Readability and Content of Patient Information Leaflets for Endoscopic Procedures

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Abstract

Background

Informed consent requires good communication. Patient information leaflets (PILs) may be helpful, although some PILs are too hard to read for the average patient.

Aims

We sought to examine the readability of PILs provided for patients prior to endoscopic procedures in 24 gastrointestinal and 16 respiratory departments of 24 Irish public hospitals.

Methods

Readability, measured using the Flesch Reading Ease and the Flesch–Kincaid Grade Level scores, and content of all PILs were examined.

Results

We received 61 PILs from 17 gastrointestinal and 7 respiratory departments, a response rate of 60% (24/40). Overall, 38 (62%) PILs met a minimum standard of a Reading Ease score of 60 or more. Only two (3%) PILs met the optimal reading standard of being comprehensible to an average 10-11 year old, while 35 (57%) PILs would be comprehensible to an average 13-14 year. There were striking differences between PILs (and particular departments) in the amount of information given regarding potential complications - in particular serious complications. With the exception of PILs for endoscopic retrograde cholangiopancreatography, less than half of PILs mentioned death as a possible rare outcome.
Conclusions

This study raises significant concerns about the readability and content of current Irish PILs, and it is unlikely that these issues are restricted to leaflets given prior to endoscopy. A standardised approach to developing PILs for common elective procedures, with minimum standards for readability and a uniform approach, based on current Irish legal requirements, to risk disclosure, might be helpful.

Keywords

Informed consent
Patient information leaflets
Readability
Risk disclosure
Gastrointestinal endoscopy
Bronchoscopy
Introduction

It is an accepted legal, professional and ethical principle that doctors should obtain consent from patients before treatment, and this requires that patients receive sufficient information about the aims, risks and benefits of the proposed intervention and of any alternatives [1,2]. In general, there is a higher standard required for communication prior to elective procedures since the constraints that may exist in emergencies don’t apply. Also, given that many elective procedures are perceived to be safe, patients may not expect and may be more likely to resort to litigation if a complication does occur, even if there is no negligence by the operator [3].

Informed consent requires good communication. While discussion between the individual doctor and patient is always at the heart of consent, patient information leaflets (PILs) may be a helpful supplement by allowing patients to consider and digest information at their own pace. Use of PILs prior to gastrointestinal endoscopy has been found to improve patient satisfaction with the quality of information without any increase in patient anxiety [4].

It is essential that the relevant information is provided in a form that most people can understand. Literacy difficulties are common in the general population, and about one in four Irish adults have such problems [5]. Many studies have found that PILs used as part of informed consent are often too complex and hard to read for the average patient [6,7]. Another concern relates to the content of communication:
large variations have been reported in the amount of information – particularly about the risks of a procedure - provided in verbal and written form by different doctors [8,9]. In this study, we examined the readability and content of PILs provided to patients prior to gastrointestinal and respiratory endoscopic procedures in Irish public hospitals.

Methods

We wrote to the consultant/manager in charge of the endoscopy unit of 24 gastrointestinal (GI) and 16 respiratory units in 24 public hospitals explaining the purpose of the study and seeking copies of all patient information leaflets (PILs) related to consent for endoscopic procedures. If there was no response after 4 weeks, we phoned the relevant hospital and unit to determine the best person to contact; direct telephone contact was made with that person when possible; if not, a letter to repeat the request was sent to the identified person.

Readability statistics

All PILs were scanned, and the text was converted to Microsoft Word 2010 digital format using commercial optical character recognition software and was subsequently corrected manually. Readability - how easy a text is to read and comprehend - was measured using the Flesch Reading Ease and the Flesch–
Kincaid Grade Level scores. These can be calculated automatically from Microsoft Word.

The Flesch Reading Ease and the Flesch–Kincaid Grade Level scores were developed for assessing the difficulty of technical manuals, and both have been extensively validated as measures of readability [10]. Both are measured using word length as well as sentence length, although they have different formulas and weighting factors. The Flesch Reading Ease is scored from 0 to 100; the higher the score, the easier the material is to read and understand. Text with a readability score of 60-70 is considered well written and easy to follow by the average reader. For example, random articles from the Sun and Star daily tabloid newspapers in Britain all had Reading Ease scores of 65 or greater, while the average for articles from broadsheet papers was 42 [11]. The Flesch–Kincaid Grade Level score corresponds to the number of years of education usually required to understand the material. The average reading age in Western populations is the 8th Grade (13-14 years old) and patient information should be aimed at 6th Grade (10-11 years old) level [12]. The reason for this target is the high prevalence of literacy difficulties even in modern Western countries,

Content Information

We examined the content of each PIL under a number of headings, including preparation for and the purpose and nature of the procedure, precautions for day
cases (for example, need to avoid driving and to get an escort home), possible failure of the procedure to achieve its purpose and the complications mentioned. Data recorded on complications included the number of side effects mentioned and whether death was mentioned as a potential outcome. We also looked for any inconsistencies or disagreements between different forms.

Results

We received 61 PILs: 54 PILs (17 oesophago-gastro-duodenoscopy (OGD), 17 colonoscopy, 14 sigmoidoscopy and 6 endoscopic retrograde cholangiopancreatography (ERCP)) from 17 GI units and 7 bronchoscopy PILs from 7 respiratory units. The overall response rate was 60% (24/40).

Readability statistics

The mean (standard deviation, range) Flesch readability score for the 61 PILs was 61.2 (4.9, 46.2 – 73.2). Overall, 38 (62%) PILs met a minimum standard of a Reading Ease score of 60 or more. Results for the Flesch–Kincaid Grade Level were 7.9 (1.1, 5.9 – 9.2). Only two (3%) PILs were grade 6 or less, while 35 (57%) PILs were grade 8 or less. There were no significant differences between scores for GI and respiratory PILs or between the PILs for different GI procedures.
Readability statistics were very similar for PILs for different GI procedures from the same department, suggesting that the same author or authors were involved in producing all PILs. The four PILs with the best readability measures (Reading Ease scores 68.8 to 73.2 and Grade Levels of 5.9 to 6.5) all came from a single GI department, as did the three PILs with the worst measures (Reading Ease scores 46.2 to 54.1 and Grade Levels of 8.5 to 9.2). Overall, no department produced PILs that all met the recommended standard (Reading Ease scores of 60 or more and Grade Level of 6 or less); four GI and three respiratory departments produced PILs that all met a less stringent minimum standard (Reading Ease scores of 60 or more and Grade Level of 8 or less), while three GI and one respiratory department produced PILs that all failed to meet this minimum standard.

**Content**

Details of the content of the PILs are shown in the Table. As with readability statistics, the content and approach to information provision of different PILs from the same unit tended to be similar. Almost all PILs included information about how to prepare for the procedure, the nature of the procedure and the need for precautions post-sedation for day cases. There were some major differences between PILs in these areas with, for example, some emphasising (or providing a separate PIL) and others not mentioning the need for special care in diabetics or those taking warfarin. The purpose of, possible alternatives to, the possibility of failing to achieve the goal of procedures and, for day cases, what to do in the event of problems arising post-discharge were less commonly explained.
There were significant variations in the amount of detail provided about possible complications especially for OGD, colonoscopy and sigmoidoscopy (Table). Of 48 PILs related to these procedures, 12 (25%) noted no complications. Although all of the other 36 PILs noted the possibility of perforation or haemorrhage - and these were the only complications mentioned in 20 (42%) of PILs related to these procedures - there was great variation in the explanation of the implications of these complications. Some PILs simply noted that bleeding from the bowel could occur or that perforation was 'a hole in the bowel' others provided a more detailed explanation of the nature and consequences of these complications, including a possible need for surgical repair and a long stay in hospital. A small number of leaflets noted that cardio-respiratory problems or sepsis could occur following OGD, colonoscopy and sigmoidoscopy. In contrast, there was greater uniformity in the discussion of the potentially serious complications of ERCP or bronchoscopy. Death was explicitly reported as a possible outcome in all ERCP PILs but in half or less PILs for other procedures. The majority of PILs (48/61 (79%)) gave risk information in both numerical and descriptive terms, although risks described as ‘rare’ varied from 1/100 to 1/25,000 and as ‘very rare’ from 1/1000 to 1/25,000.
Table: Content of Patient Information Leaflets for different endoscopic procedures

<table>
<thead>
<tr>
<th></th>
<th>OGD (N=17)</th>
<th>Colonoscopy (N=17)</th>
<th>Sigmoidoscopy (N=14)</th>
<th>ERCP (N=6)</th>
<th>Bronchoscopy (N=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of procedure</td>
<td>9</td>
<td>9</td>
<td>7</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Details of procedure</td>
<td>16</td>
<td>16</td>
<td>13</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>How to prepare for the procedure</td>
<td>13</td>
<td>16</td>
<td>13</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Day case precautions</td>
<td>15</td>
<td>15</td>
<td>13</td>
<td>N/A</td>
<td>7</td>
</tr>
<tr>
<td>Alternatives to the procedure</td>
<td>8</td>
<td>9</td>
<td>9</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Possible failure to achieve goal</td>
<td>9</td>
<td>9</td>
<td>8</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Post discharge call doctor/return if….</td>
<td>6</td>
<td>6</td>
<td>5</td>
<td>N/A</td>
<td>2</td>
</tr>
</tbody>
</table>

Complications

<table>
<thead>
<tr>
<th></th>
<th>Any</th>
<th>Serious*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13</td>
<td>12</td>
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<tr>
<td></td>
<td>13</td>
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</tbody>
</table>

*Serious* complications refer to those that were either explicitly noted in the PIL to be serious or life-threatening or where the need for further interventions or prolonged care was reported.
Discussion

Our study shows that over a third of PILs in Irish endoscopy units did not meet a minimum standard for readability of a Flesch reading ease score of 60 or more. Even of those that did meet such standards, and hence were well-written and easy to read, few met the recommended reading level for medical information, namely that it should be comprehensible by an average 10 to 11 year old. These results are very similar to those reported from other studies of PILs for different procedures and treatments [6,11]. Poor literacy is most common among early school leavers, older adults, non-English speakers and unemployed people, and all of these groups seem likely to be over-represented among those presenting for endoscopy to the public hospitals studied in this report [5]. Hence, it is likely that current PILs fail to adequately inform a significant proportion of their target audience.

The most striking differences in content between PILs (and particular units) were in the amount of information regarding complications, in particular serious complications. With the exception of PILs for ERCP, less than half of PILs mentioned death as a possible rare outcome. It is understandable that clinicians might fear that undue emphasis on rare complications could lead to unnecessary anxiety and discourage patients from accepting procedures that seem to be in their best interests. In a randomised controlled trial comparing standard and detailed risk disclosure prior to bronchoscopy, we found a small but significant increase in peri-procedure anxiety in the latter group [13]. Others have noted a common but erroneous belief by many doctors that only risks occurring in 1% or more of cases
need be disclosed [14]. However, current Irish law regarding risk disclosure prior to elective treatment does not leave much room for latitude with Deirdre Madden noting that a material risk – which must be disclosed - is ‘any risk of grave consequences *no matter how remote*’ (our emphasis) [15].

Although a combination of oral and written information is probably the best approach to obtaining informed consent, analysis of PILs, as in the current study, can never give an adequate picture of the nature of communication between doctors and patients. A justifiable criticism of all standardised information sheets is that risk and benefits for individuals always depend on personal characteristics, and placing individual risks – especially remote risks - and benefits in context will be best achieved by discussion between the doctor and patients. Furthermore, verbal communication can and should be tailored to requirements and preferences of the patient.

Nevertheless, this study raises significant concerns about the readability and content of current Irish PILs, and it is unlikely that these issues are restricted to leaflets given prior to endoscopy. We suggest that a standardised approach to developing PILs for common elective procedures be considered. This would include defining minimum standards for readability and adopting a uniform approach, based on current Irish legal requirements, to risk disclosure.

**References**


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   [http://www.nala.ie/literacy](http://www.nala.ie/literacy)


