Title: An exploratory study of the factors influencing patients' decision-making regarding aortic valve stenosis treatment.

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Background and pilot data

Informed patient consent is a 'general legal and ethical principle' that is required before starting a medical procedure or treatment, ensuring patients have autonomy over their bodies (Health, 2009). It should be given voluntarily by an informed person who has the capacity to consent, and ideally the consent should be written rather than oral (Anderson and Wearne, 2007; Health, 2009; Williamson and Martin, 2010).

Trans-catheter Aortic Valve Implantation (TAVI) is a surgical procedure where a bioprosthetic valve is inserted through a catheter and implanted within the diseased native aortic valve (Leon *et al.*, 2010). This is to correct aortic valve stenosis, where the valve opening becomes narrowed due to calcification over time – meaning blood flow is reduced. TAVI serves as an alternative to Surgical Aortic Valve Replacements (SAVR) and is deemed more appropriate for the older and frail patient, rather than more invasive cardiac surgery. It also serves as a more effective alternative to standard therapy for those unsuitable for SAVR, such as balloon aortic valvuloplasty (Leon *et al.*, 2010). Since the first TAVI surgery in 2002, the procedure has become increasingly common, with an estimated 250,000 surgeries conducted to date globally (Morís, Pascual and Avanzas, 2016). This is also true for Northern Ireland, with a retrospective analysis showing that the number of TAVI surgeries conducted increased from 21 in 2008 to 100 in 2015 (Toh *et al.*, 2017). Annual number of SAVR has also increased during this timeframe, from 207 to 338, reflecting Northern Irelands ageing population and the pressure this puts on cardiology departments; a trend which is also seen globally (Savarese and Lund, 2017). The number of these surgeries will likely continue to increase, particularly for TAVI as it is more commonly conducted on older patients. The reasoning for this is that these patients are often frail, with comorbidities which put them at a higher risk of having complications when undergoing traditional surgery (Drews *et al.*, 2013). As an alternative, TAVI has been shown to be a promising treatment option for high risk patients (Pilgrim *et al.*, 2011; Nuis *et al.*, 2012; Drews *et al.*, 2013), leading to rapid recovery of left ventricular function and a reduction in heart failure symptoms (Pilgrim *et al.*, 2011). Furthermore, quality of life in patients after TAVI was shown to improve, both through reduced symptom burden and improved life expectancy (Sehatzadeh *et al.*, 2013; Astin *et al.*, 2017).

Regarding the informed consent process for a TAVI procedure, alternative options of SAVR or standard treatments as well as inherent risks, require careful consideration and discussion. Information provided must be individualized and appropriate, which is challenging given the demographics of the patient group, who tend to be elderly and quite frail (Giampieri, 2012). As TAVI procedures become more common, it is important that the process of informed consent is well documented and understood, patient centered and where possible a process of shared decision-making between the physician and patient. Currently, there are no studies detailing the informed consent process for TAVI procedures, and as such this study will take an exploratory approach

Aim: To explore the decision-making process regarding aortic valve stenosis treatment, including the perceptions of patients and professionals, allowing potential areas for improvement to be identified.

A cross-sectional study with three phases will be conducted for this investigation.

Phase 1: A detailed retrospective case study review of all patients who underwent aortic valve stenosis treatment over a 12-month period, to map current patient-professional interactions.

Phase 2: Semi-structured interviews with 12 patients, 12 caregivers and 12 physicians will provide insight into the decision-making and consent process.

Phase 3: A Workshop with key stakeholders (patients, caregivers and healthcare professionals) to discuss findings and generate recommendations and co-design an educational resource to improve current practice.

Methodology: This is a mixed methods study involving qualitative and quantitative approaches. Importantly the study also involves a process of co-design and patients will be involved as equal partners in the entire investigation process.

Anticipated value: This study will provide a unique insight into the decision-making process, enabling discussion of innovative strategies providing the data on which to base to develop interventional approaches that improve patient-professional interactions and facilitate fully informed consent.