

REFERENCES:

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VP120 A United Kingdom Research Commissioning Framework For Devices And Diagnostics

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INTRODUCTION:

Generation of high-quality evidence on medical devices through clinical trials can be challenging. The United Kingdom's National Institute for Health and Care Excellence (NICE) has developed a research commissioning framework for producing clinical evidence where gaps in the literature prevent definitive recommendations in their medical technology guidance and diagnostics guidance. The research commissioning framework involves NICE's external assessment centers collaborating with clinical researchers to secure funding and to design, conduct, and publish a study to address research recommendations within 3 years of guidance publications. We aimed to describe the early results of the framework.

METHODS:

Publicly available information and results from an informal survey of NICE's external assessment centers were reviewed.

RESULTS:

As of December 2016, NICE has published a total of thirty medical technology guidance topics and twenty-four diagnostics guidance topics, five and twenty of which have research recommendations, respectively. A total of fourteen research commissioning framework-facilitated projects have been initiated. Two

research projects have successfully secured external funding for a clinical trial: (i) non-contact low frequency ultrasound therapy for wound healing; and (ii) Parafriacta booties for pressure ulcer prevention. Further projects have produced published outputs without external funding. Four projects have been completed and undergone guidance review; one guidance topic was withdrawn and three have been transferred to the "static list". Early experiences of NICE's research commissioning framework suggest that securing financial support from manufacturers or funding bodies for interventional clinical trials to answer single technology research questions within a short time frame is challenging but possible. The value of early feasibility studies to assess the likelihood of obtaining funding and of addressing NICE's research recommendations was recognised.

CONCLUSIONS:

NICE can facilitate independent research through its research commissioning framework initiative. Securing funding has proved challenging but recent successes have shown that approach is possible. Outputs which fill the evidence gap to an extent where a definitive guidance update is possible have been rare.

VP122 Cryoballoon Versus Radiofrequency Ablation For Atrial Fibrillation

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INTRODUCTION:

Pulmonary vein isolation (PVI) is a new effective treatment for atrial fibrillation (AF) (1). The standard of care for ablation methods using radiofrequency (RF) is time-consuming and technically challenging (2), and restricted to a few specialized centers, which causes the limited availability of ablation therapy (3). Therefore, cryoballoon (CB) ablation has been developed to