

New pathway to cheap insulin

EurekAlert

More than eight million diabetics live in Germany. Diabetes is not restricted to our prosperous society and the highest growth rates often occur in countries with aspiring economies such as in Asia. Worldwide, more than 285 million people suffer from this illness; with 50 million diabetics, India is the country with the most people affected by this disease. In Europe, Germany shows the highest prevalence in the population with twelve percent. In a German-Indo collaboration, researchers from the Helmholtz-Centre for Infection Research (HZI) in Braunschweig, Germany have now developed a new method to cheaply produce insulin for the treatment of diabetes. The group's results have now been published in the open access online research magazine *Microbial Cell Factories*. With this, all information is freely accessible for everyone and is not subject to patent law.

"As we did last year with an alternative protocol for the development of a hepatitis B vaccine, we again decided to use this way and make our knowledge available for everybody," says Ursula Rinas from the HZI, who chairs the German side of the project. Thus, people can access "insider-information" that makes it possible to cheaply produce medicine which in return can be affordable to people in developing countries.

The researchers wanted to develop a new procedure to increase the yield of an insulin precursor from which the actual insulin can be obtained, and in this way reduce costs. They found the yeast *Pichia pastoris* and modified the cells so that they produce the building block for insulin while growing on a special medium. The results were highly gratifying: "With our procedure, *Pichia pastoris* delivers high yields ? twice as much as known before", says Ursula Rinas. "Already with few cells it is possible to produce a lot of the insulin precursor."

In the early 1980s, insulin was the first recombinant product approved by the FDA for human application. Today, human insulin is produced as recombinant protein, using two major routes. One route involves the production of the insulin precursor using the bacterium *Escherichia coli* as expression host with complex subsequent isolation, solubilization and refolding procedures. The other route involves the well-known baker's yeast *Saccharomyces cerevisiae*. The advantage of the latter route lies in the secretion of a soluble insulin precursor into the culture supernatant, making it easier for isolation and chemical modification. The newly described method from Ursula Rinas and her group also uses this route. The isolation of the precursor from the culture supernatant is only followed by enzymatic finishing. Insulin produced with this new method can be used normally and is identical to human insulin. Currently, the researchers are working on a method to produce a vaccine against dengue fever using the same system as described here.

For most people in developing countries medicine is too expensive. The purchasing of insulin in those countries is often cost prohibitive. Another problem is patent law

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that makes it impossible to recreate medicine and sell it at low prices. Once a patent has expired, as is the case with insulin, the so called generic drugs can be produced cheaply. Unfortunately, emerging nations very often lack the insider knowledge to produce those generics.

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