

## Patient Information and Timing Prior to Consent for Contact X-Ray Brachytherapy (Papillon): Are we Doing the Process Right?

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### Abstract

**Aims:** A survey was carried out to assess whether our policy for consent at Clatterbridge comply with Department of Health guidance and in particular whether the patients had sufficient information prior to contact X-ray brachytherapy (Papillon). We also evaluate whether patients needed more time before their consent.

**Materials and Methods:** During our study period from February to August 2017, 103 patients with rectal cancer were referred to Clatterbridge from colorectal units around the UK. Initial information on Papillon was provided by their local colorectal team. Coordinators from Clatterbridge then gave further information over the phone. Selection of patients suitable for Papillon was determined at weekly review meetings at Clatterbridge. Patient information leaflet was also posted together with their first Papillon clinic appointment.

**Results:** Eighty two out of 103 patients (80%) responded to our survey. The majority of patients found initial information from local colorectal team useful. Sixty nine patients (84%) found the phone discussion with our Papillon co-ordinator useful. Seventy eight (95%) found information from Papillon patients booklet useful. Thirty four patients (41%) found Clatterbridge patient information video on our website useful, but 41 (50%) had not seen the video. All patients who responded found information on Papillon and discussion of treatment options with the Clatterbridge consultant useful and seventy seven (94%) found it very useful. Sixty patients (73%) found the discussions with the patients support group buddy very useful. The results of our survey showed that patients had enough information and time before consenting for their Papillon treatment.

**Conclusion:** The majority of our patients felt that they had enough information and that they do not need additional time for consent before their treatment. We now continue with our current Papillon consent policy of seeing, consenting and treating patients on the day of their first appointment at Clatterbridge.

**Keywords:** Patient Information Survey; Informed Consent; Contact X-Ray Brachytherapy; Rectal Cancer

### Introduction

We have been offering contact X-ray brachytherapy (Papillon) at Clatterbridge Cancer Centre for the past 25 years. Patients are referred from a number of colorectal units around the UK for an opinion regarding their suitability of Papillon for their rectal cancer. Patients are first identify following discussions at the local colorectal multidisciplinary (MDT) meeting. The local coordinator initiate a referral after the MDT discussion. The patients are referred to our centre for consideration of Papillon either as their first treatment for early stage (cT1/cT2), small rectal tumour (maximum size less than 3 cm) or as a boost for small residual tumour (< 3 cm) following external beam

radiotherapy (EBRT) or chemoradiotherapy (EBCRT) mainly in patients who are not suitable for surgery [1]. Initial information regarding Papillon is usually given to patients by the referring local colorectal team. Upon receiving a referral letter from the local colorectal team, we discuss all cases at our weekly Papillon review meeting at Clatterbridge and select cases that are suitable for contact X-ray brachytherapy (CXB). One of our Papillon specialist co-ordinators then contact the patient by telephone to clarify any queries that the patient may have regarding information they already received from their local colorectal units. If necessary, one of our clinicians will also contact the patient directly by telephone.

We also send a Patient Information Booklet on Papillon by post to each patient together with their first clinic appointment letter [2]. At the first visit, one of our consultants, who specialises in Papillon at Clatterbridge, meets the patient together with their carers and discuss suitable treatment options. If the patient opts for Papillon, they are requested to sign a consent form before their treatment. We discuss all of the available information related to Papillon, including possible side effects, before they sign the consent. The Department of Health have issued a range of guidance documents on consent and on the basis of these, each trust should have a consent policy in place [3]. We would like to evaluate the governance of our current consent policy for Papillon at Clatterbridge which permit reviewing patients, signing consent and delivering treatment on their first clinic appointment, since 1993. In order to test this, we carried out a survey on our patients to assess their views on our current consent process at Clatterbridge. In this paper, we report the results of this survey and make recommendations for the future.

## Materials and Methods

During the study period, which took place between 14<sup>th</sup> February 2017 and 31<sup>st</sup> August 2017, a survey was carried out using a patient information and consent questionnaire (Figure 1) on their views regarding the flow of information that was given to them regarding Papillon before consenting for their treatment. During the study period, all patients (n = 103) attending Clatterbridge for Papillon were given a questionnaire. Patients were requested to complete the questionnaire on the day of their first visit to Clatterbridge. Any queries regarding the questionnaire were explained by our staff to help with their response. The patients were allowed to complete the questionnaire at their own pace in a quiet and private room if they wished, so as to avoid coercion.

The selection of patients for referral to Clatterbridge to be considered for CXB was initially made by the local colorectal multidisciplinary team (MDT) at their regular weekly MDT meeting. All treatment options, including local surgical excision, should be discussed at the local colorectal MDT meeting. Patients were then seen by a surgeon, or an oncologist, who discussed the treatment recommendation made by the local colorectal MDT. If the patients were not suitable for surgery or refused the recommendation made by the local MDT for any type of surgery (abdomino perineal excision of rectum (APER), Anterior Resection (AR) or Trans Endoscopic Micro Surgery (TEMS), then the decision for referral to Clatterbridge was initiated. The local colorectal team provide the initial information on Papillon. The local colorectal MDT co-ordinator complete a referral form which was sent to our Papillon coordinating team at Clatterbridge. Upon receiving the referral form at Clatterbridge, our Papillon specialist coordinator contacted the patients by telephone and explained the procedure and answer any queries regarding the information on Papillon they received from the local colorectal team. If the patients requested further clarification, then one of our consultants contacted the patients directly by telephone. The patients were then given an appointment for review at Clatterbridge Papillon clinic to assess their suitability for CXB. A Patient Information Booklet on Papillon was also posted to each patient, together with their first Clatterbridge clinic appointment letter [2].

The first clinic appointment usually took place in the morning and the patients were seen by one of our consultants specialising in Papillon. Possible treatment options were re-discussed with the patients and suitable treatment for the patients were reaffirmed. We did not treat all patients referred to Clatterbridge for Papillon. The details of selection criterion for Papillon is not within the scope of this manuscript and is reported elsewhere [1,4]. The patients suitable for Papillon were requested to sign a consent form if they wished to proceed with Papillon treatment. In addition, each patient was given a chance to meet the patient support group (PAPS) Macmillan buddy, who provided additional information and emotional support. The patients, and their carers, were then advised to go for their lunch.

After lunch, the patients were invited into a pre-treatment room for bowel preparation. This gave the patients further chance to discuss their treatment with another health care professional. After successful bowel evacuation, and when mentally and physically ready for their treatment, patients were invited into the treatment room. The patients were then given another chance to clarify the treatment with the consultant whom they had met in the morning at the Papillon clinic, before proceeding with their first treatment. Finally, consent was verified by an independent health care professional before the patients commenced with their treatment. The details of how the treatment was delivered have already been published and are beyond the scope of this manuscript [1,4].

We received approval from Clatterbridge Clinical Audit Subcommittee to carry out this audit (Reference Number: 1617-42) from February 2017.

**Data analysis**

Data acquired from the questionnaire was analysed by the Clinical Effective Team (CET) at Clatterbridge, using descriptive statistics.

**Results**

Out of the 103 patients who attended Clatterbridge for Papillon treatment during the study period of six months, 82 patients (80%) responded to our questionnaire (Figure 1). Sixty six patients out of 82 (80%) found the initial information regarding Papillon given by the local referring colorectal team useful (Table 1). Forty seven out of 82 (57%) found the initial information given by the local colorectal team very useful. Seventy eight (95%) found the telephone discussion with our Papillon co-ordinator useful and sixty nine (84%) patients found it very useful. Four (5%) did not receive the telephone call (Figure 2). Sixty nine (84%) found information from Papillon patients information booklet very useful (Table 2). Thirty four patients (41%) found Clatterbridge Cancer Centre patients’ information video on our website useful and six patients (7%) did not answer [2]. Forty one patients (50%) had not seen the video (Figure 3). All patients who responded found the information on Papillon from Clatterbridge consultant useful and seventy seven (94%) found the information very useful (Figure 4). The majority of patients (73%) found discussions with the PAPS support group buddy on site at their hospital first visit helpful. Six patients (7%) did not get the chance to meet their PAPS buddy on the day of their treatment (Figure 5). Seventy eight patients (95%) replied and stated that they did not think that they would benefit from returning back another day to sign their consent form for their first treatment (Figure 6). The same number of patients did not feel that having more time to think about their treatment would improve the services currently provided by Clatterbridge Cancer Centre (Figure 6).

Patients’ comments	n	%
Very useful	47	57
Quite useful	19	23
No opinion	6	7.2
Not answered	3	4
Not helpful	2	2.4
Poor	2	2.4
Not applicable	3	4
Total	82	100

**Table 1:** Patients’ response on initial information from the local colorectal team.

Response	n	%
Very useful	69	84
Quite useful	9	11
Not received phone call	4	5
Total	82	

Table 2: Patients’ response on information from the Clatterbridge Papillon patient information booklet.

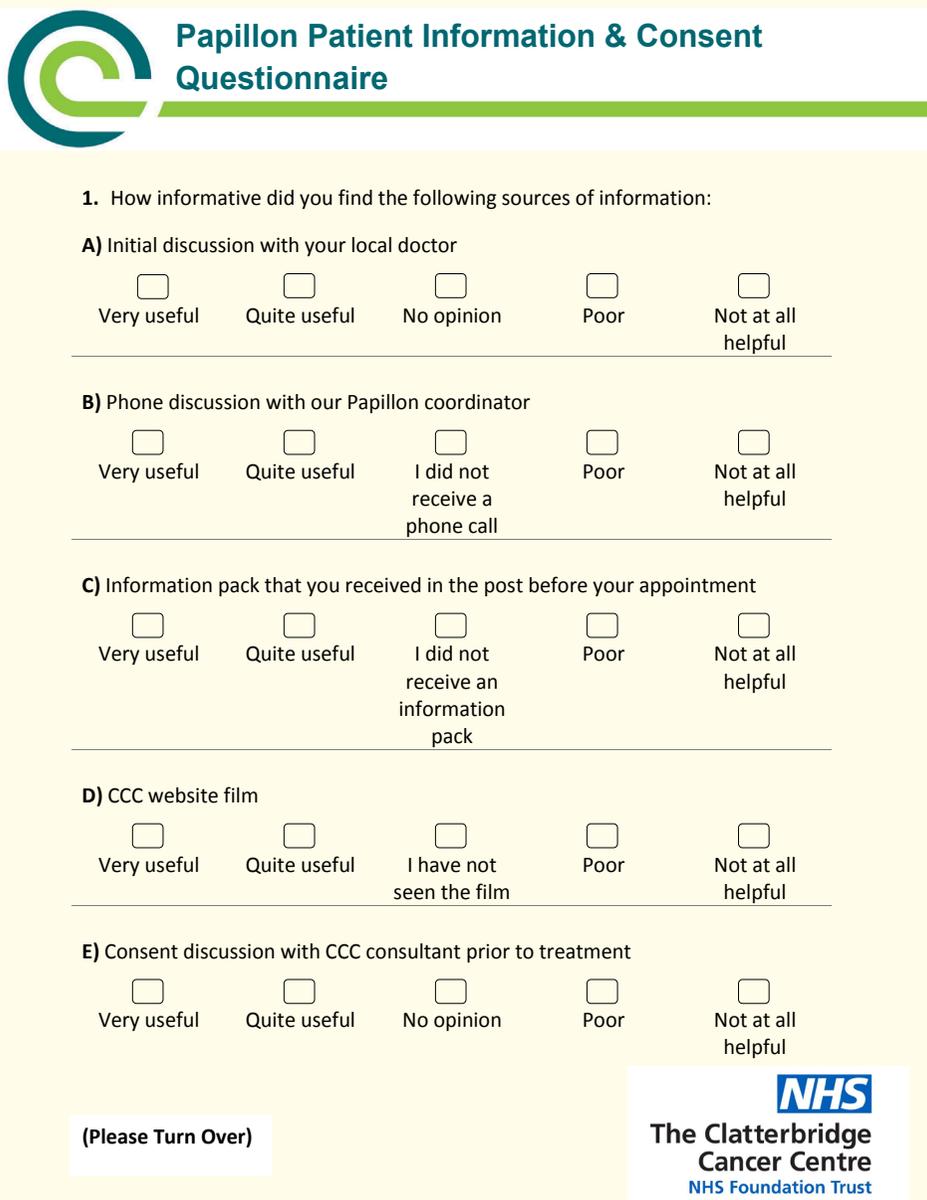
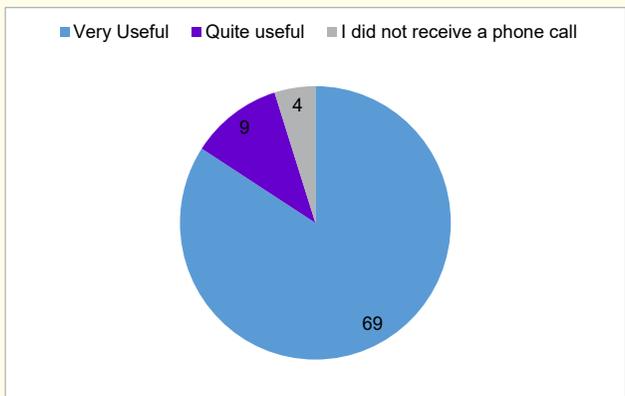


Figure 1: Papillon information and consent questionnaire.



Very Useful	69	84%
Quite Useful	9	11%
I Did Not Receive A Phone Call	4	5%
<b>Total</b>	<b>82</b>	<b>100%</b>

Figure 2: Patients' response on information from the Papillon coordinator over the phone.

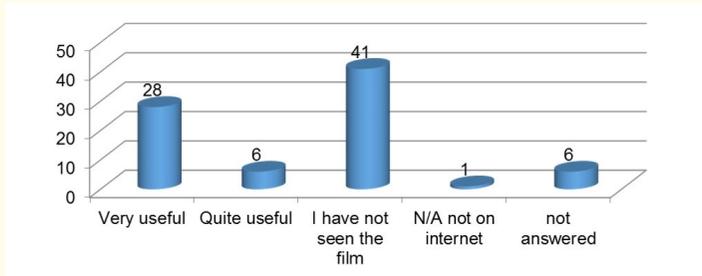


Figure 3: Patients' response on information from the Clatterbridge website video.

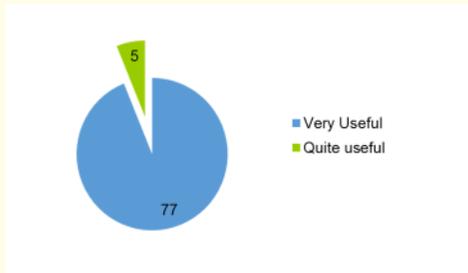


Figure 4: Patients' response on information from the Clatterbridge consultant discussions.

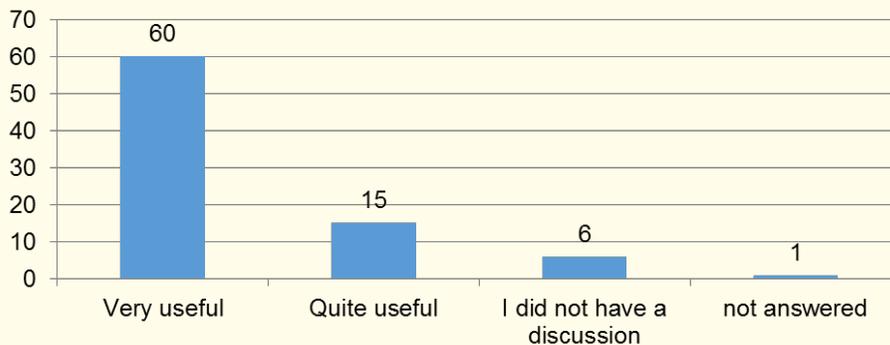


Figure 5: Patients' response on information from the Papillon patient support buddy.

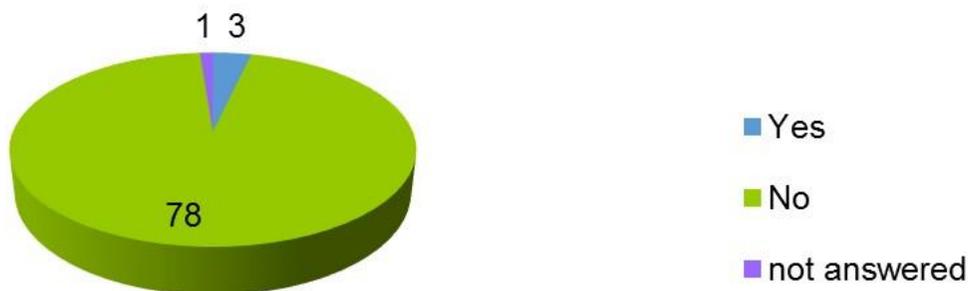


Figure 6: Patients' response on information received and time before consenting for Papillon treatment.

Patients comments	n	%
Very useful	69	84%
Quite useful	9	11%
Did not received booklet	3	3.7%
Did not answered	1	1.3
Total	82	100%

Table 3: Information from Papillon information booklet.

Response	n	%
Adequate information and time	78	95
Need more information and time	3	4
Not answered	1	1
Total	82	100

Table 4: Patients' response on information and time.

## Discussion

We evaluated our current consent policy for Papillon at Clatterbridge of reviewing patients, signing consent and delivering treatment on their first appointment comply with the Department of Health guidance documents on consent [3]. We carried out our patient information survey to test whether our patients for Papillon received enough information before consenting for their treatment and also whether they needed more time to consider before accepting their treatment. It was clear from our results that our patients did receive a lot of information from the initial referring colorectal units, which was supplemented by a telephone call from our special (Papillon) services coordinator. The majority of patients found the patient information booklet useful but almost half of our patients did not watch the patient information video as many of our patients do not have access to a home computer. Many of our older patients also found information technology (IT) quite challenging and did not wish to get involved. Therefore, we also provided our patients with a written patient information booklet prior to their first clinic appointment at Clatterbridge which 84% of our patients found very helpful.

One of the weaknesses of our survey was a small sample size. Another weakness was not including a clear information about a video on Papillon treatment in our previous version of the patient information leaflet. This could be one of the reasons why half of our patients did not watch the video on our Clatterbridge website. Therefore, we have now included a relevant information about the video in our new patient information booklet and also include this information during the telephone communication with the patients by our specialist service coordinator. We also encourage patients to get help from younger members of their family or friends to download relevant information from our Clatterbridge Cancer centre website and to watch the video, if they so wish. The patient information leaflet was last updated in March 2018 [2].

The treatment of rectal cancer is becoming more complex and we have received increase in referrals from colorectal units around the UK and some from outside the UK over the past 5 years. We request all information related to the patients including relevant histology, endoscopic findings with pictures when possible, operative notes and staging scans. We load the radiological images on to our PACS and review them with our specialist radiologist when necessary. We have regular weekly Papillon meetings to discuss patients refer for consideration of Papillon. At these meetings we discuss their treatment options that are suitable for the patients. Although we review most patients that are refer to Clatterbridge, we do not always see patients in clinic or treat patients with Papillon who are not suitable. When we see patients at their first Papillon clinic appointment, we take time to explain all the treatment options available for their rectal cancer. We show respect, share sympathy and compassion with the patients and their carers when discussing their management options. All patients found these discussions with our Clatterbridge consultant who specialised in Papillon useful and though difficult, we were able to persuade some of the patients to accept surgery when they are clearly not suitable for Papillon.

The demand for contact X-ray brachytherapy is growing. Firstly, due to increase in ageing population and many are not suitable or high risk for surgery due to their medical comorbidities. Secondly, due to increasing number of early rectal cancers been diagnosed through National Bowel Cancer Screening Programme (NBCSP) started 10 years ago. Finally, National Institute for Health and Care Excellence (NICE) has published their recommendations for CXB in patients with early rectal cancer who are not suitable for surgery [5]. Some are relatively young patients with early tumours although fit, refuse surgery as they are stoma averse. These are more complex and demanding cases for discussion at our weekly Papillon review meetings. We organise annual Papillon courses at Clatterbridge since 2010 to train other centres interested in starting Papillon facility. There are now 4 centres in the UK with Papillon facilities: Clatterbridge (started in 1993), Hull (started in 2011), Guildford (started in 2014) and Nottingham (started in 2014). We need more centres to cope with this increase demand and we are working closely with NHS England on a strategy to address the inequality of Papillon services across the UK.

We are fully satisfied that most, if not all, of our patients were fully informed before their consent for Papillon treatment (Figure 6). The majority of our patients did not wish to return on a different day for their first treatment. However, we did allow small number of patients (3%) to come back at a later date for their consent and treatment, if they did not wish to receive their Papillon treatment on their first visit. A copy of consent form for Papillon which the patients signed is given to the patients and their carers after the consultation for their information and record (Figure 7).

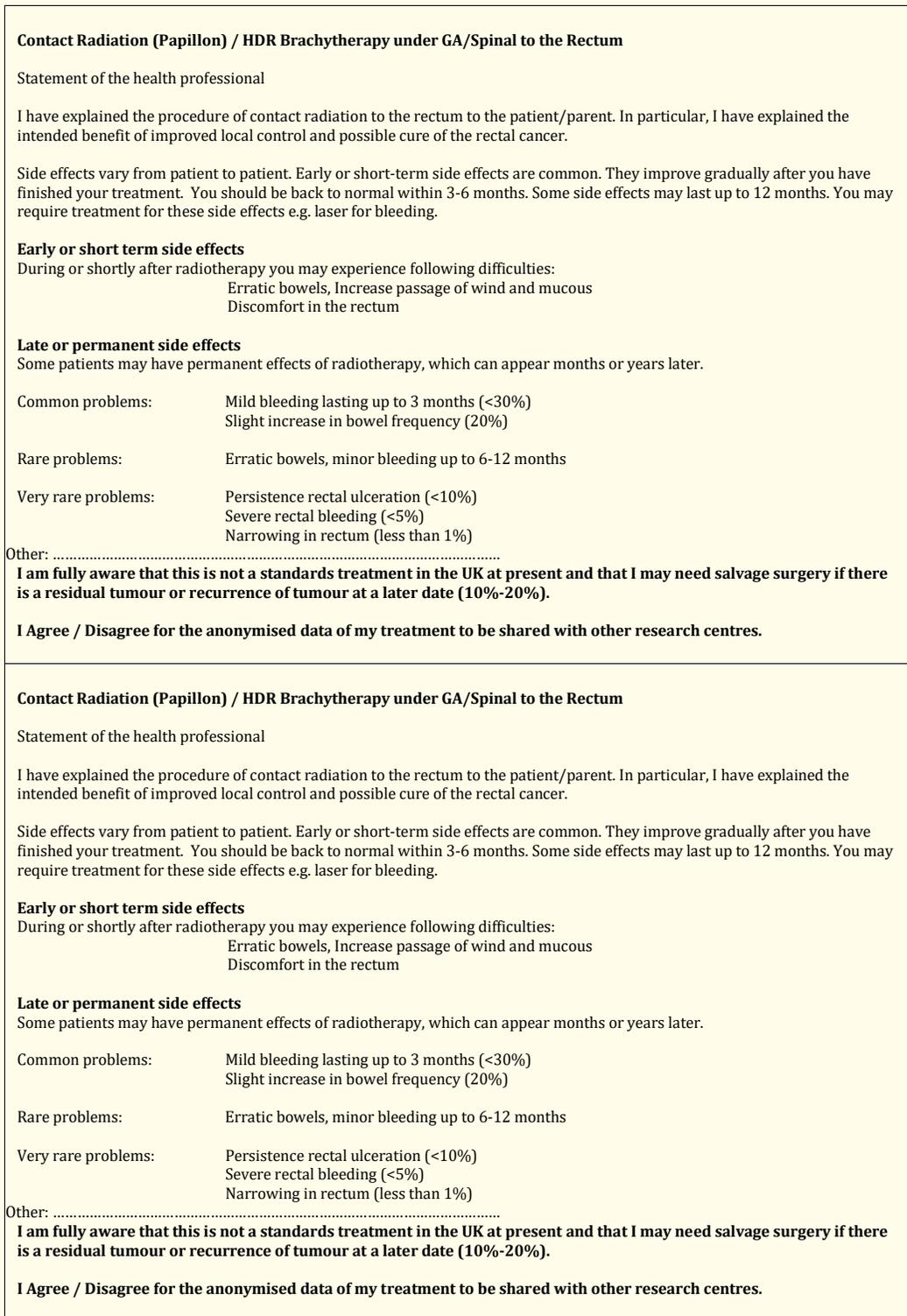


Figure 7: Papillon consent stickers.

## **Conclusion**

The results from our patient information and consent survey suggested that most of our patients were satisfied with the process that we used for consenting Papillon treatment at Clatterbridge. Moreover, the patients do not need further information or additional time for the consent prior to commencing their first treatment. The majority of patients wished to be treated on the same day of the first clinic appointment. As a result of our survey, we now continue with our current Clatterbridge Papillon consent policy to treat patients on the same day of their first attendance. In the future, we plan to carry out additional in depth patient satisfaction survey on their consent, treatment process and further research on patient-reported quality of life outcomes measures following their treatment using NICE recommended National Papillon data based at Guildford.

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