

INDUSTRY AS A STAKEHOLDER IN THE POSSIBLE IMPLEMENTATION AND NORMALISATION OF A MIXED INTERMITTENT CATHETER PACKAGE IN THE NHS: THE MULTICATH STUDY

Hypothesis / aims of study

The Mult/Cath study is investigating the feasibility of introducing a mixed catheter package (single use and re-usables) in the United Kingdom (UK) through the National Health Service (NHS). The creation of an implementation plan, should a mixed package be found to be as safe and acceptable as single use only, is a principal study output. Understanding the impact of this possible change in practice on stakeholders will be essential to successful implementation and normalisation. This paper discusses the barriers and enablers to the introduction of a mixed package identified by industry as a supply chain stakeholder.

Study design, materials and methods

A purposive sample of 16 intermittent catheter (IC) manufacturers, UK distributors and dispensing appliance contractors (DACs) were interviewed using semi-structured interviews. Interviews were conducted by a single experienced researcher between May 2014 and February 2015. The interviews were recorded, with participant consent, and anonymity assured. The recordings were independently transcribed and checked by the researcher against the original recording. The data was subsequently analysed using a process of defining and refining themes and codes. Reliability was tested through an in-depth team discussion, and the perceived barriers and enablers to implementation identified (1). Participant opinion was sought on the aspects of ICs that were thought to be important to users, healthcare professionals (HCP) and companies, the health risks associated with catheterisation and the perceived impact on the industry supply chain if there was widespread uptake of re-usable catheters as part of a mixed package.

Results

Intermittent catheters and catheterisation

Participants cited requirements of IC for patients as '*ease of use*', '*comfort*', '*discreteness*' and '*safety*'. It was thought that HCPs also look for a '*quality*' product that is '*cost effective*' and '*easy to teach with*'. Most participants described their company as wishing to supply ICs that '*made patients' lives easier*' and that getting this message across to HCPs who were the '*decision makers*' was of prime importance. Lubricity and polished eyelets were mentioned as being essential features for an acceptable product. Justification for features such as pre-lubrication and 'no touch' systems were based on the principle of designing out risk and minimising opportunity for user error (2). Packaging developments, in response to user demand, contributed to discreteness, ease of use and the desire for the catheter to '*not look like a medical product*'. The view that re-usable catheters presented an increase in risk to health was commonly held, despite lack of evidence. The promotion of re-usable catheters was seen as a '*backward step*' and that a mixed package could be '*confusing for everyone*'. Catheter design, variations in patients' needs and behaviours and initial training were all considered to impact on patient compliance, and lack of compliance afforded the greatest risk to catheter associated complications. The perceived increase in risk of urinary tract infection and the associated burden to the patient from cleaning and storing catheters were stated as reasons why re-usable catheters would be unlikely to be the preferred option for HCPs or users.

Impact on industry supply chain of a possible mixed catheter package in UK

The emerging picture of the potential impact on industry and the NHS, if re-usable catheters were widely adopted as part of a mixed package, was complex; reduced company profits were anticipated with potential knock-on effect on innovation and industry contribution to NHS continence services. Five companies interviewed manufactured uncoated flexible ICs which could be suitable for re-use, but none were CE marked as such. Although the opportunity for innovation was recognised, it was generally believed that the scope for innovation of a re-usable catheter was minimal and the consequence of reduced profits and innovation opportunities could result in some players leaving the market. Delivery of ICs to the end-user is by prescription through pharmacies or DACs. The service provided by the DACs was seen as superior to that of pharmacies, due to supply chain logistics and the expertise held within the DAC. As the main contact for the end-user after their training with an HCP, the DAC was seen as offering discrete, prompt and efficient delivery with readily available and friendly support on products and catheterisation. Concern was expressed that this support would be reduced or even become redundant if patients predominantly used re-usable catheters, and that this would be to the detriment of patient safety. Some DACs are owned by, or affiliated to, catheter manufacturers, and several participants reported that they were under the impression that some manufacturer-owned DACs inappropriately used this relationship to influence patient choice of catheter.

NHS system factors: HCPs, Drug tariff (DT), formularies and personal health budgets

HCPs who prescribe and teach intermittent catheterisation were seen as major influencers in product selection, when training a patient and when determining formularies (a list of selected products off the government reimbursement list (DT) from which HCPs can prescribe. The industry view on formularies was overwhelmingly negative, with the benefits of having a product on the formulary being outweighed by the restriction on competing for business (fewer products and reviews every 3-5 years), and concern that choice is limited. One participant stated that '*the DT is the only formulary we need*'. It was thought that adherence to formularies varied between organisations; in some the formulary was used for 'guidance' with HCPs able to prescribe which ever catheter they thought most appropriate for a patient, while in others strict adherence was encouraged. The DT was mostly seen as effective and efficient in offering choice and for introducing new products. Participants thought that many HCPs were unaware of the cost of catheters, but that this was changing. The interviews revealed that selected companies are invited to bid for contracts and that the DT price may not be a true reflection of the cost to the NHS. For some participants, the notion of significant uptake of a re-usable catheter in a health service in which end-users have a choice and do not have to pay directly,

was considered untenable as, if given a free choice, users and HCPs would choose single use IC. The (hypothetical) idea of including the purchase of ICs as part of a 'personal budget' was considered inappropriate as it could force patients to make choices on the basis of cost rather than health.

Interpretation of results

Industry participants gave responses that were a combination of personally-held beliefs and those they felt reflected their company view and/or those of industry in general; no distinction between them has been made in the analysis. The findings revealed an anticipated concern over loss of profits, but implications for the wider supply chain revealed the complexity, and lack of transparency, between industry, the NHS and patient. Barriers and enablers were identified as relating to catheter design (e.g. features that made the catheter easy to use, comfortable and discrete to carry, use and dispose of), patient factors (e.g. variations in an individual's hygiene, capabilities and life-style), NHS factors (e.g. HCPs, Drug Tariff, formularies, commissioners, NHS Health delivery organisations - some of which operate on a commercial basis) and industry supply chain factors (e.g. market size and share, innovation and investment). From this, three requirements for the successful implementation of a mixed catheter package can be extrapolated: (i) A re-usable catheter should not cause, or be believed to cause, an increase in risk to patient health (infection, stricture, bladder) compared to a single use catheter; (ii) Any increase in burden to the patient (threat to normalcy) in using a re-usable catheter should be commensurate with the perceived benefit held by patients and healthcare professionals; (iii) The development, manufacture, distribution, supply, purchase and disposal of re-usable catheters must be financially viable for suppliers (manufacturers/distributors) and purchasers (NHS/patient).

Concluding message

Successful implementation of a mixed package would depend on having a re-usable IC that is proven to be safe and does not unacceptably increase the burden to the patient. It would also require HCPs and users to positively embrace the concept of a mixed package and for industry to manufacture catheters regulated for reuse. The complexity of interdependence of the supply chain with patients and the NHS means that judicious cost benefit analysis prior to implementation of a mixed package is required; this will be examined as part of the randomised controlled trial on safety and acceptability.

References

1. (1) Trumble M. 2005 Qualitative Research Methods Chapter 6 pp121-2 in Integrating Quantitative and Qualitative Methods in Research, edited by George R. Taylor, University Press of America
2. (2) Human Factors Engineering - Design of Medical Devices, AAMI HE75: 2009

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