The development process for a new spacer device

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- Why children should use spacers with pressurised metered dose inhalers
- The issues of encouraging children to use their spacer devices
- How a product went from concept to a marketable product

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Abstract

The British Thoracic Society and Scottish Intercollegiate Guidelines Network recommend that children up to the age of five should use a pressurised metered dose inhaler with a spacer device to deliver inhaled steroids. However, large-volume spacers can be cumbersome, which is why I designed a smaller, more portable device to encourage spacer use.

After prototypes were made, the idea was presented to the local NHS innovations department. With its advice and assistance, a collapsible spacer device has been developed. This article describes the product development process.

Pressurised metered dose inhalers (pMDIs) are widely used for the long-term management of asthma. However, there are issues associated with their use, including:

- The amount of drug delivered to the lower airway can be limited by the size of the particles produced;
- Patients have difficulties with coordinating actuation and dose inhalation;
- Adverse effects can occur including oral candidiasis (CKS, 2011).

BTS and Scottish Intercollegiate Guidelines Network (2012) recommend that asthma is managed in children aged 0-5 years with the use of a pressurised metered dose inhaler (pMDI) and a spacer device for the delivery of inhaled steroids. The advantages of using a spacer device are outlined in part 1 of this series (Watson, 2012).

Most spacers are large and cumbersome, difficult to carry around and difficult for children to use (Health Enterprise East, 2009). Children may also feel embarrassed to use a spacer in front of their peers.

A compact spacer
Having seen the problems children have in carrying and using conventional spacer devices, I had the idea to develop a smaller, more portable version. The result is the Pocketflow spacer, a collapsible, pocket-sized spacer for use with standard pMDI (Fig 1). It is aimed primarily at the paediatric market, but can also be used by adults.

After creating the first prototype, the next step was to take it forward into production. This took many hours of hard work and some intense networking. It was necessary to show the product design was not only aesthetically pleasing but also a functional and efficient medical device.

Gaining a partner in the form of the Health Enterprise East moved this project forward, with HEE helping to secure funding for research and development. Without this support the project would not have been possible.

5 key points

1. The British Thoracic Society recommends that children up to the age of five should use a pressurised metered dose inhaler (pMDI) with a spacer device to deliver inhaled steroids
2. Young children find large spacers difficult to handle and carry around, which may discourage their regular use
3. The new spacer - Pocketflow - is small and collapsible and is therefore easier to use and to carry
4. The device had to be tested against existing devices through mathematical modelling and physical laboratory testing
5. The portable device is more efficient than conventional spacers, with less medication needed to achieve an optimum dose

Structure of collapsible spacer
Less medication
Trials of the device have shown an improvement in lung deposition of inhaled medication compared with other products (Khan and Chrystyn, 2009). For this reason, it is anticipated that lower amounts of medication will be required and benefits will be observed sooner than they would be with other spacer devices (Khan and Chrystyn, 2009).

The volume and shape of the spacer has been designed and tested through extensive computer modelling and evaluation, to ensure optimal flow through the chamber, changing the shape and volume to give the optimal results.

Developing the new spacer
Once designs had been refined and developed by a design company recruited by HEE, we were able to take them into initial computer testing.

It is expensive to build prototypes, and it is often difficult to tell why one works better than another. In addition, once a prototype has been made, it cannot be altered to rectify problems discovered after it has been built.

For this reason, we decided to first “test” the prototype’s efficacy using mathematical modelling. A research and development company, Fine R+D, tested our spacer against the current market leaders, using a simple computational fluid dynamics model. The results allowed us to make refinements before moving onto the physical prototype, which then went for physical testing through a cascade impactor.

Physical testing
We used an Andersen Cascade Impactor to determine the aerodynamic characteristics of the dose emitted from a pMDI. This testing demonstrated that the fine-particle dose was higher for the collapsible spacer, suggesting that lung deposition could be better than from using other spacers (Khan and Chrystyn, 2009).

Overall, the results highlight the potential of the collapsible spacer and that it is comparable to the other market-leading spacers. The full results of these trials are awaiting publication and are the subject for my doctoral studies.

Improving concordance
It is anticipated that a spacer that is easy to use and carry and more efficient than other products would increase spacer use and efficacy. The studies of patient outcomes have not been completed but forms the basis of my doctoral studies being completed at Anglia Ruskin University.

Discussion and conclusions
According to Pearce (2011), most children under the age of eight years cannot coordinate taking a breath and the release of the inhaler; spacer devices overcome this problem by taking out the difficulty of coordinating the actuation and breathing.

Spacer devices tend to be large and cumbersome and therefore difficult for youngsters to use. They also may embarrass a young child by being so large and obvious, which may deter them from regular use. The smaller Pocketflow spacer has been designed with the intention of increasing the use of spacer devices among children and young people. It has been through many stages and various changes to reach this point, and still has a little way to go before hitting the market.

As the initial designer, it is exciting to see that the final design is extremely close to that of the original concept and prototype made in a garden shed. Having gone through the design process and into computer modelling with physical testing, it is gratifying to see how this product is performing.

This innovative product was exhibited at the international Medica exhibition in Düsseldorf where it attracted the attention of Lord Darzi, a former health minister, who visited the stand and talked with managing director of Vivo, the manufacturing company running the project.

Working with Vivo, means that millions of asthma patients will now be able to benefit from this device. Once in production, cost savings to the NHS could range from £1,854,600 to £6,435,000 annually if the spacer were to replace other spacer devices, as calculated from a reduction in drug usage and lower manufacturing costs (HEE, 2009).

In addition, using a portable spacer could also result in fewer emergency admissions to hospitals, potentially saving the NHS up to £11.5m per year (HEE, 2009). NT

References