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Safer Disposable Syringe

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Dr David Swann

Output number: 2 of 2

Year of Output: 2013

Type of Output: Designed Product

Title of Output: ABC syringe project

Location:

Support Materials:

- i. Publication of Creative Practice
- ii. Exhibition of Creative Practice:
- iii. Images
- iv. Media

Outline Description

This innovative two-year study has developed an effective innovation strategy to combat the reuse of disposable syringes within a curative context for low resource settings. We have designed a transformative syringe technology that makes visible, invisible risk posed by the transmission blood-borne diseases such as HIV or Hepatitis B. <https://vimeo.com/71013509>



In 1986 a call by World Health Organisation for an immunization syringe that could not be used more than once gave rise to the auto-disable (AD) syringe. An AD syringe is purposefully designed to lock upon full injection delivery rendering it unusable. While the AD syringe has now become a prerequisite tool for mass and routine immunization programmes funded by the World Health Organisation and UNICEF (95%). Costing 200-300% more than a conventional syringe their economic has inhibited their routine use for curative purposes (5%).

In 2008, the WHO calculated the global burden of disease from unsafe medical injections. In total, unsafe injections led to 1.3 million deaths, 340,000 HIV infections,

15 million HBV infections, 1 million HCV infections, 3 million bacterial infections and 850,000 injection site abscesses.



These blood-borne infections accounted for 14% of all HIV infections, 25% of HBV infections, 8% of HCV infections and accounted for 28 million disability adjusted life years (a metric of the years of life lost to death and disability from AIDS, acute hepatitis, liver cancer and fatal sepsis). Despite its emergence almost 27 years ago the AD syringe the prevention of unsafe injection practices remains the WHO's research priority no.5.

“Research Priority No.5-Unsafe injection practices: Up to 40% of injections are given worldwide with syringes and needles reused without sterilization. In

some countries this proportion is as high as 70%. Future research should focus on understanding the epidemiology and burden of disease transmitted through unsafe injection practices and developing strategies to improve practices that are acceptable and affordable.”

History has demonstrated that achieving absolute safety through one syringe solution is illusory. This research identified two key deficiencies with current technologies designed to deter unsafe practices: affordability and a difficulty determining sterility when no packaging is present.



The outcome of the research has resulted in the development of a super-frugal innovation that improves the safety performance of any injectable: disposables, AD syringes and pre-filled syringes. The underlying hypothesis is to utilise persuasive design to visually communicate with absolute certainty the safety status of the device. This is a critical factor as human behaviour can have a significant effect on risk outcomes as people often surrender decision-making to those who know more or those individuals who are in a position of trust.

This innovation unites two proven technologies: colourimetric inks and modified atmosphere packaging (MAP). MAP is a popular technology used by food processing industries to minimize product deterioration and to extend the shelf life of food products. Inside a nitrogen-filled blister pack our syringe label remains deactivated. Exposure to air (by opening or pack failure) activates an o-crestholphthalein coated label to rapidly absorb the carbon dioxide found in the atmosphere. This provides a designated procedure window before a dramatic colour transformation takes place—changing from colourless to red in 60-seconds <https://vimeo.com/71016535>. Recolouration inhibits the operability of the syringe and serves as a visual warning of prior use to both literate and illiterate patients. The principle advantages are:

- **makes invisible risk, visible**
- **provides a unique opportunity for brand differentiation**
- **improves compliance of clinicians**

- **empowers patients to make better risk decisions**
- **reduces provider costs associated with morbidity, long –term care, retesting and litigation**

Originality

Peter Evans, Former Head of Worldwide Procurement for the World Health Organisation and project lead of the WHO's auto-disable project has endorsed the originality of the design research/ innovation:

"Teaching about the perils of reuse of syringes is a fundamental part of medical training and yet, throughout the developing world, reuse continues to be a generally accepted practice. Part of this is because the patient, and the medical professional are used to the reuse of syringes and there is no immediate feedback that something is wrong. The product you have described, an indicator showing prior exposure to air and therefore non-sterile, is to my knowledge unique."

The originality of the innovation has been rigorously tested through international peer-review. The biennial INDEX: Award is the biggest design award in the world and supported by The Danish Ministry of Children and Education, The Danish Ministry of Business and Growth and The Danish Business Authority. The importance of INDEX: Award lies in the unique, over-arching theme of Design to Improve Life – a concept which has established INDEX as a global, inspirational design beacon. From the pool of 1000+ nominations from more than 80 countries, an international jury of designers, design scholars and thinkers, business people and curators select a group of finalists for five categories: Body, Home, Work, Play and Community. In 2013 the ABC project achieved three notable successes in the INDEX: Design to Improve Life Awards:

1 of 8 finalists: Body category

1 of 15 finalist: people's choice award selected by the jury

1 of 10 INDEX investment award candidates

A second notable success was achieved in the 2013- 2014 World Design Impact Prize, an international competition organised by The International Council of Societies of Industrial Design (Icsid). Icsid is a non-profit organisation that promotes the interests of the profession of industrial design. Founded in 1957, Icsid serves as a unified voice of over 50 nations through which members can express their views and be heard on an international platform. The primary aim of the Icsid is to advance the discipline of industrial design at an international level. Following a two-stage peer review process the ABC project was nominated for consideration of the award (1 of 26 projects with the final result pending). See:

<http://worlddesignimpact.org/projects/projects-2013-list/>

To protect the originality and future commercial value of the intellectual property derived from the innovation is registered with the World Intellectual Property Office.

Swann, D., 2012. *Condition Change Syringe*. GB1213521.6

Process

The primary objectives of the design research are:

- Reduce clinical errors/ adverse events caused by the reuse of disposable syringes in a curative setting
- Improve clinical compliance
- Contribute to the UN Millennium Development Goals 4, 5 & 6

The use of precedent case studies, force-field analysis, and dialogues with global networks and specialists captured the complexity of the challenge, sharpened the acuity of our strategic approach and identified an urgent need for a frugal solution that offered unilateral benefits to patients, providers and manufacturers.

A knowledge and attitude survey on the streets of Mumbai was performed to test the innovation strategy. A comparative test presented participants with a choice. Participants were shown a conventional clear syringe and a red-coloured syringe and asked which device they perceived to be dangerous. In reality both syringes were equally dangerous as they were not sterile. However the persuasive red colouration was found to trigger an individual's innate sensitivity to risk. These findings verified our deductive reasoning, with 100% of participants perceiving the red syringe as a threat to their personal safety- with many associating its unusual colour with drug use or blood contamination.



Marc Koska OBE, the founder of Safepoint Trust and an original pioneer of the auto-disable syringe described the simplicity of our innovation as **'brilliant'**.

Rigour

The scale of the design challenge to be addressed has required a very different methodological approach to evaporate adoption barriers and corporate resistance to change. Unlike many conventional design projects a rigorous engagement process

from the very outset was required to build confidence and to attract high-level advocacy. Without traction with key stakeholders, no design research findings, no matter how innovative the design intervention is will fall. The ABC project has achieved significant traction with the WHO to advance the project towards our goal of achieving world design impact: inclusion in a new WHO draft mandate outlining the performance requirement of future injectables:

“A wide range of technologies are encompassed in the new WHO draft mandate, and our colour-change label provides a visual signal of prior use to inhibit syringe reuse in low resource settings. This innovation has great potential and is included as apart of this mandate.”

Significance

Patient safety is recognised as one of the most significant issues facing every healthcare system across the world (Canadian Patient Safety Institute, 2006). Dr David Bates, Chair of WHO’s World Alliance for Patient Safety advocates that there is an urgent need for local relevance as research and patient safety solutions for developed for transitional countries are a low priority in developed nations.

The WHO has recognised the pertinence of our design innovation to global health. And is shortlisted for inclusion in the 2014 WHO Compendium of Innovations for Low-Resource Settings. Denis Maire, who works for the World Health Organization's health systems and innovation taskforce, believes that the ABC syringe could help to make injections safer.

“The great advantage of this concept is that not only health care workers but also patients can have a visual appreciation on the safety status of the device. In my view this could be a good deterrent for practitioners to reuse.”

The most deadly clinical procedure in the world is probably a simple injection. For the WHO addressing the challenge of preventing unsafe injection practices in a curative context is the elephant in the room. For 25 years the global community has effectively turned a blind eye to effectively a patient holocaust that is occurring within curative settings. This behaviour-changing syringe innovation seeks to prevent a series of associated violations through visual design:

- Reuse of disposable syringes and syringes for curative injections
- Loading disposable syringes with multiple doses and injecting people consecutively
- Reusing the same syringe on more than one patient after changing the needle
- Using multiple-dose vial pierced with a single drawing up needle
- Soaking syringes and needles in sodium hypochlorite
- Flushing syringes with disinfectant or water to clean them prior to reuse
- Discarding syringes into general waste
- The collection and resale of used syringes from landfill

The development of locally effective and affordable solutions is seen as a top priority for all developing and transitional countries. By prioritizing affordability we have

realized significant healthcare benefit potential. In India this is a critical factor faced by public facilities who bear the burden of care with increased demand. History has shown that even the infallible AD syringe has had limited impact in the curative market due to its price sensitivity. Defining levels of acceptable risk and responding to them intelligently necessitated a multi-strategy approach and a *satifice* solution-stripping away complexity for frugality. The result is an intelligent label technology that delivers a superior product for an additional £0.008. An initial impact estimation based upon extrapolated data suggests that this intervention could prevent 700,000 fatal injections, save 6.5 million live years and \$130m in direct medical costs by Year 5 in India alone. The social and economic impact associated with the reuse of single-use medical devices is alarming. However it is surprising to learn that this is a challenge not confined to low-resource settings. In 2012 United States Government Accountability Office captured data related to the prevalence of unsafe injection practices and the transmission of blood-borne infections in hospitals <http://www.gao.gov/products/GAO-12-712> . One case particular case has highlighted the true cost of a single contaminated syringe that resulted in 63,000 patients being recalled for testing at a cost of \$13.8 million, \$1 million outbreak investigation costs and \$30,000 in treatment costs for each infected individual.

While this innovation clearly demonstrates tangible benefits for patients and providers, to leverage adoption by manufacturers the benefits have been equalised. The design research identified a practical testing problem experienced by medical device manufacturers- determining the integrity of sterile blister packages. While theoretically it is feasible to test 10,000 packs for sterility, it is impossible to test 10,000 or 1 million. FDA compliance regulations state that an acceptable level of package failure for invasive devices is 0.25%. Therefore the integrity of packaging barriers plays a critical role in delivering safe treatments. Consequently, the ABC project innovation has significant potential for the global packaging industry as the visual quality assurance monitor to verify pack sterility / integrity package; on the production line or during the distribution chain.

The importance of the design research to patient safety was communicated to a global audience following its exposure on CNN International <http://edition.cnn.com/2013/09/03/tech/innovation/smart-syringe-turns-red/index.html> and the National Danish Television network DR. The design research/ innovation since featured on 250+ websites/ blogs, and attained a significant geographical reach: USA, Dominion Republic, South Africa, Germany, India, Japan, China, UAE, Saudi Arabia, United Kingdom, France, Cameroon.

"We believe that the ABC syringe has the potential to drastically reduce the rate of disease transmission via unsterilized second-hand syringes, especially in developing countries such as the Dominican Republic. Such a product could arm patients with a simple and rapid way to identify previously used syringes on the spot."

Jordi M. Gassó, CEO of Dr. Manelic Gassó-Pereyra, S.R.L. (2013)

Subsequently, commercial interest in the design research/ innovation has been phenomenal with many organisations expressing a desire to manufacture, secured regional licensing or distribution rights:

- Peter Robinson, Accelerated Business Programme, 3M Healthcare
- Rajiv Nath, Joint Managing Director, Hindustan Syringe & Medical Devices, Top 5 manufacturer worldwide for syringes and needles
- Dr. Philipp Schieferdecker, Profol Kunststoffe GmbH <http://www.profol.de>
- Tapan Mukerji, Vice President, Biomedical Devices of Kansas www.biomedks.com
- Isabelle Seunier, Global Procurement Innovation Director, AB-inBEV
- Abhishek Hundia, CEO of Technology Concepts
- Gianfranco Pagliara, CEO Direct Med
- Pratag Kedia, Kedias Organisation

A new joint venture is presently being planned between the University of Huddersfield, Queen's University, Belfast and Hindustan Syringe & Medical Devices (HMD) to bring this innovation to market and a global audience. The primary partners include:

- Dr David Swann, University of Huddersfield
- Professor Andrew Mills, Chair of Materials Chemistry, Queen's University
- Rajiv Nath, Joint Managing Director, HMD

The significance of this future partnership with HMD cannot be under estimated. HMD is amongst the top 5 manufacturers worldwide for syringes and is Asia's largest syringe manufacturing company. HMD is the market leader in India (60%) producing 2.5 billion syringes per annum to supply a network of 4000 distributors. A second project phase is planned and will seek to perfect clinical, engineering and design performances/ specifications to ensure regulatory compliance; conduct a comprehensive technology evaluation study with key users and opinion makers; produce a batch demonstrators that proves repeatability and design robustness for clinical/ market trials. We shall continue to work closely with the Safepoint Trust, the WHO and UNICEF, with additional expertise provided by:

- Professor Charles Vincent, Professor of Clinical Safety, Research, Imperial College
- Peter Evans, Former Head of WHO Procurement Worldwide and Project Lead for Vaccine Vial Monitor Programme
- Nicholas Coutts, Former VP, Global Distribution Channel Strategy for IBM
- Marc Koska OBE, pioneer of the safety syringe and founder of SafePoint Trust

Supplementary Material:

(i) Publication of Creative Practice:

World Health Organisation 2014. *Compendium of Innovation Technologies; Medical Devices & eHealth Solutions for Low Resource Settings* (short-listed, pending final decision) The WHO seeks to raise awareness of the pressing need for appropriate design solutions through its compendium of innovative health technologies: Medical devices and eHealth solutions for low-resource settings. This annual publication serves as a showcase for emergent innovative medical devices that are not yet

widely available in under-resourced regions.

2013 World Health Organisation Draft Mandate. A new global mandate is presently being prepared by the World Health Organisation in conjunction with Safepoint Trust that seeks to homogenise the production, safety and quality of future WHO-certified AD syringes and injection devices for safety. A wide range of technologies are encompassed in the mandate, and our colour-changing label is included as part of this programme

(ii) Exhibition of Creative Practice:

Selected for Index Award Exhibition World Tour 2013-2015: Copenhagen, Singapore, Luxembourg, Helsinki, Bauhaus, Risor, Tallin, Hong Kong. INDEX: Award Exhibition has been presented in various formats in 12 countries around the world - seen by almost 10 million people.



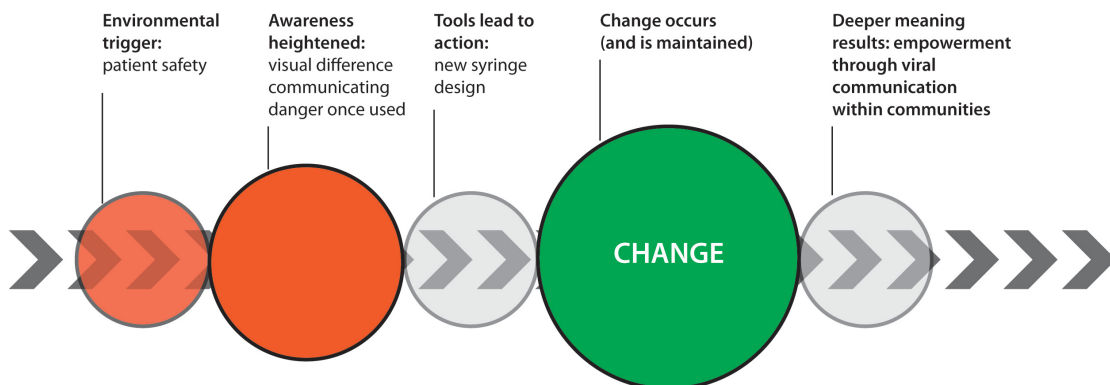
ROTOR Series: Mobilising Healthcare at Huddersfield Art Gallery 24 July-28 September 2013.

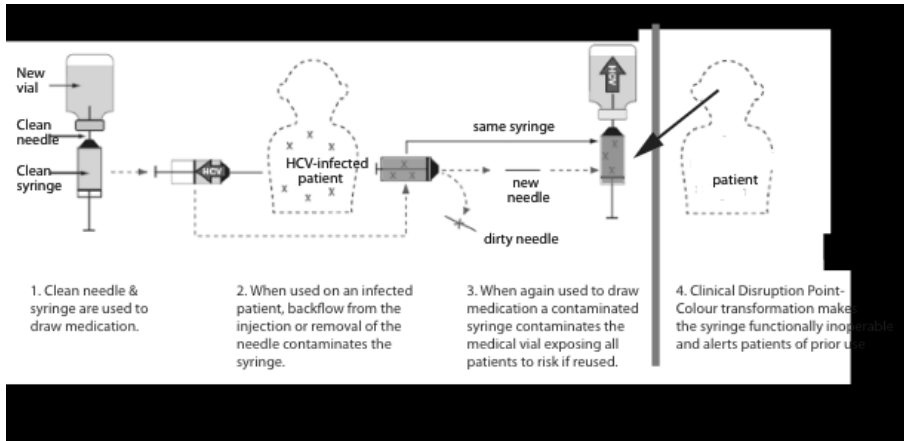
2nd European Conference on Design4Health Exhibition. Sheffield Hallam University 3-5 July 2013.



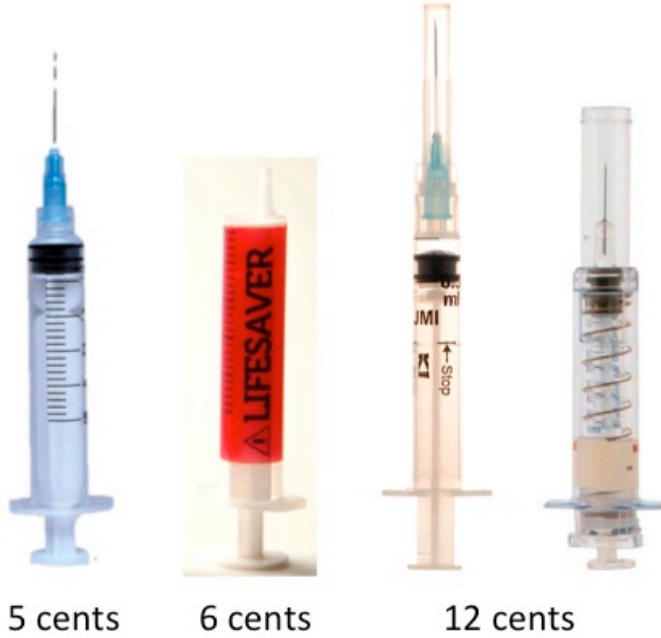
(iii) Images:







ENHANCED SAFETY FOR 1 US CENT







(iii) Media:

Interviewed (16/ 17th July 2013) by CNN International for a special programme series profiling international designers. The series will comprise a series of 90 seconds vignette films showcasing the innovative solutions designed by finalists for INDEX: Award; a theme week at CNN International and CNN.com and concludes with a half hour program special in September. The campaign will play to CNN's television and online audiences in Europe, the Middle East, Africa and the Asia Pacific. CNN has a global reach of 2 billion in a total of 200 countries and 271 million households around the world. <https://vimeo.com/73286912>

Interviewed (8th July 2013) by the Danish Broadcasting Corporation (DE) for a programme profiling five designers and their design to improve life innovations. DR is watched by 78% of Danes each week. DR due to air programme w/c 26th August 2013. <http://www.dr.dk/tv/se/design-en-bedre-verden/design-en-bedre-verden-5-5-den-roede-sproejte>

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