



Developing New Therapies: Case Study



Gel-forming injections target reduction in HIV/AIDS infections

Safer, more reliable, more effective, highly discreet: novel drug-releasing gels are opening an alternative to onerous, often complicated tablet-taking regimens.

Meeting the Grand Challenge:

Engineering and Physical Sciences Research Council

Led by Queen's University Belfast (QUB), the 'Peptide-mimetic Hydrogels for Contraception and HIV Prevention'¹ project has devised an ingenious way of simultaneously addressing two, closely related global healthcare challenges. With potential to enter clinical use within the next 15 years, a radical new longacting injection delivering a combination of contraceptive and anti-HIV/AIDS medication could help empower and save lives around the world.

Vision and Value:

Around 6000 young and adolescent women across the globe are infected with HIV/AIDS every week, while an estimated 66% of all people living with HIV/AIDS are located in sub-Saharan Africa. But raw statistics like these give only a glimpse of the complex problems this disease poses. For people at high risk of infection, preventive therapies mainly revolve around pills designed to be taken over long periods, in the right amounts and at the right times each day. Meanwhile, mother-to-child transmission (pre-, during and post-birth) is a key cause of HIV/ AIDS infection, especially in developing countries, where the need to reduce the rate of unintended pregnancies is pivotal to efforts to combat the disease.

Key Components:

Supported by a £767,000 EPSRC Standard Research grant and due to end in 2022, this three-year project dovetails with research funded by Innovate UK, the Medical Research Council and Wellcome. It also involves close dialogue with the UK's medicines regulator and ongoing collaboration with partners in the charities sector. The core concept revolves around the use of natural but specially tailored molecules similar to peptides (the building blocks of human proteins and tissues) to which drugs can be attached. When injected under the skin, the molecules create a water-based gel (a 'hydrogel') in response to natural enzymes and this releases a safe, steady amount of the drugs over a 28-day period, before the hydrogel biodegrades naturally.

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Outputs and Outcomes:

- The team has demonstrated the practicality of producing biocompatible, biologically stable hydrogel-forming molecules that avoid producing an initial drug-release 'burst' – a problem affecting many existing long-acting drug delivery mechanisms.
- Because the molecules are biologically stable, neither storage nor transportation will adversely affect their quality or efficacy – a key consideration for a product designed for use all over the world.
- This innovative drug delivery concept secured a prestigious People's Choice Award at the Controlled Release Society's Annual Conference in 2020.
- The group's work on peptide hydrogels has already attracted extensive media interest, including coverage by the BBC in the UK and ABC News in the US.

Impacts and Benefits:

- More effective HIV/AIDS prevention. Eliminating problems linked to individuals' ability to remember when to take tablets (and removing the risk of taking too many or too few), the hydrogel method will maximise the efficacy of drugs used to prevent infection by a condition currently affecting around 38 million people worldwide.
- **Fewer unintended pregnancies.** Longacting release of contraceptive drugs will avoid the risks that result from forgetting to take contraceptive medication, while fewer unintended pregnancies,

combined with more effective delivery of anti-HIV/AIDS medication, will reduce rates of mother-to-child transmission.

- Lower disease burden in developing countries. The new drug delivery mechanism will be especially valuable to developing nations bearing the brunt of HIV/AIDS, with less pressure on health systems producing social and economic, as well as medical, benefits.
- Greater gender equality and social justice. The mechanism will help women take control of their sexual health, especially where use of other contraception methods is limited due to issues of availability or cultural acceptability, for example.

Next Steps:

The team is currently focusing on formulating multiple drugs into one injectable gel-forming product and on proving this can deliver the required level of drug release over 28 days. They will also harness neutron-scattering techniques to further probe the hydrogels' drug-diffusion properties. Following establishment of collaborations with pharma firms to enable scale-up and manufacture, and after eventual completion of extensive clinical trials, it is hoped the new drug-release mechanism could potentially begin to enter real-world use in as little as 12 years' time.

Behind the Project:

Dr Garry Laverty is the project's Principal Investigator. Key colleagues include Professor Karl Malcolm, Professor Helen McCarthy and Dr Louise Carson at QUB and Dr Katharina Edkins at the University of Manchester. "Our ambition is for our work to make a real difference to society and to people's lives," Garry says. "Our drug delivery mechanism has huge potential to be adopted not just where patients find it hard to adhere to medication regimens – as in the case of cancer, Alzheimer's, depression and malaria, for instance – but also where sustained delivery is needed to specific locations in the body."

770,000:

the annual number of global deaths due to HIV/AIDS

Relevant EPSRC Research Areas:

- Clinical Technologies
- Biophysics and Soft Matter Physics
- Polymer Materials