

Institution: The University of Huddersfield		
Unit of Assessment: 3		
Title of case study: Influencing national guidance and transforming the international coronary angioplasty consenting process to benefit patients and cardiology services.		
Period when the underpinning research was undertaken: 2014 to 2016 (Grant period)		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): Professor Felicity Astin Dr John Stephenson	Role(s) (e.g. job title): Professor of Nursing and Applied Health Research Senior Lecturer in Biomedical Statistics	Period(s) employed by submitting HEI: 02/2015-present 01/2010-present
Period when the claimed impact occurred: 2016 to 2020		
Is this case study continued from a case study submitted in 2014? No		
<p>1. Summary of the impact Three million people worldwide consent to coronary angioplasty (CA) treatment annually. Research at the University of Huddersfield (UoH) has shown that people often agree to CA without fully understanding the possible consequences, contravening international guidance. UoH research has 1) driven improvements in CA services and consent practice in six National Health Service (NHS) Trusts, benefiting patients and yielding an estimated £11k in savings, 2) increased 'consent' knowledge levels of 130 leading cardiology health professionals, in 16 countries, which led to improved patient education processes in Greece, Austria and Poland; for the first time patients received written information to inform them about CA treatment ahead of consent discussions, 3) informed the updated 2020 General Medical Council guidance on decision making and consent, which now reinforces the importance of greater patient involvement, and is circulated to over 335,000 UK doctors for implementation.</p>		
<p>2. Underpinning research Over three million CA procedures are performed annually across the world. Planned CA and medications are effective treatments for people with coronary heart disease (CHD) who suffer from angina (a specific type of chest pain). However, medication offers a more conservative approach and avoids the serious risks and discomfort of a costly and uncomfortable procedure. About one-in-ten patients treated with CA are readmitted to hospital within 30 days. Importantly, for most people, there is no difference between CA and medication when it comes to comparing patient outcomes five years on.</p> <p>Global policy mandates that patients and health professionals 'work' in partnership to make treatment decisions. In practice, patients need support from health professionals to make sense of their treatment options and weigh-up the potential treatment risks and benefits. However, the ideal information sharing process, outlined in legal, ethical and clinical practice guidance about consent, does not happen consistently in clinical practice.</p> <p>Research led by Astin, Professor of Nursing, with collaborators (the University of Leeds, the University of Salford, Mid Yorkshire NHS Foundation Trust (MYFT), Sheffield Teaching Hospitals NHS Foundation Trusts and service users), provided a new and in-depth understanding of the CA consent process in England [3.1, 3.2]. These studies, published in 2017 and 2019, were the first studies conducted in England to simultaneously explore the perspectives of CA patients and attendant cardiologists. Astin collaborated with nurse scientists to explore consent practices in the USA. Findings [3.3] added to the evidence that demonstrated a pressing need to improve the consent and decision-making process for CA, which did not align with international guidance. The research [3.1, 3.2], led by Astin, with aforementioned collaborators, was supported by National Institute of Health Research (NIHR) funding [2014-2016, £287,000].</p>		

Study 1: Findings from qualitative interviews with 19 cardiologists and 41 patients undergoing acute or elective CA, and 37 audio-recorded consent discussions from two NHS Trusts, highlighted the need for transformation in the CA consent process [3.1]. Consent was often seen as an 'event' rather than a 'process'. Patients often saw it as a bureaucratic requirement that once completed gave access to treatment. They often misunderstood their role in the consent process and were passive recipients. Sometimes patients reported feeling that they had 'Hobsons choice' (i.e. no choice) regarding their treatment. Treatment benefits were often overestimated and CA mistakenly seen as a 'fix' for heart disease. The quality of the information provided to patients about treatment risks was variable and often generalised, rather than individualised. Because of the way cardiology services were planned, cardiologists often sought patient consent on the day of treatment, giving limited time for deliberation. Consent practice for planned CA did not consistently reflect the current consent guidance or the principles of person-centred care. This highlighted the need for improvement.

Study 2: Building on study 1, a survey study was conducted to evaluate the generalisability of qualitative findings. Over 300 patients from 10 NHS Trusts in England, and 118 cardiologists from a national database, completed surveys to evaluate their attitudes, practices and preferences for CA informed consent. Stephenson conducted the statistical analysis with Astin. Survey findings [3.2] supported the qualitative findings [3.1] confirming that significant improvements of the current CA consent process were needed. Patients and cardiologists often gave low priority to discussions about alternative treatment. The majority of patients misunderstood vital information about the implications of CA treatment. They drastically overestimated the benefits of CA and mistakenly perceived it as a cure for CHD. Patients also incorrectly thought that CA treatment would reduce their heart attack risk and prolong their lifespan. The research showed that a large proportion of patients agreeing to CA treatment did not fully understand the implications. This was supported by one third of cardiologists who agreed that most patients did not understand all the health information provided.

Study 3: Research findings [3.1] received interest from Nurse Scientists in the USA. This led to a collaboration in which a doctoral student at Massachusetts General Hospital, Boston, USA, conducted a survey study with 82 CA patients to evaluate their consent experiences. Findings were presented in 2018 at the international EuroHeartCare Annual Congress in Dublin [3.3]. Similar limitations in the CA consent process were identified [3.3]. Patients frequently misunderstood important details about their treatment limiting their capacity to make an informed decision; a circumstance evident in countries other than England.

In response to findings a research-derived consent improvement toolkit (RdCIT) was developed by UoH and research funding from Grow MedTech secured for the development of a digital Patient Decision Aid for Coronary Angioplasty and Stenting.

3. References to the research

- 3.1** Probyn, J., Greenhalgh, J., Holt, J., Conway, D., **Astin, F.** (2017). Percutaneous coronary intervention patients' and cardiologists' experiences of the informed consent process in Northern England: a qualitative study. *BMJ Open*, 7: doi.org/10.1136/bmjopen-2016-015127
- 3.2** **Astin, F.**, **Stephenson, J.**, Probyn, J., Holt, J., Marshall, K., and Conway, D. (2019). Cardiologists' and Patients' Views About the Informed Consent Process and Their Understanding of the Anticipated Treatment Benefits of Coronary Angioplasty: A Survey Study. *Eur J Card Nurs.* <https://doi.org/10.1177/1474515119879050>
- 3.3** Blanchard, HT., Carroll, DL., Albert J., and **Astin, F.** (2018) Giving consent for percutaneous coronary intervention: the patient perspective of a complex process. *Eur J Card Nurs* (published conference abstracts vol 17 (S1); 94, abstract 315) doi.org/10.1177/1474515118787764.

Evidence of research quality: The research was funded by the NIHR (Research for Patient Benefit) (£287,000) and outputs rigorously peer reviewed before publication in high quality journals. Survey findings [3.2] received attention from multiple media outlets; the European Society of Cardiology press release was accessible to 95,000 health professionals from 57

countries. Astin won an award from the journal that published the survey study [3.2] because it generated the highest Altmetric score of any published study in 2019.

4. Details of the impact

Every year, 3 million invasive CA angioplasty procedures are performed across the world. Our research has shown that a large proportion of patients consenting to CA do not understand important treatment details. Our research has 1. Transformed coronary angioplasty services and consent practice at NHS Trusts leading to patient benefit and financial saving, 2. Improved international coronary angioplasty consent processes, underpinned by health professional and patient education, and 3. Informed the update of the General Medical Council (GMC) guidance that sets professional practice standards for decision-making and consent in the UK.

Transformed coronary angioplasty services and consent practice at NHS Trusts, leading to patient benefit and financial saving

In 2014 a 'community of practice', comprised of specialist nurses and cardiology consultants, was convened at Mid Yorks NHS Trust as a result of the NIHR research being hosted there. Meetings with the group to discuss preliminary research findings led to increased knowledge about the 'ideal' CA consent process and a greater awareness of the patient perspective [5.1].

The 'community of practice' at Mid Yorks led to the redesign of the CA service in 2018 [5.1] to improve consenting practice and improve patient education and information provision. A new specialist nurse role was introduced for delegated consent-taking [5.1]. Patients benefitted because their appointment time was extended by 15 minutes, giving extra time for therapeutic patient education [5.1]. In tandem, the NHS Trusts "Angioplasty Patient Information Leaflet" was changed in response to the research [5.2a]. New content addressed common misunderstanding to better inform patients. The leaflet was posted out to patients earlier than before, to give more time for comprehension and deliberation [5.1]. Over 800 patients have used it to date [5.1]. Subsequently, feedback from a service evaluation, conducted in 2019, showed that patients were very satisfied with discussions about treatment options [5.3]. The Trust also benefitted from the service redesign because consultant time was released, giving an extra 190 outpatient appointments annually [5.1]. This increased efficiency led to an estimated cost-saving of £11k per year [5.1].

A national conference, convened by Astin and colleagues in 2016 [5.4a] was a driver for improvements in CA consent processes at Mid Yorks, and more widely. Research was shared with 70 delegates and workshops with cardiology health professionals and service-users led to the co-production of research-informed improvement plans. Evaluation feedback showed that health professionals' knowledge and awareness about the 'ideal' consent process improved. Almost all (96%) opted to change their consenting practice and the style of patient interactions [5.4b]. Eighty-five percent would use "Teaching techniques – being patient centred when giving information" and "Add consent information to the patient letters" to improve the quality of the CA consent process [5.4b].

A consultant cardiologist, who presented at the 2016 conference, described the impact at Mid Yorks. He explained that "An important change that occurred directly as a result from the research collaboration was a greater awareness about the consent process from the patient perspective. Understanding the patient perspective more clearly has led to improvements in the way consent takes place. We have made sure that we have better documented information that is comprehensible to patients and a process that ensures that the information is shared in advance of the procedure. We now look at the whole consent process to make sure each step follows recommendations. Over half of cardiology staff now use enhanced communication techniques such as 'teach-back' to check patient comprehension and recall as part of the informed consent process for elective coronary angioplasty" [5.1]. He concluded that improvements in the CA consent process had put his organisation "ahead of the curve" compared to cardiology departments in other international hospitals [5.1]. The improvement of CA consent processes at Mid Yorks impacted on services beyond the cardiology department. Consenting processes for other invasive procedures were also reviewed. Consequently, the generic "Consent to treatment" Patient Information Leaflet, which is sent to all patients scheduled for any planned procedures, was updated with new content in 2018 [5.2b]. The research showed that patients tended to play a passive role in the consent process, so new content focused on encouraging greater patient involvement in the consent process,

emphasising the concept of patient autonomy and the refusal of treatment as an option; 60,000 copies of the updated leaflet have been printed for distribution [5.1].

Astin expanded the 'community of practice' in 2020, to include cardiology health professionals from NHS Trusts in other regions. To maximise impact, a research-derived consent improvement toolkit (RdCIT) was developed by UoH [5.5]. It included an on-line training resource entitled 'Optimising consent in interventional cardiology' [5.5a], service evaluation questions, [5.5b] and a simplified Angioplasty Patient Information Leaflet (co-produced with service users, health professionals and designers) [5.5c]. To date, 6 NHS Trusts in England and Scotland, including Mid Yorks, have used the consent improvement toolkit [5.6].

Improved international coronary angioplasty consent processes underpinned by health professional and patient education

In 2020, the research findings led to improvements in the consent processes in the cardiology departments of 8 hospitals in Greece, Poland, Austria and the USA. This was achieved through the further expansion of the 'community of practice', by Astin, to a larger international 'Person Centred Care in Cardiology' (PCCC) network [5.7]. This increased the capacity of research-informed cardiology health professionals who worked as 'change agents' and catalysed improvements to the CA consent process using the RdCIT [5.5].

The network comprised international cardiology health professionals and opinion leaders and included: 1) Professor and Head of Faculty of Postgraduate Studies, Department of Public Health, Wroclaw Medical University, Poland; 2) Chair of Association of Cardiovascular Nurses and Allied Professions Education Committee and Specialist Cardiovascular Nurse in Salzburg, Austria; 3) Board Member of the Cardiovascular Section of the Hellenic Regulatory Body of Nurses and Member of the National Representative Team in the Presidency of the European Union and World Health Organisation meetings, Athens, Greece; 4) Nurse Scientist, Massachusetts General Hospital affiliated with Harvard Medical School [5.7].

The 'Optimising consent in interventional cardiology' training resource [5.5a], which was part of the improvement toolkit (RdCIT) [5.5], was accessed by 100 leading cardiology professionals, from 16 countries. Pre-and-post surveys following completion of the resource, showed an increase in users' knowledge levels, about the principles of valid consent and the value of shared decision-making [5.8]. Users' confidence to use advanced communication techniques in consent discussions also increased. Over 70% said they would identify potential improvements in the planned CA consent process through a departmental review [5.8]. Importantly 66% said they would start to ask patients about 'what matters to them about (their) treatment' [5.8]. It was evident that the routine elicitation of patients' preferences was not consistently addressed in CA discussions; a practice that marks a high-quality decision-making and consent process.

PCCC network members influenced the leadership of key professional organisations by sharing the research findings [5.7a, 5.7b]. This influenced topics for continuing education, training and conference syllabi in the UK and Poland with the addition of sessions on consenting processes, which previously received little attention [5.9a]. The British Cardiac Society circulated research findings to 600 cardiologists in a newsletter and invited Astin to present the research to 70 cardiology trainees as a national event [5.9b].

Research findings were used to improve health information provision for CA patients in 8 hospitals across 3 countries through discussions with leading cardiologists [5.7]. Cardiologists recognised the need to improve the consent process, based on the research, and agreed to implement the simplified Angioplasty Patient Information Leaflet, from the RdCIT resource [5.5]. To enable this, 'change agents' translated the resource into Polish, Greek and German [5.5]. For the first time, patients considering CA treatment had access to simplified written information that highlighted common patient misunderstandings about CA to better inform them.

Patient education was improved in the cardiology departments of 3 hospitals in Poland. The PCCC network member said "For the first time we have started to implement this tool into our hospital's procedure. Additionally, two other hospitals in Poland have declared their willingness to use this tool for their patients" [5.7a].

The PCCC member from Austria, said “For the first time patients scheduled for coronary angioplasty in Salzburg hospitals in Austria have access to written health information to help them to understand important details about their treatment and recovery” [5.7b]. Feedback from a patient treated with planned CA previously reported “He found the leaflet very helpful and wished he had had it at the time as it made everything that happened more understandable. The post-care information was very helpful, especially the section on medications as he did not like taking pills, but now knew why we emphasised to him the importance of taking his medication. He was impressed with the visuals and layout” [5.7b].

The PCCC member from Greece initiated improvements in two hospitals. She said “The research findings have led to changes in cardiology policy and clinical practice”. More specifically she explained “The Patient Information Leaflet about coronary angioplasty has been translated into Greek and we started using this in two hospitals as a pilot study of the translated version” [5.7c]. Leaders in the Greek Ministry of Health were made aware of the research. As a result they planned to standardise the consent documentation used in hospitals across Greece [5.7c]. The research was also discussed on a national radio program, broadcasted from Athens, which aimed to raise the public’s awareness of the consent process. The discussion was “fruitful” but demonstrated that “we still have way to go” to improve patient education [5.7c]. The research prompted health professionals to “Look at how we can improve cardiology care and provide health information to patients before CA so they have a better understanding of their health condition” [5.7c]. The PCCC member from the USA reported that the research “helped to focus on improving the quality of the informed consent process at Massachusetts General Hospital” [5.7d]. The survey study had been replicated by a cardiac specialist and presented locally and internationally. Several recommendations followed which included a review of current health information, the identification of standardised core educational content for CA patients and their families. Greater patient and family involvement in CA consenting were also recommended [5.7d].

Research-informed update of the General Medical Council (GMC) guidance that sets professional practice standards for decision-making and consent in the UK

Astin was invited to join the GMC Task and Finish group in 2016 and influenced the updated 2020 guidance through research and expert contribution [5.10a]. For the first time, the guidance stressed that patients needed support to better ‘understand their role in the consent process’ and should be made aware that ‘no action (i.e. no treatment)’ is an option open to them [5.10b]. The changes reflect findings from the research presented at the Effective Consent Practice Healthcare Conference UK in February 2016, chaired by the GMC policy lead [5.10c] and discussed at Task and Finish group meetings. Astin highlighted research findings that “shed light on both patients’ and health professionals’ attitudes and beliefs about informed consent, providing valuable information to inform the revision of current GMC guidance” [5.10d]. The updated guidance applies to all 335,873 doctors across the UK who conduct over 14 million surgical treatments annually.

5. Sources to corroborate the impact

- 5.1. Testimonial (Consultant Cardiologist Mid Yorks NHS Trust).
- 5.2. a-b Research Informed Patient Information Leaflets used at Mid Yorks NHS Trust.
- 5.3. Angioplasty Service Evaluation Report Mid Yorks NHS Trust.
- 5.4. a. Conference flyer, b. Conference evaluation 2016 UK conference event.
- 5.5. a-c Research-Derived Consent Improvement Kit (RdCIT)
- 5.6. Emails from NHS Trusts re: Adoption of RdCIT.
- 5.7. a-d Testimonials from the Person-Centred Consent in Cardiology network.
- 5.8. Pre and post training survey results to show improvements in consent knowledge.
- 5.9. a&b Evidence of influencing continuing education and conference programs
- 5.10. a-d Evidence re: Task and Finish group and General Medical Council guidance