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1 Title  
2 Evaluating Canadian radiation therapists' and UK therapeutic radiographers' experiences  
3 and opinions of a safety strap to secure patients during radiotherapy

4 Keywords  
5 safety; fall; service evaluation; radiation therapy; evidence-based radiography  
6

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38 **Abstract**

39 Introduction: A serious patient safety incident at a cancer centre in Ontario, Canada saw a  
40 patient fall from an elevated treatment couch. A regional investigation recommended the  
41 use of a securing safety strap. The authors evaluate the value of the strap through the  
42 experiences of the radiation therapists' who use it. A secondary aim is to explore the  
43 potential for using a securing safety strap with UK therapeutic radiographers.

44  
45 Methods: A two stage design was guided by an evidence-based practice (EBP) framework.  
46 Stage one used a questionnaire to capture treating radiation therapists' experiences and  
47 opinions of the strap at a single cancer centre. Quantitative data was analysed descriptively  
48 and free-text data via a content analysis. Stage two used semi-structured interviews with  
49 thematic analysis to explore views of three UK therapeutic radiographers.

50  
51 Results: Twenty-five out of approximately 130 eligible staff responded to the Canadian  
52 questionnaire. Of the respondents, 24% (n=6) 'strongly disagreed', 28% (n=7) 'agreed' and  
53 48% (n=12) 'neither agreed nor disagreed' that they would recommend the strap to other  
54 departments. Most of the respondents think strap use should be at the staffs' discretion,  
55 with patients with dementia/cognitive impairment ranked as the group benefiting most.  
56 Ninety two percent (n=23) of respondents confirmed that patients sometimes refuse the  
57 strap. Themes arising from stage two interviews are: patient benefit (use for select patients  
58 only); patient safety versus control (restraint); practical implementation issues.

59  
60 Conclusion: The policy of universal use of the strap should be reviewed. Those who use it  
61 are equivocal about its value and feel it should be reserved for select patients at the treating  
62 professional's discretion. Full evaluation of the effectiveness and acceptability of the device  
63 for different patients may promote both staff enthusiasm towards the device and EBP.  
64 Adequate resources are required to evaluate implementation of such safety initiatives.

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77 Introduction

78 Immobilisation devices are designed to achieve a level of reproducibility in a patient's  
79 position throughout a course of radiotherapy. Physical comfort contributes to  
80 reproducibility, but patient comfort can also be considered as a broader construct  
81 encompassing psychological and environmental aspects:<sup>1,2</sup> for example, distress  
82 experienced by a significant minority of patients immobilised with a head shell.<sup>3</sup> The need  
83 for falls risk assessment has been widely considered in acute healthcare setting.<sup>4</sup> Straps,  
84 foam wedges and detachable couch cot-sides may be used selectively in the radiotherapy  
85 setting, to promote comfort and safety for patients at greater risk of falling from the  
86 treatment couch. Patients perceived to be at an increased risk of falling include the anxious,  
87 obese or cognitively impaired<sup>5-7</sup> or those with lateral target volumes. The use of cot-sides is  
88 limited by beam attenuation issues and gantry-couch conflicts for radical treatments.<sup>8</sup>

89 A regional cancer centre in Canada experienced a safety incident in 2012, when a patient  
90 sustained a serious injury in a fall from an elevated treatment couch.<sup>9</sup> The incident triggered  
91 a comprehensive investigatory root cause analysis. A resultant (2015) collaborative report  
92 by regional stakeholders includes a position statement that recommends the routine use of  
93 a patient securing strap device<sup>10</sup> – referred to here as the strap (Fig 1). The purpose of the  
94 strap is to prevent a patient from unintentionally rolling off the couch. A functional and legal  
95 distinction between the strap and a restraint is that the former allows self-release (by a  
96 velcro™ fastening).<sup>10,11</sup> The implementation strategy outlined in the 2015 report states that  
97 all patients undergoing external beam treatment or simulation (apart from with a fixed head  
98 shell) would benefit from use of the strap.



99  
100 **Figure 1** The patient securing safety strap

101 All 15 regional cancer centres in Ontario have implemented the strap within their treatment  
102 protocols, with early indications of a positive reception from staff and patients.<sup>9</sup> Despite the

103 importance of evidence protocols in radiography,<sup>12</sup> to our best knowledge, no evaluation of  
104 the perceived value and acceptability of the device has been published. The aim of this  
105 study is to evaluate radiation therapists' (RT) experiences of and opinions on the strap at a  
106 Canadian cancer centre. A second aim is to explore the perceived strengths and weaknesses  
107 of a securing strap device with United Kingdom (UK) therapeutic radiographers (TR) who do  
108 not use it and consider potential use in the UK.

109

## 110 **Methods**

111 Study approval was granted by Cardiff University School of Healthcare Sciences Ethics  
112 Committee (07/2018): UK NHS REC approval was not required. Site approval to access staff  
113 was gained at each site. A two-stage survey design was guided by an evidence-based  
114 practice (EBP) framework.<sup>12</sup> EBP provides a framework for quality health practices that  
115 integrate professional's clinical experience with patient preferences and the best available  
116 external evidence. Consideration of these three components guided the current study  
117 service quality improvement study.

118 *Stage one* was a questionnaire that captured RT opinions and experiences of using the strap  
119 at a large urban cancer centre in Ontario, Canada. Approximately 130 potential participants  
120 were identified as working RT at the centre in 2018. The sampling frame excluded RT not  
121 regularly working with patients at the time of recruitment but included pre-treatment staff  
122 that rotate through treatment units. The authors developed a questionnaire based on  
123 relevant literature and anecdotal reports from radiographers that have used securing  
124 devices. Questionnaire clarity, content validity and internal consistency was piloted with  
125 two RTs at the study site. Pilot data was not included in the main analysis as question  
126 phrasing was modified as a result of feedback. The final questionnaire, which was  
127 distributed and returned online [[www.smartsurvey.co.uk](http://www.smartsurvey.co.uk)], comprised 17 five-point Likert-  
128 like questions – knowledge of the strap origin; practical experience; patient selection;  
129 perceptions of utility and patient acceptability – with opportunities to provide free-text  
130 explanation for Likert responses. All eligible RT were emailed the survey. A participant  
131 information sheet outlined that responses were anonymous, that consent was assumed on  
132 voluntary survey return and participant's right to withdraw.

133 *Stage two* consisted of face-to-face interviews with three TR at a major UK cancer centre  
134 who have no experience of using a strap device. The rationale was to provide a more  
135 theoretical perspective on the value of safety restraint devices. Participants were selected  
136 from a convenience sample of willing participants based on them being experienced linac-  
137 based therapeutic radiographers that represented different bands of seniority/professional  
138 responsibility. The exploratory nature of the second study aim meant that sample size was  
139 not based on data saturation. Interviews were informed by stage one findings, but remained  
140 semi-structured within the bounds of an interview guide to avoid arbitrarily missing  
141 insightful perspectives.<sup>13</sup> Written consent was provided by participants prior to interviews,  
142 which were conducted in a quiet room at the study centre. Transcripts were returned to

143 participants to check for accuracy and intended meaning. Data was pseudo-anonymised,  
 144 and identifiable data was deleted on study completion.

145 *Data analysis*

146 The questionnaire data (addressing the primary aim) was analysed descriptively for close-  
 147 ended responses and via a simple content analysis for free-text.<sup>14</sup> Interview recordings were  
 148 transcribed verbatim. Data analysis followed Braun and Clarke (2006),<sup>15</sup> who outline a  
 149 method to identify and analyse data themes that is not tied to a specific theoretical  
 150 framework. Transcripts were independently reviewed by another member of the research  
 151 team. Final themes were grouped and agreed by discussion.

152 **Results**

153 *Stage one – Canadian experience of the strap*

154 Twenty-six questionnaires were returned, equating to a response rate of 21%. Four  
 155 respondents (16%) worked in pre-treatment and 20 (77%) on treatment units. Two  
 156 responses were from managerial staff, one of whom was deemed ineligible and excluded  
 157 from analysis. Six of the remaining 25 participants had worked at the centre for 1–5 years  
 158 and the remainder for 6–25 years.

159 **Staff opinions of the strap**

160 Radiation therapist’s (RT) opinions about the acceptability of the strap are summarised in  
 161 Table 1.

Statement	strongly agree	agree	neither agree/disagree	disagree	strongly disagree
I would recommend other departments use the SS	0	7 (28)	12 (48)	6 (24)	0
I would rather leave the SS out of the set up	6 (24)	6 (24)	9 (36)	4 (16)	0
I would feel comfortable treating a routine patient without the SS	11 (44)	11 (44)	3 (12)	0	0
The SS should be used for all patients	0	4 (16)	11 (44)	9 (36)	1 (4)
The SS adds time to the patient set up	1(4)	3(12)	5(20)	15(60)	1(4)
I would prefer to use other securing devices (eg. metal cot rails)	1 (4)	2 (8)	9 (36)	13 (52)	0

162 **Table 1** Radiation technologist’s opinions about the securing strap (SS) [data are n (%)]

163 Only seven (28%) of the participants would recommend that other departments use the  
 164 strap: twelve (48%) were neutral on this. No participant was uncomfortable at the prospect  
 165 of treating a routine patient without the strap. Free text comments reflected and qualified  
 166 the apparent mixed opinions:

167 *‘Untested security measure that may or may not prevent a patient falling off the bed.’*

168 *‘I think it was initially implemented to prevent falls but I don't think the amount of*  
 169 *falls has been reduced in our department since introducing the strap.’*

170 *'we were fine without it for many years, but I don't mind putting it on the patients.'*

171 *'annoying, unsanitary'*

172 *'useful as tool to remind patients not to get up.'*

173 *'... uncooperative and unstable patient would benefit from using strap.'*

174 *'I don't think the strap actually provides adequate safety in our department. It is*  
175 *usually loosely placed over a pt's clothing and provides the pt with a false sense of*  
176 *security.'*

177 *Who gets the strap in their treatment set up?*

178 Eleven (44%) of the participants (correctly) believed that use of the strap was mandated by  
179 treatment protocols; nine (36%) disagreed with this statement and five (20%) were unsure.  
180 Twelve (48%) and nine (30%) agreed and disagreed respectively with the statement that use  
181 of the strap is ultimately at RT discretion, with four respondents being unsure. Multiple free-  
182 text comments clarified that:

183 *'A strap is used for ALL patients per protocol unless the patient refuses ...'*

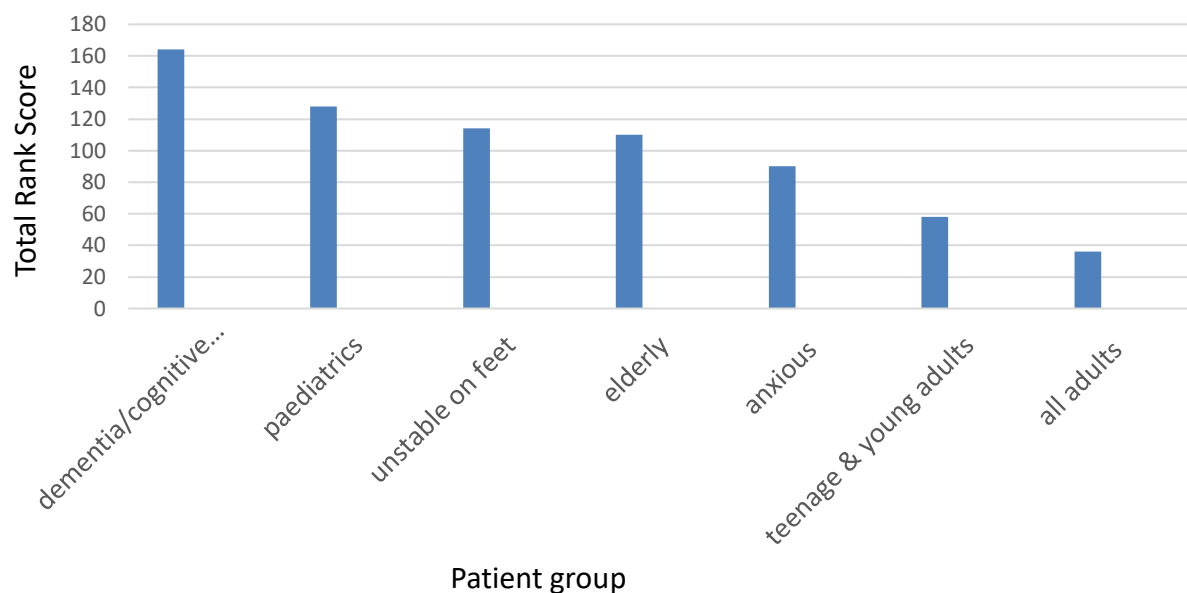
184 Many participants used different words to indicate they felt that the RT should be the  
185 decision maker regarding use, and/or many patient groups could be excluded from its use:

186 *'I feel like it should be up to the radiation therapist discretion.'*

187 *'Useful for certain patient population - not necessary to use it for everyone.'*

188 Participants ranked patient groups according to which would benefit most from the strap.  
189 The scores presented in Figure 2 represent a weighted sum of all rank counts with items  
190 ranked first given a higher 'weight.' The patient group for whom the strap was seen as most  
191 useful was 'patients with dementia or cognitive impairment' with a cumulative score of 164  
192 and the lowest score was 36 for 'all adult patients'.

193



194  
 195 **Figure 2** Patient groups ranked by perceived utility of the securing strap [Total Rank Score is a  
 196 weighted calculation. The score is a sum of all weighted rank counts - items ranked first are valued  
 197 higher than the following ranks]

198 **Staff experiences of the strap**

199 Experiences of the practical implementation of the strap are summarised in Table 2. A range  
 200 of conflicting experiences were evident, except for unanimous agreement that a dose  
 201 correction factor is not applied (or needed) to account for beam attenuation.

Question	yes	unsure	no
Are patients aware the SS will be used at their CT planning scan?	9 (36)	10 (40)	6(24)
Is the SS ever positioned within the treatment field?	10 (40)	1(4)	14(56)
Is an attenuation factor applied at planning to account for the SS?	0	0	25 (100)
Are patients aware the SS will be used for their treatment?	10(40)	8(32)	7(28)
Is the SS cleaned after each patient?	7 (28)	4 (16)	14 (56)

202 **Table 2** Treating radiation technologist’s experience of using the securing strap (SS) [data are  
 203 n (%)]

204 Multiple free text responses indicated that the device should be disinfected after each  
 205 fraction, but that this does not always happen:

206 *‘Not all therapists clean the strap after every patient, but I do’*

207 *‘Not placed in contact with skin. Drape sheet barrier used.’*

208 **Perceived acceptability of the strap for patients**

209 Staff perceptions of the acceptability of the strap for patients was gauged by asking if, in RT  
 210 experience, patients ever refuse/decline the device. Twenty-three (92%) responded ‘yes’,  
 211 with two reasons provided being ‘some [patients] think it's unnecessary’ and  
 212 ‘claustrophobia’. Six (24%) of respondents felt patients were less anxious about falling when



213 the strap was used, whilst 14 (56%) were neutral about this. Only four respondents agreed  
214 with the statement that patients ‘never comment on the strap’ with another stating that  
215 *‘patients do comment on it. Some do not like it.’*

216 *Stage two – UK perceptions of the strap as a securing device*

217 ? The three TR interviewed were labelled as P1-P3 to protect anonymity: P3 was band 5  
218 (registered graduate level), P2 band 6 (senior), and P1 band 7 (advanced/team leader).  
219 Findings were summarised in three themes.

220 Variable patient benefit

221 All participants felt securing devices were not suitable for every patient as *‘the majority of*  
222 *our patients can follow instruction’* (P1). Use *‘on an individual basis’* (P2) was preferred,  
223 with patient groups considered to be at a higher risk of falls, and therefore potentially  
224 benefiting from the strap, described as *‘bariatric, ‘dementia’, ‘palliative’* and *‘on a lot of*  
225 *pain meds’*.

226 Safety versus control

227 All participants confirmed they had used or seen methods to secure patients. A distinction  
228 was drawn between a device that prevents a fall from the couch (cot sides) and one that  
229 limits movement/restrains (micropore tape). Reservations were expressed about the  
230 purpose of the strap:

231 *‘might feel a little claustrophobic, in terms of a lack of control. If you liken it to the*  
232 *head and mask [sic] in that you’re removing that element of control.’* (P1)

233 *‘no point in tethering someone to the bed if they’re absolutely fine. Maybe for*  
234 *dementia patients or palliative patients that are wriggling. But if they’re wriggling*  
235 *that much should you be treating them?’* (P2)

236 It was suggested that the strap could be used in conjunction with existing immobilisation *‘...*  
237 *things like the wingboard, you get like some people who can’t really hold it so you could get*  
238 *something to just support their hand’* (P2), provided placement did not limit patient control:

239 *‘how would a patient tell you if something is wrong if their arms are tied.’* (P3)

240 Implementation

241 Perceived practical implementation issues were *‘infection control’, ‘cost’* [if disposable],  
242 *‘dosimetry’* and *‘time’* [for training]. The device must be *‘wipeable’* and beam attenuation  
243 would be easily avoidable if *‘used outside the treatment area’* (P1). More substantive, was  
244 the wider set of resources required to adequately evaluate a new device:

245 *‘...how long have you got to trial for? That was an issue for the other one [a sling device], we*  
246 *only had it for 20 days. By the time we found somebody to treat after it had been through*

247 *infection control, we then only had 5 days left. ...Whether you have got to hand it over to*  
248 *physics, if they've got to do another assessment of the device?*

## 249 Discussion

### 250 *Ambivalence after experience*

251 Ambivalence about the strap was evident with only 28% of the professionals that use the  
252 device daily saying they would positively recommend adoption by other departments.  
253 Almost half held a neutral professional opinion on this, with free-text comments reinforcing  
254 a sense of equivocation. Just 16% of respondents would personally prefer to include the  
255 strap in treatment set ups. RT acceptance of the strap in the current study does not appear  
256 to be as enthusiastic as suggested by a brief report from 2015.<sup>9</sup> Most of the respondents  
257 had worked at the centre in the 'pre-strap era', when a device had occasionally been used  
258 to help select patients keep still or to provide support. Successive use of the strap does not  
259 seem to have led to the intended staff acceptance of the device.<sup>10</sup>

260 The free-text comment that the device remains 'untested' and therefore 'may or may not'  
261 prevent a fall is insightful. The strap implementation strategy developed by Cancer Care  
262 Ontario had identified the importance of staff training, patient education and device  
263 monitoring.<sup>10</sup> Implementation science suggests that inadequate evaluation of a new  
264 device/procedure can create a feedback void to be filled with subjective or historical  
265 opinion.<sup>16,17</sup> This situation may underlie or contribute to the equivocal views in our study.  
266 Objective evidence about the value of service innovations serves to counter this and is a  
267 requisite for evidence-based radiography.<sup>12,18</sup> A second issue is that safety in this context is  
268 the absence of harm or a non-event.<sup>19</sup> A number of respondents were skeptical of the value  
269 of the strap as there had not been patient falls at the department before or after the strap  
270 was mandated.

### 271 *Perception of purpose(s)*

272 An influential opinion about the value of the strap was that it was not sufficiently strong to  
273 prevent a patient fall: the intended function of the device. The concern, as expressed by one  
274 RT, was that it provides a 'false sense of security.' A 2016 report of a serious patient fall in  
275 neighbouring Manitoba<sup>20</sup> confirmed that the original 2012 Ontario incident is not an  
276 isolated event. It also identified an inadequacy in their strap device and implied  
277 complacency around its use. These events raise questions as to the intended versus  
278 perceived purpose(s) of the strap. Perception of purpose is important here as a modifier of  
279 staff and patient behaviour.<sup>21</sup> The 2015 Ontario implementation report alludes to multiple  
280 rationale for the strap – as immobilisation, to prevent sitting up prematurely, a reminder to  
281 stay still – all of which were raised in our data. Whether the strap can or cannot de facto  
282 prevent a patient fall or instead has value as a safety reminder requires clarification. More  
283 than one participant perceived the device to primarily be a medico-legal protection against  
284 staff litigation. Safety risks can never be eliminated, but clarity surrounding the explicit  
285 rationale and capabilities of the strap – whether as physical safety, psychological comfort or  
286 as a reminder – is important in a scenario where the '*frequency of occurrence* [of the fall

287 event] *is low*, [but the] *the severity can be high*'.<sup>10</sup> Most of the participants had worked in  
288 the pre-strap era and so were aware that the strap policy had originated from an incident at  
289 another institution. The views of newer members of staff are less well represented in our  
290 data. An important generic point is that training continues to reinforce the rationale for  
291 therapeutic practices, or conversely that service evaluation removes obsolete practices.<sup>18,22</sup>

### 292 *Not for all*

293 A common thread running through all quantitative and qualitative data was that the strap  
294 should not be used for all patients. This was despite uncertainty regarding the actual  
295 protocol prescription of use for all (except where a head shell fulfils this function or patients  
296 refuse.) The clear position from the participants was that use of the strap should be at  
297 professional discretion. Standardisation is a strong feature of radiotherapy,<sup>23</sup> however  
298 universal application of the strap has created tension with the application of EBP through  
299 decision-making informed by professional experience. The two patient groups perceived to  
300 derive most benefit from the strap were those with dementia/cognitive impairment  
301 followed by paediatric patients. A pragmatic approach suggested by the data might be to  
302 default to strap use for these groups, but use according to treating TR discretion for other  
303 patients. However, the use of restraint can be notably distressing for people with  
304 dementia.<sup>24</sup>

### 305 *Patients as the third component of evidence-based radiography*

306 This study's data is clear that patients can and do occasionally refuse the strap, as  
307 anticipated by the original implementation guidance.<sup>10</sup> This choice is recorded in patient  
308 records and acted upon each day unless the patient changes their mind. Some respondents  
309 attributed enhanced patient relaxation and reassurance to the strap. Against this was the  
310 concern that ambulatory, able people were being secured with little benefit for the patient,  
311 thus threatening the autonomy that is vital for cognitive and physical health.<sup>5</sup> A balanced  
312 evaluation of the strap would appreciate how alien the treatment environment can be to  
313 the uninitiated patient.<sup>2,25</sup> One person may welcome the strap when elevated in a darkened  
314 room with few familiar landmarks: for another it may heighten the darkness of their  
315 predicament. Actively listening to both these patients and incorporating their perspectives  
316 into our care is key to EBP. This study's data clarified that patients were informed verbally  
317 about the strap and this often happened just before the first fraction. Including this  
318 information in written materials delivered at an early point in the treatment pathway would  
319 enable adequate consent for the strap and promote patient autonomy.<sup>26</sup>

### 320 *UK opinions on potential use of the strap*

321 Views of therapeutic radiographers about practical implementation of the strap in the UK  
322 were very similar to those based on Canadian experience. Infection control was the practical  
323 implementation issue raised by all participants. The interviews added a distinct, broader  
324 theoretical perspective on securing devices. Participants were unanimous that the decision  
325 for their use should be at the individual patient level. The point at which increasing levels of

326 restraint become an indicator of a patient who is inherently unsafe/unready to treat was an  
327 intriguing point of discussion. It was proposed that the move to universal strap use could be  
328 viewed as a failure of radiographers to conduct an adequate risk assessment. Overall, the  
329 potential for using this particular device in the UK was viewed as limited. The importance of  
330 the broader patient safety debate was however noted given that falls are excluded from  
331 radiotherapy error coding in the UK,<sup>27</sup> despite anecdotal reports that this has happened.  
332 Evaluating patient safety incidents and service responses is vital for service quality  
333 improvement.

#### 334 *Limitations*

335 As a single centre evaluation, we cannot assess how generalisable our data is to other  
336 centres: a survey of all regional centres is indicated. The 21% response rate and small  
337 sample size suggest the representativeness of our data should be treated with caution. Our  
338 sample does encompass a range of staff experience and seniority including managerial level  
339 but is skewed towards more experienced staff.,so We have relied on staff perception of  
340 patient acceptability as our ethical approval did not extend to patient participation. The  
341 interview sample was very small and participants were partly chosen based on a subjective  
342 judgement of their reflexivity, but this was considered acceptable to address the exploratory  
343 aims.

#### 344 **Conclusion**

345 Despite straps being used for years in some radiotherapy departments, this study is the first  
346 reported evaluation of the value of the safety strap based upon the views of those who use  
347 it. Benefits of the strap were identified for select patients, but our data suggest its use is not  
348 supported for most and its purpose is not sufficiently clear. We recommend that the policy  
349 of universal use is reviewed. A comprehensive service evaluation with a service quality  
350 improvement purpose would take account of the best available research evidence, staff  
351 experience and patient views. The direct patient voice is needed, which can often surprise.  
352 Routinely recording patient incident data is crucial to evaluate safety developments;  
353 especially in a context where safety is a dynamic non-event and the incidence of fall events  
354 is extremely low. Implementation of devices such as the strap are most likely to be accepted  
355 and accrue patient benefit when based on principles of EBP. This requires adequate  
356 resources to integrate data of effectiveness with the tacit knowledge of professionals and  
357 particularly patients.

358

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369 approved the study.

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