Auto-disable syringes for immunization: issues in technology transfer

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WHO and its partners recommend the use of auto-disable syringes, "bundled" with the supply of vaccines when donor dollars are used, in all mass immunization campaigns, and also strongly advocate their use in routine immunization programmes. Because of the relatively high price of auto-disable syringes, WHO's Technical Network for Logistics in Health recommends that activities be initiated to encourage the transfer of production technology for these syringes as a means of promoting their use and enhancing access to the technology. The present article examines factors influencing technology transfer, including feasibility, corporate interest, cost, quality assurance, intellectual property considerations, and probable time frames for implementation. Technology transfer activities are likely to be complex and difficult, and may not result in lower prices for syringes. Guidelines are offered on technology transfer initiatives for auto-disable syringes to ensure the quality of the product, the reliability of the supply, and the feasibility of the technology transfer activity itself.

Keywords: disposable equipment; immunization programmes; quality control; syringes, economics, supply and distribution; technology transfer.

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Introduction

In response to a request in 1986 from WHO, various auto-disable (AD) syringe designs have been developed in accordance with a standard performance specification. WHO was concerned that conventional disposable syringes were being widely reused and believed that, unless a physical barrier to syringe reuse was introduced, economic necessity and cultural resistance to waste would ensure continued reuse in developing countries, regardless of training, advocacy and regulatory factors. The aim was to make available for immunization injections a disposable syringe and needle that could not be used more than once.

Performance and design

In 1987 a WHO panel examined 35 responses to the initial request. The proposals were made in accordance with a performance specification requiring that the syringe, once filled with a single standard dose of vaccine, would be able to deliver that dose but not a subsequent whole or partial dose. These AD syringes and over 400 other designs proposed later involved a variety of mechanisms that either immobilized the plunger, blocked the needle, or caused the syringe to leak when a second injection was attempted. The

Meeting the need for safety

The AD syringe prevents reuse and therefore helps to prevent transmission of bloodborne pathogens between patients. The syringe does not significantly affect transmission between patients and health workers attributable to accidental needle-stick, nor does it present a lower risk of accidents in the community when incorrectly disposed of. However, it does prevent resale after use. In many situations where syringes are commonly reused, the introduction of the AD syringe necessitates an increase in the number of syringes purchased and a corresponding increase in expenditure. The AD syringe contributes to safety predominantly in developing countries where the reuse of standard disposable syringes is widespread, disposal systems are inadequate, and the resale of used medical equipment is common.

Current policies for use of AD syringes

WHO, UNICEF and the International Federation of Red Cross and Red Crescent Societies have signed a commitment (5) to budget for and supply AD

Ref. No. 0130

syringes were also made with a permanently fixed needle, thereby ensuring that the needle too was used only once. The performance of AD syringes has been tested in an independent laboratory (f) in order to qualify for listing in the WHO/United Nations Children's Fund (UNICEF) product information sheets that guide policy on the purchasing of equipment for immunization programmes (f). Some AD syringe designs have also been tested under field conditions (f), f) to assess the training requirement and acceptability to health workers and managers.

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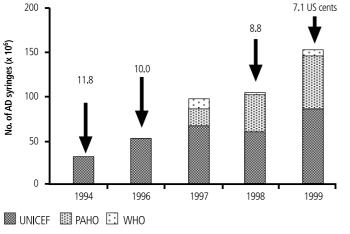
syringes and puncture-proof safety boxes with all injectable vaccines procured through them for mass immunization purposes. The determination to reduce the risks associated with the supply of disposable syringes and with the supply of inadequate numbers of syringes is being extended by WHO and UNICEF to all routine immunization with injectable vaccines. No international policies have yet been recommended to extend further the use of AD syringes to all skin injections, including all curative injections, but certain countries are considering this move and several states in the USA have recently introduced regulations in favour of safety syringes that have a specification different to that of AD syringes.

AD syringe production Market development

Despite the great number of design proposals and the existence of several hundred patents, only four models of AD syringe are currently being manufactured; two more are in the pre-production stage. This partly reflects the large investment needed to take a new design into production (usually over US\$ 1 million). More important have been the small size and slow growth of this market, almost exclusively confined to the public sector, in developing countries. Until recently the purchasing of AD syringes was almost entirely channelled through UNICEF. Fig. 1 illustrates the development of the market: until 1998 it was largely concentrated in 8 of the 51 (6) developing countries ordering these syringes. Governments recently began to purchase AD syringes, but previously the market was almost entirely driven by external partner agencies supporting immunization and attempting to eliminate the reuse of syringes.

The price of the AD syringe has been high in relation to the price to UNICEF of the standard

Fig. 1. Market and price developments for auto-disable (AD) syringes, 1994–99



Sources: WHO, Pan American Health Organization, United Nations Children's Fund.

disposable syringe and needle (US\$ 0.03–0.04) and to the commodity cost-per-use of the sterilizable syringe (US\$ 0.01–0.02). Furthermore, less than half of the one billion (1000 million) immunization injections given annually in the developing world are administered with disposable equipment.^a Thus the market share for AD syringes (ca 160 million) in countries choosing disposables (under 500 million) is around 30%.

Market prospects

The rather low market share occupied by AD syringes within immunization services can be expected to rise more rapidly in the next two years. WHO immunization policy favours the introduction of AD syringes and compliance with this is increasing among national governments and other international partners in immunization programmes. WHO will support and encourage the use of sterilizable syringes in countries that have decided to continue with them. There are, however, indications that the share of the global market held by these syringes will decrease. The only other alternative to AD syringes appropriate for mass immunization injections is the multidose reusable needle-free injector, which has proved to be economic and practical. However, this device cannot be employed in immunization programmes because of the risk of contamination between patients, and the prospects are uncertain (7).

The AD syringe may soon be used more generally for skin injections on a trial basis. This would open a market for AD syringes in developing countries that would be ten to twelve times greater than the immunization market.

Price sensitivity

The key factor affecting the uptake of AD syringes in the future can be expected to be price. The cost of mass production of AD syringes is estimated to be only US\$ 0.01–0.02 higher than that of standard disposable syringes, yet the amortization of development costs and the relatively small size and uncertainty of markets have kept the price of AD syringes relatively high. The cost of treating disease transmitted by syringes and needles has been estimated at US\$ 0.06-0.20 per unsafe injection, which now constitute up to one-third of immunizations and over half of other injections (8). The margin of benefit is in favour of the extra cost of AD syringes, yet the price sensitivity of purchasing for the poorer countries suggests that this market will develop rapidly only when the cost is within US\$ 0.02 of that of the currently available disposable syringe. This is expected to happen by the year 2000 as prices of AD syringes continue to fall.

^a Bangladesh, China, India, Indonesia, Nigeria, and Pakistan use sterilizable equipment for routine immunization, and account for 52% of live births in developing countries.

Need and potential for technology transfer

Recommendations on technology transfer

In 1998 WHO's Technical Network for Logistics in Health recommended that AD technology should be transferred to developing countries in order to accelerate the implementation of the initiative for improving the safety of injections (9). Given the slow development of the international market and the reluctance of health ministries to embrace the policy on AD syringes, it was felt that, where feasible, local industry would adapt more quickly to local demand and build more effectively local awareness of the need to invest in safety. Two owners or manufacturers of AD syringes currently offer their intellectual property for technology transfer:

- UNIVEC, New York, USA;
- Pharma-Plan GmbH, Bad Homburg, Germany.

Market autonomy

The rationale for transfer of this technology rests largely on the development of market autonomy in the manufacture of disposable syringes in most large countries. Over 60% of the population of the developing world is in countries that have a national industry for the manufacture of disposable syringes (10). In those developing countries with the largest markets for disposable syringes, local industry does not usually control the entire local market but usually receives a large share of government orders for syringes. This relationship between producer and government permits changes in specification to meet local requirements. Countries whose health ministries have shown an interest in technology transfer and which have appropriate local industries include Brazil, China, Egypt, India, Indonesia, Pakistan, and the Philippines.

Feasibility

AD syringe technologies vary widely. However, those now being offered by intellectual property owners in Europe and the USA are relatively easily incorporated into existing production lines. An extra tool is inserted into the current mould, the current mould is easily modified by machining, or a completely new mould is produced. Some designs require additional assembly steps, for which machines are offered. The required investment in the physical changes to the production line ranges from a few thousand to several hundred thousand US dollars, depending on the model of syringe. In all cases the change to AD syringes requires only commonly available injection moulding equipment for syringe manufacture and adjustments to the assembly procedure. Small syringe industries usually operate two-shift to three-shift production lines in order to remain economically afloat.^b It is therefore vital that

the work of converting a line to AD technology be quickly and successfully completed.

Price reduction prospects

The most likely scenario for economic sustainability is that, for safety reasons, a commitment be made by a government to buy economic quantities of AD syringes and that the manufacturer will be able to produce the new syringe at a price acceptable to the government concerned. The manufacture of disposable syringes in industrialized and emerging economies is highly automated. The prices of local, smaller-scale manufacturers need to compete with those of the international market driven by large manufacturers producing at high speed and high efficiency. This, however, is not always possible, even allowing for import taxes and shipping; the local price for a disposable syringe and needle is therefore often higher than the price of the imported counterpart. On the other hand, if local industry has already achieved the necessary international standards of good manufacturing practice and operating efficiency and has established relationships with decision-makers in the health ministry and with the purchasing authorities, competitive pricing may be possible. This is expected to be true of AD syringes from China and India, although final prices for AD syringes have not been made public by any local industry.

Barriers to technology transfer

Most considerations of technology transfer cover only technical matters, how well it will be done, what machinery and experience are needed, and how long it will take to begin operating. We consider below other potential barriers in addition to these important factors.

Technical feasibility and time frames

Technical feasibility depends on the existence of a technology holder and a ready potential recipient/ partner. For modern production of disposable syringes, introduction of the new technology allowing production of AD syringes may not require a large step. It is necessary to consider capacity and the need for expansion, the type of syringes (e.g. syringe volume) already being produced in comparison with those needed for national needs, the ability to meet other presentations required for the national immunization programme, the sterilizing process, national licensing requirements (if any), and the need for imported raw materials. The legal status of the manufacturer may be an issue in connection with joint venture or licensing agreements or the participation of local manufacturers. Each of these factors influences timing: simple technology transfer probably requires at least two years, and appropriate time frames must be included in market and cost estimates.

^b Production plants operate up to three 8-hour shifts per 24 hours.

Corporate interest

Technology donor. There may be barriers to generating sufficient interest in technology transfer on the part of the intellectual property holder. Some of the questions to be considered by a potential technology donor are shown below.

- Will technology transfer allow access to a new market that would not ordinarily be available?
- Is this market sufficiently rewarding in terms of royalty stream or other revenues?
- What investment costs would be required to make transfer happen (minor investment for transfer of intellectual property rights versus major investment for transfer of technology)?
- What is the risk involved in such a venture, what are the opportunity costs and what is the potential competitive situation in the market?

Technology recipient. It is not always an easy decision for the recipient to participate in a technology transfer agreement. Consideration has to be given to potential markets, investment and the impact on existing production. Below are shown some of the factors involved.

- Does the recipient company have a protected market?
- Is it interested in sales to the public sector?
- Is there interest in expanding the production base?
- Can the product mix be changed without reducing profitability?
- What are the considerations related to loss of independence through a technology transfer agreement?
- Is there a market for AD syringes in the country?

Price

Although the cost of some inputs for AD syringe production may be lower in developing or industrialized countries, local independent producers may not be able to compete in an open market because of the impact of large syringe manufacturers on their local licensees and because of the cost structure for local production. Some of the largest syringe manufacturers are preparing to increase production of AD syringes and to reduce costs. These manufacturers may control supply in many developing countries either through their import agents or through ownership of local producers. The willingness of local independent manufacturers is often substantially modified by the behaviour in the national marketplace of international producers who, in the case of AD syringes, may have an interest in creating a global market for the product based on a few, rather than many, production sites.

Since production costs are generally extremely scale-sensitive, it is unlikely in this respect that an independent local producer could compete with international producers. With some exceptions, syringe manufacture is not labour intensive and may depend on imported components that have to be purchased with hard currency. Thus there may be no

incentive from the cost standpoint for independent local producers to embark on the manufacture of AD syringes. Although support for local production may lead to transfer of AD technology, projects in other health commodity sectors based exclusively on this factor have not been very successful.

Purchase commitment

The single greatest barrier to the development of the market for AD syringes has been the lack of national demand. Awareness of the risk of syringe reuse and concern about the safety of injections have remained at a low level despite repeated international warnings by WHO since the Yamoussoukro Declaration (11) in 1994 and sustained pressure by UNICEF in favour of purchasing only AD syringes for immunization. Even governments demonstrating concern about safety have rarely translated their commitment to safer injections into the purchase of these syringes, probably for the reasons given below.

- AD syringes have been available only for immunization injections, and the creation of a special policy for immunizations has been rejected by certain governments lobbied by WHO.
- The price of AD syringes has been two to three times higher than that of conventional disposable syringes and this has been seen as representing a significant increase in the budget for immunizationrelated supplies. In countries where health expenditure is under US\$ 5 per capita this extra cost would be insupportable.
- The demand for AD syringes is not clearly expressed by health managers, who should influence the process of budgeting and purchasing choices. The efforts of UNICEF offices to advocate the provision of AD syringes to national staff are often seen as external pressure rather than as a logical response to the problems regularly encountered in the field.

Quality assurance

The quality of locally manufactured disposable syringes varies widely between and within developing countries. Certain manufacturers are scarcely able to achieve or maintain the sterility of their syringe products: few quality checks are made during production and consequently the rate of malfunctioning syringes in the market is high; in one case it was reported that syringes were already contaminated on being unpacked. Other manufacturers adhere to good manufacturing practice and are certified compliant by ISO 9002, the European Committee for Standardization (CEN) or the US Food and Drug Administration (FDA). International standards are seldom cited in national purchasing by health ministries, and national requirements are often outdated and inferior to international quality standards.

In many countries there is no close regulation of syringes. Technology transfer requires regulatory systems to be in place. Although there may be a requirement for original registration and demonstration of compliance with specifications, there may be no check that syringes consistently meet the standards laid down. In general, quality standards imposed would be ISO standards for syringes and needles, plus standards for toxicity and sterilization, and for quality systems to be in place during manufacture. In many countries this ongoing monitoring is left to the manufacturer without supervision. Problems have been reported concerning defects, sterility and lack of consistency and robustness, even in relation to production in industrialized countries and purchasing by international agencies. Dealing with this matter requires national regulatory authorities to have a strong supervisory capability so as to ensure compliance with good manufacturing practice and adequate responses to complaints made by customers.

Guidelines for technology transfer

Some investigation is needed before transfer of AD technology takes place in order to establish whether certain standards are met.

Characteristics of the technology donor

In general it is important to ascertain that the technology donor has access to the appropriate intellectual property and the technical ability to carry out the transfer. There should also be evidence that the donor has a track record of establishing reliable production that meets international specifications, a willingness to invest and to see the product through to completion, and a sound business plan to achieve the transfer.

Characteristics of the recipient

Some of the considerations that have been developed for the local production of vaccines also apply here (12).

Adequate market. The national public sector market for immunization syringes is the starting point. Unless the portion of this market that could be met by local production is more than about 20 million syringes a year, there is little economic basis for transferring AD technology to more than one local manufacturer.^c If the national tendering process requires more than one manufacturer to compete but the market cannot support more than one, it may not be worth while establishing local production of AD syringes.

Compliance with good manufacturing practice. It is essential that manufacturers of medical devices be able to comply with good manufacturing practice and ISO standards, since national regulation in this field is less developed than with other medical products. Many local manufacturers of syringes do not meet this requirement and would need investment and management changes to achieve it before technology transfer could be considered.

Reliability of supply. A manufacturer of injectable equipment who has a market share for immunization syringes can be expected to be a reliable source of supply. Technology transfer should not interfere with this state of affairs. Reliability of supply demands that neither breakdowns nor shortages should interrupt production. Injection moulding machines, associated assembly machines and sterilization plant all require specialist maintenance and immediate availability of spare parts and repair expertise. Companies should be able to demonstrate a record of reliable operation and only short interruptions of production.

Credibility of product quality. Not only should AD syringes be produced under standards of good management practice, preferably ISO 9002, and under the various ISO standards covering the design of syringes and needles and the sterilization process, but also there should be a monitoring mechanism to ensure that the quality of the product is maintained. For vaccines this is done by national regulatory authorities, but this kind of external control does not always exist for devices.

Ability to access technology. The process is easier if the recipient has previously been involved in technology transfer activities or has demonstrated a history of taking on new processes. A meeting should occur in which the intellectual property owner presents the technology in question, and the implications of altering tools, assembly lines, quality-checking procedures, packing and personnel should be discussed and quantified. The cost of the technology should be examined, including both the initial capital outlay, the purchase of rights, and product costs such as royalty payments and materials or recurrent tooling costs.

Management. Management is often poor in local production facilities, especially in the public sector. For a technology transfer agreement to work there must be an ability to manage the process on site.

Legal status. Local producers must have the legal ability to enter into outside agreements for the purpose of technology transfer. Some public sector manufacturers may need government approval for such agreements.

Assistance of WHO

WHO is willing to assist the process of technology transfer through:

- manufacturer assessments;
- liaison between intellectual property owners and manufacturers;
- market assessment in collaboration with health ministries;
- provision and modification of specifications;
- laboratory qualification testing.

^c This threshold has been quoted during meetings between one of the authors and potential manufacturers in two emerging economies.

Résumé

Utilisation de seringues autobloquantes pour les vaccinations : un problème de transfert de technologie

Les seringues autobloquantes ont été mises au point à la demande de l'OMS afin d'accroître la sécurité des injections effectuées dans le cadre des programmes de vaccination. Ces serinques sont conçues de telle manière qu'elles ne peuvent être réutilisées, ce qui réduit le risque de transmission d'agents pathogènes véhiculés par le sang. L'OMS et ses partenaires ont recommandé l'utilisation de seringues autobloquantes — livrées avec les vaccins fournis au titre de l'aide des donateurs dans toutes les campagnes de vaccination de masse et en préconisent vivement l'utilisation dans les programmes de vaccination systématique. Deux éléments ont freiné l'utilisation de ces seringues : leur prix relativement élevé par rapport à celui d'autres types de seringues et aiguilles (US \$0,07 contre US \$0,03-0,04 pour les seringues et aiguilles jetables) et leur part de marché plutôt restreinte (actuellement d'environ 150 millions par an). A cause de cela, le Réseau technique de l'OMS Logistique et Santé a recommandé que soient prises des mesures pour le transfert des techniques de production des serinques autobloquantes afin d'encourager l'utilisation de ces seringues et d'améliorer l'accès à la technologie qu'elles représentent. Si l'on considère que plus de 60% de la population du monde en développement vit dans des pays dotés d'une industrie pour la production de seringues jetables, cette approche pourrait beaucoup favoriser l'emploi de la seringue autobloquante. Ceux qui détiennent actuellement la technologie nécessaire à la fabrication de seringues autobloquantes ont manifesté leur intérêt pour ce transfert de technologie. Cet article passe en revue les obstacles à surmonter, notamment aux niveaux de la faisabilité, des intérêts des entreprises concernées, du coût, de l'assurance de la qualité, des questions de propriété intellectuelle et des délais de mise en œuvre. Ces opérations de transfert de technologie, qui s'annoncent complexes et difficiles, ne conduiront pas forcément à une baisse du prix des seringues autobloquantes. Il faudra veiller au respect des principes des bonnes pratiques de fabrication et de l'assurance de la qualité afin que les produits obtenus satisfassent aux normes de qualité. Les activités à exécuter pour assurer le succès du transfert de technologie et obtenir un produit de qualité constante peuvent prendre des années. Les auteurs de l'article proposent des lignes directrices à suivre pour garantir la qualité du produit, un approvisionnement régulier et la faisabilité du transfert proprement dit. Dans ce but, l'OMS s'emploie à encourager la création de partenariats, l'exécution d'études sur les fabricants et les marchés, l'établissement de spécifications et la mise à disposition de services de contrôle en laboratoire.

Resumen

Jeringas autodestruibles para inmunización: cuestiones relacionadas con la transferencia de tecnología

Se desarrollaron jeringas autodestruibles en respuesta a la petición de la OMS de que se mejorara la seguridad de las inyecciones en los programas de inmunización. Las jeringas se han diseñado de manera que no pueden volverse a usar, lo que ayuda a prevenir la propagación de patógenos de transmisión hematógena que se produce como resultado de su reutilización. La OMS y sus asociados han recomendado el uso de jeringas autodestruibles, suministradas junto con la vacuna cuando se emplee dinero de los donantes, en todas las campañas de inmunización masiva, e insta encarecidamente a que también se haga uso de ellas en todas las campañas de inmunización sistemática. El uso de estas ieringas ha tropezado con dos dificultades: su precio relativamente alto en comparación con el de otras jeringas y agujas (US\$ 0,07 frente a los US\$ 0,03-0,04 que cuestan las jeringas y agujas desechables), y el mercado relativamente reducido que representan las inyecciones de inmunización (actualmente unos 150 millones anuales). Debido a estos factores, la Red Técnica de Logística Sanitaria de la OMS ha recomendado que se emprendan actividades para promover la transferencia de tecnología de producción de jeringas autodestruibles a fin de promover su uso y de facilitar el acceso a la tecnología. Dado que más del 60% de la población del

mundo en desarrollo se halla en países que poseen una industria nacional de fabricación de jeringas desechables, esta opción podría potenciar considerablemente el uso de las autodestruibles. Los actuales poseedores de la tecnología de fabricación de estas últimas se han mostrado interesados en la posible transferencia de la tecnología. En el presente artículo se analizan los obstáculos que dificultan esa transferencia, teniendo en cuenta la viabilidad, los intereses empresariales, los costos, el aseguramiento de la calidad, los aspectos relacionados con la propiedad intelectual y los plazos previsibles de implementación. Esas actividades de transferencia de tecnología, además de resultar probablemente complejas y difíciles, podrían no dar lugar a unas jeringas autodestruibles más económicas. Hay que prestar atención a los principios de las prácticas adecuadas de fabricación y al aseguramiento de la calidad para que los productos resultantes satisfagan las normas de calidad. Pueden hacer falta varios años para que esas actividades propicien una transferencia exitosa de tecnología y un producto coherente. Se presentan directrices para las iniciativas de transferencia de tecnología de fabricación de jeringas autodestruibles a fin de asegurar la calidad del producto, la fiabilidad del suministro y la viabilidad de las propias actividades de

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transferencia. La OMS ha empezado a trabajar en ese terreno a fin de promover formas de colaboración, realizar evaluaciones de los fabricantes y del mercado, formular especificaciones y proporcionar servicios de pruebas de laboratorio.

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