

WELSH WOUND INNOVATION CENTRE



ANNUAL REPORT

July 2020

Leading the Field in
Wound Prevention & Treatment

The Welsh Wound Innovation Initiative Limited Company Report as of 31 July 2020

SITUATION

The Welsh Wound Innovation Initiative Limited (WWIL) is a not-for-profit company limited by guarantee and was incorporated on 4 November 2013 with Cardiff University as its sole member. To better reflect WWIL's All-Wales role, the membership was broadened to include an additional Higher Education Institute, Swansea University and 2 NHS organisations; Cardiff & Vale University Health Board and Cwm Taf University Health Board. The process for admitting a further academic institution, Cardiff Metropolitan University has been finalised with existing membership approval and its inclusion on the company register at Companies House to be completed in October 2020. The new membership arrangements enabled the triangulation of WWIL's offering to the NHS, commercial and academic agenda. This was particularly evident during the pandemic wherein WWIL's relationships with NHS organisations, Cardiff & Vale University Health Board in particular, were strengthened.

As we are all aware 2020 has been a challenging year for WWIL and its constituent Members with the pandemic impacting significantly on our respective modus operandi. The World Health Organisation and International Monetary Fund have collectively described the pandemic as having plunged the world into a 'crisis like no other'. Indeed, the impact continues to be felt across commercial, academic and health care organisations as each of us grapple with challenges, many of which are outside our direct control. Similarly, for WWIL the pandemic has had significant consequences. As of March 23rd, the UK entered a 12-week lockdown period wherein the campaign for staying at home, protecting lives, and protecting the NHS was paramount. As at that date WWIL's income generating opportunities were effectively switched off; outpatient clinics ceased resulting in the loss of research activities, travel restrictions impacted on the commercial courses and consultancy work abated as company's business requirements changed. It is testament to WWIL's innovative and collaborative approaches that the company survived the first wave of the pandemic, principally through seconding clinical staff to support wound care in the community setting in Cardiff & Vale UHB for the 3-month period as well as rental of the lower ground floor to supporting NHS activities. Notwithstanding the ongoing effects of the pandemic, the WWIL team remain confident that the company can continue to offer innovative and viable solutions to advancing wound care and service delivery, a different delivery model may however be required to sustain its activities beyond 2021, particularly given that a second wave and a world-wide recession is anticipated.

Fortunately, since its inception, WWIL has benefited from stable leadership at Board level. However, several changes in non-Executive and Director positions were signalled at the July Board meeting. Fiona Peel, OBE, the founding Chair of the company confirmed her intention to retire. The Board thanked Fiona for her continued stewardship and support proffered to the company from its establishment. The post will be advertised in early August and interviews are planned for 1 September 2020. Further, Professor Ceri Phillips, the Director representing Swansea University confirmed his retirement from his post as Head of the College of Human and Health Sciences. Swansea University are expected to confirm its nomination for the Director position in September. Owing to a number of organisation challenges, Dr. Kelechi Nnoaham, the Director representing Cwm Taf Morgannwg has struggled to attend Board meetings and whilst he remains committed to representing the Member's interest, he is discussion with the CEO and will confirm the Health Board's representation in due course.

Each Member is represented by a nominated Director who represents its constituent organisation and contributes to supporting the company's objectives as well as ensuring that governance processes are robust. The purpose of this report is to summarise the company's achievements over the past year such that Directors can report back to their respective Member organisation.

BACKGROUND

WWIL uniquely brings together the key voices on wounds in Wales, spanning government, NHS, academia, business and industry and the Third Sector, all of whom play a key role in overcoming the challenges of wound healing and the maintenance of skin health. Following from the broadening of the Company Membership, the revised objects are as follows: -

1. the co-ordination and triangulation of wound care pathways such that care, and treatment is optimised and delivered efficaciously in a safe, cost effective, innovative, and efficient way, which may include: -
 - i. entering into arrangements with several stakeholders, including NHS entities and Welsh Government in connection with funding and the provision of wound care services;
 - ii. being involved in the co-ordination and the treatment of all wounds, including education, training and development;
 - iii. working with commercial partners and looking for commercial investments in the field to develop new treatments and diagnostics;
 - iv. providing multidisciplinary integrated clinical services and supporting the set-up of others; and
 - v. being a hub for research and development, clinical innovation and academic activity aligned to and associated with wound healing; and

2. to engage with patients' and stakeholders to provide a model that accelerates innovation, translation, improvement and commercialisation in wound prevention, care management and healing; and
3. one of the Company's primary goals is to conduct fundamental research, industrial research, or experimental development and to disseminate a range of results by way of teaching, publication or technology transfer.

The Board meets on a quarterly basis and its role is summarised as follows:

- providing entrepreneurial leadership and setting and supporting the company's strategy;
- ensuring the human and financial resources are available to achieve company objectives;
- reviewing governance arrangements;
- actively contribute to and promote the success of the company;
- ensuring that obligations to stakeholders are understood and met.

ASSESSMENT

WWIL is involved in the co-ordination and the treatment of chronic wounds, including training and development, and is working with commercial partners on new treatments and diagnostics. Despite the challenges presented by the pandemic, WWIL has performed well against the 6 delivery pillars of its operational plan as follows:

Pillar 1: Sustainable funding

Welsh Government grant funding ended in March 2018; the company ended the 2018/19 financial year with a small surplus through income generated from its activities. In the period August 2019-March 2020 the company's business diversification strategy to include R&D laboratory work; subletting and consultancy agreements supported its financial delivery plan. However, the implementation of lockdown had immediate detrimental financial consequences for WWIL, in particular:

- Education courses planned and expected for March to July were postponed. Three companies had courses arranged with a cumulative income of £64k, and further courses were being discussed.
- All recruitment of patients for clinical trials has stopped, which forestalled any income being generated. Specifically, WWIC was due to receive £70k on the recruitment of the 15th

patient for a large debridement trial, 9 patients had been recruited at the end of February with a further 6 planned over the following 3-month period.

- Subletting of office space ceased with a loss of income of £1700/month.

Due to the proactive thinking of the Management Team the financial situation was somewhat relieved by offering WWIC staff and resources to the NHS. The company facility has afforded the continuity of the vital blood donation service to the end of March and provided an excellent temporary extension for the Haematology department and day treatment service for Cwm Taf Morgannwg.

With the support of Len Richards, CEO Cardiff & Vale UHB, the clinical staff provided a welcome addition to the Health Board's community nursing team as well as providing additional infrastructure to supporting the evaluation and learning of cross-cutting activities to inform the UHB's organisation development plan. Unlike other SME's, WWIL was unable to avail of any financial support via the furlough scheme as 85% of WWIL employees' substantive contract of employment is with Cardiff University. WWIL employed staff, including a part-time receptionist and housekeeper, were required to support the facility; whilst those on Consultancy contracts significantly reduced their hours. These measures combined covered most of the ongoing operational costs. The financial position to the end of July 2020 forecast a deficit of £100k, the preliminary draft accounts identify a deficit of £132k as of 31 July 2020.

The key part of the company accounts is cash flow which stood at £190,995 as of 2 April 2020. Based on the income and expenditure forecast the company predicted a cash balance of £176k at the end of the financial year. A balance of £202k was achieved, principally through additional limitations on expenditure and additional income from consultancy work. Despite the deficit, the medium-term financial outlook into the new financial year is relatively stable but requires the reinstitution of income generating activities from October/November 2020.

Pillar 2. Partnerships & Collaborations to drive R&D

In collaboration with our NHS partners, up to 23 March 2020 WWIL's clinical trial programme remained active with 59 patients recruited to clinical trials/product evaluation studies. The company has engaged in supporting the development, design, and delivery of several innovative products, principally in wound debridement. Further, the growth in patient recruitment potential has been supported through collaborations with Podiatry and Community clinics in Cardiff & Vale and Aneurin Bevan University Health Boards'. A further exciting development over the past year is the utilisation of WWIL's expertise in acting as a Clinical Research Organisation (CRO) for wound studies. WWIL is uniquely placed to be a centre of excellence for CRO activities and is the nominated lead for a multi-centre Accelerate grant, which is an EU funded initiative, for the evaluation of a novel wound compression device.

The company continues to partner with commercial entities, academic institutes, and the NHS in developing grant applications. Through the auspices of Professor Harding, WWIL is involved in an NIHR Research and Innovation for Global Health Transformation application exploring the transformation, treatment and prevention of leprosy and Buruli Ulcers in low- and middle-income countries. Excitingly, we are also collaborating with Imperial College on a study looking at skin substitutes from cadavers. The study is funded by the JP Moulton Charitable Trust and is referred to as DAVE which stands for Decellularised Autologous Graft for the treatment of chronic venous leg ulceration. Aligned to this development has been the resurgence of ‘first-in-man’ studies being able to be accommodated from within Aneurin Bevan UHB as a result of the sub-specialty interest of a Consultant Vascular Surgeon and EU Consultant who were previous wound healing fellows. The additional medical capacity to support these types of studies is welcomed as it provides future growth opportunities which will benefit patients, research activity returns as well as enabling the company to achieve its objectives in advancing wound healing treatments and services.

Two further studies of note include a collaboration with Huntleigh and Lohmann and Rauscher. The former relates to the securing a large clinical research trial across 3 centres in the UK and 1 in Germany for a wound express device. The latter relates to a first in man-study for a novel debriding agent. In addition, grant submissions continue to be developed in partnership with University and SME’s with 2 out of the 4 submissions being successful. The Accelerate bid being one and the other is an NIHR Research and Innovation for Global Health Transformation – Transforming the Treatment and Prevention of Leprosy and Buruli Ulcers in Low and Middle-Income Countries.

In respect of the healthy volunteer programme of works, the institution of the social media platform, YAMMER, by Cardiff University has yielded significant interest and access to a large population which ensures that such studies can be completed in an effective and timely manner.

Pillar 3. Business Continuity

Reassuringly the company’s business continuity plan was adequate to withstand the enforced changes generated by the pandemic. Our IT manager ensured that staff were equipped to enable them to work from home, regular team meetings were instituted as well as a WhatsApp group to ensure that staff did not feel isolated. Equally staff were appropriately supported on their return to the workplace.

Importantly during the period, the clinical team kept in contact with patients as many struggled with lack of access to the complex wound clinic service, their GP and community wound team. A

reflection of the experiences is being developed as there are valuable lessons to be learned for the future management of patients with chronic conditions during a pandemic.

The company, through its Medical Director, Commercial Director and Research and Development Director ensured that we maintained regular communication with our commercial collaborators. We considered this vital in terms of the company's recovery plan such that we were aware of any challenges that the companies were enduring whilst at the same time we could keep them informed of what was happening locally, particularly in respect of the reinstatement of activities in a safe and effective manner.

Pillar 4. Innovation & Improvement Outputs

WWIL has built up an extensive Wound Registry and is leading the way in terms of wound data to inform clinical practice as well as to support future investigative/exploratory research. In the past year we have moved from a digital based pen technology data capture system to an integrated digital form that provides a wound electronic patient record on an individual basis. The technology also allows for wound photographs to be stored. Several glitches in the system were being worked through, just as COVID hit and these will be continued to be advanced as digital data capture recommences.

2019/20 witnessed a significant increase in the number of publications from the team with 57 articles in publication at the time of the report. All members of the Executive Management Team contributed to or indeed were the lead author which demonstrates the depth and breadth of capacity and expertise. Further, despite the impact of COVID on conferences and meetings 71 presentations and workshops were delivered, more laterally in the form of webinars. Abstract submissions remained at a level with 2018/19's performance with 20 being submitted in the reporting year.

WWIL in collaboration with a commercial organisation supported Anna Galazka in undertaking a PhD which centered on the socio-economic review of the effectiveness of a social enterprise approach to wound care in the form of the Lindsay Leg Club. Anna was successful in gaining a Senior Lecturer post in Liverpool which she will commence in September. Over the 10-month period Anna made numerous contributions to knowledge in the wound care community, both independently and in collaboration with academic colleagues and practitioners from the Leg Club community. Anna conducted and completed the service evaluation of the Lindsay Leg Clubs, prepared an article and a society update note for a community nursing journal, pushed forward work on five manuscripts submitted to high impact journals in the fields of organisation studies and social sciences, and engaged with the wider community through presenting her research to non-academic audiences. WWIL is very proud of Anna's achievements.

In respect of the Innovation and Improvement Agenda, through the auspices of the CEO of Cardiff & Vale UHB, WWIL was engaged to support a clinical review of the Dragon's Heart Hospital, the evaluation has been submitted to support future learning. Additionally, as part of the review members of the WWIL team in collaboration with the UHB's patient experience team conducted a review of patients and family/friends experience of their hospital stay during the pandemic. As a result of lockdown, restrictions of movement and activity impacted significantly on the NHS. Across NHS Wales, no hospital visits were allowed from 25 March 2020 with a small number of exceptions: visits to those at end of life could be allowed at the discretion of the nurse in charge, one parent or legal guardian could visit an ill child and one birth partner could attend deliveries (Welsh Government 2020). At this time, volunteer staff were also excluded from hospitals. The widespread use of personal protective equipment (PPE) introduced new experiences for staff and patients. The purpose of the review was to provide greater detail on the experience of hospital patients during this period and to explore how hospital stays could be improved while restrictions on access to hospitals remain in place during the coronavirus pandemic. Further a publication is anticipated in the Autumn period.

Aligned to this agenda is the advancement of the 5I's Institute, a pioneering concept which Professor Harding is leading in collaboration with Cardiff and Vale UHB, Cardiff University and a number of Institutes in Singapore; principally the LKC Medical School, Tan Tock Seng Hospital and Skin Research Institute of Singapore. The 5I's concept builds on the concept of the holy trinity of the NHS; Academia and Commercial worlds to both advance and accelerate the development, translation and adoption of 'stuff that makes a difference' to patients and clinicians as well as providing an incubator space for health focused start-up companies underpinned by a skilled and capable work force. The 5I's straddles Invention, Innovation, Improvement, Implementation and Impact and the Institute will form part of the UHB's Health Science Quarter capital development programme.

Pillar 5. Engaged Customers

Despite COVID limiting the number of new commercial contacts, the company developed a small number of new contacts and promoted relations with established contacts. The latter being vital for the company's future. Over the previous year however our number of social media contacts and website hits have mushroomed with 500 additional social media contacts and an impressive 5,000 extra hits on the website when compared to 2018/19. The significant increase has been a direct result of the Board's secretary's influence in website and social media updates. The company would further wish to harness these activities in the 2020/21 year to promote and market our services.

Pillar 6. Education and Training

The company's education and training programme was severely hampered by COVID, both from a commercial education and clinical placement perspective. The former had a significant impact on the company's income profile, however the company has, like many other organisations, adapted and will be offering the courses via a virtual platform in the Autumn period. Further staff members have contributed to a number of Webinar's and has been commissioned to provide a WWIC webinar at the latter end of November. Clinical placements, given the infection, prevention and control procedures currently employed remain a challenge. WWIL will be happy to support once it is safe to do so as this type of experience is unique and invaluable to clinical professional development.

The team continue to support Cardiff University's successful MSc in wound healing and tissue repair in terms of teaching, marking and supervision. Over 60 people have achieved an MSc and of the 19 students who commenced the programme last year, seven are completing modular components and seven intend to progress to the Dissertation level. 23 students are expected to join the 2020 programme.

Finally, members of the Executive Management Team (EMT) continue to contribute to academic and journal reviews, with a 50% increase in activity, from 41 to 82, being observed across the reporting period. Further the EMT also support external examinations and MSc Academic reviews.

RECOMMENDATION

The Board is asked to:

Note and **Share** the paper with its respective Member organisation.