

<b>Institution: King's College London (KCL)</b>
<b>Unit of Assessment: 3B - Pharmacy and Nutritional Sciences</b>
<p><b>a. Context:</b> Staff included in this return contribute to the discovery and development of medicines (<b>Pharmacy</b>) and the modification of diet and lifestyle (<b>Nutrition</b>) from conception to old age, to prevent and manage disease. By actively engaging with our NHS partners, patients, carers and the public, regulatory agencies and industry, we improve patient care, inform health care and public health policy, and create new medicines and interventions.</p> <p><b>Impact through clinical partnerships:</b> The creation of King's Health Partners (KHP) and the award of Academic Health Science Centre status enhanced the synergy between KCL researchers and relevant clinical services. KHP is unique, with clinical academic groupings (CAGs) in the Pharmaceutical Sciences, Diabetes, Obesity and Nutrition and in Women's Health, which bring together basic and clinical scientists, dietitians, midwives, pharmacists, clinical pharmacists, psychologists, nurse educators and medical practitioners. The NHS Foundation Trusts of KHP are major tertiary referral centres for diabetes (especially problematic Type 1), haemochromatosis, coeliac and inflammatory bowel disease including oro-facial granulomatosis, mental health and for the prevention of pre-term birth/pre-eclampsia. For our research groups, there are specific benefits in forging closer links with successful (in terms of outcomes) clinical services caring for large cohorts of people with relevant conditions, such as pregnancy, diabetic pregnancy, hypoglycaemia-prone Type 1 diabetes, severe obesity and endocrine cancers. This has led to tangible benefits such as the development of an award winning research-based prematurity surveillance clinic for women at risk of pre-term birth, and a CLAHRC (Collaboration for Leadership in Applied Health Research and Care) award to KHP with themes in Women's Health and Diabetes (led by <b>Amiel</b>), both of which focus on the translation of research to the improvement of health at the community level. Furthermore, the recently awarded Academic Health Sciences Network has identified diabetes/obesity as one of its six themes in which to achieve global excellence, building on our framework of translational research in this area.</p> <p><b>Impact through interaction with patients and patient based charities:</b> We engage with patients and patient-led charities such as Diabetes UK (<b>Amiel</b>), HEART UK (<b>Sanders</b>, Honorary Nutritional Director), Maternity Worldwide (<b>Shennan</b>, Director) and Tommy's Charity (<b>Poston</b>, Tommy's Chair KCL) to ensure that our research outputs are contextualised in relation to the needs of users. The information books we have developed with Tommy's Charity led to the dissemination of more than 50,000 copies in 2012/13; "Having a Premature Baby" was the 2012 BMA Patient Information Resource of the Year Award Runner Up. Further examples of impact include dietary advice for teenage pregnancy based on the findings of the About Teenage Eating Study (<b>Poston, Sanders, Seed</b>). These include <a href="#">The Young Woman's Guide to Pregnancy and Pregnant Teenagers and Diet: A Guide for Professionals</a>.</p> <p><b>Impact through public involvement &amp; engagement:</b> We have actively engaged in disseminating research findings to the public through the media. <b>Long</b> has appeared on the BBC's <i>Horizon</i> series describing his work on the identification of biologically active molecules from the Australian Coral Reef. <b>Amiel</b> appeared on the popular science programme BBC <i>Bang Goes the Theory</i> on an item on glucose and insulin. <b>Sanders</b> featured in a discussion of research behind the <i>Five-a-Day</i> campaign on BBC Radio 4 <i>You and Yours</i>. <b>Lawrence</b>, as Chief Science Advisor to the Royal Pharmaceutical Society, is frequently invited to comment on national radio and television programs on matters relating to medicines discovery, development and use. <b>Nicolaides'</b> research was featured in the BBC <i>Life before Birth Series</i>, and <b>Shennan</b> and <b>Poston</b> appear frequently on TV News and radio programmes to provide expert opinion on premature birth and pre-eclampsia. <b>Shennan, Poston and Sanders</b> have all contributed to the BBC Radio 4 "Case Notes" series. There has also been active engagement with the British Nutrition Foundation, a charity with a major reach in the area of communicating findings to the public with regard to nutrition, and also has impact on the teaching of nutrition in Schools. <b>Sanders</b> (a trustee and scientific governor) gave the Annual British Nutrition Foundation Lecture in 2009, and Chaired the British Nutrition Foundation <a href="#">Task Force on Nutrition and Development</a> in 2013.</p>

**Influencing National and International Policy and Practice:** We engage in influencing policy and practices by actively contributing through participation in committees both nationally and internationally. For example:

**a) Medicines Use: Lawrence's** appointment (50% FTE) at the Royal Pharmaceutical Society facilitates a direct influence on both the pharmaceutical sciences and the practice of pharmacy. **Wolff** sits on a number of Government committees overseeing substance abuse and influencing legislation in this area, and **David Taylor's** research informs the "Prescribing Guidelines in Psychiatry". **Hylands** is a member of an Expert Advisory Group of the British Pharmacopoeia Commission of the Medicines and Healthcare Products Regulatory Agency, and **Martini** is Chair of the European Industrial Pharmacists Group.

**b) Clinical Guidelines:** Contributions to clinical guidelines provides one of the most important conduits for translation of research into clinical impact, and our approach includes continuous audit of our involvement. **Amiel** and **Pickup** have been involved in the development of guidelines for the management of diabetes (NICE guidelines, International Diabetes Federation position statements, National Technology Adoption Centre pump service guide), and **Cruickshank** is involved in the development of guidelines for the prevention of hypertension in youth for the European Hypertension Society. **Ciclitira** has helped develop guidelines for the management of coeliac disease for both the American and British Societies of Gastroenterology, and **Nicolaides** has made a major contribution to methods for the early detection of Down's Syndrome that has contributed to NICE guidelines (Antenatal Care CG 62, 2008). **Shennan** is the Chair of the NIHR, Reproductive Health & Childbirth Specialty Group, has contributed to the WHO Technical consultation on pre-eclampsia in 2013, was a member of the WHO committee on Blood Pressure Measurement in Low Resource Settings (2008-10) and contributed to the NICE Hypertension Guideline Development Group (2009). **Pasupathy** was author of the RCOG Greentop Guidelines for Management of Sepsis in Pregnancy (2012), and **Poston** was an author of the NICE guidelines on 'Weight management before and after pregnancy (2010). **Williamson's** work contributed to the RCOG guideline on Obstetric Cholestasis (2011).

**c) Dietary Guidelines: Sanders** was a member of the Joint WHO/FAO Expert Consultation on the [Fats and Fatty Acids in Human Nutrition](#) in 2008 which formulated international dietary guidelines for population intakes of fatty acids, and has been involved with Food Standards Agency and Department of Health policy with regard to diet and cardiovascular disease prevention. **Whelan** has contributed to guidelines for the management of irritable bowel disease for the British Dietetic Association.

#### **Impact through partnerships with industry:**

**a) The Pharmaceutical Industry:** Our Professor of Pharmaceutical Innovation (**Martini**) has a remit to initiate and promote potentially high-impact partnerships. KCL Business and Innovation has successfully supported the commercialisation of research assets associated with any intellectual property generated, as exemplified by our successful spin-out companies MedPharm and Proximagen. The international clinical research company, Quintiles, is partly based at KCL, and is widely acknowledged for its expertise in pre-clinical and regulatory strategy combined with innovative Phase I study design. The unit's Director, Professor Tim Mant, is a member of the Pharmaceutical Sciences CAG and of the Executive Committee of the Institute of Pharmaceutical Science. Pharmacy and Nutrition also have a large number of CASE studentships (averaging 14 per year), and a number of studentships from other industry-funded schemes such as KTP and TSB. IPS also takes a leadership role in industry-academia networks, and examples include the APSGB "Drugs in the Lungs" Network (**Forbes**) and the biannual "Blood Brain Barrier-Industry" Network of 12 companies (**Abbott, Begley, Preston**). Some academics take on roles in start-up companies (e.g., **Page** in Verona Pharma PLC [2004 to present], and **Thurston** in Spirogen Ltd [2000 to 2012] and Transcriptogen Ltd [2013 – present]). The *King's College London Industrial Impact Fellowship in Drug Discovery*, the first of its kind to be awarded by the BBSRC, was given to a KCL staff member (**Christie**, a part-time programme manager) in 2009 for increasing the economic value of the research and training activities of the Centre for Integrative Biomedicine. In the "Changing Diabetes at KHP" programme (**Amiel**), we are collaborating with NovoNordisk (investment to date ~£0.5m) to create a data base of clinical outcomes in people with diabetes attending KHP's specialist diabetes services, with a view to re-designed these for the evolving NHS.

**b) The Food Industry:** Major food companies (e.g., Abbott Nutrition, Archer Daniel Midland, Nestle, Premiere Foods, Tate and Lyle, and Unilever) are currently, or have, been involved in research projects, and are acknowledged in publications. These activities have led to a BBSRC DRINC award (**Ellis**) and a Technology Strategy Award with GlaxoSmithKline (**Hall**). **Sanders** is a member of the Heinz PLC Food Council, and the [Scientific Advisory Panel of the Global Dairy Platform](#). **Poston** was a member of the Tate and Lyle Research Advisory Board (2009-2011), and **Poston and Sanders** have been involved with the food industry sponsored Institute of Life Sciences (ILSI) in Europe and North America, contributing to workshops and publications (e.g., ILSI Healthy Lifestyles: [Healthy Lifestyle Nutrition and Physical Monograph](#) 2012 [Sanders]; Obesity in pregnancy: implications for the mother and lifelong health of the child. A consensus statement [Poston, 2011]).

**c) Medical Devices and Diagnostics Industries:** Ongoing collaborations with medical devices and the diagnostics industry include **Shennan's** work on developing BP measuring devices for use in pregnancy (MicroLife), **Cruickshank's** devices to measure ambulatory pulse wave velocity (Fukuda, Japan), and work on new predictive and diagnostic tests for premature birth (**Shennan**; Hologic) and pre-eclampsia (**Chappell, North, Poston, Shennan**, with Alere Ltd). **Choudhary** and **Amiel** are working with Medtronic in the development of closed loop insulin delivery systems and with Roche and CellNovo (**Choudhary**).

#### **b. Approach to Impact**

Previous examples of our research with outstanding impact include the Human Islet Transplantation programme to stop hypoglycaemia in the treatment of diabetes (**Amiel**, 2005), and the use of the measurement of fetal nuchal translucency thickness, determined by ultrasound scan, to detect Down's syndrome (**Nicolaides**, 2003). We recognise that engagement with stakeholders throughout the research process is important for impact and this is illustrated by how we are working to develop impact by better detection of peptides that trigger coeliac disease (gluten-sensitive enteropathy). Coeliac disease affects 1% of the population in the UK, Europe and the US, and induces damage to the lining of the small intestine, resulting in malabsorption, diarrhoea, nutrient deficiency and an increased risk of cancer. Children suffer growth retardation, delayed development and poor educational achievement. Treatment of coeliac disease involves a strict life-long gluten-free diet with avoidance of wheat, rye, barley and, in some cases, oats. The majority of commercially available gluten-free foods in the UK are based on purified wheat starch. The maximum permitted level of gluten in such foods was 200 ppm gluten, but KCL research has shown that even lower levels are needed to prevent enteropathy, and that as little as 1 mg in the diet can trigger enteropathy. The prolamin analysis committee (**Ciclitira**, core member), part of WHO *Codex Alimentarius Commission*, has had a proposal accepted to ensure that the maximum permitted level of gluten should be reduced from 200 to 20 ppm for foods sold as gluten-free, and 100 ppm for those marketed as gluten-reduced. **Ciclitira** has developed a cocktail of monoclonal antibodies for the improved detection of coeliac toxic peptides in food, now being tested in bioassays in patients with coeliac disease. This research has already improved food labeling for patients with coeliac and the new tests being developed will help industry measure coeliac toxic peptides more accurately. Thus health care providers, regulatory authorities, industry and patients are involved in the process to generate impact that has substantial reach both nationally and internationally.

#### **Developing an enthusiastic and informed work force**

We generate *impact* by encouraging and supporting our staff to engage and collaborate with our stakeholders at an early stage of the research process to ensure that our activities have practical relevance, and will produce useful results for the end-users and non-academic communities. For example, all new clinical research proposals in Women's Health are discussed prior to inception with our Patient and Public Involvement (PPI) stakeholder group and the South London Diabetes Study has created a PPI group to inform future research. Kings' Business and Innovation also helps by providing staff with introductions to non-academic partners. Staff are encouraged to participate in training provided by Business and Innovation's Enterprise Connect, which promotes entrepreneurship by hosting regular seminars, workshops and networking events and supporting young entrepreneurs in their business ideas. Our staff members have been successful in obtaining competitively awarded internal funds (e.g., the Lion's Den for King's Entrepreneurs and Innovators). The acknowledgements in our published outputs and our partnerships with industry provide evidence of entrepreneurial activity. Staff who conduct research on human subjects are

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required to undergo Consent Training and complete courses in good clinical practice provided by the KHP Clinical Trials Office, and BRC courses are available to train staff in qualitative research methods and other general research issues. Pump-priming funding is, and will always be, critical for exploring new ideas. KHP (e.g., Research and Development Challenge Funds) and our BRC (e.g., 1 year fellowships for clinical and allied health professional staff) have an array of short term funding schemes available for this purpose.

**Dissemination strategy**

Staff are encouraged to develop a dissemination plan for their research and to publish their research in the highest impact journals with robust peer review processes. Our staff and research students are trained in CONSORT and PRISMA guidelines required for human studies, in order to be considered by high impact journals. We provide staff training on how to deal with the requests of journalists, and do radio and TV interviews. Researchers at all levels are encouraged and supported to showcase their research to lay audiences, and to write articles for the lay press. Our research students showcase their research to non-academic audiences at annual Postgraduate Symposia. The King’s College London Public Relations Office works with staff to prepare press releases on new research findings, and logs all radio, TV and news coverage. Staff are also encouraged to be actively involved with the [Science Media Centre](#) which promotes the voices, stories and views of the UK scientific community.

**c. Strategy and plans**

Our vision is to provide better medicines and diet and life-style advice to prevent and manage disease. A local challenge is the awareness that many people on low incomes and in black and minority ethnic groups are not benefitting from the advances we make in science and medicine. With the CLAHRC award, we will specifically address local barriers to uptake of structured education programmes and develop new pathways of community based health promotion in our local population. Through new ventures, such as our Gates Global Development Grant we aim to extend our efforts further afield, towards improving global health. Our research must be translated appropriately for each target audience, and it is critical that, as we progress, we ensure our technologies are developed for the setting in which they are likely to be used. We shall continue to strengthen our engagement with patients by development of additional PPIs in irritable bowel/inflammatory bowel/coeliac disease and newsletters /open access web pages for all our major clinical trials. However, we recognise that the quality of our research is inexorably linked to impact. To this end, we will continue to place an emphasis on improved research staff training so that our research conforms to the increasingly stringent requirements laid down by regulatory authorities and medical publishers. In parallel, we will ensure that our staff are encouraged to reflect on the potential impact of their research from the outset, to identify testable hypotheses, and to use an experimental approach with clearly defined primary and secondary outcomes. Their early consideration of the potential for commercialisation will create heightened awareness of the need for protection of intellectual property. One of our aims is to look at the impact of increasing information available to patients on their lifestyle choices and mental health. The reach of our research will be widened, particularly to those who may benefit the most, by the recent adoption by KCL of an [Open Access Policy](#) to all our published research outputs.

**d. Relationship to case studies**

We have selected ten Impact Cases to illustrate the breadth of our research, and to highlight the different audiences and the approaches to **impact** that we have taken. These range from the development of new drugs and therapies, to medicines use, diagnostic tests, diabetes care and dietary advice for disease prevention:

Title of Case Study	Type of Impact	Beneficiaries & Audiences	Approaches Used
<b>A. The development of RPL 554, a novel inhaled mixed PDE3/4 inhibitor for the treatment of respiratory disease (Spina &amp; Page).</b>	New drugs/therapy	Patients, health service providers, practice guidelines, industry.	Partnerships with industry, commercialisation and patents.

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<b>B. Impact of primate-based research on drug discovery (Salvage &amp; Jenner).</b>	New drugs/therapy	Patients, health service providers, practice guidelines, industry.	Partnerships with industry - spin out company Proximagen.
<b>C. Iron chelators and hepcidin analogues for therapeutic use in patients with thalassaemia (Bansal, Hider &amp; McKie).</b>	New drugs/therapy	Patients, health service providers, practice guidelines, industry.	Engagement with patients, NHS partners, partnerships with industry, influencing practice and nationally internationally.
<b>D. Refining the use of psychotropic medicines (David Taylor).</b>	Medicines use	Patients and care givers, health service providers, practice guidelines.	Engagement with patients and NHS partners, influencing prescribing practice nationally and internationally.
<b>E. Optimising recovery and adherence to treatment in patients with major physical health problems (Weinman).</b>	Medicines use	Patients and care givers, health service providers, practice guidelines.	Engagement with patients and NHS partners, influencing prescribing practice nationally and internationally.
<b>F. Carbohydrate Deficient Transferrin (CDT) as a diagnostic tool for the detection of continued drinking in high risk drink drivers (Wolff).</b>	Diagnostic tests	Patients, health service providers, practice guidelines, Department of Transport.	Engagement with NHS partners, industry and transport sector.
<b>G. Screening tools to detect risk of preterm birth and pre-eclampsia (Shennan &amp; Chapell).</b>	Diagnostic tests	Patients, health service providers, practice guidelines, industry.	Engagement with patients, NHS partners and industry, influencing practice nationally and internationally.
<b>H. Managing hypoglycaemia to improve quality of life in people with diabetes (Amiel).</b>	Diabetes care	Patients, health service providers, practice guidelines.	Engagement with patients and NHS partners, influencing policy and practice nationally and internationally.
<b>I. Development of psychological treatments to improve diabetes control and depression (Ismail).</b>	Diabetes care	Patients, health service providers, practice guidelines	Engagement with patients and NHS partners, influencing practice nationally and internationally.
<b>J. Dietary fat advice for cardiovascular disease prevention (Sanders).</b>	Dietary advice	General public, industry, policy and practice, public engagement	Engagement with the Food Standards Agency and industry, dissemination of the research to industry, patient groups and the general public, influencing policy and practice national and internationally.