

ORIGINAL PAPER

Impact of animation-supported consent on complaints and serious incidents due to failure to inform

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Summary

Background: Introduction of digital animations to explain medical procedures before consent to treatment (animation-supported consent) has been shown to improve patient-reported understanding of a procedure's benefits, risks and alternatives.

Aim: We examined whether introduction of animation-supported consent is associated with a change in the incidence of complaints and serious incidents due to failure to inform.

Methods: Multi-language animations explaining 10 cardiac procedures, in coronary intervention, electrophysiology and cardiac surgery, (www.explainmyprocedure.com) were introduced at a London cardiac centre from April 2019. Complaints and serious incidents due to failure to inform were identified from the hospital Datix database for the two years before introducing animation-supported consent (no animation group) and the two years afterwards (animation group), together with the total number of procedures and major complications recorded during these periods. We compared the incidence of complaints and serious incidents, expressed as a proportion of the number of major complications, recorded during each period.

Results: There were 580 complications among 21 855 procedures performed in the no animation group and 411 complications among 18 254 procedures in the animation group. There were 14 complaints or serious incidents due to failure to inform in the no animation group and 3 in the animation group; rates of 2.41% (14/580) and 0.73% (3/411), respectively ($P < 0.001$ for difference).

Conclusion: In this observational comparison, introduction of animation-supported consent was associated with a 70% reduction in complaints or serious incidents due to failure to inform before consent. This has significant quality and cost implications for improving consent pathways in clinical practice.

Introduction

Failure to inform patients before consent to medical treatment is regarded as a failure of clinical care and costs the NHS approximately £60 million each year in settled claims.^{1,2} These costs are rising steeply and do not include the costs of handling associated complaints and serious incidents which

may not lead to a claim but nonetheless consume substantial time and resources.

Use of digital animations explaining medical procedures, known as animation-supported consent, is a method of improving communication and reducing the likelihood of litigation in the event of a complication. This approach has been shown to substantially improve patient-reported understanding of a

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procedure, its benefits, risks and alternatives in both the elective and urgent care pathways.³⁻⁵

Whether or not improved understanding translates into reduced reports of failure to inform is unclear. This prompted us to examine the number of complaints and serious incidents for failure to inform before and after introducing animation-supported consent before cardiac procedures at a single large cardiac centre.

Methods

Animation-supported consent

Animation-supported consent has been described previously.^{3,4} In summary, animations, consisting of narrated hand-drawn films describing cardiac procedures (Explain my Procedure Ltd),

were introduced into the consent pathway from April 2019 at St Bartholomew's Hospital, London, as part of a quality improvement project seeking to improve patient understanding before consent to treatment. Figure 1a shows the consent pathway before (no animation group) and after (animation group) introduction of animation-supported consent for elective procedures. In the no animation group, patient information was left to the specialist team and generally involved an initial clinic consultation by a doctor, a pre-assessment consultation by a nurse and the signing of a consent form on the day of the procedure. In the animation group, the same standard care was provided but patients were also sent a link and QR code to access their procedure-specific animation following the initial clinic appointment. Patients chose from the five languages (English, Bengali, Turkish, Polish and Hindi) most commonly spoken at the hospital, and could view the animation as often

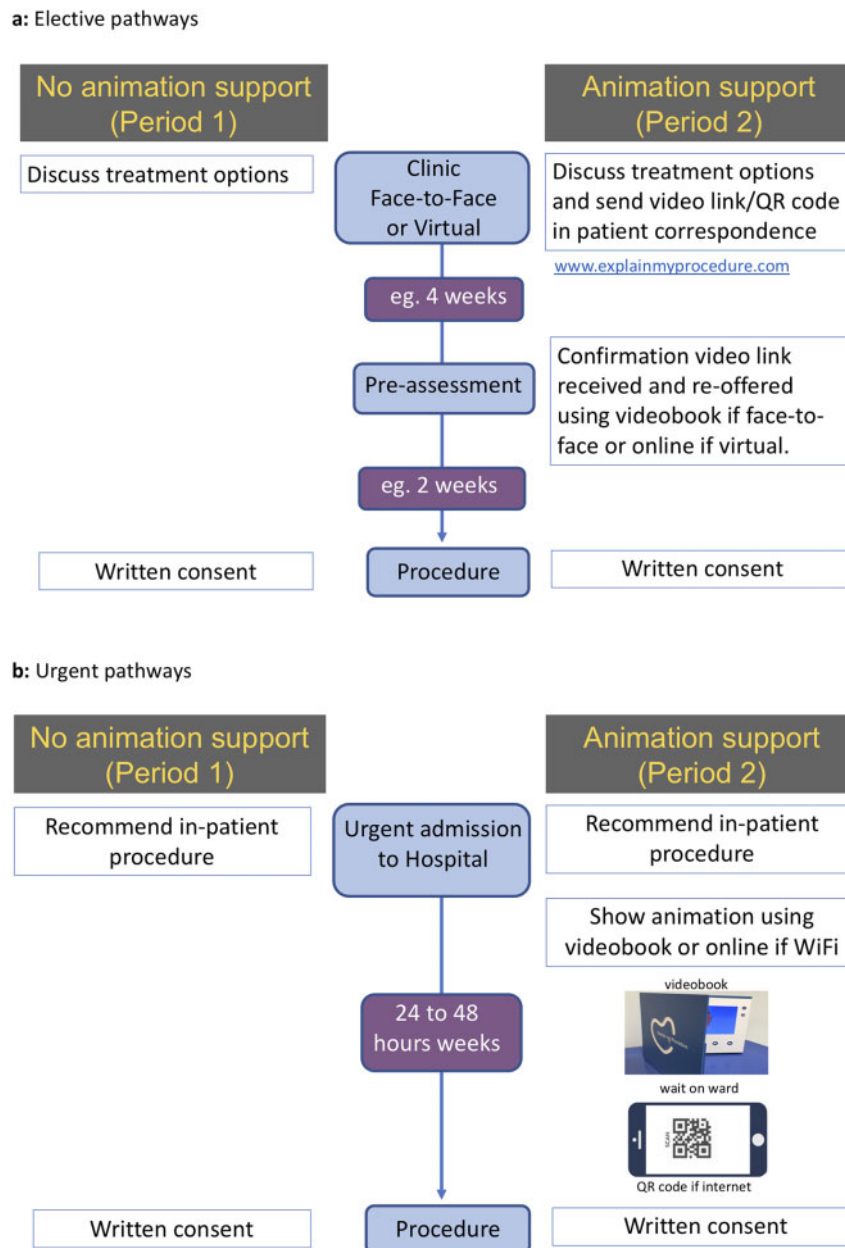


Figure 1. Consent pathways before and after introducing animation-supported consent. (a) Elective pathways; (b) Urgent pathways.

as needed and with family. At the pre-assessment consultation, the animation was re-offered either using an internet-free video-book if the meeting was face-to-face or online if by telephone. Watching the animation was encouraged but not compulsory. [Figure 1b](#) shows the respective consent pathways for urgent procedures, following an unplanned admission to hospital.

Audit

A retrospective audit was undertaken to evaluate the quality improvement project using data collected between 1 April 2017 and 31 March 2021, divided into two periods; Period 1 (1 April 2017 to 31 March 2019) before introducing animation-supported consent and Period 2 (1 April 2019 to 31 March 2021) after introducing the animations into the consent pathway. We considered 10 cardiac treatments for which animations were made available, in three therapeutic areas; coronary intervention (angiography and percutaneous coronary intervention), electrophysiology (permanent pacemaker, internal cardioverter-defibrillator, cardiac resynchronization therapy pacemaker, cardiac resynchronization therapy defibrillator and AF ablation) and cardiac surgery (coronary artery bypass surgery, aortic valve replacement and coronary artery bypass surgery plus aortic valve replacement as a combined procedure).

The hospital Datix database was searched using 'consent' as both a search category and a key word. Records were examined manually to identify complaints and serious incidents where failure to inform before consent was a reported concern. The flow diagrams for managing reports are shown in [Supplementary Appendix S1](#). Anonymized records were classified according to which of the key General Medical Council requirements⁶ were allegedly deficient from the consent discussion, namely the description of the procedure, its potential benefits, risks, alternative treatment options and whether material concerns were considered. Data were examined by two investigators independently and any disagreements resolved by discussion. We also reviewed the total number of procedures performed and the number of major complications recorded in the hospital audit databases for each of the 10 procedures over the project time frame. [Supplementary Appendix S2](#) gives the major complications recorded according to procedure.

The analysis was a comparison of the incidence of complaints and serious incidents in Period 1 (no animation group) with Period 2 (animation group), expressed as a proportion of the number of major complications recorded during each period. Proportions were compared using Fisher's exact test and differences judged significant at P values <0.05 . The project was part of a quality improvement project that did not require ethical approval and was registered with the Clinical Effectiveness Board at Barts Health NHS Trust.

Results

[Table 1](#) gives the number of procedures carried out in each time period, before and after introduction of the animations, together with the number of major complications recorded according to procedure. There were 21 855 procedures in Period 1 (580 complications) and 18 254 in Period 2 (411 complications); complication rates of 2.65% and 2.25%, respectively.

[Table 2](#) summarizes the complaints and serious incidents relating to failure to inform, classified according to whether disclosure of the procedure, its benefits, risks or alternatives were reportedly lacking before consent. There were 14 reports in Period 1, including 12 complaints and 2 serious incidents, and in Period 2 there were 3 complaints.

[Figure 2](#) shows the number of complaints and serious incidents expressed as a proportion of the total number of complications in each time period; 2.41% (14/580) vs. 0.73% (3/411); a statistically significant 70% reduction ($P < 0.001$ for the difference).

Discussion

The results of this analysis show a substantial reduction in complaints and serious incidents due to failure to inform before consent following the introduction of animation-supported consent into the patient pathway. Before animation-supported consent about 1 in 40 complications triggered a complaint or serious incident compared with about 1 in 140 following its introduction.

The animations were structured to provide details of the procedure, the potential benefits, risks and alternatives to the treatment offered and were designed to support understanding

Table 1. Number of procedures and complications in Period 1 (1 April 2017–31 March 2019) before introducing animation-supported consent and in Period 2 (1 April 2019–31 March 2021) after introducing animation-supported consent

Procedure	No animation group		Animation group	
	Period 1		Period 2	
	Number of procedures	Number of complications	Number of procedures	Number of complications
Angiogram	7192	104	5402	62
Percutaneous coronary intervention	6483	183	5735	154
Coronary artery bypass graft surgery	1833	74	1545	54
Aortic valve replacement	501	33	399	18
Coronary artery bypass graft + aortic valve replacement surgery	266	24	177	16
Permanent pacemaker implant	2257	67	1881	41
Internal cardioverter-defibrillator implant	986	23	593	7
Cardiac resynchronization therapy defibrillator implant	552	18	542	17
Cardiac resynchronization therapy pacemaker implant	253	14	352	12
AF ablation	1577	40	1198	30
Total	21 855	580	18 254	411

Table 2. Complaints and serious incidents in Period 1 (1 April 2017–31 March 2019) before introducing animation-supported consent and in Period 2 (1 April 2019–31 March 2021) after introducing animation-supported consent, classified according to whether disclosure of the procedure, its benefits, risks or alternatives were reportedly lacking before consent.

	Category	Reported failure to inform on:				
		Procedure	Benefits	Risks	Alternatives	Other
Period 1 procedures						
Percutaneous coronary intervention	Complaint	Yes	No	No	No	No
Coronary artery bypass graft	Complaint	Yes	Yes	Yes	No	No
Pacemaker	Complaint	Yes	No	No	No	No
AF ablation	Complaint	Yes	Yes	No	No	No
Aortic valve replacement	Complaint	Yes	No	Yes	No	No
Aortic valve replacement	Complaint	Yes	No	No	Yes	No
Angiogram	Complaint	No	No	No	No	Material concerns not considered
Percutaneous coronary intervention	Complaint	Yes	No	Yes	No	No
Aortic valve replacement	Serious Incident	No	Yes	Yes	yes	Material concerns not considered
Angiogram	Complaint	Yes	No	Yes	No	No
Percutaneous coronary intervention	Serious incident	No	No	Yes	Yes	No
Internal cardioverter defibrillator	Complaint	Yes	No	Yes	No	No
Coronary artery bypass graft + aortic valve replacement	Complaint	No	No	Yes	No	No
Pacemaker implant	Complaint	Yes	Yes	No	Yes	No
Period 2 procedures						
AF ablation	Complaint	Yes	No	Yes	No	No
AF ablation	Complaint	No	No	Yes	Yes	Change of plan on day of procedure
AF ablation	Complaint	Yes	No	Yes	No	No

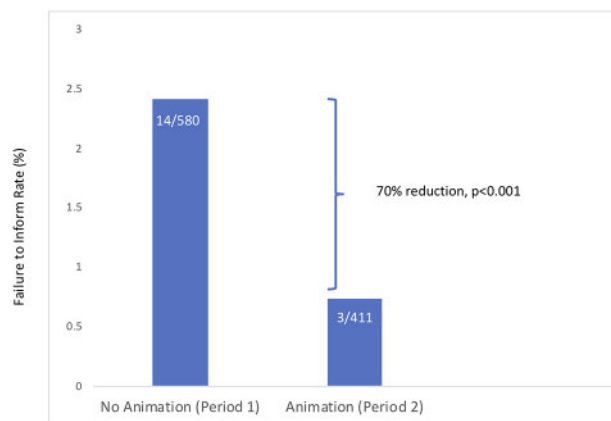


Figure 2. Failure to Inform rate (complaints and serious incidents/number of complications) before and after introduction of animation-supported consent.

rather than replace a doctor's duty to inform. The goal was to uniformly improve the quality of information and to free up staff time to focus on individual concerns. Multiple language options widened access and aimed to reduce health inequalities. By including a link (a URL and QR code) to the animation within usual patient correspondence, no significant additional administrative work was created. By providing the link immediately after the offer of treatment and again at pre-assessment, the time for reflection between referral and procedure was maximized—time which was previously largely wasted. These are factors that may have contributed to the observed differences.

A strength of digital animation over a paper leaflet is its low cost, scalability and simplicity in supporting virtual and

telephone clinics which became more common during the pandemic. The use of images over text has been shown to improve patient understanding and satisfaction.^{7–11} Video is becoming the natural and often expected medium for information. The animations were viewable on portable devices anywhere, and embedded in any patient pathway without the need for new software or hardware. Previously, studies have shown improvement in patient-reported understanding across different procedures following introduction of animation-supported consent^{3–5} and the present results extend this to reduced complaints and serious incidents in the event of complications.

The main aim of this project was quality improvement but cost implications are important. Based on the flow diagrams in [Supplementary Appendix S1](#), showing the steps involved in managing a complaint (7 steps and about 20 days) and a serious incident (11 steps and about 60 days), supported by examining our own reports, conservative estimates are £500–1000 and £3000–5000, respectively. This excludes costs to the patients and relatives. A 70% reduction in such costs when applied to most procedures undertaken in a hospital, rather than just the 10 considered here, and across most hospitals, would make significant savings. The costs do not necessarily end once a report has been closed. One of the serious incidents in our series for example, subsequently led to a coroner's inquest requiring additional time and resources. The steep rise in the number and cost of settled legal claims due to failure to inform before consent over the past 4 years is well documented.¹ This is likely to reflect the tip of an iceberg of costs currently met by NHS institutions themselves.

The comparison between the no animation and animation groups was not randomized and therefore prone to confounding by other activities that may have coincided to improve consent. Animation-supported consent was however the only

systematic intervention distinguishing the two time periods for the procedures considered. There were fewer procedures and complications in Period 2 because of the reduction in elective procedures due to the COVID-19 pandemic in 2020. However, by expressing the number of complaints and serious incidents as a proportion of the total number of complications, any bias due to comparing absolute numbers is minimized. We may have missed some complaints due to failure to inform before consent, because not all cases will have been correctly coded in the Datix database; however, use of a free-text word search for 'consent' and manual searching of every serious incident reduced the chance of omissions, which would apply equally to both time periods, so the proportional differences in reports is unlikely to be materially in error. Adherence to the improved consent pathway in Period 2 is unknown, so the impact observed may have potential for further improvement. The number of animation views in Period 2 (19851) exceeded the number of procedures (18254), so whilst we do not know which patients watched the animation and who declined, uptake was reasonably high overall. The results relate to a single large centre so may not be generalizable, but may prompt other centres to undertake similar quality improvement initiatives and their own evaluations.

In this observational comparison, improving the consent pathway using animation support was associated with a substantial reduction in complaints and serious incidents due to failure to inform. The approach is not limited to cardiac procedures and can be applied to any specialty and clinical pathway with the potential to improve patient understanding and reduce costs in the event of a complication, simultaneously.

Supplementary material

[Supplementary material](#) is available at QJMED online.

Conflict of interest

D.W. directs and owns Explain my Procedure Ltd and the educational videos used in this project and provided by Explain my Procedure Ltd (www.explainmyprocedure.com).

Acknowledgements

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