**////Title: Charting How Research Leads from Discoveries to Improved Health**

**////Stand-first**:

Interventions designed to improve health, including targeted drugs and medical devices, typically undergo a complex and lengthy process of development. In a collaboration between the University of Wisconsin-Madison, Cornell University, the National Institutes of Health and Case Western Reserve University in the USA, experts Dr Clara Pelfrey [Pell-free], Dr Linda Scholl [Shōl] and colleagues have designed a case study protocol to improve understanding of this process.

**////Bodytext:**

When the COVID-19 pandemic hit, the development of vaccines that could lower the risk of hospitalisation and death became a high global priority, and such vaccines were developed at an unprecedented speed. Although often unseen by the general public, the development of interventions designed to improve health – for example, targeted drugs, medical devices and behavioural interventions – involves a very complex and often extended process that may start with cells in the lab, move through animal studies and human trials, be tested in real-world settings, and finally brought to market and to communities to improve health.

This entire process is known as translational science. But what factors help that translational process work well and what critical challenges must be overcome to bring important health interventions to the people that need them?

In a collaboration between the University of Wisconsin-Madison, Cornell University, the National Institutes of Health and Case Western Reserve University in the USA, Dr Clara Pelfrey, Dr Linda Scholl and colleagues designed a case study protocol that will allow the scientific community to answer those questions and, ultimately, better facilitate the process of translational science.

A case study is an intensive analysis which involves the collection of data to allow an in-depth understanding of a specific process or situation. A *retrospective* translational science case study looks back over the development of a successful health intervention to systematically assess the complex processes involved in effectively translating scientific research.

Data collection for a case study can include many different media, including for example, public records, interviews, reviews of data, peer-reviewed publications and news stories. Such studies provide excellent evaluation tools that can highlight the key factors that contribute to success and also identify those factors that might hinder the translation of scientific research into healthcare. Translational science case studies are an effective way to tell a compelling story about how research has led to human health benefits.

Building on research methods used by social scientists, political scientists, historians, criminal investigators and investigative journalists, Dr Pelfrey, Dr Scholl and colleagues designed a protocol for carrying out retrospective translational science case studies focusing on health interventions.

The methodology set out by the researchers introduces an iterative process whereby case details are progressively collected until no *additional* significant factors can be found. The process is rigorous and combines corroborating evidence to generate a full report describing the complex processes involved in the successful translation of scientific research into routine public healthcare.

Conducting a translational science case study first involves identifying an existing, successful intervention or therapy that addresses an important health issue, such as blood cancer, falls among the elderly, or devices that can help individuals rehabilitate after stroke. Next, background information is gathered which describes the current need for the intervention or therapy in public healthcare, the severity and global prevalence of the health issue, and who can benefit from the use of the intervention.

A timeline is then traced showing the milestones, markers of progress, and key events and dates that led to the intervention. These can include early discoveries, research grants, animal studies or human clinical trials, the publication of results in scientific journals, and the final implementation of the therapy or intervention in medical centres and communities.

Next, the factors that enabled the successful translation of science into a therapy or an intervention need to be identified. These enabling factors or facilitators may include the key stakeholders that worked on the intervention at different phases of development. Facilitators could also include the development of ground-breaking technologies or clinical and scientific research infrastructure that made the intervention possible, as well as beneficial multidisciplinary collaborations among scientists, partnerships between scientists and community health organisations, and critical funding to support the science.

Following this, barriers to implementation of the intervention are documented such as failed research directions, major challenges and how they were overcome. Examples of barriers include the lack of key research infrastructure or technology, a misalignment of organisation operations, and limited access to funding, all of which can severely hinder the effective translation of scientific research.

The current status of dissemination and implementation of the intervention may also be reported. This includes how the intervention is currently being used, by whom, how far-reaching the treatment or intervention is globally, and how the intervention has impacted different populations to date.

Finally, the case study should describe how the research is progressing, including potential future directions for the intervention, as well as any remaining knowledge gaps that could be addressed to improve further implementation.

Dr Pelfrey, Dr Scholl and colleagues suggest that the overall narrative of the translational science case study should describe clearly how and why the intervention was developed, what led to the successful achievement of key milestones, what challenges were encountered, and how those challenges were overcome.

To ensure effective communication of the findings, the researchers provide a protocol that can be used as a guide for reporting how the process of translational science unfolds in specific cases. Since publishing this protocol, the researchers have successfully engaged with the Journal of Clinical and Translational Science at Cambridge University Press to create a new category of manuscript: the Translational Science Case Study. This type of manuscript can now be published free with Gold Open Access, ensuring maximum availability to the public.

The researchers further suggest the use of an archiving strategy for all translational science case studies to enable cross-case analysis. Such a central repository could be used to ensure the accessibility of the translational case study reports and to support performing meta-analyses that could lead to broader generalisations about the factors that influence successful translational research.

The effective use of the translational science case study protocol already has been demonstrated by several research groups. For instance, Dr Pelfrey and colleagues described the successful invention and implementation of a new technology that can rapidly and inexpensively screen infants for sickle cell disease, saving many thousands of lives every year from this deadly disease. Similarly, Dr Scholl and colleagues reported on the development of a dietary intervention to improve the nutritional health of individuals with phenylketonuria [feh·nuhl·kee·tuh·**nur**·ee·uh], a rare disease that, left untreated, can lead to developmental delays and mental health disorders.

Other researchers from the University of Michigan, Ann Arbor, have also confirmed the utility of the protocol – for example, in work published in 2022 reporting the success of an expanded access program that enabled the rapid introduction of different treatments and medical devices used to fight COVID-19. Most recently, a team at Tufts University used the protocol to describe how researchers at one academic medical centre engaged a broad range of stakeholders to establish evidence-based treatment for the growing number of neonates suffering from opioid withdrawal following birth.

By studying how research technologies and methods are successfully translated into health interventions we can gain a better understanding of what barriers exist, what methods are most effective and what kind of improvements can be made during the complex process of translating scientific research into advances in healthcare.

The protocol created by Dr Pelfrey, Dr Scholl and colleagues provides a framework that can be used in cross-case analysis to make important comparisons between cases that could help identify commonly occurring barriers as well as exemplary practices. Ultimately, this could lead to a greater understanding of translational science and the faster delivery of life-saving healthcare.

This SciPod is a summary of the paper ‘A protocol for retrospective translational science case studies of health interventions’, from the Journal of Clinical and Translational Science. DOI: <https://doi.org/10.1017/cts.2020.514>.

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