Institution: University of Warwick

Unit of Assessment: A1 – Clinical Medicine

a. Context: Warwick Medical School (WMS) made its first clinical medicine research appointment in 2003. The hallmarks of our developing impact in clinical medicine are excellent investigator-led research across our focused areas with collaborations involving groups from the local, national and international health economies. This delivers wide-reaching and significant impact for some of today's key clinical issues. Impacts have been delivered during the current REF period from our Metabolic and Vascular Health and Reproductive Health research divisions. Researchers in our new Microbiology & Infection Division bring a strong track record of impact, e.g. having previously invented MLST, a method for fingerprinting bacteria that has been widely adopted in healthcare bacteriology, and will continue this at WMS. Our Biomedical Cell Biology research informs underpinning science and will contribute to future impact.

Our focus on research impact is epitomised by our Science City Research Alliance (SCRA, 2008–2018) with University of Birmingham. *Inter alia* this has funded £10M translational research capacity in clinical trials and experimental medicine to work with businesses in the West Midlands to expand the knowledge economy. SCRA has exceeded its targets, to date creating and safeguarding >110 jobs and providing ~170 new business assists and collaborations in translational medicine. The Warwick Healthcare Partnership (WHP, 2012-) is another vehicle for our research impact, combining the expertise of University of Warwick (UoW), UHCW NHS Trust (UHCW), Coventry City Council and GE Healthcare to improve health using high quality healthcare technology. WHP is currently focusing on improving clinical pathways (working with Omnyx's digital pathology platform European demonstrator site at UHCW) and care pathways (various cancers including a new Breast Cancer Centre of Excellence). Overall, WMS has had 99 disclosures, 9 patents (most licensed, assigned or in market development), and 4 spinout companies. Examples of our main non-academic user groups and types of impact during the current REF period are given below.

Informing the commercialisation of drugs and therapies: we have long-term relationships with big pharma worth ~£2.5M in new research collaborations between 2008-2013. Our cardiovascular, obesity and diabetes research has contributed to diabetes therapeutics with Novo Nordisk [McTernan] and Astra Zeneca [Tripathi, Zammit]); testosterone therapy for obese men with Bayer [Barber]); and functional food development with Unilever [Thornalley]. Our research on prediction and prevention of pregnancy disorders is contributing to treatments for uterine dysfunction and pre-term labour with Ferring and GSK [Blanks], and for PCOS with Novo Nordisk [Randeva]. Our neurosciences research and spinout Neurosolutions Ltd. (now worth >£900k) contributed to drug development for a range of neurological disorders (GSK and Pfizer [Spanswick]). Our research on cancer is contributing to our WHP work and anticoagulation therapy development with Bayer [Poole and others], anticancer drug development with Astra Zeneca [Zammit], anticancer Phase 2 clinical trials through contract research with Roche [Zammit] and a new 'health-buddy' for supporting cancer care in the community with Bosch.

Shaping the management of significant diseases and conditions: in 2006 we established the Certificate in Diabetes Care which has become the UK's leading foundation course in this subject, with over 10,000 clinical diabetes professionals enrolled to date (2,700 during the REF period). Our spin-out social enterprise Apnee Sehat CIC, tailoring lifestyle programmes to the needs of Britain's South Asian community, won the Big Venture Challenge award in 2013. Phase 2 trials of our improved management of preterm labour [Hartshorne, Blanks] show a significant decrease in preterm births, which is a major cause of neonatal mortality (1M babies p.a.); and our work on antibody incompatible kidney transplantation [Zehnder] means UHCW now has the best results in Europe for this. We are developing a global health impact: our work on maternal and newborn clinical services in sub-Saharan Africa [O'Hare, Quenby] has trained 150 non-physician clinicians, resulted in national curriculum changes in Malawi, and more development requests in East Africa.

Informing media and public debate: we are regularly consulted by opinion-formers in UK and international media (e.g. BBC, Guardian, Huffington Post, The Conversation). Our contributions on recurrent miscarriage [Quenby, Brosens] raise awareness of the range of treatment options, resulting in >500 UK couples attending our Implantation Research Clinic; we regularly inform the public and policy debate on multi-drug resistant bacteria in hospitals [Pallen]. Many of us use Twitter, YouTube and blogs to contribute. Pallen has authored a best-selling popular science book and instigated an award-winning DVD (Rough Guide to Evolution); our 2012 Science &

Technology for Health *Ideas Café* attracted over 100 members of the public; and our Whole Body Calorimeter (WBC) was used to illustrate the potential for metabolism research to the public and media at the 2010 British Science Festival (attendance 55,000).

Shaping national and international policy and practice: >20 of our clinical academics are expert advisors to influential public policy bodies in the UK, Europe and internationally. Cappuccio's work on dietary salt has contributed to National Institute for Health and Clinical Excellence (NICE) guidelines for CVD prevention (NICE Guidance Expert Testimony Paper) and UN WHO Nutrition Advisory Group priority-setting for dietary salt (Expert Group); Quenby is Chair of the European Society for Reproductive Endocrinology Special Interest Group on early pregnancy which provide the guidelines used across Europe for management of early pregnancy, and is a core member of MHRA's womens' health group which identifies what medicines to licence for obstetrics and gynaecology in UK.

b. Approach to impact: WMS is an integral part of UoW, which prides itself on its economic, cultural and social engagement with a wide range of communities, so this vibrant culture of research impact is embedded in WMS from our early career researchers to the professoriate. Research impact resources are promoted in our HR induction. Impact is professionally managed from the beginning of the research lifecycle. Staff are encouraged to build relationships with external stakeholders and engage actively in policy and practice change. Our main approach to supporting research impact is through providing excellent facilities and signposting staff to the many sources of expert advice within UoW.

Investment in excellent research platforms and facilities: we have access to cutting-edge multi-user campus facilities such as the Learning Lab and our NHS partners' resources. We also invest in our own resources. In 2010 we co-funded the £2M custom-built Human Metabolism Research Unit (HMRU) with SCRA and UHCW to study how human energy is created and used, including the most advanced whole body calorimeter in Europe, and a Bod Pod. HMRU is a significant benefit for our metabolic and vascular research, and for biomedical engineering and food crop research at UoW, and is engaged in public understanding of science in the area of obesity. It has generated data in collaboration with industry; the first locally developed nutriceutical will go into human trials in HMRU in 2014. We intend to invest in infrastructure for early phase clinical trials for new drugs in the area of metabolic health, and novel magnetic resonance imaging techniques for human brown adipose tissue.

WMS and UHCW invested £500K in an independent Biomedical Research Unit in Reproductive Health (BRU-RH) for systematic sample collection (biobank), deep clinical phenotyping (database), advanced ultrasound imaging and laboratory analyses. Women at risk of reproductive failure/obstetric complications are, uniquely, seen in dedicated research clinics before pregnancy. The BRU-RH supports a broad range of research impact in reproductive health: we have developed and demonstrated the value of uterine natural killer (uNK) cell testing, and completed a feasibility trial of prednisolone treatment which will go forward to a multicentre randomized clinical trial; we have a drug discovery project for parturition disorders (with MRC-T, Ferring and GSK [Blanks]); and the BRU-RH provides a forum for user integration between clinician academics, scientists, Warwick Clinical Trials Unit, Warwick Ventures, and industry.

Future plans include investment in bioinformatics to support impact from the Warwick Infectious Disease Epidemiology Research (WIDER) Centre, and in facilities to support the new multi-user Centre for Nutrition & Health.

Exploiting institutional support: UoW invests heavily in research impact: our staff exploit this funding from Institute for Advanced Studies, Research Development Fund (7 awards), and HEIF Impact Fund (9 awards) for different stages of research impact from pump-priming to commercialization. Our staff use UoW's UNTRAP partnership with users of health and social care services, carers and the NHS, to support engagement with end users. For international impact, we encourage staff to capitalise on UoW's investment in strategic research partnerships with Boston University (USA), Monash University (Australia) and the Liverpool School of Tropical Medicine (CAHRD). These enable us to secure impact from our clinical medicine research by accessing technologies, expertise and user groups available through our NHS and industry partners.

UoW professionally manages research impact. Research Support Services (RSS) WMS faculty-facing team works with our staff to develop strategies to realise research impact before a project starts; Corporate Relations provides business introductions and support; and Warwick Ventures Ltd commercialises UoW innovations by linking businesses and investors to our intellectual

property, supporting technology development through proof of concept, protecting and licensing IP, and creating spin-out companies. Our staff work with the WMS Communications Office satellite to place and profile their research impact in a wide range of print, visual and electronic media. To these resources, WMS has invested in an Impacts Officer (100%FTE) to provide dedicated advice and formal impact training to all staff.

Promoting our external profile: in 2011 UoW established cross-campus Global Research Programmes (GRPs) to foster collaborative research around global priorities. The Science & Technology for Health GRP has supported clinical medicine research impact by enabling collaborative research utilising analytical science, healthcare technology and research-to practice approaches around *Healthy Ageing*, *Early Diagnosis and Treatment*, and *Improving Health in Resource Poor Settings*. To date, the Health GRP has increased multidisciplinary collaboration within the University, publicised our research, attracted business partners, and supported ~£50M bids for research and research impact funding, including the successful AHSN and CLAHRC bids. The GRP is described as an exemplar for fostering inter-disciplinary work in EPSRC's Maxwell report on the interactions between engineering and physical sciences, and health and life sciences.

c. Strategy and plans: As WMS consolidates in its second decade, our goal is to enhance our existing clinical medicine impact by developing more structured mechanisms to realise broader and deeper impact. Our 2012 *Research Impact Strategy* has five objectives that build on our clinical medicine research strategy:

1. To foster world-leading clinical research that delivers significant benefit for human health, by:

* Consolidating our research relevant to drugs and therapies for diabetes and human reproduction, and developing our research in microbial genomics, cancer and nutrition.
* Enhancing our impact on clinical management of disease through our adoption and innovation work in the new West Midlands Academic Health Sciences Network (WM-AHSN) (2013 – 2023) and Collaboration for Leadership in Applied Health Research and Care West Midlands (CLAHRC-WM) (2013 – 2018).

2. To enhance our culture of clinical research impact relevant to a wide range of users beyond academia, by:

* Appointing research excellent staff across our research groups, and building impact objectives into future academic job descriptions.

3. To provide the best support to the next generation of clinical research impact innovators, by:

* Supporting high potential early stage research impact.
* Using cross-campus networks (such as the Health GRP) to increase interdisciplinary working.
* Encouraging strategic secondments with industry and policy organisations.

4. To benchmark our impact activities against the highest international standards, by:

* Introducing systematic evaluation of clinical research impact.

5. To raise the profile of WMS clinical research impact locally, nationally and internationally, by:

* Increasing structured engagement with NHS partners, industry and other key stakeholders.

d. Relationship to case studies: Our four case studies exemplify the impact of our clinical medicine research. Our case studies demonstrate how our clinical scientists build on their investigator-led research to deliver significant and far-reaching impact by developing long-term relationships with key end users using support from UoW. Thornalley disseminated his leading work on GDP-dicarbonyl widely, enabling relationships with all three international PD-manufacturing companies; over a period of twenty years, this has led the sector to switch towards low GDP containing PD fluids, with concomitant reduction in treatment costs and decreased damage in PD patients. WMS supported this by funding dedicated technicians for the group's [MC-MS] facility, and UoW allocated HEIF Impact Funds. Spanswick followed a similar approach for his electrophysiological work to elucidate mechanisms of action of novel drugs, using a successful `spin-out' company as the vehicle (for which he received a nomination for *BBSRC Entrepreneur of the Year* in 2011). Via this route, Spanswick's work has impacted worldwide on therapeutic approaches to targeting neurological disorders, a number of which are in pre-clinical development by big pharma. UoW's Warwick Ventures Ltd ensured the successful establishment of the spinout and protection of associated IP. Zehnder and Cappuccio followed similar approaches, ensuring their investigator-led research in kidney transplantation and cardio-vascular disease respectively reached the appropriate audience and receiving technical and financial support from WMS, UoW and local NHS partners.