
IDF Position Statement Animal, Human and Analogue Insulins

IDF - International Diabetes Federation

POSITION STATEMENT

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Insulins are now available in different molecular forms, some because of species differences and some by design through molecular engineering. Modern highly purified animal insulins are safe, effective and reasonably reproducible in their actions. Human insulins, prepared usually by genetic engineering, are similar to highly purified pork insulins. Concerns that hypoglycaemia problems are greater with human insulins have not been substantiated by research. There is no overwhelming evidence to prefer one species of insulin over another and patients should not be changed from one species of insulin to another without reason. Genetically modified insulin analogues may provide advantages in patients with problematic hypoglycaemia but they are expensive and there are no long term safety data.

Early animal insulins were effective but had imperfect absorption profiles. There were also concerns about their ability to induce an immune response (immunogenicity), which increased the variability of their action profiles. The highly purified "mono-component" insulins reduced the immunogenicity, resulting in faster, shorter actions. Disappointingly, the immunogenicity of human insulin is similar to that of highly purified pork insulin, to which it is clinically equivalent.

Highly purified animal insulins are effective agents to treat diabetes. Human insulin is at least as good as highly purified pork insulin. In many parts of the world, beef insulin provides access to a low cost insulin. While their prices remain lower, highly purified pork and to a lesser extent beef insulins are entirely acceptable and there is no reason to convert. Human insulin has the theoretical advantage that it can be synthesized in limitless quantities at relatively low cost.

All insulins have slightly different properties and patients should not be changed from one to another insulin type unless there is a clear advantage. No insulin type will suit every patient and it is important that variety is maintained in order to find the insulin that suits each patient best.

More recently, genetically modified insulins are being introduced in which the human insulin gene is deliberately altered to confer some specific desirable properties, including a more reproducible action profile. Rapidly acting analogues give better post-prandial (after meal) glucose control and contribute less to nocturnal hypoglycaemia than earlier short acting insulins.

New "background or basal" insulins have flatter action profiles and are less prone to cause hypoglycaemia in the night. These insulins are more costly and it is important to recognize that they have not delivered overall improvements in glucose control in large studies. They may have different properties from human insulin and animal insulins and are likely to prove most beneficial in intensified therapy, when good control cannot be achieved without problematic hypoglycaemia.

All insulin therapy is associated with the risk of hypoglycaemia, sometimes severe. There is no evidence that this is worse with human rather than animal insulins. Concerns have been raised in some countries that human insulin use was associated with a different and higher risk of hypoglycaemia. The evidence for this has remained anecdotal, despite serious attempts to document it and find a mechanism. Patients with problematic hypoglycaemia need careful monitoring. Their insulin regimen should be prescribed with knowledge of the expected actions of the insulins involved. Insulin regimens should take into account risk factors such as exercise, alcohol ingestion and illness and these should be clear to the patient. Problematic hypoglycaemia can generally be treated effectively without changing insulin species although patient choices should be respected. Despite the lack of scientific evidence, some patients do better on specific insulin types and some older insulins may have individual benefits in some settings.

Conclusion

People with insulin deficient diabetes require adequate and secure supplies of safe and affordable insulins. Genetic engineering, currently used to make human insulin, should be able to deliver this, as its production capacity is theoretically limitless. Animal insulins remain a perfectly acceptable alternative and indeed some patients prefer them.

Newer insulins offer potential advantages but until these are proven to deliver real long-term benefits safely and affordably, it seems appropriate to use them in patients experiencing specific problems that a specific analogue might reasonably be expected to address. IDF believes that this ability to choose is important and should be supported.