

GUIDELINES FOR INSULIN DONATIONS IN LOW- AND MIDDLE-INCOME COUNTRIES

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Can Insulin Donations Contribute to a National Diabetes Programme?

In 2015, support programmes with donated insulin for people with type 1 diabetes (mostly children) operated in 43 low- and middle- income countries (LMICs), treating around 35,000 children and young adults up to 26 years of age (1). In the absence of public supply or health insurance systems, many of these people would probably not have survived without the insulin donations. Globally, those receiving donated insulin represent about one-third of all children with type 1 diabetes in need of support (1). Most programmes are supported by two initiatives: The International Diabetes Federation (IDF) Life For A Child (LFAC), supported by donations mostly from Eli Lilly and Company, and Novo Nordisk's Changing Diabetes in Children (CDiC).

In several countries, such as Guinea, Mali, Tanzania, and Rwanda, national programmes now claim that nearly all new children and adolescents living with type 1 diabetes are diagnosed and treated. These programmes have therefore delivered a very important proof of concept: it is possible that children with type 1 diabetes can successfully be diagnosed and treated in LMICs, and that most of them (up to 80-90 percent) can survive till early adulthood (2 – 9).

For young people living with diabetes and their families, free insulin is probably the most visible aspect of these programmes, as it acts as an incentive to visit health clinics and basically saves their lives. However, free insulin is not enough, as the price of insulin represents only one quarter of total supply costs, which also include: syringes, the glucose meter and testing strips, as well access to HbA1c testing (2). Apart from supplies, the support programmes have invested in other essential activities, such as education and support of people living with diabetes, advocacy, awareness building, health worker training, and general health system support. So free insulin has been an essential condition for success; but it is not sufficient on its own and must be placed alongside the need for many other essential programme components.

What Is The Impact of Insulin Donation Programmes?

The health impact of programmes with a component of donated insulin has been reported from several LMICs. Some of these countries report an increase in mean body weight (e.g. from 53 to 61 kg in Cameroon (3,4)) and Body Mass Index (e.g. from 15.4 to 19 kg/m² in India (3)); a reduction in mortality (e.g. from 24.5 to 2/1000 patient years in Uzbekistan (2)); a reduction in average HbA1c values over the first years of the programme (median starting value 11.45 percent, median current value 8.55 percent (1)); and a reduction in the frequency of acute and chronic complications (e.g. a reduction in serious keto-acidosis from 10 percent in 2011 to 0.6 percent in 2014 in Tanzania (6-7)). Some studies report on school performance of the children, with mixed results (1).

The public health impact of the programmes can also be considerable. In most countries the number of enrolled (and surviving) children has increased dramatically. For example, in Rwanda, the programme started with 25 children with type 1 diabetes in 2004 and included 699 children in 2014 (8 -9). Most programmes report similar increases in the number of treatment centres or participating health facilities. The 2016 LFAC factsheet mentions that 20 LFAC country programmes now claim near-universal national coverage of children with type 1 diabetes (12). In most of these countries, the diabetes programmes have become a visible and recognised part of the national health system.

What Are The Challenges of an Insulin Donation Programme?

Quality of care: Although 80-90 percent of children with type 1 diabetes supported by these programmes have survived after 5-10 years, their blood glucose levels are often not very well controlled and their school performance can lag behind. The frequency of acute and chronic complications is still too high. Only nine out of 34 LFAC country programmes have agreed evidence-based clinical guidelines (13).

Supporting adults living with type 1 diabetes: Most country programmes have difficulty in supporting individuals beyond their age of eligibility (18-21 years with CDiC and 25 years with LFAC). Various solutions are being tried in different countries, and some with success. Several programmes include activities to train the adolescents to earn a living and ultimately pay for their own treatment.

Sustainability of donation programmes: Although insulin donation programmes can never create a sustainable system, in several LMICs they currently make an important health contribution. There are currently no signals that the major donors are considering to withdraw their support. Recently, CDiC is even expanding into five new countries (Cambodia, Ivory Coast, Myanmar, Senegal, and Sudan). Ways and means to hand over to national health insurance systems must be developed.

Reporting on programme impact: Public reporting is widely scattered, largely incomplete, and sometimes inconsistent. Types and quantities of donated products are rarely specified; when financial amounts are disclosed it is not clear whether these amounts are based on retail sale prices in OECD countries, or on international not-for-profit wholesale prices. There is even less information available about the various differential pricing programmes. The scientific quality of papers on health impact is not very high. For example, none of the papers had a control group, about two-thirds were simple “pre-post” reports on key health statistics; other studies only reported current health indicators.

Practical Recommendations

Many challenges identified in the published literature and by the national programmes staff consulted, relate to diabetes programmes in general, and often go far beyond the aspect of insulin donations only. In the following section some practical recommendations are presented which are directly linked to insulin donations, and mainly directed to donor agencies and national recipient programmes.

1. Donor agencies should ensure that all donations of medicines, diagnostics and equipment follow the World Health Organization (WHO) Guidelines for Medicine Donations

Justification and explanation: Not all insulin donations follow the WHO guidelines. Some organisations, such as Insulin for Life, send products collected from pharmacies, or products not registered for use in the recipient country, and sometimes close to expiry. The sale and use of such medicines is illegal in many donor countries; as donations they undermine national quality regulations, national clinical guidelines, and national standardisation efforts.

Practical implications: Most recurrent problems are identified and addressed in the WHO guidelines (Annex 1). Most importantly, the type of donated insulin should follow national clinical guidelines, the national list of essential medicines, and national quality standards; and insulin donations should always be planned in close collaboration with the recipients, and should respect and support national health systems and programmes. The cost of diagnostic tools, such as glucose strips and HbA1c testing, has become the main barrier to good quality care; programme efforts should now also focus on long-term donations or price discounts of such diagnostic materials.

2. Donor agencies should report regularly on programme targets, the number of people living with diabetes covered, health outcomes, key health system data, the role of partners, and project financing

Justification and explanation: Current experiences prove that cost-effective diagnosis and treatment of type 1 diabetes in LMIC is very possible and yield great health benefits, at moderate costs. However, most programme reporting is scattered and largely incomplete. Good reporting will create the necessary data to support the case for inclusion of diabetes care in national health and health insurance schemes.

Practical implications: Key data to be collected and published on a routine basis include: programme aims and targets, number of treatment centres benefitting from insulin donations; number and basic characteristics of patients; number and type of diagnostic tests and treatments supplied; health outcomes, such as mortality and cause of death, mean body weight, mean level of HbA1c, type and frequency of morbidity and mortality per year and over time; the roles and expectations of programme partners; transition strategies for people living with type 1 diabetes after the end of the eligibility; and programme financing mechanisms such as insurance schemes, direct subsidies and donations, and out of pocket payments.

3. National diabetes programmes and donor agencies should plan well in advance the transition of recipients of donated insulin beyond their eligibility to programme support. This transition should be supported with specific investments and programme activities; links with existing insulin discount programmes should be strengthened

Justification and explanation: Eligibility for the two most important donor-supported programmes ends at age 19-21 (CDiC) or age 26 (LFAC). Many country programmes cannot offer support in managing this transition, although some promising examples of vocational training have been reported from Bangladesh, Haiti, India, Rwanda, and Tanzania. The long-term solution is to include standard diabetes diagnosis and

treatment in national health insurance packages. In the interim, practical support to all people living with type 1 diabetes remains very much needed.

Practical implications: Solutions must work in two directions: creating a situation of gaining employment and functioning normally in society on the one hand through activities such as offering vocational training; and on the other hand, improving access to affordable good quality adult diabetes care. The first is often seen as part of the support programme for people with type 1 diabetes in collaboration with local diabetes associations; the latter is a matter of national health policy and, ultimately, national health insurance. In the interim, programmes should strengthen their links with insulin discount programmes for adults, such as Novo Nordisk's Base of the Pyramid programme, or its general insulin discount programme for least developed countries.

4. Donor-supported programmes such as LFAC and CDiC should be continued and expanded in countries in need, as long as the diagnosis and treatment of type 1 diabetes and its complications are not yet included in national health insurance schemes

Justification and explanation: Several national programmes with a component of donated insulin have given proof of concept that diagnosis and treatment of type 1 diabetes in LMIC is possible, with large improvements in survival, mean body weight, mean HbA1c values, and frequency of complications; and various possibilities for transitioning out of the support programme. The programmes have also made contributions to the health system in participating countries, especially in those countries where most children with type 1 diabetes are now diagnosed and treated. Continued donor support is justified by the health benefits listed above, and because further valuable health system experience can be gained from the screening, early diagnosis and treatment of complications, and from integration with national comprehensive NCD services.

Practical implications: The discussion with the national government on the development of a national diabetes policy, and the inclusion of standard diabetes care in national health insurance schemes, needs to continue. The proof of concept, the increasing practical experience, the proven cost-effective treatment, and pressure by surviving patients, will all help in this regard. Ten steps to phase out an insulin donation programme are presented below.

Ten Steps To Phase Out An Insulin Donation Programme

A donor-supported programme for the diagnosis and treatment of type 1 diabetes in LMICs could have the following trajectory towards a fully independent and sustainable national programme. The order in which these steps are presented below could reflect a natural course of events in a country, starting with free diagnosis and treatment for an increasing number of children and adolescents with type 1 diabetes (as is currently the case in many countries) and ending with a full-fledged national system (the ultimate goal). The assumption is that donor-supported programmes, after successful achievement of steps 1-5, would be in a strong position to convince and encourage national diabetes associations and government authorities in taking subsequent steps towards a national programme.

Donor agencies should:

- 1) Support, in selected LMICs in need, a programme with a free basic package of education, diagnosis and treatment for as many children with type 1 diabetes as

possible, thereby preventing the almost certain death these children would otherwise face; and create a national patient register for follow-up and reporting;

- 2) Collaborate with the national government, diabetes associations, people living with diabetes and other donors to create a national continuum of care for type 1 diabetes from childhood to early adulthood, e.g. by combining in every eligible country the CDiC donation programme (till age 18-21), the IDF/LFAC donation programme (till age 25) and the Base of the Pyramid and other insulin discount programmes for adults;
- 3) Assist national authorities in creating systems to prevent, diagnose and treat acute and chronic complications of type 1 diabetes in children and adults;
- 4) Provide detailed information on key aspects of the support programme, such as the number and basic characteristics of recipients; the number, type and value of diagnostic tests and medicines donated; the nature and cost of other programme activities supported; and basic health outcomes such as mortality, weight gain, mean HbA1c levels, and frequency of complications;
- 5) Deliver to national authorities, donor organisations, and national health insurance systems, the proof of concept that type 1 diabetes can successfully and cost-effectively be diagnosed and treated in LMICs;
- 6) Encourage national authorities to develop and implement a national diabetes policy, as a commitment and a guide for action to achieve universal access to decentralised health services for the prevention, diagnosis and treatment of diabetes, as part of the progressive realisation of the right to health;
- 7) Encourage national authorities to create systems, whereby young adults are empowered to procure affordable standard diabetes care after their eligibility for the donation programme ends;
- 8) Work with the national government towards inclusion of standard diagnosis, care and treatment of diabetes in national health insurance programmes;
- 9) Encourage the national government to integrate the prevention, diagnosis and treatment of diabetes and its complications with the delivery of nutritional advice and other services for the prevention and treatment of other chronic conditions such as HIV, tuberculosis, leprosy, and hypertension;
- 10) Phase out donor involvement as soon as these objectives have been achieved.

Annex 1. Summary of WHO Interagency Guidelines for Medicine Donations, 2011

Core principles that form the basis of good medicine donation practice

- Donations of medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need. Unsolicited medicine donations are to be discouraged.
- Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country.
- There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties.
- There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

WHO Interagency Guidelines for Medicine Donations¹

1. All medicine donations should be based on an expressed need, should be relevant to the disease pattern in the recipient country, and quantities should be agreed between donor and recipient.
2. All donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines or equivalent or in the national standard treatment guidelines, if the NEML is not updated. Or, if a national list is not available, it should appear on the WHO model lists of essential medicines, unless specifically requested otherwise and provided with a justification by the recipient.
3. The presentation, strength, and formulation of donated medicines should, as far as possible, be similar to those of medicines commonly used in the recipient country.
4. All donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donor and recipient countries. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.
5. No medicines should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or that have been given to health professionals as free samples.
6. After arrival in the recipient country all donated medicines should have a remaining shelf-life of at least one year. Large quantities of donated medicines become a logistical challenge, even with a long shelf-life. Therefore, based on the national consumption and available quantities in stock or in the supply chain pipeline, all donated quantities should match the needs to be consumed before they are expired.

¹ Detailed information on the justification and practical implications of these guidelines is given in the full WHO / Interagency publication: Guidelines for Medicine Donations, 3rd Ed. Geneva: World Health Organization, 2015. ISBN 978 92 4 150198 9

7. All medicines should be labeled in a language that is easily understood by health professionals in the recipient country. The label on each container should contain at least the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, country of manufacture, quantity in the container, storage conditions and expiry date.
8. Donated medicines should be presented in pack sizes that are suitable for the recipient and appropriate to the setting in which they will be distributed or dispensed.
9. All medicine donations should be packed in accordance with international shipping requirements and should be accompanied by a detailed packing list that specifies the contents. The weight per carton should preferably not exceed 30 kilograms. Shipments of medicines should not be mixed with other supplies, unless they are shipped as kits with predetermined contents.
10. Medicine donations should be jointly planned, and collaboration between donors and recipients should begin early. Medicines should not be sent without prior consent of the recipient.
11. In the recipient country the declared value of a medicine donation should be based on the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.
12. Costs of international and local transport, warehousing, port clearance and (customs) storage, handling and disposal or reverse logistics of expired donated products should be paid for by the donor agency, unless specifically agreed otherwise with the recipient in advance.

References

1. Hogerzeil HV, Recourt S. Company and company-supported programmes with a component of donated insulin in low- and middle-income countries. Health Action International, ACCISS study (in print)
2. Rakhimova GN, Alimova NU, Ryaboshtan A, et al. Epidemiological data of type 1 diabetes mellitus in children in Uzbekistan, 1889-2014. *Pediatric diabetes*, 2017 (in print)
3. Dehayem M. Impact of the 'Changing diabetes in children' project in Cameroon. Presentation at the Third African Diabetes Conference, 19-22 April 2017, Yaoundé.
4. Dehayem M, Takogue R, Mapa Tassou C et al. L'Insuline gratuite améliore significativement l'HbA1c des patients inclus dans le programme "Changing Diabetes in Children" in Cameroun. *Diabetes Metab* 2012; 38: A99-100. Abstract P-294
5. Baldé N. Presentation at the Third African Diabetes Conference, 19-22 April 2017, Yaoundé.
6. Ramaiya K. Insulin programs in sub Saharan Africa: Tanzania. Presentation at the Third African Diabetes Conference, 19-22 April 2017, Yaoundé.
7. Muzi KC, Majaliwa ES. Type 1 diabetes updates: Tanzania. *Indian J Endocr Metab*, 2015; 19: Supplement 1
8. Sibomana L, Orchard T. Challenges and opportunities in managing type 1 diabetes in Rwanda. *IDF World Diabetes Congress, Vancouver 30 November – 4 December 2015*; abstract 0704-P
9. Marshall SL, Edidin DV, Arena VC et al. Glucose control in Rwandan youth with type 1 diabetes following establishment of systematic, HbA1c based, care and education. *Diabetes research and clinical practice* 2015; 107: 113-122
10. Ogle GD, Kim H, Middlehurst AC, Silink M, Jenkins AJ. Financial costs for families of children with Type 1 diabetes in lower-income countries. *Diabet. Med.* 2016; 33: 820–826
11. Gupta S, Gupta JK, Kumar S et al. Comprehensive management of type 1 diabetes in a marginalized population in Northern India: a seven year retrospective review. *J Diabetology* June 2016; 1:1 (<http://www.journalofdiabetology.org>)
12. LFAC Fifteen years of progress: 2000-2015. LFAC Factsheet, 2016
13. Atkinson S, Sigfrid L, Eeles M, Atkinson Z, McKee M. From Surviving to Thriving: Evaluation of the International Diabetes Federation – Life for a Child Programme. London School of Tropical Medicine and Hygiene, 2015. <http://www.idf.org/sites/default/files/attachments/LFAC-Evaluation-with-Finances-2014-final.pdf>