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Title

The current role, and perceived benefits and barriers of secondary care pharmacists facilitating patient participation in Clinical Trials of Investigational Medicinal Products (CTIMPs) conducted within the NHS: A cross-sectional survey.

Running title

Pharmacists facilitating CTIMP participation

Keywords

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Abstract

Rationale, aims and objectives: Secondary care pharmacists are well positioned within the healthcare system to communicate with patients, and provide guidance and advice regarding drug treatments. They are able to broaden the opportunities to raise the profile of CTIMPs, and positively influence research. This research aimed to investigate the perceived benefits and barriers of secondary care pharmacists being involved in Clinical Trials of Investigational Medicinal Products (CTIMPs), their current role, and the perceived benefits and barriers of developing their role in facilitating patient participation for CTIMPs (e.g. by identifying or recruiting potential participants).

Methods: A cross-sectional quantitative online survey circulated to pharmacy professionals within the UK.

Results: Involvement in CTIMPs and the facilitation of patient participation offered several benefits including improved communication and relationships with other healthcare professionals, developing the profession, developing training and knowledge, and exploring a personal interest. The main barriers to involvement included a lack of opportunities or awareness of opportunities, time, and funding or resources. Those employed at sites with a larger number of CTIMPs agreed more with the disadvantages, however they also showed greater agreeance towards the benefits of pharmacy being involved in facilitating patient participation.

Conclusions: Most respondents do not currently have a role in identifying or recruiting potential participants. Despite this, being involved in CTIMPs and the facilitation of patient participation was suggested to offer several benefits. Given many participants agreed there are barriers to their involvement, future research should focus on exploring organisational and individual challenges with the aim of enabling pharmacists to support recruitment activities.

Introduction

At a time when the NHS is experiencing an increased demand on resources, it is essential that all possible avenues for support are explored. Research has the potential to improve patient care [1] and as the quantity of research studies such as clinical trials increases internationally [2], those involved in the delivery of care may become more involved in research.

Secondary care pharmacists are employed within a hospital setting and form a pivotal part of a multidisciplinary patient care team; they tend to visit wards daily to fulfil their responsibilities [3] and therefore are likely to see their patients at various times during their time in hospital. Involving patients in decisions regarding their care is considered desirable [4], and this frequent contact may result in pharmacists establishing a relationship with their patients. Research has shown that patients who talked to their pharmacist at least a few times a year were 96% more likely to be interested in receiving information about clinical trials than those who do not [5].

Many factors must be considered for a clinical trial to be successful. Particularly, a study must select and enrol suitable participants through the process of recruitment to be representative of the population that may benefit from the treatment [6]. Medical practitioners tend to have the most active role in recruitment currently; however other healthcare professionals are involved in the process. Donovan et al. (2003) discovered that nurses were as effective at recruiting men with localised prostate cancer to a randomised trial, and more cost-effective than surgeons. The nurses were able to spend more time with their patients, and were less expensive [7]. The involvement of allied health professionals is highlighted by Gul and Ali (2010) who discuss the

important link a nurse can provide between a study Principal Investigator and patient, and cite research by McKinney and Vermeulen (2000) who state nurses in their study improved recruitment and retention [6]. Similarly, the role of pharmacists has developed internationally to include involvement in informed consent, screening and recruiting patients [8]. This highlights the successful integration of allied health professionals, such as pharmacists, into the research process. Missing eligible patients affects the success of clinical trial recruitment [9], and secondary care pharmacists can facilitate patient participation in CTIMPs conducted within the NHS.

We aimed to investigate the views of secondary care pharmacists employed within the NHS, in relation to their opinions of being involved in CTIMPs, their current role, and their potential for facilitating patient participation (e.g. by identifying or recruiting potential participants).

Methods

We used a cross-sectional quantitative online survey to investigate the current role, and perceived benefits and barriers of secondary care pharmacists being involved in CTIMPs and facilitating patient participation. To determine if opinions differ between sites with fewer CTIMPs open in comparison to those with a greater quantity of studies open, the views of participants employed at sites with ≤ 50 CTIMP studies were compared to those with ≥ 51 CTIMPs open, and a two-tailed Chi-squared test was applied. To decide the numerical point at which to cut the data to allow a comparison, we contacted the Yorkshire & Humber National Institute for Health Research Clinical Research Network to establish if there was a defined quantity of studies associated with being a small or large research active site. Our contact advised that the average number of

studies per Trust in 2014/15 was just over 77, and suggested a classification based on this as a mean value. We therefore decided to compare the views of pharmacists employed at sites with ≤ 50 CTIMP studies (low research activity); against those with ≥ 51 CTIMPs open (medium - high research activity).

A standard measure was not available to address the aim of the research, therefore a survey was created. The survey was generated following a review of literature that described the benefits and barriers to pharmacy research (Awaisu and Alsalimy (2014) [10] and Shaheed et al., 2014 [11]). The survey contained closed questions and where appropriate, provided participants with the option to express their opinions further if they found the responses available to be restrictive. The bespoke survey was reviewed by one chief pharmacist and one clinical trial pharmacist prior to wider distribution. The survey was deployed using Bristol Online Surveys, and was available for five weeks during January and February 2016. Ethical approval was given by the University Of Leeds School Of Medicine Research Ethics Committee (MREC15-015). Informed consent was sought using the online survey tool and participants were advised that the survey should take no longer than 10 minutes to complete.

The survey was circulated by the Royal Pharmaceutical Society National Pharmacy Clinical Trials Advisory Group (RPS NPCTAG) and National Institute for Health Research (NIHR) Research and Pharmacy Network. Responses were received from staff employed within NHS pharmacy departments across England, Scotland and Wales. Thirty nine respondents completed the survey, including 28 clinical trial pharmacists and four chief pharmacists. Seven responses were received from participants who described themselves as fulfilling other roles within pharmacy at

an NHS hospital. Of the 39 participants, most (79%) had previously completed research specific training (excluding Good Clinical Practice (GCP) training).

Results

The benefits of being involved in CTIMP studies

Most participants strongly agreed or agreed that being involved in CTIMP studies provides a variety of benefits. The majority suggested their involvement is advantageous to them personally as it improves relationships with other healthcare professionals, provides the opportunity to develop training and knowledge, and provides the opportunity to explore a personal interest. Whilst most participants believe being involved develops the pharmacy profession, fewer indicated they believe their involvement benefited the patient (Table 1).

No large variations were observed when the data was analysed in relation to the quantity of CTIMP studies open. Overall, 14% stated they neither agreed nor disagreed with some of the benefits; representing one in seven participants not expressing a judgement on the various matters discussed (Table 2).

The barriers to being involved in CTIMP studies

Approximately three-quarters of participants strongly agreed or agreed that there are barriers to their involvement in CTIMP studies at an organisational level including a lack of opportunities or awareness of opportunities, time, and funding or resources. Around half of participants suggested

they were affected by personal barriers such as a lack of confidence, interest, and knowledge or expertise (Table 3).

Participants from sites with a greater number of CTIMP studies agreed with the barriers more than those with fewer CTIMPs open. Overall, 67% of those employed at sites with ≥ 51 CTIMPs strongly agreed or agreed with the barriers, in comparison to participants employed at sites with ≤ 50 CTIMPs of whom 40% strongly agreed or agreed, and 41% strongly disagreed or disagreed (Pearson's Chi-square statistic=25.07, degrees of freedom=1, two-tailed p=0.0001). As 17% of participants stated they neither agreed nor disagreed with the barriers, this represents one in six participants not expressing a judgement on the matter (Table 4).

The role of secondary care pharmacists in facilitating patient participation in research

One fifth of participants stated some pharmacists at their site are involved in identifying potential participants to the research team; however fewer were involved in recruitment. Specialist pharmacists were most commonly involved in the roles. Pharmacists were most commonly engaged with discussing potential patients with other healthcare professionals at multi-disciplinary team meetings.

The benefits of being involved in the facilitation of patient participation for CTIMPs

Most participants strongly agreed or agreed that being involved in the facilitation of patient participation for CTIMP studies provides a variety of benefits. The majority suggested their

involvement is advantageous to them personally as it improves communication with other healthcare professionals, provides the opportunity to develop training and knowledge, and provides the opportunity to explore a personal interest. Whilst most participants indicate being involved develops the pharmacy profession, fewer participants indicated they believe their involvement benefited the patient (Table 1).

Irrespective of the number of CTIMP studies open, most participants strongly agreed or agreed with the statements, and only a minority showed a level of disagreement. Overall, 23% of participants stated they neither agreed nor disagreed with the benefits representing a quarter of all participants not expressing a judgement on the matter (Table 5).

The barriers to being involved in the facilitation of patient participation for CTIMPs

Approximately three-quarters of participants strongly agreed or agreed that there are barriers to their involvement in facilitating patient participation for CTIMP studies at an organisational level including a lack of opportunities or awareness of opportunities, time, and funding or resources. Around half of participants suggested they were affected by personal barriers such as a lack of confidence, interest, and knowledge or expertise (Table 3).

Forty-nine percent of those employed at sites with ≤ 50 CTIMPs open strongly agreed or agreed with the barriers, in comparison to 73% of participants from sites with ≥ 51 CTIMPs (Pearson's Chi-square statistic=6.74, degrees of freedom=1, two-tailed p=0.0094). As 17% of participants

stated they neither agreed nor disagreed with the barriers, this represents one in six not expressing a judgement on the matter (Table 6).

Discussion

Given their enthusiasm to be involved in research, secondary care pharmacists could potentially enhance the success of clinical trial recruitment for CTIMP studies. This comprehensive survey of opinions among secondary care pharmacists within the NHS, and found that most participants agreed with the proposed benefits and barriers to pharmacy involvement. The main benefits of being involved in CTIMPs and facilitating participation include improved relationships and communication with other healthcare professionals, developing training and knowledge, exploring a personal interest, and developing the pharmacy profession. However, participants seem to feel that a lack of opportunities or awareness of opportunities, time, and funding or resources are the main barriers to their involvement.

Sites with a greater quantity of studies agreed more when responding to the benefits and barriers of being involved in facilitating patient participation; this may be associated with participants having had experiences of this, in comparison to the majority of pharmacists who are not yet involved. To improve engagement, the potential barriers to involvement will need to be addressed with the aim of minimising the impact on their activities. Our research suggests that efforts should be focussed on the amount of time, funding and training opportunities available.

Lack of time

Our research found that approximately three-quarters of participants agreed that a lack of time was one of the many barriers to being involved in CTIMPs and facilitating participation. The results suggest that time is an issue affecting pharmacist involvement generally; more so at sites with a greater quantity of studies open. Pharmacists have shown an enthusiasm to research collaboration previously, however enthusiasm declined over time due to competing clinical and business priorities [11]. They recognise that involvement in research enables the potential for contribution to care, however many cite a lack of time or prioritising their core clinical activities as barriers to their participation [12]. Shaheed et al. (2014) identified time pressure as the main barrier to pharmacists involved in patient recruitment, with too little time available to go through the recruitment process with patients [11]. It is suggested that pharmacy culture needs to change to support protected time and funding for research, enabling core duties to be conducted by staff able to backfill the role [12]. Funding for protected research time has the potential to improve recruitment and if this is not possible, then the workload associated with recruitment must be minimised to prove successful [13]. This is supported by research that showed that midwives who had funded protected time, intensive training, and regular updates and contact visits increased recruitment by 69% [13]. Despite this effect, additional funding may prove difficult to obtain at a time of increasing pressures on the NHS.

Lack of funding or resources

Our research found that approximately two thirds of participants indicated they believed that a lack of funding or resources was a barrier to involvement in CTIMPs and facilitating participation. The results suggest that this is an issue affecting pharmacist involvement generally; more so at sites with a larger quantity of studies open. Inadequate staffing, recruitment problems with insufficient training and education, and unclear funding mechanisms have previously been highlighted as issues by key stakeholders from a Comprehensive Local Research Network [14]. Previously research inactive areas of the UK have overcome the barriers they experienced such as a lack of funding, lack of research emphasis, and a limited time for consultant involvement, with support from the National Institute for Health Research Comprehensive Local Research Network (NIHR CLRN) [15].

Lack of opportunities or awareness of opportunities

Our research found that approximately three-quarters of participants expressed that a lack of opportunities or awareness of opportunities proved a barrier to their involvement in CTIMPs and facilitating participation. The findings suggest that a lack of opportunities affects pharmacist involvement generally; more so at sites with a greater quantity of studies open. Lowrie et al. (2015) reported a greater external motivation to become involved in research within pharmacists qualified for a longer period of time, possibly due to research providing personal benefits early in the career and progressively becoming incorporated into the role with career development. Those participating in the research advised that peer support and research networks could allow pharmacists to identify research opportunities [12]. Whilst trial investigators have the opportunity to interact with colleagues, exchange ideas and gain clinical experience of new drugs [16], a lack of

opportunities for pharmacists could have a negative impact on research as pharmacists may be restricted in their collaboration with other healthcare professionals.

Participants identified with the proposed personal benefits of being involved in CTIMPs and the facilitation of patient participation, and barriers to their involvement were suggested to be at an organisational level. Several participants indicated they neither agreed nor disagreed with the benefits and barriers, suggesting limited awareness within pharmacists. Future research would benefit from exploring the barriers to recruitment activity in more depth, and examining potential methods to overcome them.

Our research suggests that while most of the pharmacy professionals sampled do not currently have a role in facilitating participation in CTIMPs, there is a sense of enthusiasm for their involvement as many can identify with the benefits of being involved in CTIMPs and facilitating participation. For those that are involved, the associated tasks appear to be limited at this stage. In times requiring the efficient use of public money for research, it is important that pharmacists, as professionals with high levels of contact with patients and an eagerness to participate in research, are engaged effectively. While secondary care pharmacists continue to have an important role in patient care, their role in clinical trials has scope to evolve. As the NHS continues to promote patients contacting their pharmacist, the relationship between pharmacists and patients will hopefully strengthen. With appropriate support, this may result in pharmacists becoming more involved in clinical trials and improving recruitment; an aspect of research that has generally struggled. Further research focussing on the views of service users and the practicalities of pharmacist involvement may provide greater insight into these activities.

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Table 1. Pharmacist views on the benefits of pharmacy being involved in CTIMP studies and facilitating participation

Benefits	Involvement	Response		
		Strongly agree/ agree	**Neither agree nor disagree**	**Strongly disagree/ disagree**
Enables you to provide enhanced services to patients (n = 39)	CTIMP involvement	28 (72%)	7 (18%)	4 (10%)
	Facilitating patient participation of CTIMPs	25 (64%)	12 (31%)	2 (5%)
Improves patient interactions (n = 39)	CTIMP involvement	24 (62%)	12 (31%)	3 (8%)
	Facilitating patient participation of CTIMPs	27 (69%)	12 (31%)	0 (0%)
Improves communication/relationships with other healthcare professionals (n = 39)	CTIMP involvement	38 (98%)	1 (3%)	0 (0%)
	Facilitating patient participation of CTIMPs	33 (85%)	6 (15%)	0 (0%)
Provides the opportunity to develop training and knowledge (n = 39)	CTIMP involvement	35 (89%)	2 (5%)	2 (6%)
	Facilitating patient participation of CTIMPs	32 (83%)	7 (18%)	0 (0%)
Provides the opportunity to explore a personal interest (n = 39)	CTIMP involvement	33 (85%)	4 (10%)	2 (6%)
	Facilitating patient participation of CTIMPs	32 (82%)	7 (18%)	0 (0%)
Develops the pharmacy profession (n = 39)	CTIMP involvement	37 (95%)	2 (5%)	0 (0%)
	Facilitating patient participation of CTIMPs	33 (85%)	5 (13%)	1 (3%)

Financial support or funding for pharmacy (n = 39)	CTIMP involvement	29 (75%)	9 (23%)	1 (3%)
	Facilitating patient participation of CTIMPs	23 (59%)	13 (33%)	3 (8%)

Table 2. Pharmacists views on the benefits of pharmacy being involved in CTIMP studies (presented by number of CTIMPs open)

Benefit	Number of CTIMPs open	Response		
		Strongly agree/ agree	**Neither agree nor disagree**	**Strongly disagree/ disagree**
Enables you to provide enhanced services to patients	≤ 50 (n = 14)	10 (72%)	4 (29%)	0 (0%)
	≥ 51 (n = 25)	18 (72%)	3 (12%)	4 (16%)
Improves patient interactions	≤ 50 (n = 14)	8 (57%)	6 (43%)	0 (0%)
	≥ 51 (n = 25)	16 (64%)	6 (24%)	3 (12%)
Improves relationships with other healthcare professionals	≤ 50 (n = 14)	14 (100%)	0 (0%)	0 (0%)
	≥ 51(n = 25)	24 (96%)	1 (4%)	0 (0%)
Provides the opportunity to develop training and knowledge	≤ 50 (n = 14)	12 (86%)	2 (14%)	0 (0%)
	≥ 51 (n = 25)	23 (92%)	0 (0%)	2 (8%)
Provides the opportunity to explore a personal interest	≤ 50 (n = 14)	12 (86%)	1 (7%)	1 (7%)
	≥ 51 (n = 25)	21 (84%)	3 (12%)	1 (4%)
Develops the pharmacy profession	≤ 50 (n = 14)	13 (93%)	1 (7%)	0 (0%)
	≥ 51 (n = 25)	24 (96%)	1 (4%)	0 (0%)

Financial support or funding for pharmacy	≤ 50 (n = 14) ≥ 51 (n = 25)	11 (79%) 18 (72%)	3 (21%) 6 (24%)	0 (0%) 1 (4%)

Table 3. Pharmacist views on the barriers to pharmacy being involved in CTIMP studies and facilitating participation

Barriers	Involvement	Response		
		Strongly agree/ agree	Neither agree nor disagree	Strongly disagree/ disagree
Lack of time	CTIMP involvement (n = 38)	29 (76%)	2 (5%)	7 (18%)
	Facilitating patient participation of CTIMPs (n = 38)	28 (73%)	4 (11%)	6 (16%)
Lack of funding/resources	CTIMP involvement (n = 36)	24 (67%)	5 (14%)	7 (20%)
	Facilitating patient participation of CTIMPs (n = 38)	27 (71%)	5 (13%)	6 (16%)
Lack of guidance/support	CTIMP involvement (n = 37)	19 (52%)	9 (24%)	9 (24%)
	Facilitating patient participation of CTIMPs (n = 37)	21 (57%)	8 (22%)	8 (22%)
Lack of knowledge/expertise	CTIMP involvement (n = 38)	17 (45%)	7 (18%)	14 (37%)
	Facilitating patient participation of CTIMPs (n = 38)	22 (57%)	8 (21%)	8 (21%)
Lack of training	CTIMP involvement (n = 37)	20 (54%)	6 (16%)	11 (29%)
	Facilitating patient participation of CTIMPs (n = 38)	26 (68%)	7 (18%)	5 (13%)
Lack of confidence	CTIMP involvement (n = 38)	20 (53%)	8 (21%)	10 (26%)
	Facilitating patient participation of CTIMPs (n = 38)	20 (53%)	8 (21%)	10 (26%)
Lack of interest	CTIMP involvement (n = 37)	17 (46%)	9 (24%)	11 (29%)
	Facilitating patient participation of CTIMPs (n = 38)	20 (53%)	7 (18%)	11 (29%)
Lack of opportunities/awareness of opportunities	CTIMP involvement (n = 37)	26 (70%)	5 (14%)	6 (17%)
	Facilitating patient participation of CTIMPs (n = 38)	30 (79%)	4 (11%)	4 (10%)

Table 4. Pharmacists views on the barriers to pharmacy being involved in CTIMP studies (presented by number of CTIMPs open)

Barriers	Number of CTIMPs open	Response		
		Strongly agree/ agree	Neither agree nor disagree	Strongly disagree/ disagree
Lack of time	≤ 50 (n = 13)	7 (54%)	2 (15%)	4 (30%)
	≥ 51 (n = 25)	22 (88%)	0 (0%)	3 (12%)
Lack of funding/resources	≤ 50 (n = 13)	6 (46%)	3 (23%)	4 (30%)
	≥ 51 (n = 23)	18 (78%)	2 (9%)	3 (13%)
Lack of guidance/support	≤ 50 (n = 13)	4 (31%)	4 (31%)	5 (38%)
	≥ 51 (n = 24)	15 (62%)	5 (21%)	4 (17%)
Lack of knowledge/expertise	≤ 50 (n = 13)	3 (23%)	3 (23%)	7 (53%)
	≥ 51 (n = 25)	14 (56%)	4 (16%)	7 (28%)
Lack of training	≤ 50 (n = 13)	5 (39%)	2 (15%)	6 (46%)
	≥ 51 (n = 24)	15 (62%)	4 (17%)	5 (21%)
Lack of confidence	≤ 50 (n = 13)	5 (39%)	2 (15%)	6 (46%)
	≥ 51 (n = 25)	15 (60%)	6 (24%)	4 (16%)
Lack of interest	≤ 50 (n = 13)	5 (38%)	1 (8%)	7 (53%)
	≥ 51 (n = 24)	12 (51%)	8 (33%)	4 (17%)
Lack of opportunities/awareness of opportunities	≤ 50 (n = 13)	7 (54%)	2 (15%)	4 (31%)
	≥ 51 (n = 24)	19 (79%)	3 (13%)	2 (8%)

Table 5. Pharmacists views on the benefits of pharmacy being involved in facilitating patient participation of CTIMPs (presented by number of CTIMPs open)

Benefits	Number of CTIMPs open	Response		
		Strongly agree/ agree	Neither agree nor disagree	Strongly disagree/ disagree
Enables you to provide enhanced services to patients	≤ 50 (n = 14)	7 (50%)	6 (43%)	1 (7%)
	≥ 51 (n = 25)	18 (72%)	6 (24%)	1 (4%)
Improves patient interactions	≤ 50 (n = 14)	8 (57%)	6 (43%)	0 (0%)
	≥ 51 (n = 25)	19 (76%)	6 (24%)	0 (0%)
Improves communication with other healthcare professionals	≤ 50 (n = 14)	10 (72%)	4 (29%)	0 (0%)
	≥ 51 (n = 25)	23 (92%)	2 (8%)	0 (0%)
Provides the opportunity to develop training and knowledge	≤ 50 (n = 14)	9 (65%)	5 (36%)	0 (0%)
	≥ 51 (n = 25)	23 (92%)	2 (8%)	0 (0%)
Provides the opportunity to explore a personal interest	≤ 50 (n = 14)	10 (71%)	4 (29%)	0 (0%)
	≥ 51 (n = 25)	22 (88%)	3 (12%)	0 (0%)
Develops the pharmacy profession	≤ 50 (n = 14)	10 (72%)	4 (29%)	0 (0%)
	≥ 51 (n = 25)	23 (92%)	1 (4%)	1 (4%)
Financial support or funding for pharmacy	≤ 50 (n = 14)	8 (57%)	6 (43%)	0 (0%)
	≥ 51 (n = 25)	15 (60%)	7 (28%)	3 (12%)

Table 6. Pharmacists views on the barriers to pharmacy being involved in facilitating patient participation of CTIMPs (presented by number of CTIMPs open)

Barriers	Number of CTIMPs open	Response		
		Strongly agree/ agree	Neither agree nor disagree	Strongly disagree/ disagree
Lack of time	≤ 50 (n = 14)	7 (50%)	4 (29%)	3 (21%)
	≥ 51 (n = 24)	21 (88%)	0 (0%)	3 (13%)
Lack of funding/resources	≤ 50 (n = 14)	7 (50%)	4 (29%)	3 (21%)
	≥ 51 (n = 24)	20 (83%)	1 (4%)	3 (13%)
Lack of guidance/support	≤ 50 (n = 14)	6 (42%)	4 (29%)	4 (28%)
	≥ 51 (n = 23)	15 (65%)	4 (17%)	4 (17%)
Lack of knowledge/expertise	≤ 50 (n = 14)	4 (28%)	5 (36%)	5 (36%)
	≥ 51 (n = 24)	18 (75%)	3 (13%)	3 (13%)
Lack of training	≤ 50 (n = 14)	7 (50%)	4 (29%)	3 (21%)
	≥ 51 (n = 24)	19 (79%)	3 (13%)	2 (8%)
Lack of confidence	≤ 50 (n = 14)	7 (50%)	3 (21%)	4 (28%)
	≥ 51 (n = 24)	13 (55%)	5 (21%)	6 (25%)
Lack of interest	≤ 50 (n = 14)	7 (50%)	3 (21%)	4 (28%)
	≥ 51 (n = 24)	13 (54%)	4 (17%)	7 (29%)
Lack of opportunities/awareness of opportunities	≤ 50 (n = 14)	10 (71%)	3 (21%)	1 (7%)
	≥ 51 (n = 24)	20 (84%)	1 (4%)	3 (12%)