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Review

Psychosocial aspects of post-treatment follow-up for stage I/II melanoma: a systematic review of the literature

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Abstract

***Background*: Patients treated for melanoma are advised to have lifelong full body skin examinations. Extended intervals between examinations have been proposed, but although this may be clinically effective, psychosocial aspects of follow-up are not well understood. This systematic review summarised patient and clinician preferences, experiences and adherence with recommended follow-up of stage I/II melanoma.**

***Methods*: Medline, PsycINFO, CINAHL, Embase, Cochrane Library, ACP Journal Club and NHS Economic Evaluation Database were searched from database inception to week 3 April 2010, to identify original studies of psychosocial outcomes of follow-up after treatment of stage I/II primary cutaneous melanoma, as reported by patients or clinicians. The results were synthesised, and characteristics likely to maximise patients' well-being and adherence to follow-up schedules were proposed.**

***Results*: We found 15 studies that met the inclusion criteria. Anxiety with melanoma follow-up was common; patients valued reassurance, information and psychosocial support, but long-term adherence to schedules was variable. Some wanted more emotional support from their clinician than was provided. Clinicians sometimes ordered additional blood and imaging tests to reassure patients. GPs were hesitant to conduct melanoma follow-up, but a trial providing technical training and protocols reported positive outcomes. Both patients and GPs wanted prompt access to melanoma specialists when suspicious lesions were found.**

***Conclusion*: Psychosocial aspects of follow-up impact on patient well-being and potential adherence to schedules, and may influence clinician practice. If follow-up schedules or personnel are to be revised, psychosocial impacts on patients must be explicitly addressed, as well as guidance and specialist support for clinicians.**

Keywords: systematic review; melanoma; follow-up; psychosocial; cancer; oncology

Introduction

Cutaneous melanoma is a growing and significant disease burden worldwide [1] and the fourth most common cancer in Australia [2]. Although those diagnosed with melanoma stage I or II have relatively high survival rates [3], patients face ongoing risk of a recurrence and increased lifetime risk of new primary tumours [4,5]. Clinical guidelines recommend routine post-treatment follow-up, comprising clinical and full body skin examination by a physician, supplemented with regular patient (or partner-assisted) self-examination [4]. The objectives of follow-up include early detection of recurrent and new disease, education for patients about skin examination and sun safe behaviour, and provision of reassurance and other psychosocial support [6–8]. Clinical guidelines also recommend routine monitoring of melanoma patients to identify those requiring additional emotional assistance [6], with prevalence of clinically relevant psychological distress among patients with melanoma (all stages) at approximately 30% [9].

There is limited evidence of the optimal frequency and duration of follow-up [5], but schedules pose considerable demands on patients and clinicians; that is, patients with a stage I/II melanoma may be seen every 3–4 months in the first 2 years, every 6 months until 5 years, and annually for the rest of their life [4]. Although patients are mostly reassured by follow-up, they also experience substantial anxiety associated with follow-up consultations [4,8,10]. It has recently been suggested that less frequent monitoring may be equally effective in detecting recurrent disease or new primary tumours [11,12]. This has potential to considerably reduce the burden of follow-up, yet lengthening the time between visits may impact on other important components of care, including provision of information and reassurance. When changes to clinical protocols are considered, evidence of potential impact on psychosocial (emotional, social, cognitive and behavioural) as well as clinical outcomes should be examined [13].

Prior reviews have described melanoma patients' responses, needs, coping strategies and quality of life

associated with their melanoma diagnosis and treatment [9,14,15]. Long-term psychosocial impacts of melanoma and post-treatment follow-up are relatively new and important topics for further research [5,16]. To date, no reviews have examined the psychosocial aspects of melanoma follow-up or adherence to follow-up guidelines. The purpose of this review was to enhance understanding of the follow-up of stage I/II melanoma, suggest optimal components of follow-up that maximise patient's psychosocial well-being and adherence to schedules, and to inform future deliberation of potential changes to follow-up.

Methods

Review questions

1. What are patient preferences, experiences and other psychosocial outcomes associated with follow-up after surgical treatment of stage I or II melanoma (including adherence to guidelines)?
2. What are clinician preferences and experiences of providing follow-up care to patients after surgical treatment of stage I or II melanoma (including adherence to guidelines)?

Search strategy

Medline, PsycINFO, CINAHL, Embase, Cochrane Library, ACP Journal Club and NHS Economic Evaluation Databases were searched from database inception to week 3 April 2010. Reference lists of existing reviews and papers recommended through personal communication were examined for additional relevant articles. The search combined 'melanoma' as a text word and database-specific subject headings (e.g. melanoma/ or hutchinson's melanotic freckle/ or melanoma, amelanotic/) and terms specific to follow-up (e.g. monitoring, immunologic/, monitor$.tw., follow-up.tw., schedule.tw., surveillance.tw.) with an extensive range of search terms to identify psychosocial outcomes. (The Medline search strategy is outlined in Appendix A.)

Inclusion and exclusion criteria

The review included all empirical studies that considered psychosocial factors as anticipated or experienced outcomes of routine follow-up after treatment of stage I/II primary cutaneous melanoma and as reported by patients or clinicians. Articles published in languages other than English but catalogued with an English abstract were included. The detailed inclusion and exclusion criteria are listed in Appendix A.

Appraisal and reporting

The final search identified 1143 papers, of which 225 were duplicates; thus, 918 were reviewed by title and abstract, and of these, 74 underwent full-text review (Figure 1). The full-text reviews were independently conducted by two reviewers (LR and KM). Issues of uncertainty or discrepancy about the inclusion or exclusion of an article were resolved in consensus meetings attended by all authors.

Data from the final articles included in the review were extracted into a standardised template by one reviewer (LR), reported study findings were independently extracted by a second reviewer and areas of discrepancy were resolved in group discussions. All studies that met the inclusion criteria were appraised for study quality using either the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool [17] or the Consolidated criteria for reporting qualitative studies (COREQ) framework [18].

The results were synthesised in narrative form, as the heterogeneity of the literature did not support pooling results [19]. The narrative structure was empirically derived from the research focus of the included studies (Appendix A, *Tables A1 and A2, column 2*). The identified characteristics of melanoma follow-up were then summarised and cross-tabulated against four predefined psychosocial categories (emotional, social, cognitive and behavioural) [13] plus one new category (economic) identified as a patient-important outcome in this review. Application of these categories was conducted independently by two reviewers (LR and KM), and discrepancies were resolved in discussion. Finally, a meta-synthesis [20] of patient and clinician preferences, experiences and outcomes of follow-up was conducted to propose characteristics of 'optimal' follow-up, that is, characteristics likely to maximise patients' well-being and adherence to follow-up schedules. This was derived from the tabulated results with contribution from all of the authors and is presented in the discussion.

Results

Fifteen articles reporting psychosocial outcomes of melanoma follow-up were identified. Nine were from a patient perspective, three from a clinician perspective and three from both patient and clinician perspectives. The key characteristics of these studies and their methods are summarised in Appendix A (*Table A1. Summary of quantitative studies*, and *Table A2, Summary of qualitative studies*); two articles [21,22] were based on one survey. Of the 15 articles, 12 reported quantitative findings and three reported qualitative findings. The studies were primarily cross-sectional surveys ($n = 9$), although two included multiple measurement points [23,24] and one included prospective observational data [25]. There was also one 5-year retrospective audit of follow-up of clinic records [26] and one randomized controlled trial (RCT) [27]. The three qualitative articles were linked to the RCT; one reported data collected during the intervention development and the others reported clinician and patient experiences among those in the intervention arm of the RCT [28–30].

Overall, the studies were of relatively good quality (Appendix A, *Table A3. Quantitative studies appraisal*, and *Table A4. Qualitative studies appraisal*). The majority of quantitative studies had defined study populations ($n = 6$ clearly defined, $n = 4$ partly defined),

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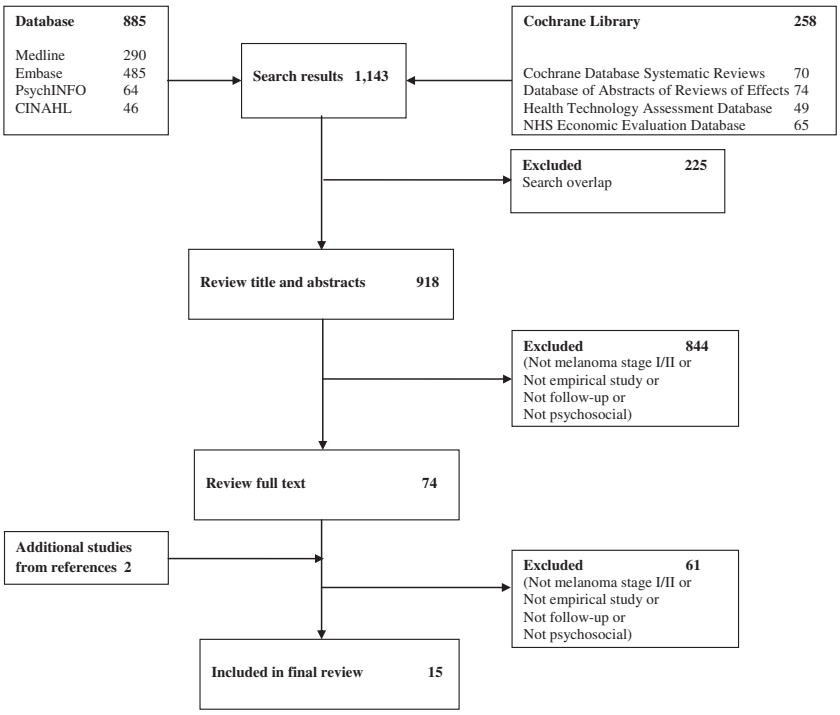

Figure 1. Results of search strategy and identification of studies included in review

with the study samples very likely ($n = 6$) or somewhat likely ($n = 4$) to be representative of the target population. Participation rates were acceptable in seven studies (80–100% $n = 5$; 60–79% $n = 2$; not reported $n = 3$), and eight studies provided details of the data collection instruments. Only one study scored poorly across the quality criteria [25]. The qualitative studies were rigorous; the methods were appropriate to the research objectives, and each met the quality of reporting criteria, that is, researchers and target populations were clearly described, the methodological orientation articulated and the sampling strategy, data collection and data analysis methods were clearly documented.

The findings are presented separately for patients and clinicians under three broad headings reflecting the scope of the available literature, listed with the number of articles addressing each topic in parentheses

- *Preferences for follow-up*: patient ($n = 5$) and clinician ($n = 2$);
- *Experiences of follow-up*: patient ($n = 8$) and clinician ($n = 1$); and
- *Adherence to follow-up schedules/protocols*: patient ($n = 4$) or clinician ($n = 3$).

Findings from individual studies are summarised in Appendix A (*Table A5. Summary of key patient findings from individual studies*, and *Table A6. Summary of key clinician findings from individual studies*). An overview of all psychosocial outcomes of melanoma follow-up, as identified across all studies by patients and clinicians respectively, has been compiled in the main text (Tables 1 and 2).

Table 1 includes patients' preferred characteristics of follow-up, positive and negative experiences (or concerns), and aspects of patient adherence with follow-up protocols. Table 2 reports clinicians' (mostly primary care physicians, referred to in this literature as GPs) requirements, concerns, anticipated benefits and experiences of conducting follow-up, including factors that made the experience positive or negative. It also includes reported adherence to protocols by GPs, specialists and junior hospital doctors. Tables 1 and 2 also identify how the findings correspond with the five categories of psychosocial outcomes (Box 1). Emotional and behavioural aspects of follow-up were the most frequently described among patients, whereas cognitive and behavioural aspects of follow-up were the primary focus among clinicians. Finally, the findings in Tables 1 and 2 indicate a range of characteristics of melanoma follow-up that enhance (and limit) patient satisfaction and well-being, and thus also potential adherence to recommended schedules. The suggested characteristics of 'optimal' follow-up are considered in the following discussion.

Box 1. The five categories of psychosocial outcomes were defined as follows:

Emotional:feelings associated with follow-up such anxiety, stress, depression or reassurance and well-being.
Social:interpersonal relationships between patients and clinicians, or patients and doctors social roles.
Behavioural:attendance at follow-up, practical aspects associated with getting to appointments and risk-related or disease-related behaviours.
Cognitive:knowledge, understanding, beliefs and perceptions related to melanoma.
Economic:financial and other resource implications of follow-up.

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Table 1. Psychosocial characteristics of melanoma follow-up from patients

Patients	Psychosocial characteristics of follow-up and monitoring	Patient outcomes of follow-up and monitoring				
		Emotional	Social	Behavioural	Cognitive	Economic
Preferences (five studies)	Want reassurance from follow-up [30]	✓				
	Consistent, familiar, trusted clinician [30]	✓	✓			
	To have full skin exam conducted [30]			✓		
	Opportunity to ask questions [30]				✓	
	Adequate expertise/training for clinician on melanoma follow-up [30]				✓	
	Local appointments for reduced travel and associated costs [30]			✓		✓
	Fast access to specialist care for suspicious lesions [30,31]			✓		
	Regular scheduled clinic appointments preferred over drop-in option [10]			✓		
	Interest in emotional support counselling, medical specialist preferred versus psychotherapist [22]	✓				
	Interest in complementary therapies correlated with need for emotional support [21]	✓				
Experiences (eight studies)						
Positive	Satisfaction high with follow-up among attending [25,28,30] higher in GP care than hospital [27]	✓				
	Reassurance obtained from attending follow-up [8,23,28,32] anxiety reduced over time [28]	✓				
	Attending follow-up considered worthwhile [10]	✓			✓	
	Feeling in control, that is, knowing what to do and who to contact if worried (GP care) [28]	✓			✓	
	Melanoma considered in context of other health issues (GP care) [27,28]			✓	✓	
	Access to additional prescriptions as required (GP care) [27,28]			✓		
	Familiar, friendly clinician/clinic (GP care) [27,28]	✓	✓			
	Convenient, that is, proximity, time and accessibility (GP care) [27,28]			✓		✓
	Easy appointment system (GP care) [27,28]			✓		
	Clinician availability, that is, same day (GP care) [27,28]			✓		
	Short/acceptable waiting time at clinic [10,27]			✓		
	Adequate time with doctor and opportunity to ask questions [8,10]			✓	✓	
	Fully examined for new disease [8]			✓		
	Recall system valued, for example letter [25]			✓		
	Follow-up improved knowledge of melanoma [10]				✓	
	Modified behaviours, that is, sun cream, shade, covering up, advise others and self-examination [10,32]			✓		
Negative/concerns	Anxiety prior and on day of appointments — some 'very' or 'extremely' anxious [8,10]	✓				
	Symptoms associated with anxiety, for example diarrhoea, nausea, sleeplessness [10]	✓		✓		
	Anxiety during and between appointment, not correlated with intensity of follow-up [23]	✓				
	Consultations too short [30]			✓		
	Poor continuity of clinician, for example changing doctors [30]		✓	✓		
	*Clinic waiting times too long [25]			✓		
	*Practical problems with attendance — driving time, parking, transport and associated costs [8,25]			✓		✓
	*Recall letter arriving too late [25]			✓		
	Uncertain reassurance — less definitive diagnosis of suspicious lesions (GP) [28]	✓				
Adherence (four studies)	Variable adherence (~50%) with recommended follow-up [25,26]			✓		
	Non-adherence primarily associated with practical concerns (identified above with *) [8,25]			✓		
	Note: attendance for follow-up may occur with multiple practitioners [32]			✓		

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Table 2. Psychosocial characteristics of melanoma follow-up from clinicians

		Clinician outcomes of follow-up and monitoring				
	Psychosocial aspects of follow-up and monitoring	**Emotional**	**Social**	**Behavioural**	**Cognitive**	**Economic**
General Practitioners						
Preferences (two studies)	A prior reluctance to undertake GP-led melanoma follow-up [8,30]			✓	✓	
Requirements	Extra training [30]			✓	✓	
	Clearly defined protocols [30]			✓	✓	
	Specialist support [30]			✓	✓	
	Reimbursement [30]					✓
Concerns	Concern about lack of time, resources, workload and few advantages for their practice [8,30]			✓		✓
	Concern about reduced reassurance for patients [30]	✓				
	Concern about GPs limited experience [8,30]	✓			✓	
Benefits	Potential to improve convenience and continuity for patients [30]		✓	✓		
	Potential for greater involvement by GPs in melanoma care [30]			✓		
	Potential for increased knowledge and skills of GPs [30]				✓	
	Potential to free up specialists time [30]			✓		
Experiences (one study)						
Positive	Comfortable conducting GP-led melanoma follow-up, few reported problems [29]	✓				
	Importance of training, protocols, recall system and rapid referral pathway to specialists [29]			✓	✓	
	Perceived advantage of specialist training/interest in dermatology, but not required [29]				✓	
	Ideally placed to deliver follow-up care [29]			✓		
	Minimal disruption of GP practice [29]			✓		
	GP-led care applicable in all locations, although rural GPs more enthusiastic [29]			✓		
	Patients' experiences perceived as positive [29]	✓				
	More efficient use of skin specialist [29]			✓		
Negative/concerns	Maintaining adequate level of expertise if patient numbers small [29]			✓	✓	
	Consumption of limited resources [29]					✓
	Workload and increased potential for transfer of other tasks to GPs in future [29]			✓		
	GP on leave when patient recall letter sent out [29]			✓		
	Patients introducing other matters to follow-up consultation [29]			✓		
	Patients pre-empting melanoma follow-up as part of consultation on other matters [29]			✓		
Adherence (one study)	Better adherence with follow-up schedule under GP-led care than hospital clinic [27]			✓		
Specialists						
Adherence (two studies)	Variable protocols among consultant specialists [24]			✓		
	Variable knowledge and application of protocols among junior doctors [24]			✓	✓	
	Routine diagnostic tests ordered to provide reassurance on requests from patients [33]		✓	✓		

Patients

Patient preferences for follow-up

Patients expressed interest in trialling GP-led follow-up as an alternative to their regular hospital outpatient clinic as long as the GPs received appropriate training [30]. Anticipated benefits of GP-led care were based on preferences for reduced travel and related costs; better access to appointments; better continuity in terms of seeing the same doctor at each visit; a less intimidating environment than a hospital; and more time to have full skin examinations, learn more about melanoma and ask questions. Patients wanted rapid access to a specialist if a suspicious lesion was found [30,31], but for routine follow-up, they preferred scheduled over 'drop-in' appointments. [10] Over half of the patients were interested in professional emotional support, and the majority preferred to get this from their doctor than from a psychiatrist or psychologist [22]. Requests for support were also associated with greater interest in complementary therapies [21].

Patient experiences of follow-up

Patients' experiences of follow-up were grouped as follows: (i) satisfaction with follow-up; (ii) anxiety and reassurance; and (iii) impact on knowledge and behaviour.

Satisfaction with follow-up: Patients reported higher levels of satisfaction as well as psychosocial and practical benefits in an RCT of GP-based follow-up compared with

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hospital controls [27,28,30]. Contributing factors included GP availability and ease of making GP appointments, shorter clinic waiting times, more thorough skin examinations, access to additional prescriptions and knowing the doctor well [27]. GP-led care was also described as more convenient, familiar, friendly and less clinical than the hospital, with GPs better able to consider melanoma in the context of the whole person and patients feeling more in control of their care [28,30]. Otherwise, overall satisfaction with hospital-based follow-up was also high [8,10,25], with patients finding it worthwhile [10] and useful because they felt reassured and were able to ask questions [8]. Those attending hospital-based follow-up also reported difficulties with attending appointments, including transport, parking and associated costs [8]. Patients liked the system of a recall letter for follow-up appointments, and those who did not comply with recommended schedules said this was due to the long drive, long clinic waiting times, or the recall letter arrived too late [25].

Anxiety and reassurance: Around half of surveyed patients reported anxiety associated with attending follow-up appointments [8,10]. Around a third of anxious patients said it began over 24 h prior to their appointment, and approximately one in 10 reported associated physical symptoms such as diarrhoea, nausea and sleeplessness [10]. Some patients reported extreme anxiety related to follow-up, which started several weeks prior to appointments [8]. Around one in five follow-up patients had clinically significant levels of chronic anxiety that persisted between appointments and did not appear to be related to frequency of follow-up [23]. Attending follow-up has also been reported by patients as an important source of reassurance [28,32]. A few of those attending GP-led care said they felt less confident than with a hospital-based specialist, particularly in receiving a definitive diagnosis and immediate reassurance if a new lesion was identified during the appointment [28].

Knowledge and behaviour: Follow-up was an important source of patient information about sun-related behaviours including increased use of sun screen, seeking shade or covering up, and advising children, grandchildren and others of the dangers of excessive sun exposure. The three main sources of information were the clinic doctor, books and magazines, and the clinic nurse [10]. Many patients attended follow-up with more than one healthcare provider, that is, a hospital clinic as well as their own dermatologist or family doctor, or all three [32]. Around three quarters of patients also conducted skin self-examination [32].

Patient adherence to follow-up schedules

Around half of surveyed patients participated in melanoma follow-up in accordance with recommended schedules [25,26]. The cumulative proportion of patients attending at 5 years post-diagnosis was just over 50%, and of these, half did not adhere with the time schedules [26]. Less than half of the patients attending a dermatology clinic for melanocytic naevi (17% melanoma) agreed to join a follow-up programme with a recall letter for scheduled appointments at 3, 6 or 12 monthly intervals, depending on risk of primary melanoma, and the majority only agreed to join the programme for 1 year or less [25]. As noted earlier, non-adherence with follow-up schedules was mostly attributed to the logistical difficulties related to attending appointments [8,25].

Clinicians

Clinician preferences for follow-up

General practitioners were reluctant to take on the responsibility of melanoma follow-up, citing concerns about their skills, resources and workload [8,30]. Although GPs recognised the potential for GP-led follow-up to improve the convenience and continuity of care for patients, they anticipated few advantages for themselves. They also identified potential disadvantages for their patients, including reduced reassurance and a greater chance of being put at risk because of limited GP experience [30]. Only a third of GPs said they would be willing to conduct melanoma follow-up as part of a shared care arrangement [8], and there was wide agreement that GPs need extra training, defined protocols, specialist support and additional resources to trial GP-led care [30].

Clinician experiences of follow-up

General practitioners who took part in a trial of GP-led melanoma follow-up reported it to be a positive experience both for themselves and for their patients and a more efficient use of skin specialists [29]. These positive experiences were attributed to the training received, structured protocols for conducting follow-up, a patient recall system and a rapid referral pathway to specialists when required. Although GPs with prior specialist training or a special interest in dermatology and/or minor surgery believed this was an advantage in delivering follow-up, all felt able to function effectively in the role. The GPs did report some concerns about maintaining adequate levels of expertise given the small numbers of patients and potentially opening the door for other roles to be transferred to GPs. Practical issues that needed to be addressed included being on holiday when the reminder letters were sent to patients, patients introducing unrelated matters during the melanoma follow-up or pre-empting issues related to melanoma follow-up during consultations for another matter. Overall, GP-led follow-up caused little disruption of GP practices and appeared equally applicable in rural and urban settings [29].

Clinician adherence to follow-up guidelines

A trial of GP-led follow-up compared with hospital-based controls found significantly that more of the patients attending GPs were seen in accordance with the

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guidelines on frequency of follow-up relative to tumour thickness and time since diagnosis [27]. Specialists responsible for melanoma patients at a regional hospital had variable follow-up policies, and the junior doctors conducting follow-up had poor knowledge and compliance with those policies. The main errors by junior doctors were failure to check the date of the diagnostic excision or recognise the presence of a second primary lesion, resulting in those patients being seen less frequently than recommended [24]. Specialists ordering diagnostic tests as part of routine follow-up in deviation from guidelines primarily did so in response to expectations or requests from patients [33]. Specialists' local institution protocols aligned with the guidelines, and only one clinician disagreed with the content, believing the recommended frequency of follow-up was too high. Although physical examinations and frequency of routine follow-up were conducted in accordance with the guidelines, a quarter of patients received additional blood tests and three quarters received diagnostic imaging (X-ray, CT scan of chest or ultrasound of liver). Sixty percent of the clinicians said the diagnostic tests had an important reassuring effect for patients, and three quarters said patients asked for these tests [33].

Discussion

In summary, recommended follow-up for stage I/II melanoma requires a considerable commitment of time and resources. Many patients experience substantial anxiety associated with follow-up visits but overall find it reassuring to have regular skin checks and the opportunity to ask questions. Patients also report a degree of unmet need for emotional support, which they prefer to receive from the doctor rather than a psychiatrist or psychologist. Some clinicians order additional tests (e.g. blood tests or imaging) as part of routine follow-up as a way of reassuring patients. Patient adherence to follow-up schedules can be variable, with up to half dropping out of recommended follow-up programmes in the first 5 years. Although attendees report high levels of satisfaction with their care, many face problems with attending hospital-based appointments because of the time and costs of travel, transport and parking difficulties, and long clinic waiting times. A proportion of patients attend follow-up with more than one healthcare provider, sharing appointments between a hospital clinic and a local dermatologist or GP, or even all three.

Both patients and clinicians emphasise the importance of having appropriately skilled clinicians to conduct follow-up to ensure quality of care and provide the reassurance and education about self-examination that is sought by patients. GPs have expressed concerns about their capacity to conduct follow-up, but when as part of a trial they were provided with specific training, structured protocols and back-up support from melanoma specialists, their experience has been positive and with good outcomes for their patients. Patients' preference for GP-based follow-up compared with hospital clinics was attributed to the accessibility and flexibility of GP-based care, GPs' capacity to address psychosocial and other health needs, and established, trusting patient–doctor relationships. Both GPs and patients emphasise the need to retain prompt access to melanoma specialists as required, particularly when a suspicious lesion is found.

Clinical implications and future research

The findings of this review point to the advantages of flexible follow-up systems that support a combination of specialised (often centralised) and local follow-up services. The results suggest that 'optimal' follow-up for stage I/II melanoma would not only address clinical objectives but also incorporate the following clinician and health service characteristics to address psychosocial needs:

Clinician characteristics

Skilled and experienced in conducting melanoma follow-up; willing to conduct full skin examination; familiar to the patient and able to provide ongoing care; able to provide education on self-examination and other aspects of the disease; able to identify unmet emotional needs and willing to provide emotional support and counselling if required; and able to consider melanoma in the wider context of other health concerns.

Health service characteristics

Adequate consultation times for full skin examination and to address patients' questions or concerns; continuity of care with the same clinician over time; patient-friendly appointment systems that are readily accessible and with a recall letter for scheduled appointments; short clinic waiting times; capacity to accommodate requests from patients to return ahead of schedule; regional locations to reduce travel time and expenses associated with follow-up; fast access to specialist care when required (e.g. rapid referral system and short waiting times for definitive diagnosis and treatment if suspicious lesions found); and provision of clear information on referral pathways and who to contact if the patient has concerns.

It is apparent that patient anxiety about recurrent or new melanoma is an important factor in determining participation in follow-up, and specialists and GPs regard provision of reassurance as an essential component of care. Clinical guidelines for stage I/II melanoma recommend against additional blood tests or diagnostic imaging in routine follow-up; but if clinicians order such tests to provide additional reassurance, future recommendations could include explicit guidance on managing patient anxiety and expectations of diagnostic testing during routine follow-up. The majority of recurrences are self-detected [34], and patients value attending follow-up to improve their skill in self-examination;

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hence, the importance of this should also be emphasised over additional tests. Summaries of the benefits, harms and recommended usage of diagnostic technologies in routine follow-up could also be included in patient education material.

Finally, this review has implications for research on follow-up intervals for stage I/II melanoma, reinforcing the importance of measuring psychosocial outcomes within clinical trials of new protocols. That some patients experience follow-up-related anxiety and report difficulties in attending hospital-based appointments would support longer intervals if these are clinically effective. As demonstrated, follow-up has other important functions and relies on establishing trusted patient–doctor relationships. This is likely to require a certain level of contact, particularly in the first year, and clinicians may prefer to retain more frequent visits than may be indicated by clinical prognosis alone. Further, as improved treatment options for melanoma recurrence become available, it may influence considerations of the frequency of follow-up for thicker tumours. A trial in the Netherlands is evaluating the effects of a 33% reduction in the number of follow-up visits for melanoma stage Ib or II. The primary outcome is patients' well-being, expressed in health-related quality of life, level of anxiety and satisfaction with the follow-up schedule, and secondary outcomes include sufficiency to detect recurrences and second primary melanomas [35]. Further research may examine the impact on psychosocial outcomes of different schedules in the first year of follow-up. There is also potential to compare current schedules with those with less frequent but longer appointments that give additional weight to psychosocial issues, that is, establishing rapport and trust, addressing concerns and questions, and providing additional emotional support if required.

Strengths and limitations of the review

This is the first review to focus on the psychosocial aspects of melanoma follow-up, and a more complete picture was provided by considering clinicians' perspectives alongside those of patients. The findings of the review were also enhanced by the inclusion of all empirical studies. Trials, surveys and qualitative research each provided a different perspective and presented a multi-dimensional view of the psychosocial aspects of follow-up. There were also some important limitations in the evidence available. Firstly, some findings are derived from single studies only, and their generalisability is as yet unknown. For example, clinicians' motivations for ordering diagnostic tests in routine follow-up need to be more widely examined. Further, a number of the studies were from countries where specialised melanoma services are centralised in hospital-based outpatient clinics, many of which are publically funded. It is uncertain, therefore, how patients' concerns about the logistics and limitations of follow-up in public hospitals translate to other settings. Finally, much of the early literature is composed of surveys, and because of inherent limitations of survey-based designs, those findings are mostly descriptive rather than explanatory. This was greatly improved with the recent addition to the literature of an RCT and associated qualitative studies, which illustrated the value of a strong study design and mixed methods to provide direct comparisons, explanatory details and important caveats about reported patient and clinician experiences of melanoma follow-up. We strongly recommend the use of intervention studies and mixed methodologies in future psychosocial research.

In conclusion, 15 studies have considered psychosocial aspects of routine follow-up of stage I/II melanoma from patient or clinician perspectives. Psychosocial factors impact on patient experiences and participation in follow-up and GPs' willingness to contribute to follow-up, and may impact on clinicians' adherence to follow-up guidelines. If the frequency of schedules or personnel providing follow-up are to be revised, psychosocial aspects of follow-up as well as clinical outcomes should be explicitly addressed. Key factors include additional reassurance through patient education and comprehensive skin examinations, retaining capacity to establish trusting patient–clinician relationship, and provide emotional support and assurance of technical training and specialist support for clinicians.

Appendix A. Medline search strategy and detailed inclusion/exclusion criteria

#	Searches	Results
Ovid MEDLINE(R) 1950 to April Week 3 2010		
1	melanoma/ or hutchinson's melanotic freckle/ or melanoma, amelanotic/	55 260
2	melanoma.tw.	58 539
3	1 or 2	72 158
4	Monitoring, Immunologic/	779
5	monitor$.tw.	368 263
6	follow-up.tw.	432 794
7	schedule.tw.	40 198
8	surveillance.tw.	67 792
9	4 or 5 or 6 or 7 or 8	872 587
10	psychology/ or psychology, medical/ or psychology, social/	22 579
11	behavioral sciences/ or behavioral medicine/ or behavioral research/	3842
12	social sciences/ or sociology, medical/	5310

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Appendix A. *Continued*

#	Searches	Results
13	"behavior and behavior mechanisms"/ or adaptation, psychological/	59 376
14	attitude/ or "attitude of health personnel"/ or attitude to health/ or Health Knowledge, Attitudes, Practice/	200 466
15	behavior/ or behavioral symptoms/ or depression/ or stress, psychological/ or communication/ or communication barriers/ or disclosure/ or information dissemination/ or information seeking behavior/ or health behavior/ or patient compliance/ or self-examination/ or illness behavior/ or personal satisfaction/ or risk reduction behavior/ or social adjustment/	287 965
16	psychology, applied/ or counseling/ or psychology, educational/ or resilience, psychological/	25 130
17	mental disorders/ or adjustment disorders/ or anxiety disorders/ or mood disorders/ or depressive disorder/	167 332
18	mental health/ or mental processes/ or cognition/ or awareness/ or comprehension/ or intention/ or learning/ or perception/ or thinking/ or decision making/ or uncertainty/ or volition/ or resilience, psychological/	191 676
19	health education/ or consumer health information/ or patient education as topic/	103 309
20	"Quality of Life"/	81 728
21	(psychology or psychosocial or psychological).tw.	140 822
22	(needs or unmet needs).tw.	133 629
23	emotion$.tw.	74 926
24	reassurance.tw.	2693
25	(cognition or cognitive).tw.	126 603
26	patient education.tw.	8490
27	patient knowledge.tw.	603
28	anxiety.tw.	73 763
29	quality of life.tw.	89 541
30	risk perception.tw.	1162
31	or/10–30	1 248 390
32	health services research/ or health care surveys/ or "health services needs and demand" / or needs assessment/ or organizational case studies/	93 119
33	Patient-Centered Care/	6220
34	31 or 32 or 33	1 303 261
35	3 and 9 and 34	288
Additional search conducted after 'compliance' added as outcome factor in inclusion criteria		
Database(s): Ovid MEDLINE(R) 1996 to October Week 1 2010		
1	(compliance and melanoma).mp. [mp = title, original title, abstract, name of substance word, subject heading word, unique identifier]	76
2	from 1 keep 9, 74	2

Inclusion/exclusion criteria

Included

- Empirical study (any design) AND
- Population = stage I or II cutaneous melanoma undergoing post-treatment follow-up AND
- Study factor (intervention) = routine follow-up (services/care/processes/procedures) AND
- Outcome factors = expectations and preferences, or experiences, effects and/or psychosocial outcomes of melanoma follow-up. Also included were studies of patient and clinician adherence with follow-up schedules.

Excluded

- Reviews, opinion pieces or editorials OR
- Did not include stage I/II cutaneous melanoma OR
- Not routine post-treatment follow-up OR
- Study of routine follow-up but no psychosocial factors examined OR
- Psychosocial factors examined in patients with melanoma but not in relation to follow-up (e.g. studies of the effects of the diagnosis and/or treatment and/or experience of melanoma OR psychosocial factors as baseline predictors of clinical outcomes).

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Table A1. Summary of studies — quantitative:

Study	Focus	Country and year	Study design	Population	Sample (*response rate*)	Psychosocial variables	Data collection
Baughan *et al.* [10]	Experiences (patients) Preferences (patients)	England	Cross-sectional survey, part of larger audit of clinic and recurrence	Patients from pigmented lesion clinic, mel stage 1	133 (*83%*)	Emotional (anxiety, value follow-up); Behavioural (clinic function, sunbathing); Cognitive (knowledge, sources of information)	Mailed questionnaire
Brandberg *et al.* [23]	Experiences (patients)	Sweden 1989–1990	Observational — repeat survey at three periods (3, 10 and 23 months)	Patients of Oncology department, mel stage 1	Three periods: 1 = 144 (*95%*)/117 (*92%*)/100 (*83%*)	Emotional (anxiety, depression, sleeping problems, psychosomatic complaints); Cognitive (interest in nevi)	Self-complete questionnaire and HADS, first one in clinic, other two mailed
Dancey *et al.* [8]	Experiences (patient) Preferences (patient and clinician)	England	Cross-sectional survey	Patients on records of hospital clinic mel 0.1–15 mm and local GPs	231 (*76%*) patients 50 (*81%*) GPs	[Patients] Emotional (anxiety, feelings about and benefits follow-up) [GPs] Behavioural (willingness to participate shared follow-up care)	Mailed multiple choice questionnaires
Hombrey *et al.* [24]	Adherence (clinician)	England	Audit of practice — pre and post introduction of revised FUP policy	Consultants and junior doctors in hospital dept plastic surgery	4 consultants, 10 junior doctors, 50 patient episodes (pre and again post) (*responses not reported*)	Cognitive (knowledge of follow-up policies); Behavioural (compliance with policies)	No details
Kittler [26]	Adherence (patient)	Austria 1993–2001	Retrospective cohort — audit 5 years of patient records	Patients with university dermatology, invasive mel <1.5 mm	513 patient records (*all diagnosed 1993–1996*)	Behavioural (compliance with attending follow-up)	Review of patient records
Mijnhout *et al.* [33]	Adherence (clinician)	Netherlands 1998	Cross-sectional survey and retrospective audit of practice	Clinicians at academic and nine regional hospitals	20 (100%) clinicians (13 surgeons, 5 dermatologists and 2 internists)	Cognitive (awareness, agreement with guidelines); Behavioural (ordering routine diagnostic tests and reasons)	Mailed survey. Plus audit of patient records
Murchie *et al.* [27]	Experiences (patient) Adherence (clinician)	Scotland 2005–2006	RCT of GP-led follow-up — with outcomes measured by pre–post patient survey and GP practice audit	GP patients and GPs participating in RCT	142 (*68%*) patients, 35 (*42%*) GP practices participated in RCT (*follow up 96% patient survey, 100% audit GP practice*)	[Patients] Emotional (anxiety, depression, satisfaction with follow-up) [GPs] Behavioural (adherence to follow-up protocol)	Mailed survey on satisfaction SF-36, HADS. Plus audit of practice from patient files
Nashan *et al.* [32]	Experiences (patient)	Germany	Cross-sectional survey	Patients from university hospital skin cancer clinic, mel stages 1, 2 and 3	462 (*response not reported*)	Emotional (reassurance, use of psychosocial support); Behavioural (follow-up received, self-examination)	Self-complete questionnaire in waiting room
Schiffner *et al.* [25]	Adherence (patient) Experiences (patient)	Germany	Cross-sectional survey and 6 months observation of compliance (part of larger cohort study)	Patients with melanocytic naevi (17% with mel) in dermatology clinic	140 (*46%*) joined FUP programme 101 (*33%*) completed survey	Behavioural (uptake and participation in follow-up, compliance with schedule, reasons for non-compliance), Emotional (quality of follow-up)	Mailed questionnaire and audit of compliance

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Sollner *et al.* [21,22]	Preferences (patient)	Austria	Cross-sectional survey	Outpatients in dermatology clinic and inpatients (with 9% treated for metastases), including all mel stages 1, 2, 3 and 4	215 (*91%*)	Emotional (anxiety, satisfaction with received psychosocial support, interest in additional support and alternative therapies)	Self-complete questionnaires — authors own, Hornheide and Freiburg
Qureshi *et al.* [31]	Preferences (patient)	USA 2002	Cross-sectional survey	Patients from dermatology clinic, mixed group of mel and psoriasis patients	50 with psoriasis 42 with melanoma (*response not reported*)	Behavioural (willingness-to-pay hypothetical for telemedicine with faster access and convenience)	Face-to-face questionnaire completed at hospital

Table A2. Summary of studies — qualitative

Study	Focus	Country and year	Study design	Population	Sample	Psychosocial variables	Data collection	Data analysis
Murchie *et al.* [28]	Experiences (patient)	Scotland 2005–2006	Qualitative evaluation in RCT of GP-led follow-up	GP patients, mel 1–4 mm diagnosed 3–10 years prior	18	Practical experiences and feelings about GP-led melanoma follow-up	Telephone interviews	Thematic analysis
Murchie *et al.* [29]	Experiences (clinician)	Scotland 2005–2006	Qualitative evaluation in RCT of GP-led follow-up	GPs in RCT intervention arm	17	Practical experiences, pros and cons for GP-led melanoma follow-up	Telephone interviews	Thematic analysis
Murchie *et al.* [30]	Preferences (patients and clinician) Experiences (patients)	Scotland	Qualitative description of intervention planning and pilot study	GPs and their patients	14 GPs 9 patients 6 patients in pilot	Feasibility, desirability and essential components of GP-led melanoma follow-up	Telephone interviews	Thematic analysis

Table A3. Study appraisal — quantitative[a]

Study	Target population clearly defined?	Are the individuals selected to participate in the study likely to be representative of the target population?	What % of the selected individuals agreed to participate?	Were the data collection tools shown or are they known to be valid?
Baughan *et al.* [10]	Yes — patients by clinic, condition, time since diagnosis and dates	Very likely — all patients with follow-up appointments in 6 months period (dates not given), survey mailed prior to appointment	80–100%	No — details not provided
Brandberg *et al.* [23]	Yes — patients by clinic, condition, time since diagnosis and dates	Very likely — consecutive patients visiting clinic for first follow-up in 12 months period	80–100%	Yes — questionnaire used in authors previous study, plus validated HADS instrument

Table A3. *Continued*

Study	Target population clearly defined?	Are the individuals selected to participate in the study likely to be representative of the target population?	What % of the selected individuals agreed to participate?	Were the data collection tools shown or are they known to be valid?
Dancey *et al.* [8]	Partly — patients by clinic and condition, clinicians as GPs in local area serviced by clinic	Very likely — all patients on current clinic records and random sample of local GPs	Patients 60–79%, GPs 80–100%	Yes — both questionnaires provided in paper, patient survey piloted
Hormbrey *et al.* [24]	Partly — clinicians by hospital, conducting follow up	Somewhat likely — audit of practice based on previous 50 patient episodes	Not reported	No — details not provided
Kittler *et al.* [26]	Yes — patients by clinic, condition, time since diagnosis and dates	Very likely — all records of consecutive patients in defined time period	80–100%	Yes — audit classification criteria provided in paper
Mijnhout *et al.* [33]	Yes — clinicians by hospital, conducting follow-up and dates	Somewhat likely — unclear from text how selected or if all involved in follow-up	80–100%	Yes — questionnaire provided in paper
Murchie *et al.* [27]	Yes — GP practices by region and date, patients by GP practice, region, condition and date	Very likely — all patients eligible for follow-up from hospital and GP records. All GP practices invited, participants randomized, stratified by size of practice	Patients 60–79%, GP practices less than 60%	Yes — questionnaire has some reliability data, plus validated SF-36 and HADS instruments
Nashan *et al.* [32]	Partly — patients by clinic and condition	Somewhat likely — unclear from text	Not reported	Yes — questionnaire provided in paper
Schiffner *et al.* [25]	No — patients by clinic only, and% with melanoma in sub-study unknown	Not likely — composition of patients in compliance study sample unknown but not >17%	Less than 60%	No — details not provided
Sollner *et al.* [21,22]	Partly — patients by clinic and region	Very likely — representativeness of sample to region confirmed	80–100%	Yes — questionnaire piloted and validated by authors, plus validated Hornheide and Freiburg instruments
Qureshi *et al.* [31]	Yes — patients by clinic, condition and dates	Somewhat likely — letters and ads, selected on first come first served basis	Not reported	Yes — WTP scenarios and nature of questions provided in paper

[a]**Criteria adapted from Quality Assessment Tool for Quantitative Studies, EPHPP, McMaster University (http://www.ephpp.ca/tools.html) [17].**

Table A4. Study appraisal — qualitative[a]

Study	Were the researcher characteristics described?	Was the methodological orientation to the study described?	Was the target population clearly defined?	Was the sampling strategy clearly described?	Were data collection methods clearly described	Was data analysis clearly described
Murchie *et al.* [28]	Yes — interviews and analysis conducted by first author, GP who designed intervention	Yes — rationale derived from framework presented in earlier paper [30]	Partly — all patients in RCT intervention arm attending rural and urban GP practices in Grampion region north west Scotland,	Yes — purposive sampling, representative of RCT participants	Yes — single telephone interview, taped	Yes — staged thematic analysis, with second researcher conducting

	and conducted RCT. Second GP contributed to analysis		melanoma stages not identified, dates not given	by personal characteristics and place of residence	and transcribed, topics for interview schedule provided	independent coding with good concordance.
Murchie *et al.* [29]	Yes — interviews and analysis conducted by first author, GP who designed intervention and conducted RCT. Second GP contributed to analysis	Yes — rationale derived from framework presented in earlier paper [30]	Yes — GPs participating in RCT from rural and urban practices in Grampion region north west Scotland, dates not given	Yes — all participants in the RCT intervention arm	Yes — single telephone interview, taped and transcribed, topics for interview schedule provided	Yes — staged thematic analysis, with second researcher conducting independent coding with good concordance.
Murchie *et al.* [30]	Yes — first author, GP, conducted interviews, and composition of steering group responsible for developing intervention provided	Yes — first two stages of UK MRC framework	Partly — composition of steering group given, partial criteria for patients attending hospital follow-up and GPs involved in pilot	Partly — steering group representatives of stakeholders, patient sampling not detailed, GPs — purposefully sampled by geographic location	Partly — development stages of MRC framework described, interview schedule not provided	Yes — thematic analysis, with specific focus on practical points to refine intervention and discordant views relative to participant characteristics

[a]**Criteria adapted from Tong *et al.* [18].**

Table A5. Key findings from individual studies — patients

Review section	Country (study type)	Findings from individual studies
Patient preferences	US (willingness-to-pay) [31]	73% preferred telemedicine over face-to-face consultations if former provided a faster response, 95% willing to pay $25 (range $5–500) for this option. Less value placed on convenience of telemedicine as 19% preferred this when the waiting time was equal.
	England (survey) [10]	84% preferred regular scheduled appointments compared with 'walk-in when necessary clinic' (7%) or both (5%).
	Austria (survey) [21,22]	60% wanted emotional support counselling (sample included people with all stages of melanoma) and of those 64% preferred it to be from their oncologist than a psychiatrist or psychologist (36% preferred both).
	Scotland (qualitative interviews) [30]	Anticipated benefits of GP-led care: reduced travel and related costs, better access to appointments, continuity in seeing the same person at each visit, GP less intimidating than hospital and more time to do full skin examinations, provide education about melanoma and answer questions. Patients wanted GPs to receive training and rapid referrals to specialist when required.
Patient experiences: satisfaction	Scotland (RCT) [27]	Satisfaction with GP-led follow-up (hospital control) significantly greater due to ease of making appointments, same day doctor availability, shorter waiting times, thorough examination by doctor, access to additional prescriptions, knowing the doctor well. No significant difference in health status, anxiety or depression between intervention and control at baseline or outcome.
	Scotland (qualitative interviews) [28,30]	GP-led care more convenient (proximity, time and accessibility), familiar, friendly, less clinical. GP better able to consider melanoma in context of whole person. Patients also felt more in control of their care as GPs gave detailed instruction on self-examination and what to do and who to contact if they became worried.
	England (survey) [10]	86% rated follow-up as 'very worthwhile', with 5% reporting it was 'more trouble than it's worth' or 'waste of time'. 98% felt waiting times were 'short' or 'acceptable', 95% that length of time with the doctor was 'adequate'.
	England (survey) [8]	98% found follow-up 'useful' because they were reassured (90%), examined for new disease (72%) and able to ask questions (71%). Reported problems included: attending the clinic site (23%), parking (19%), transport (8.7%) and finances (7.4%).
	Germany (survey) [25]	76% reported clinical examinations were 'very good', 20% 'good' and 1% 'satisfactory'. 86% said recall letter system 'very good' or 'good'. Reported obstacles: 'driving time too long', 'waiting time in clinic too long' and 'recall letter came too late'.

Table A5. *Continued*

Review section	Country (study type)	Findings from individual studies
Patient experiences: anxiety and reassurance	England (survey) [10]	54% reported anxiety; of these for 32% it began over 24 h prior to appointment and 9% had associated physical symptoms including diarrhoea, nausea, and sleeplessness.
	England (survey) [8]	53% reported anxiety prior to follow-up; with 6% feeling 'very' or 'extremely' anxious. 41% were anxious mostly on the day of the appointment, but 7% reported feeling anxious up to several weeks prior to appointments.
	Sweden (longitudinal survey) [23]	16%, 20% and 19% scored above the clinical cut-off point for anxiety, and 6%, 6% and 7% scored above cut-off points for anxiety and depression at 3, 10 and 23 months post-diagnosis.
	Scotland (qualitative interviews) [28]	Follow-up valued as source of reassurance but some expressed less confidence in GP compared with hospital-based specialists who they believed better able to provide definitive diagnosis or immediate reassurance if a new lesion was identified.
	Germany (survey) [32]	90% said follow-up was important source of reassurance. Reported use of psychosocial support services: 21% Munster, 11% Cologne.
Patient experiences: knowledge and behaviour	England (survey) [10]	51% said they knew 'much more' than pre-diagnosis, 38% 'a little more' and 11% 'no more'. Main sources of information: follow-up clinic doctor, books and magazines, and clinic nurse. 74% reported increased use of sun screen, seeking shade or covering up, and 71% advised children, grandchildren and others of the dangers of excessive sun exposure.
	Germany (survey) [32]	25% Munster and 54% Cologne attended hospital clinic plus dermatologist; 3% Munster and 5% Cologne attended clinic plus family doctor; 2% Muster and 4% Cologne attended all three. 76% Munster and 70% Cologne conducted own skin checks between visits.
Patient adherence to schedules	Austria (audit of records) [26]	Cumulative proportion attending 5 years post-diagnosis was 55%; of these, 50% not compliant with time schedule, that is, extended interval >1 year at least once over a 5-year period. Mean annual drop-out rate (11%) not influenced by age, sex or tumour thickness.
	Germany (survey) [25]	46% those with melanocystic naevi agreed to join follow-up programme (17% had melanoma). Of those who joined programme, 14% did so for more than 3 years, 23% for 2 years, 48% for 1 year and 15% less than 1 year. 92% reported always keeping examination date.

Table A6. Key findings from individual studies — clinicians

Review section	Country (source)	Findings from individual studies
Clinician preferences	Scotland (qualitative interviews) [30]	GPs not initially enthusiastic to take on follow-up; concerns included workload and limited experience, with reduced reassurance and greater risk for patients. Identified potential benefits for GPs: involvement in melanoma care, increased skills and knowledge, and freeing up of specialists. Wide agreement GPs needed extra training, defined protocols, specialist support and additional resources to participate in trial of GP-led care.
	England (survey) [8]	30% GPs willing to conduct melanoma follow-up as part of a shared care arrangement with annual reviews of patients in hospital outpatient visits. Majority did not wish to participate because of lack of time (25%), lack of experience (27%) and lack of resources (16%).
Clinician experiences	Scotland (qualitative interviews) [29]	GPs participating in RCT of GP-led care reported feeling comfortable in the role and able to function effectively, with little reported disruption to their practice. Positive experience attributed to training, protocols, patient recall system, and rapid referral pathway to specialists.
Clinician adherence to schedules	Scotland (RCT) [27]	98% of those attending GP-led follow-up over 12 months were seen according to the guidelines on frequency of follow-up relative to tumour thickness and time since diagnosis, compared to only 81% of those attending the local hospital. In the 12 months preceding the intervention, 85% of patients in both the intervention and control group had the recommended number of follow-up visits.
	England (audit of records)[24]	Specialists ($n = 4$) responsible for melanoma patients each had different follow-up policies, and one in 10 junior doctors aware of those policies. 48% patient episodes not conducted according to consultant's policy, and of these, 26% were incorrectly followed up. Following brief intervention to standardise practice, 28% of patient episodes not conducted according to new standardised policy, and of these 12% incorrectly followed up.
	Netherlands (survey and audit) [33]	Clinicians knew about consensus guidelines, $n = 1$ disagreed with content saying recommended frequency of follow-up too high. No institution protocols differed to the guidelines that recommended no routine imaging or laboratory tests. Additional blood testing performed in 25% of patients and additional diagnostic imaging (X-ray, CT scan of chest or ultrasound of liver) performed in76% patients. 60% clinicians said diagnostic tests had important reassuring effect for patients, and 75% reported patients requested the additional tests.

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Conflict of interest

The authors have no financial or commercial interests in the subject of this study.

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