA technology, Watson and Crick. Much PR activity, May 1976 Lilly Symposium, first approval August 1982, 1980 first volunteers, Erol Wood, Surrey, Lilly.
 - 28) Insulin therapy in last decade, Paediatric perspective – JV

Santiago. 1970's 30% of children previously on beef or pork insulin, reddening, itching, inflammation, lipoatrophy at injection site. Insulin resistance 20-30% noted in puberty.

- 29) Immunogenicity and allergenic potential of animal and human insulins- G Scherthaner. From 1922 insulins were impure, anti-insulin antibodies identified as IgG and IgE. Human insulin is not totally immunogenic. Irregular administration can lead to higher risk and allergy reaction. Intermittent insulin therapy may be a patient stimulus for immunogenicity.

6. Public Health Involvement

- 1) 28 years of diabetes research since 1994 and discovery 2020 that 25-30% of Covid-19 deaths in England and Scotland are patients with diabetes. Any Covid-19 Public inquiry should address the following background statistical patient information and review any immunogenic risk link.
- 2) Is patient Type 1 or Type 2 diabetes?
- 3) If treated with insulin for how long? What type of insulin and dose?
- 4) Patient weight and BMI? Height? Diet / Alcohol intake?
- 5) Complications of diabetes details, Vascular disease, Hypertension, Neuropathy, Retinopathy, Mental Health state?
- 6) Link to Diabetes and death from Covid-19 within 28 days of positive Covid-19 test.
- 7) Update from Indian study presented 12 November 2020 at World Diabetes 2020. Covid-19 deaths linked to Hypertension. Vitamin D deficiency identified along with Zinc and Magnesium. Generally, 80% of the Indian population are deficient in Vitamin D.
- 8) Disclosure in September 2022 from a study at the University of Paris into Thyroid Cancer Iodine treatment has recognised the serious fear and paranoia mental health issues associated with patients with Thyroid Disease including Addison's Disease often undiagnosed but with likely Genetic Inheritance and often symptom emerging in patients in late 30's early 40's.
- 9) A further grave concern exists just published that young children from a statistical sample of children not given any Covid-19 vaccine a further risk exists of the likely possibility that Covid unvaccinated children may have a high-risk possibility of developing T1D Diabetes identifying the Public Health need to justify knowledge disclosure to parents when it is known that Diabetes and Endocrine issues exist in families. This leaves a Duty of Care with parents to take care in regular observation of

children when parents have Diabetes or Thyroid disorder to ensure knowledge and information shared in most instances for the general welfare concern of the children in any family and when offered is not meant as nor should be suggested as any form of harassment but clinically published scientific often peer reviewed when disclosed in the best interests of patient and children welfare to benefit future generations.

- 10) With Global interest in Hypoglycaemia in medical conditions which can also affect athletes, the elderly where appetite is less, and premature infants and very young babies where sadly many tragic deaths have been reported, an opportunity now exists to publish possibly in book form this work for Clinical and Education Learning use for further research especially with Hypoglycaemia Mental Health link to assist clarity in Social, Civil and Criminal Law Statute identified as lacuna or hollow law in 2000 but which Public Health Awareness is the driving force for improved welfare and public knowledge to address Hypoglycaemia Emergency Events.

7. Low-Risk Differentiated Thyroid Cancer: toward an evidence-based use of Iodine 131

A dreadful stigma about mental health in Endocrine Health disorders appears to exist in the UK since British Empire days in late 1860's when Addison's Disease was discovered by Thomas Addison. The same stigma may apply in other countries eg Malaysia, India, Pakistan, Africa eg Nigeria, and others. A cover up of Mental Health stigma in Addison's Disease and similar Thyroid Disorders has occurred since year 2000 when an incidence of 600 Addison Disease patients existed in the UK (ref S Shalet, Christie Hospital, Manchester). In 2021 the UK Department of Health identified 10,000 Addison's Disease patients in UK with 50% undiagnosed and some frightened to seek help from GP General Practitioner but happy to wrongly blame others when referral to Endocrinologist, Psychologist or Psychiatrist is required to diagnose monitor treatment regularly.

- 1) A clinical interest exists in Scotland to explore this with NHS Scotland and Police Scotland following casual discussion with encouragement in Mental Health understanding in Endocrinology as we emerge from Covid-19 Pandemic.
- 2) A similar patient attitude in France, Germany, Italy, Austria, and other European Countries to this Mental Health stigma in Endocrinology Health Disorders including Addison's Disease and Diabetes appears to exist with social address required to benefit patients and carers being a priority.
- 3) T1D Patient 44 years with 50 years' experience in Healthcare, Endocrinology, Respiratory, Radiology, has identi-

fied helpful references including:

- 4) Coping with Thyroid Problems; Gomez, 1994, London
- 5) Thyroid Dysfunction; Godden, Volpe, 1975, Toronto
- 6) Essentials of Clinical Medicine, Kumar Clark's 7th Edition, Zammitt, Sandilands, 2022
- 7) The Genome Odyssey, Ashley, Cardiologist, Stanford, 2021

8. Treatments in Thyroid Disease

Iodine 131 is a possible treatment which hopefully will offer patient benefits. The author has treated with daily diligence T1D Diabetes for 44 years. The author's ex-wife was diagnosed with Addison's Disease pre 1978 in Australia. She was born India 1941 and returned to Lancaster. She had a younger sister and 2 brothers older than her. She said Diabetes is NOT an illness, which it is. She had zero relationship with 2 brothers. This is a typical Case Study of the dreadful stigma about mental health in Endocrine Health disorders in the UK since British Empire days late 1860's when Addison's Disease was discovered by Thomas Addison. The suggestion in Manchester in the year 2000 by the Court that investigation of a patient diagnosed with Addison's Disease by request for medical notes disclosure to the Court, Solicitors and Barrister of NHS England patient notes being 'A Fishing Trip' when the Court was asked to agree to such to enable diagnosis of Fear, Paranoia, Agoraphobia, in Addison's Disease and Mental Health stigma in Addison's Disease and similar Thyroid Disorders occurred when in 2000 an incidence of 600 Addison Disease patients existed in the UK (ref S Shalet, Christie Hospital, Manchester). In 2021 the UK Department of Health identified 10,000 Addison's Disease patients in UK with 50% undiagnosed and frightened to seek or offered help from NHS GP General Practitioners when referral to Endocrinologist or Psychologist or Psychiatrist is advised to diagnose and monitor treatment on a regular basis. There is clinical interest in Scotland in exploring this with Police Scotland interest and support for the author as we emerge from Covid-19 Pandemic. This patient social attitude in France, Germany, Italy, Austria, and other European Countries to this Mental Health stigma in Endocrinology Health Disorders including Addison's Disease and Diabetes appears to be identified in these countries requiring more public awareness.

Prof Martin Schlumberger, Paris, recently presented an informative and interesting lecture on Iodine 131. Experience disclosed from Poland suggests if there were to be radiation leakage from nuclear accident that Potassium Iodide can be effective with very prompt treatment to children and young adults. A UK Thyroid study is planned for disclosure October 2022. It is tragic that the UK Court System in 2000 refused to allow as evidence and prepared by Prof S Shalet, Christie Hospital, Manchester, a leading research centre, to be investigated in Law. In 1980's the author was involved with Clinicians studying MRI Brain Neurology

Scans with the first MRI Neurology research on a Picker 0.5 Tesla MRI Scanner at London National Hospital and Manchester, then presented at MRI Radiology Conferences in Europe, Berlin, USA, Canada, which kick started MRI understanding of neuroscience. It is shocking that what could have been done in Thyroid disorders has not been disclosed and shared but covered up by ignorance.

The author witnessed and gave first aid at a fatal car crash 1976, in Bricket Wood, St Albans, when a Rolls Royce hit a lorry. Sadly, the driver died. There was a fatal accident inquiry. This traumatic event may have triggered T1D Diabetes plus possible immunogenic infection from times in Nigeria, Kenya, Zambia? The PTSD injury was successfully treated by psychological counselling caused by the near fatal Diabetes Hypo Event 23.2.1994 and ex-wife Addison's Disease Hypo. Covid is a mental health issue affecting many. The author received Cognitive Therapy years ago by a psychologist who treated survivors of the Watford Train Crash and it worked but flash backs still occur. In 1994 when warning signs of impending Hypoglycaemia returned, in prayer a big Problem with Insulin and Diabetes and Hypoglycaemia Unawareness was identified with the message - go fix it! That is what the author and others have tried to do for 28 years but many do not believe this. The author's daughter has lost 28 years of fatherhood caused by this disgraceful social attitude caused by ignorance and refusal to understand. The author's dad was a POW in Italy and Germany during WW2. A poem in his possessions 'The Miracle of Friendship' is an amazing thanks to God for friendship. Many people and friends are now supporting this work to which the author extends grateful thanks. The author has been a member of IDDT Independent Diabetes Trust, www.iddntinternational.org when the Co-Chairs were saviours in 1994. At group meetings all this mental issue is discussed. There is one patient with both T1D Diabetes and Addison's Disease and an interesting example of a combined complex health issue.

9. Positive Life

Exercise is good. Sensible diet is good. Healthy eating is good. Occasional treat of dark chocolate is good. Any alcohol should be minimal. If balance deteriorates with age never be embarrassed about walking with a supporting walking stick and keep upright. Try and prevent need for emergency ambulance and paramedic help. In the UK there are around 95,000 NHS Ambulance Service Red Alert Hypoglycaemia calls per annum, 63-73% are treated on site; 27 - 37% require Emergency Red Alert transfer to hospital; 2-7% require repeat Red Alert Ambulance attendance in 2 days. Ref: Role and prevalence of impaired awareness in ambulance service attendances to people who have had severe hypoglycaemic emergency: mixed methods study; Duncan et al Stirling 2018. The ambulance service is often amazed by the number of Diabetes patients requiring help when experiencing problems with leg and feet problems associated with Diabetes. It is important to check feet daily and rub cream on feet especially the underside to prevent

dry skin, but not between toes. If any cuts or ulcers are noted seek prompt advice from a health professional.

Otitis Externa and Osteomyelitis in 2016 with painful infection on his skull the author required IV antibiotic delivery in hospital and at home. The Dental issue of saliva duct cortisol secretion can lead to dental plaque and gum disease. Research has led to 'A Listening Ear'. A magnesium supplement can make a significant difference and calcium electrolyte balance is important. Hearing in diabetes can be affected by certain loud sounds, eg motorbike, shouting. Relaxation after an evening meal helps. A treat can be a single square of Dark Chocolate 85% and a small whiskey diluted 50% tap water which the author has found to stabilise hearing.

10. Diabetes and Thyroid Research Opportunities after Covid has been identified as:

- a) The Dental Link
- b) The Ear Link
- c) The Ophthalmic Link
- d) The Vascular and Heart link
- e) The Legs and Feet link
- f) The Diet Link
- g) The Vitamin Link
- h) The Exercise Link
- i) The Legal Bit
- j) The Alcohol Bit
- k) The Car Crash Trauma with PTSD Bit
- l) The Hypoglycaemia and Antibiotic Link
- m) The Murder bit (Vincent Marks work was focussed in this area as he was a forensic pathologist and often called by the Police in England and USA to give expert opinion).
- n) The Unexplained Baby and neo-nate Death with Hypoglycaemia and Parental Genetic Link

All these clinical forensic areas in Clinical Medicine are relevant in society as we emerge from the crisis of the Covid Pandemic to develop a Diabetes Encyclopaedia to support 'T1D Winning in Insulin Chicanes after 100 years - Hypoglycemia Forensics Post Covid'.

11. Thyroid Update 2022

Prof Martin Schlumber, University of Paris

- 1) In 1977 Thyroid Carcinoma was identified with hormone therapy required to treat T3 and T4 deficiency. 5% of patients were treated with Iodine 131 with good survival. Research and patient treatment was implemented at the Mayo Clinic, USA, 1966-90.
- 2) World incidence is 586,000 Tumour cases, 55% in the USA. In 2015 Government Guidelines were issued in the USA and 95% of low-risk patients have been cured.

- 3) There has been a lack of clinical trials in Thyroid Disease, 25 years ago from 1997 with trials visible through patient associations. In 1999 the Thyroid and Pituitary Foundation in the UK was started with an inaugural meeting at the University of Manchester attended by the author along with Dr Peter White – The Psychological/Psychiatric Problems Associated with Thyroid Disease and Prof Stephen Shalet What is the Best Way to Treat a Pituitary Tumour? And who in year 2000 produced an Expert Witness Report commissioned by the author with attempt to place with the Court in Manchester with public immunity interest but which the Court and the Crown declined describing such as a 'Fishing Trip!' The author's ex-wife admitted under oath to have been treated for Addison's Disease since before 1978 with diagnosis when nursing in Australia early 1970's. Clinical Research Trial publications have continued with reports 2000, 2012, 2022.
- 4) Thyroidectomy to remove cancerous Thyroid Tumour was commenced in France 3 May 2012. Ablation success led to 92% of patients successfully ablated.
- 5) EMA European Medicine Association approval was 2006; 2010 and 2012.
- 6) FDA approval was 2007 and 2014.
- 7) Update trials were published in the Lancet in 2018 and in Diabetes Endocrinology and a positive Phase 3 Trial Published in the Lancet in March 2022 which required to have been addressed 21 April 2022 in St Albans as the research demonstrated anxiety and peace of mind in patients also associated with Fear, Paranoia, and Agoraphobia.
- 8) A low-risk trial with results expected soon identifies prognostic events included elevated Thyroglobulin with abnormal neck issues.
- 9) Mayo Clinic USA Hay et al 2022 identified tiredness and stress which improved on treatment with improved life quality for 700 patients. Improved Patients were allowed access to diagnostic tests with opportunity to educate physicians and patients and offer Lobectomy treatment. Patients were followed up more closely.
- 10) Chernobyl Nuclear Accident – In the event of such with likelihood of spread of nuclear dust patient treatment with Potassium Iodide children and adults less than 45 years should be treated as quickly as possible. After Chernobyl some contamination was noted in certain areas in Poland with Potassium Iodide treatment and few side effects.
- 11) Invasive surgery when used can leave a scar behind the neck which heals with time.
- 12) In Thyroid disease there has been poor quality of data showing successful treatments. With good quality data

this encourages patients to do as advised.

- 13) In Japan there is increased awareness of Thyroid Cancer and scanning is offered.
- 14) Low cognitive mood and fatigue are experienced where research is being done.
- 15) Thyroid eye disease patients must be seen by a doctor.
- 16) WHO 7,000 Rare Diseases, 80 are Thyroid Diseases. Migraine occurs in 33% of patients.
- 17) In the UK T3 can be available by NHS prescription on diagnosis.
- 18) In England a new report is to be published on 17 October 2022 by Lord Kamal and Lord Hunt.
- 19) Decision taken in St Albans, April 2022, was too soon and with Rule 12 GMC Investigation disclosed July 2022 proposing a Judicial Review ongoing at the time. Conduct by failed understanding of complex clinical knowledge in Thyroid, Addison's Disease and Diabetes, has been detrimental to this ongoing research since 1994 by the author. An opportunity exists to disclose this research update to SHARE – The Scottish Health Research Register and Biobank.

12. Global Summit on Physiology and Metabolism of Thyroid - 3 October 2022 - Summary Notes

- 1) Nuclear Medicine, Thyroid Cancer - Dr Andreas Lim: Symptoms when patient presents may justify Thyroidectomy surgical procedure to treat Thyroid Cancer. Addison's Disease is often diagnosed based on Human Behaviour.
- 2) Radiation Therapy - Dr Neha Sharma: Ebert radiation procedure or surgery.
- 3) 12,000 Patients Study Rougier. 1983 Required Thyroid Carcinoma. 73 patients required total Thyroidectomy.
- 4) 1998 – 2004 Metastatic, Addison's Patients need constant monitoring.
- 5) Antioxidant, Obesity – Chili pepper treatment reduces slightly cardiovascular, helps in Diabetes.
- 6) Helps in T1 and T2. Capsaicin in diet with Travi can help control Diabetes and reduces obesity.
- 7) Hypothyroidism in Pregnancy – Dr Sufia Athar, Qatar – This is an overlooked health concern.
- 8) Parathyroid gland, Hyperparathyroidism shows as tumorous lips, tongue, Familial Medullary Thyroid carcinoma.
- 9) Ultrasound Diagnosis, Thyroid Cancer. Histology confirmation. CT scan can show adrenal lesions. Calcitonin test before 6 years of age. Thyroid in family, Hyperparathyroidism, Genetic Testing, and counselling is required.

- 10) T3 and T4 Assay required. T3 and T4 increased in Pregnancy. Hypothyroidism is Overlooked in Pregnancy. Incidence 0.5 – 3.5% of pregnant ladies. Postpartum Thyroiditis is 5-17%
- 11) High risk noted from screening.
- 12) Familial inheritance of Thyroid Autoimmunity of Addison's Disease in families. Pregnancy causes Hypothyroidism with estimated 38.9% pregnant ladies affected. In France only 51% of ladies diagnosed are treated.
- 13) TSH – in 2,000 patients signs increase with age, elderly patients. Clinical Hypothyroidism, TSH T4 rises, picked up with new assays.
- 14) Papillary thyroid carcinoma as first and isolated tumour in a young woman with MLH1 gene mutation, Dr Antonella Carbone, Italy.

13. Conclusion, Findings and Way Forward

The author's initial findings were based on ongoing research reading, attendance at Diabetes and Endocrinology Patient and Professional Clinical Meetings from 1994 along with involvement with diabetes charities Diabetes UK and IDDT, Independent Diabetes Trust. This was enhanced by attendance and participation at meetings of the All-Party Diabetes Group at the Scottish Parliament for several years. When Covid-19 hit in March 2020 after the author's presentation on his behalf at World Diabetes 2020, Sydney, Australia, and St Albans Voluntary Diabetes UK Support Group the author focused on possible inhaled nebuliser delivered therapy using nebuliser drug delivery attached to a ventilator system which had been successfully used in Costa Rica to treat some Covid-19 affected patients prior to the Covid vaccine introduction programme from the UK in late 2020 and success in 2021.

The Journal of Diabetes and Metabolism published 'Diabetes and Covid-19 Pandemic – A T1 Patient Perspective' which attracted attention and invitation to present the research by webcam. Disclosure to the Scottish Parliament and Government led to recommendations for further research applications to take the research forward. Unfortunately in late 2020 information was disclosed to the author from Hertfordshire, England, which has caused much unnecessary stress and wasted time to address, and which remains outstanding in legal statute in England and caused by failure in 1995 – 2000 to understand disclosures in the public domain by certain courts in England who refused to allow certain Clinical Evidence associated with Addison's Disease, Diabetes, and Hypoglycaemia, relevant to the author's near fatal diabetic hypoglycaemia and neuroglycopenia seizure event of February 1994, and this has dramatically delayed further research and sharing of research in the Clinical and Public Environment. Those responsible have been identified to justify further Judicial Review Investigation to address errors which have affected the author and others for many years.

Major Legal and Judicial concern has been raised in 2022. In Clinical knowledge, research and understanding we have moved forward from the True-Life Case Work in Vincent Marks and Caroline Richmond published 2007 entitled *Insulin Murders with Forward* by Nick Ross, TV and Radio Presenter and Journalist.

We must be grateful for the excellent publications of 'Forensic Aspects of Hypoglycaemia' Vincent Marks, 2019; 'Type Awesome' Fighting Highs, Fighting Lows by Jo Fox 2020; 'The Genome Odyssey' Euan Ashley 2021 and 'Clinical Medicine' Kumar Clark's 7th Edition Zammitt and Sandilands 2022. These texts bring Clinicians, Nurses, Lawyers, Judges, Police, the NHS, Councils, those delivering Social Service Welfare Care to patients and communities where impaired mental health illness can at times be a challenging issue in society. Very importantly in recent investigations to understand the cause of many tragic unexplained issues for example sad unexplained neo nate and young baby deaths. Attracting significant interest, we must move forward from the time of the tragic Beverly Aylett case of 1991 and address the facts that insulin was discovered in 1922 by Banting, Best and Macleod with input from Collip with the objective of saving lives of patients with Diabetes and only those few with troubled unsound mind who chose to use it as a weapon to commit murder hopefully not to be discovered. The other complications of many sad deaths of patients who are treated with insulin and other approved medication in all cases required detailed forensic investigation is required to include interference by other prescribed medication, eg antibiotics where Blood Glucose imbalance and Hypoglycaemia or Hyperglycaemia may occur and can easily be caused by medication errors, lifestyle, exercise, and traumatic chemical change caused by for example electrolyte imbalance. The author has worked with many fully qualified clinicians, nurses, radiographers, respiratory staff, GP's over the years but sadly within certain NHS areas in the UK a sad bullying type attitude towards nursing and similar type medical and clinical staff can exist leaving individuals exposed to false interpretation of clinical evidence and NHS Management exposed to errors which have been apparent.

In 2022 these issues in healthcare must be addressed by professional investigation of factual evidence as clearly demonstrated in recent disclosure and post Covid offers many opportunities for further clinical and diagnostic research to understand experience in recent years and publish awareness to improve patient welfare for the future.

Presentation of Diabetes and Thyroid findings in 2022 has achieved a massive boost into the awareness and complex clinical areas of Hypoglycaemia and Mental Health in Clinical Medicine and the author is delighted and honoured now to be associated and linked to the Monash University in Malaysia where a 3 year project is ready to be launched to enable students and post graduate students to take this research further by working with helpful published research to date with plan to incorporate into a published text to help

learning and understanding for future generations.

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15. Funding and Conflict of Interest, Copyright Issues

No support funding or sponsorship funding has been obtained for this work all of which has been undertaken on a voluntary basis. All references used to obtain information is published in the public domain or on the internet. No tables or content has been copied from other published disclosure and so no copyright permission is required. For legal protection this work is copyright protected by the author's company Aston Clinton Scientific Ltd working in conjunction with Monash University, Malaysia. The author confirms that the University of Edinburgh from where the author graduated has been updated on developments in this work, as has the Scottish Parliament, and opportunities are likely to exist for Commonwealth interest shared between the UK and Malaysia in mutual healthcare interest.

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