



Menopause APPG Inquiry into The Menopause Revolution Session 4: Menopause, HRT and Testosterone

Date: Tuesday 7th December 2021

Time: 14:00 pm – 16:00 pm

Location: Virtual, Zoom

Minutes taken by: Erza Llumnica and Sarina Kiayani, DGA Interel UK

Members Present:

- Carolyn Harris MP – Chair of the APPG
- Jackie Doyle-Price MP – Vice Chair of the APPG

Guest Speakers:

- Dr Louise Newson – Leading menopause specialist and founder of free Balance app for menopausal women
- Dr Shirin Lakhani – Aesthetics doctor specialising in “alternative” HRT
- Jacqui McBurnie – NHS England/Improvement Menopause Group Chair
- Michael Buckley – CEO/Medical Director, Lawley Pharmaceuticals, Perth Australia
- Professor Matthew Cripps – NHS England/ Improvement, Director of Behaviour Change
- Alistair Darby – CEO, Newson Health

External Guests:

- Jo Lloyd – Office of Carolyn Harris MP
- Lucy Chatwin – Newson Health
- Dr Sarah Ball – Newson Health
- Rebecca Lewis – Newson Health
- Emily Jane
- Dr Radhika Vohra – GP
- Bryony Kingsland – City and Guilds
- Katherine Morgan – DGA Interel UK
- Sarina Kiayani – DGA Interel UK
- Victoria McNish – DGA Interel UK
- Erza Llumnica – DGA Interel UK

Minutes of the meeting 14.00pm – 16.00 pm:

Carolyn Harris MP welcomed everyone and introduced the meeting.

Dr Louise Newson introduced herself by stating that she runs a private menopause company, a non-profit company and the Balance app. She also said that she takes HRT and has had first-hand experience with perimenopause, and that HRT helped her to function in daily life. She noted that around 1/100 women under 40 have an early Menopause and 1/1,000 women under 30, and it takes around seven years for young women to receive a diagnosis. Based on this, she stated that we need to be thinking of menopause as a female hormone deficiency syndrome, as Menopause is a huge problem, it is a real inequality issue and every women goes through it. She noted that women and healthcare professionals remain concerned about HRT due to years of misinformation, which has led to healthcare professionals prescribing away from it. To help tackle misinformation and track menopausal symptoms, she has launched a free app, Balance, which tracks symptoms, tackles misinformation and offers treatment options and assistance with consultations, and provides health reports. Dr Louise Newson added that training for health care professionals has been neglected and limited, but over 18,000 health care professionals have downloaded the app in last 6 months, showing that they want to know more. She added that we need to think about local commissioners and healthcare providers and GMC Guidance and consent, as patients must be involved in decisions and a lot of



women are denied HRT, often for the wrong reasons, risking their future health (leading to conditions such as depression, heart disease and osteoporosis).

Carolyn Harris MP thanked **Dr Louise Newson** and stated her shock about the number of people who have contacted her to talk about their negative healthcare experiences. She then introduced **Dr Shirin Lakhani**.

Dr Shirin Lakhani said that she prescribes both licensed and compounded HRT, depending on the patient. She is a former GP who left the NHS in 2017, and has an aesthetics clinic in Kent. She has a particular interest in women's health, saying that this is neglected in NHS, particularly after childbirth and Menopause. She said that education for health care professionals is lacking, and came into prescribing HRT to tackle menopause symptoms, and that the age demographics of women seeking her for cosmetic work tends to be menopausal. She works to educate people on what their symptoms are and the help they can get, stating that she sees so many people who get "fobbed off" by healthcare professionals.

Jacqui McBurnie mirrored the comments already said, outlining how the NHS England Improvement Group have hundreds of members that all articulate the struggle in achieving the recognition of menopause and peri-menopause symptom management, but also attempting to navigate the refusal to be prescribed HRT and dealing with anti-depressants being the first medication prescribed. She stated that there was a financial impact in accessing menopause expertise and testosterone. She added that there are issues around access to menopause clinics.

Carolyn Harris MP thanked **Jacqui McBurnie** and introduced **Michael Buckley**.

Michael Buckley stated that he is a pharmacist by training, who opened one of the first compounding pharmacies in Australia. He realised that there was a large unmet clinical need from this, moving into manufacturing. He established Lawley Pharmaceuticals 25 years ago, and it was they who got testosterone cream licensed in Australia. In November 2020, testosterone became licensed as an international product with an export license, so it became popular in the UK. He stated that women's health and hormones is a major under-addressed area of health, as Australia only had synthetic progestogens, not testosterone.

Carolyn Harris MP said that she uses testosterone, and introduced **Alistair Darby**.

Alistair Darby is CEO of Newson Health, and his wife is a patient in the Newson Clinic. His role is to support Louise and Rebecca in running the clinic. He stated that his wife struggled with menopause and was prescribed anti-depressants before going to the Newson Clinic, which "transformed" her menopause experience. He is interested in how menopause can transform women's lives and experiences.

Carolyn Harris MP thanked **Alistair Darby** and introduced **Matthew Cripps**.

Matthew Cripps introduced himself as Director of Behaviour Change at NHS England/Improvement. He met **Dr Louise Newson** 2-3 years ago and she helped him to recognise that menopause care is a significant opportunity for population healthcare improvement. He stated that there is a lack of awareness amongst clinicians and patients about HRT and testosterone, and that which does exist commonly features stigmas and misconceptions around them. He added that misogyny is a reason behind inefficiencies in the NHS offerings around Menopause. He stated that behaviours must change, so that more women and clinicians can "think menopause" and act accordingly. This is the tagline of the national menopause improvement programme. He stated that both patients and clinicians are unaware of the full impact of menopause, which can affect menopause care. He stated that we should design a series of education packages on menopause, from schools to frontline clinicians. We should also design an optimal clinical pathway once women receive a menopause diagnosis. This should focus on general population awareness, and on women in the workforce. We should also improve wider clinical awareness and the number of wider menopause specialists in healthcare. He stated that more supportive workplace environments are needed to prevent women cutting their working hours and leaving their jobs due to menopause. Optimal clinical pathways will lead to an increase in HRT prescribing and the right testosterone prescribing.

Carolyn Harris MP thanked **Matthew Cripps** and spoke about her personal experience and not knowing she was menopausal. She talked about her positive impact on testosterone and her lack of menopause education leading to her misdiagnosis with depression, and criticised why GPs are not prescribing HRT.

Dr Shirin Lakhani stated that GPs remain insufficiently educated on HRT and still refer to flawed studies from 20 years ago. She also said that attitudes that women should "just get on with" the menopause need to change, and would not be there if men went through menopause, adding that taboos around menopause have contributed to this. There is still reluctance and resistance to change amongst healthcare professionals, as they remain convinced that HRT leads to issues such as breast cancer.



Jackie Doyle-Price MP mentioned that she struggled with thyroids before she was diagnosed, and that a revolution in women's health generally is needed, as well as Menopause. She stated that she was keen to encourage the NHS and Department of Health to liberate pharmacies to do more in the space of menopause, as people may feel more comfortable to speak to their pharmacists.

Dr Louise Newson stated that pharmacists and nurses should be running menopause care, however an issue includes limitations in MHRA guidance. She stated that prescribing HRT is still raised as an issue on medical systems, leading clinicians to prescribe antidepressants as they are considered to be "safer". Clinicians therefore need the right tools to prescribe HRT.

Jackie Doyle-Price MP responded by saying that conditions such as osteoporosis, dementia and heart disease stemming from menopause create future demands on the NHS, which must be considered.

Carolyn Harris MP suggested that greater funding could be provided to improve GP training on menopause to improve diagnosis and care.

Dr Radhika Vohra stated that, as a GP focused on women's health, GPs frequently undertake off-license prescribing. She stated that trainee GPs are the best group to train, as learning and improving their knowledge is directly on their radar, so we should start with them.

Dr Louise Newson stated that issues such as vaginal dryness can lead to women feeling extremely uncomfortable and affect their daily lives. She stated that vaginal oestrogen can improve daily life and significantly ease these symptoms, and that vaginal treatments should be made available over-the-counter. "Checking layers" by pharmacists can, however, put women off taking medication, if they are being questioned too thoroughly about their choices. She said that women frequently wait until their symptoms are very bad to take HRT.

Jacqui McBurnie stated that women tend to read HRT leaflets and get scared, but would not do the same with routine medication such as paracetamol. She stated that education should be given on oestrogen, progesterone and testosterone so that women can make informed decisions about their menopause care.

Carolyn Harris MP stated that the bottom line of the discussion is that improved education on HRT is needed, and we need to find funding for GPs to do more menopause training.

Matthew Cripps stated that there is significant health inequalities between ethnicities and levels of deprivation in menopause care, and that most good access to menopause care is via private clinics. A major issue is with GP referrals, as this is the main gateway for health issues. The majority of pharmacists and nurses currently cannot prescribe HRT, and changing this may go some way to improving menopause care. Educating GPs on all clinicians on spotting menopause symptoms is key, along with a focus on getting pharmacists and nurses to become menopause specialists.

Carolyn Harris MP stated that the Welsh Government is looking into introducing better pathways for menopause care, and helping to effectively diagnose menopause.

Dr Shirin Lakhani expressed concerns around the widespread distribution of HRT through pharmacies without women being assessed properly, as hormones must be balanced as well as replaced, particularly since many of her patients have issues when they first go on HRT. She therefore advocated the creation of menopause specialists who can effectively diagnose menopause based on symptoms.

Lucy Chatwin stated that innovation should be measured so that it effectively gets done. She called for local champions in health networks to improve menopause care, to provide a strength in opinion around making menopause matter.

Dr Radhika Vora stated that other health professionals can be involved in menopause care through group consultations. Many women can join one call, note their questions and experience and follow up with shorter, individual calls. She noted that there was a shortage of GPs, but the menopause needs bespoke care, with the decision to prescribe hormones needing to be made based on individual cases. Patient and clinician education also needs to be matched up so that women do not give up. She also noted that women tend to like the community feel of working together.

Sarah Ball stated that she met **Dr Louise Newson** when she was a GP working in the NHS, and had to pay out of her own pocket to pay for her menopause specialist training from the British Menopause Society. Four years later, she remains on their waiting list and had not yet received her training certificate so was forced to leave the NHS. She criticised how she had to be trained herself at her own expense to become a menopause



specialist, and it is ironic that she has extensive knowledge and teaches GPs about menopause but does not yet have the certificate herself. Her overwhelming opinion is that education needs improving.

Dr Louise Newson stated that there is a ripple effect with empowered women spreading information through word of mouth, and that the majority of women using the Balance app receive the treatment that they want. She added that women in their 40s and 50s have a sevenfold increased rate of suicide, so balancing hormones must be a priority to prevent this.

Carolyn Harris MP expressed her desire for **Michael Buckley's** products to become licensed in the UK, and that she will work to assist this.

Michael Buckley then presented a slideshow on testosterone use in women. He detailed the history of testosterone use in women, with the first clinical trial in the 1940s being undertaken on men and women. He noted that ovaries are the primary source of producing testosterone in women. Ireland, Australia and the UK were the initial markets for testosterone implants, so the market has always been popular here. The development and licensing of Viagra to address erectile dysfunction in men in the late 1990s shifted the focus US pharma to an equivalent product for female sexual dysfunction. This led Proctor and Gamble to develop and extensive clinical trial program of a testosterone patch treating Hypoactive Sexual Desire Disorder in women. HSDD is a sub-set of generalised low sex drive. P&G's pilot study of 75 women decided that a 300mg patch was most effective, and this became the gold-standard patch for the subsequent batch of studies in the next 10 years. A year after the P&G study Lawley Pharmaceuticals showed that their testosterone cream worked the same as the patch for women with HSDD. P&G went to the US FDA in 2005, however the FDA expressed concerns around cardiovascular effects and the long-term effect of testosterone in women, so the FDA did not approve the patches. The data was then sold on to another company (Warner-Chilcott) and taken to the European Medicines Agency, which approved the T patch for surgically postmenopausal women with HSDD using estrogen in 2006. The testosterone patch was marketed in the UK, Ireland, Germany, France, Spain and Italy) from 2007 until the company withdrew the license for the drug in 2012 for commercial reasons. He added that, in February 2019, the British Menopause Society created a toolkit for physicians on testosterone use in treating menopause. The big change came in July 2019 with the publication of a systematic review and meta-analysis into testosterone use in women, which covered multiple safety aspects. It found that testosterone is effective in post-menopausal women with low sexual desire, and the trans-dermal route of dosing is the most effective. Later in the year, the Global Consensus Position Statement on the Use of Testosterone marked another turning point, setting out 12 recommendations on the use of testosterone therapy in women. Lawley Pharmaceuticals then submitted its AndroFeme® 1 testosterone cream dossier to the Australian Government in September 2019, which was licensed in November 2020. The testosterone options that UK female patients currently have are off-label use of male-approved products or the use of the Lawley product as an unlicensed medicine prescribed privately. He said that he is working to get his products licensed in the UK. The company met with the MHRA in September 2021, saying that there is now a clear regulatory pathway with the UK leaving the EU, providing the MHRA with more decision-making independence away from Europe. It is aiming to submit its dossier on testosterone in the first or second quarter of 2022, which will be very similar to that presented to the TGA in Australia.

Carolyn Harris MP asked what she and **Jackie-Doyle Price MP** could do to help.

Michael Buckley added that the company's dossiers were virtually complete. He also noted that that big pharma is not interested in developing a female-specific testosterone formulation as there is no patent protection.

Jackie Doyle-Price MP stated that we should urge the MHRA to move forward with licensing a testosterone, and that it has let women down before, including regarding prescribing the Pill. **Carolyn Harris MP** agreed, stating that they will write to the MHRA with the help of **Dr Louise Newson** and **Michael Buckley**. Mr Buckley noted that Lawley could not assist with drafting or being party to a letter.

Matthew Cripps stated that issues around testosterone focus on licensing, increasing supply chain production as demand increases and consensus around the extent of the use of testosterone. There remains a range of opinions around testosterone as there has not been enough research around testosterone use to create a consensus that can help convince regulators, and he noted that this was one area that parliamentarians can assist with.

Michael Buckley stated that he believed the body-identical hormones at the best option to be prescribed to regulate bodily systems, and we should work towards this. He stated that, right now, approving testosterone



for treating HSDD in postmenopausal women was Lawley's main focus. Thereafter, clinical focus will shift to other areas of testosterone use such as the perimenopause, bone, heart, and early menopause.

Dr Louise Newson stated that safety is key, but prescribing testosterone to treat low libido is essential, as this is a key side-effect of menopause. She added that we must convince people that off-license prescribing is safe, as this is how many treatments are prescribed.

Carolyn Harris MP thanked attendees and closed the session.