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Implementing personalized medicine in hospitals

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Imagine a patient with a rare genetic disorder that makes their arms and legs have imprecise and slow movements. For years, the patient has faced serious restrictions in day-to-day life. They tried several treatments, but all have failed to ease the symptoms.

Now imagine a university team discovering a therapy that could tackle this condition, with a solution that lies in the patient's own body. The patient's blood would be collected, some key cells would be separated in a laboratory, gene-editing techniques would be applied, and personalized medicine, produced with specialized equipment, would be injected back into the patient's body.

A biological process would then be triggered in which all faulty genes would be corrected, reducing the disease's severity, perhaps correcting it all together. The modification would be restricted to the patient and would not be passed on to their children, since it would not affect reproductive cells.

Our story has a catch, though: the blood cells needed for the personalized medicine are very fragile and do not live very long outside the human body. This means there's little time to take the blood to the specialized laboratory, transport the cells to the production facility, and take the medicine back to the hospital where the patient is.

But what if all these production steps were quickly performed in the same place—that is, in the hospital?

Our story is ceasing to be just imagination because this way of producing medicines in the hospital is actually emerging. It's what specialists call point-of-care manufacture. And there are several notable examples of it already in use.

For instance, a medicine for multiple myeloma (a type of bone marrow cancer) is being produced in the Hospital Clinic in Barcelona, Spain. Products for severe burns are being manufactured in Lausanne University Hospital in Switzerland.

At the University of Colorado in the U.S., researchers are developing a

therapy for hard-to-treat lymphoma, a type of blood cancer. In the U.K., an NHS Blood and Transplant laboratory is investigating the manufacture of red blood cells—which, if successful, could be carried out in hospitals and other clinical settings for the treatment of cardiac diseases.

These illnesses might not have been treated if the medicines had needed to be frozen and transported over long distances, instead of being made in the hospital.

Are we ready for it?

Given that these therapies have such a short shelf life and will need to be produced at the patient's bedside, there are many things we need to consider before we can deploy them on a wider scale. For example, what measures should hospitals, companies, and regulators take to adopt this model and make it work? This is what our research team has been investigating.

It's vital that the same safe and high-quality production methods are used in different hospitals so that all patients receive the best possible care. This is why regulatory agencies in the U.K. are already proposing new ways of managing this model.

For example, it has been suggested that to begin with, manufacturers could oversee the medicine's production in several different hospitals from a central site. They could also be responsible for providing training and quality control in the hospitals that have rolled out point-of-care manufacture to ensure that the products are safe and high-quality.

But just because a new policy has been made, doesn't mean it will be successfully implemented. This will mean hospitals and companies will need to change how they operate for these new technologies to be

implemented safely and efficiently.

Our research, in collaboration with the Medicines and Healthcare Products Regulatory Agency (MHRA) and several public and private sector organizations has also looked at what benefits and challenges there may be in implementing this innovative approach to the production of medicines.

In a recent publication, we put forward several steps that need to be taken by regulators, hospital staff, and companies to make the production of personalized therapies in hospitals a reality. First, trusts, clinical centers and hospital staff will need to investigate how best to make therapy production happen in medical wards. They will also need to identify any issues—such as staff training and data management—which may stop this from happening.

Companies already developing these advanced treatments can also supply hospitals with manufacturing equipment and production system know-how, making it easier to start developing personalized therapies in hospitals with as little disruption to day-to-day operations as possible. Regulators may need to provide guidance for different therapies to ensure quality control and patient safety.

Now, let us return to our patient's story. After receiving the therapy produced in the hospital, the patient goes on to live a healthy life and have a child that is diagnosed with the same genetic condition. But now, the way to receive treatment is much clearer.

The child will be treated in a specialized hospital where certified equipment and trained staff are available for producing and delivering an enhanced version of the personalized therapy. With more experience and better infrastructure in place, the child will receive a treatment that yields faster outcomes with fewer side effects.

But this will only be possible if everyone—including hospital staff, manufacturers, scientists and policymakers—work together to ensure point-of-care manufacture is successfully rolled out.

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