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Resources for Child Health
REACH

FAIL-SAFE SINGLE USE INJECTION DEVICES

REACH's involvement in this activity grew out of the costing study on new injection technologies which was done for AID/REACH by Drs. Jean Perrot and Pierre Lefebvre of the University of Quebec at Montreal. The purpose of the costing study was to identify the respective cost categories of an EPI and then to identify the impact of pre-filled and auto-destruct, single use injection devices on those cost categories. Current WHO/EPI data on costs of presently available reusable/disposable devices, cold chain and transportation costs, storage requirements, etc., were used as a baseline.

To administer the EPI vaccines, the primary technology currently in use are glass or plastic syringes which must be sterilized prior to each injection. This can be done by boiling for at least 20 minutes or by steam sterilization. Re-use of up to 200 times is possible for the plastic re-usable syringes. In addition, sterile packaged syringes and needles are in use in some EPIs. These devices are intended to be used only one time and then disposed of after that use. Nevertheless, experience shows that in field conditions, these syringes are sometimes reused, often without being properly handled or sterilized, in spite of the well known risks this practice implies. To mitigate the consequences of the improper use of existing injection devices, the development of fail-safe technologies are being promoted in a joint plan of action by PATH/AID and WHO/EPI. Two tracks of development appear promising in terms of single-use injection technologies. They are:

1) <u>Pre-filled devices</u>- these can be either:
   a) completely self-contained w/vaccine, or
   b) a reusable holder with an integrated needle/vaccine cartridge.

2) <u>Auto-destruct devices</u>-
   a) a plunger capture device,
   b) a break-away plunger,
   c) vaccine chamber destruction,
   d) needle destruction,
   e) fluid path blockage.

The present reusable and disposable devices serve as both an assumed control and a known baseline in terms of costs, manufacturing, training, and other program implementation issues.

However, to date the auto-destruct syringes are only intended for use with DPT, Measles and Tetanus vaccines. No provisions are currently being made for the administration of BCG with any of the new technologies. Additionally, for the pre-filled syringes, only liquid vaccines (DPT and Tetanus) are presently under consideration although devices which use freeze-dried vaccines are theoretically possible, albeit more difficult to develop and manufacture.

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After careful scrutiny, it stands out that these new injection devices, at least in the short run, are not yet complete substitutes for the conventional injection technologies but rather are complements to them.

Some issues crucial to the further development of single use devices are:

1. Procurement

Prefilled syringes: taking into account the higher degree of manufacturing complexity and the necessity of a filling operation, the prototype pre-filled syringes could have a higher price than current devices. On the other hand, adaptation of currently available production technologies used for non-medical, pre-packaged liquids could eventually result in pre-filled devices with prices competitive with or even slightly less than conventionally packaged vaccines. Because of their stage of development, the pre-filled device's prices are not yet stabilized. If a market for these devices develops, we could expect to see their price fall in the years to come. Correspondingly, the auto-destruct syringes should not be appreciably more expensive than current disposable syringes.

2. Storage

With the auto-destruct syringes, storage considerations are not significantly different than those found with conventional devices. Although, since the auto-destruct devices are intended for a single use (vs. re-use of up to 200 times with conventional devices) the storage volume of syringes will obviously be larger. But as previously stated, the pre-filled devices would be expected to take up much more volume (per dose) in the cold chain than the traditional vaccines. The dimensions and/or numbers of refrigerated storage devices must consequently be increased. Accordingly, as the size and complexity of the cold chain is expanded, so will recurrent induced costs such as maintenance, spare parts, energy. A final consideration in this regard is the effect of failures or breaks in the cold chain. With conventional vaccine packaging, only the vaccine itself would be lost in the event of a cold chain failure. With pre-filled devices, the administration device would be lost as well. While it is difficult to quantify this consideration, operational experience suggests that cold chain failures commonly occur, and with pre-filled devices, the financial and operational consequences of such failures will be magnified.

3. Transport

For the pre-filled device, the bulk/volume conveyed between each level of storage will likely prove to be much higher. However, what truly distinguishes a pre-filled device from auto-destruct one, is that in the

pre-filled's case, transport implies a cold chain while the auto-destruct device does not necessitate transport of syringes with any particular precautions in terms of the cold chain. The consequences of refrigerated transport and storage of the syringe and needle in addition to the vaccine itself, places pressure on air freight costs as well as transport and storage at both the central and local levels. For an outreach strategy, the use of single-use syringes in comparison to to conventional sterilizable syringes is simplified in that no provisions need be made for their sterilization. On the other hand, when using pre-filled devices in an outreach setting, the number and volume of isotherm vaccine carriers and cold boxes needed for a given number of doses would necessarily rise.

4. Sterilization

The need for sterilization of syringes is eliminated with the pre-filled device as it is for the auto-destruct device. Nevertheless, sterilization remains a requirement for conventional BCG vaccine administration devices (and perhaps Measles vaccine as well if the pre-filled devices are unable to accommodate it). Therefore, investment in sterilization equipment continues to be a factor. Albeit, the operating costs will be lower as it is utilized less and the equipment's life expectancy should be correspondingly longer. Also less energy for sterilization will be used. Operationally, the tasks of health personnel would also be simplified, especially in outreach settings.

5. Social costs

The new technologies (especially the pre-filled) will demand increased production sophistication. There is a risk that developing countries will be unable to produce these devices and will thus become more dependent on developed countries for the basic material inputs necessary for an immunization program. This is paradoxical given the increased emphasis on program sustainability along with decreased reliance on long term donor supports.

Finally, one of the essential reasons mitigating against the continued use of sterilizable syringes is the risk of contamination/infection, most notably from AIDS and hepatitis B. The auto-destruct syringe, and the pre-filled syringe could logically reduce, if not altogether eliminate these risks of contamination. While it was beyond the scope of the REACH study to quantify the costs and benefits in this regard, they are ultimately among the most important, and they deserve serious and continuing consideration.

To summarize:

1) Unit cost of pre-filled devices: projected costs for volume production currently vary by a factor of nearly 30. Obviously, such a wide range in costs says more about the present lack of firm

information/understanding than it does about true production and procurement costs. The original REACH costing study made a cost assumption of $0.25 and $0.50 per unit for the pre-filled device (with the caveat that the price could be expected to drop considerably below even the $0.25 level in volume production).

2) Storage/transport volume of the pre-filled device: There is no avoiding the fact that most, if not all, pre-filled devices will carry a considerable cost penalty in terms of the increased storage volume they will require. The projected volume of some pre-filled devices are up to 10 times as bulky per vaccine dose compared to conventional packaging. This means 10 times the volume to store and transport. The cold chain and transport cost ramifications will obviously be significant.

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