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Xiaohang Wu and Haotian Lin*

State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangzhou, China

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***Corresponding author:** Haotian Lin, Zhongshan Ophthalmic Center, Xian Lie Nan South Road #54, Guangzhou, Guangdong Province, China, 510060; E-mail: gddlht@aliyun.com; haot.lin@hotmail.com

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Research Article

Patient Adherence to Follow-Up in Clinical Research: A Systematic Review of Measurements, Associated Factors and Intervention Strategies

Abstract

Objectives: A patient's adherence to follow-up (AFU) plays a key role in the implementation of clinical research with respect to cost and validity. Most present studies focus exclusively on some specific steps during clinical research implementation, regardless of the synthetic action of patient-society-medicine system. The objective of the study is to provide a comprehensive systematic review of the measurements, associated factors and intervention strategies of AFU across a broad spectrum.

Methods: A search was performed for studies that reported AFU in English in Medline, EMBASE, PubMed or the Cochrane Library from January 1995 to February 2014. Given the huge variety in study design and multifold complexity, a qualitative systematic review instead of meta-analysis was performed for the measurements, associated factors and intervention strategies of AFU according to Cochrane methodology.

Results: A total of 125 included studies identified six measurements of AFU according to different definitions and calculations; the majority of studies used follow-up rate, with calculation methods varying in numerators but with the same denominator. The factors associated with AFU were assigned to 5 major categories, of which "individual patient characteristics" and "research design and practice setting" were most studied, with respect to having the most subcategories (12) and most related studies (76/125) respectively. The most studied type of the 3 major interventions used to improve AFU was information system and interaction improvement (56/99).

Conclusions: The number of published studies regarding the measurements, associated factors and intervention strategies of AFU is increasing, which contributes to improving the final quality of clinical research. Individual patient-centered information system and interaction improvement have been gaining most attention, and would be the most important direction of development to improve patient AFU. While, the function of multiaspect environment factors and research design enhancement remain to be noticed.

Introduction

The term follow-up refers to the timely surveillance of health status and guidance on a medication regimen for patients who have been treated by medical staff through a variety of methods [1]. It is now well accepted that follow-up plays an irreplaceable role in chronic disease management, detecting complications associated with a surgery, collection outcome data and diagnosis of recurrent disease [2-5]. Increasing numbers of studies have reported that the treatment effect and prognosis of disease are significantly related to adherence to follow-up (AFU), including studies of coronary artery diseases [2], cerebral infarction [6]. Diabetes [7], asthma [8], chronic kidney disease [3], obesity [9], chronic sinusitis [10], cataract [11], and amblyopia [12]. In addition to the treatment effect [13]. AFU can seriously affect clinical research, such as by undermining the internal and external validity of the findings and causing bias, increasing the cost or duration of the trial or delaying important results [14]. However, the measurement of AFU varies in different studies, and there is still a lack of research focusing on standardizing methods for calculating AFU. Moreover, various influencing factors of AFU have been reported in different studies, in which different intervention strategies for AFU were used. The increasing variety of measurement, associated factors and intervention strategies of AFU existing in published studies reflect an increasing awareness of the importance of AFU by clinical investigators. Gaining a systematic understanding of these considerations will be an important step in improving the quality of clinical research. As we previously reported, mobile information technology, short message service (SMS) and telephone included could significantly improve FUR [15]. However, to our knowledge, there is still no systematic review addressing this goal. In the present study, we aimed to systematically assess the meaning of AFU, evaluate the measurement methods used in previous studies, identify influencing factors associated with AFU and explore effective intervention improvements, which would offer guidance in development directions to improve patient AFU.

Methods

Literature sources

A comprehensive search of databases from January 1995 to

February 2014, including Medline, EMBASE, PubMed, and the Cochrane Library, was conducted using the combined following key words searched in the title or abstract: "follow-up"; "adherence" or "compliance"; "clinical research"; "measurement", "follow-up rate" "factors" or "intervention". These databases were selected because they were considered to contain a high proportion of widely read and practice-changing clinical studies covering a broad range of medical aspects. We also searched conference abstracts and the reference lists of the studies identified by the search. Only English-language journal articles or those with English abstracts containing adequate information to be extracted were included. Two authors independently screened titles and abstracts to determine potential eligibility for this systematic review. When screening discrepancies occurred, consensus was achieved after further discussion.

Inclusion and exclusion criteria

We carefully reviewed all potentially relevant articles that included studies of measurement, associated factors and intervention strategies of AFU. The inclusion of the studies was not restricted to study design ranging from observational study (retrospective and prospective included) to randomized controlled study, relevant comments and reviews are also included to achieve a better coverage. The studied patients or population size were not restricted. For the studies relevant to measurement to AFU, specific AFU calculation formula or measurement strategy should be mentioned to be included; The eligible articles concerning associated factors and intervention strategies of AFU should have collected or statistical data to indicate direction and magnitude of associated factors or intervention strategies to AFU, so as to guarantee methodological rigor and validity of this study. Studies with duplicate data were excluded, and the newest and most informative article was selected when multiple studies were conducted by the same authors.

Date extraction and outcome measure

Adhering to the international systematic review guidance of the Cochrane Collaboration, the data from each eligible study were extracted independently by two reviewers to rule out subjectivity in the data gathering and entry processes. The extracted data were independently recorded into separate databases by both investigators. The two completed databases were compared and discussed between the two investigators until a consensus was reached. We did not contact the authors of the eligible studies for additional data. AFU (or a related term) was a primary outcome of our study. Previously designed data abstraction forms and data manuals were used to capture information regarding study methodology, measurements, associated factors and intervention strategies of AFU. We identified all definitions, measurements and calculations of AFU. The factors associated with AFU were classified into major categories and subcategories. Intervention strategies to promote AFU were also recorded, classified and sub-classified.

Statistical analysis

Trends in published AFU studies were compared across study periods (2005–2014 versus 1995–2004). The studies were also classified by study design. Studies that focused on measurements, associated factors and intervention strategies of AFU were classified, calculated and analyzed. Diversity in category and sub-category strategies for each part can mostly be explained by the differences in the collected information from included studies, and the innate nature for each item. 6 methods for measurement of AFU are derived according to definition of follow-up, ranging from a consultation with a physician to completion of all recommended testing or diagnostic resolution. Category method for intervention strategies was consistent with the major aspects of associated factors, however less items were listed than the latter, for the included study appeared in smaller number and more focused research objectives. Associated study number for each sub-category was counted respectively. Total numbers for the major categories were calculated considering the overlap for the subcategories among the studies, for instance, a study which talked of age as an associated factor will possibly mention sex, or education, meanwhile. All statistical analyses were performed using the software SPSS version 17 (SPSS Inc., Chicago, IL, USA).

Results

Study selection

Of the 12359 articles initially identified, 18 articles were excluded because they were duplicate publications. After screening the titles and abstracts, an additional 11974 articles were excluded. The remaining 367 articles were reviewed in full text. After the full text review, 242 articles were excluded because they did not involve AFU. At the end of this culling process, 125 articles were selected for the systemic review. Figure 1 shows a flow diagram of the selection process for the relevant studies.

Study characteristics

The number of published studies that were related to AFU showed a significant increasing trend from 47 studies during 1995-2004 to 78 studies during the last decade. The study types that

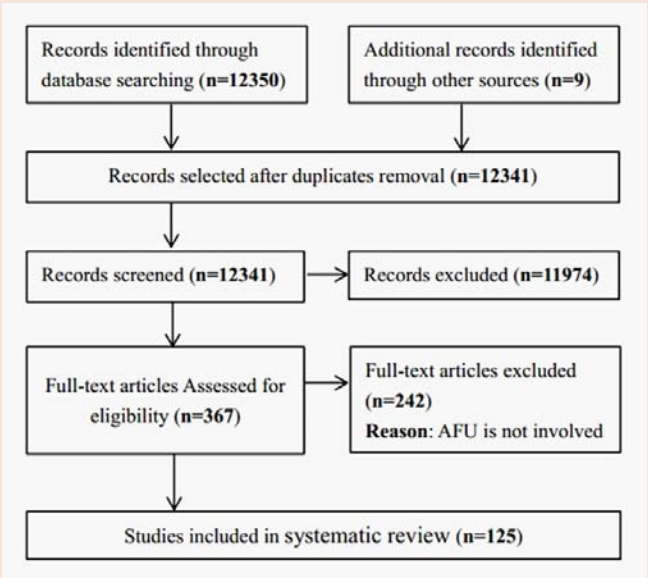

Figure 1: Flowchart of the literature search for the included and excluded studies.

were included consisted of 36 reviews, 35 observational studies, 32 randomized controlled trials, 17 retrospective studies, 4 comments and 1 prospective study. The included studies originated from the United States (85), Europe (22), Asia (8), Australia (8) and Canada (2). Providing great diversity in study design for the studies included, together with the purpose to illuminate different aspects of considerations for AFU, the present systematic review was performed.

Quantitative measurements of AFU

The follow-up rate (FUR) was the most widely accepted and recognized measurement index of AFU, while attendance rate, retesting rate and screen rate were also identified in various research backgrounds. Six different calculation methods were identified in the included studies (Table 1). FURs were identified in the majority of studies (123/125); although the numerators varied, all shared the same denominator. Only two studies marked the FUR with a corresponding "time label"; for a clinical trial in which outcome data will be collected at different time-points, the corresponding FUR should be given at the same time.

Factors associated with AFU

The factors associated with AFU that were identified in our included studies were classified into 5 major categories: individual patient characteristics, social supports, medical staff characteristics, research design and practice setting and public health care policy. Each of these major categories was subcategorized into 12, 3, 7, 5 and 3 subcategories, respectively (Table 2). The factor of "individual patient characteristics", "research design and practice setting" were most studied, with respect to having the most subcategories (12) and most related studies (76/125) respectively.

Intervention strategies to promote AFU

In the included studies, the intervention strategies that were designed to promote AFU were classified into 3 major categories: patient and family support management, information system and interaction improvement and research design enhancement. Each of these categories was subcategorized into 4, 3 and 3 subcategories, respectively (Table 3). Information system and interaction improvement was the most studied intervention strategy (56/99), and research design enhancement was the least studied.

Discussion

Clinical trials differ from laboratory studies in that clinical trials involve human beings, who usually require follow-up at different time points to collect information for the study objectives [16]. Therefore, the AFU of the participants seriously affects the implementation of clinical research [17], can undermine the internal and external validity of the findings and can cause bias. Participant loss to follow-up usually necessitates higher participant enrollments to attain adequate power for valid trial results. Higher enrollments may increase the cost or duration of trials or delay important results [16]. In our present systematic review, we provided a systematic review of the measurements, associated factors and intervention strategies of AFU, offering guidance in development directions to improve patient AFU, which is an important step toward improving the quality of clinical research.

Most of the published "follow-up" studies measured patient AFU, but the calculation methods differed according to the definition of "follow-up" and ranged from a consultation with a physician to the completion of all recommended tests and diagnostic resolution. In the present study, we identified six different calculation methods of AFU. Although, the majority of studies used FURs, here we emphasize and discuss the last two of these methods. Conventionally, patient loss to follow-up accumulates over time. A prospective, controlled Swedish study of obese subjects aimed to evaluate the persistent effect of bariatric surgery on lifestyle and metabolic and cardiovascular risk after 2 and 10 years; the follow-up rates for the laboratory examinations were reported as 86.6 percent at 2 years and 74.5 percent at 10 years [18]. In a prostate cancer study, 176 of 187 eligible patients had records available for follow-up (follow-up rate: 94%), but only 52 patients were followed for more than 10 years (follow-up rate: 30%) [19]. For multiple calculations, a study compared the measurement of complete diagnostic evaluations after a positive fecal occult blood test by utilizing external chart review, internal chart audit, administrative data review and a combination of chart and administrative data review. Depending on the methods used to obtain different measurements, the patient rates of receiving diagnostic tests ranged from 44 percent to 56 percent [20]. Yet one limitation should be emphasized here when evaluating the measurements of AFU. The relevant articles included in the systematic review are restricted to studies which mainly focus on measurement, associated factors and intervention strategies of AFU. However, each clinical research displays its own image in the area of follow-up, which makes it a complexity. For example, for a long term follow-up study, a randomized individual possibly has reached a time point before he has the chance of loss to follow-up [21]. It is entirely consistent with follow-up for vital status in cancer trials, while contributes to underestimation of probability of loss to follow-up. Further detail studies remains to be seen. In addition to the six quantitative calculation methods of AFU that are presented in Table 1, AFU was also qualitatively evaluated with six follow-up scales. Qualitative evaluation is often observed in studies that are designed to evaluate the influence of AFU on treatment efficacy

Table 1: Calculation methods of AFU.

Index defined	Calculation methods	Studies
Follow-up rate	Number of patients completing recommended follow-up ÷ Number of eligible patients enrolled	30
Follow-up rate	Number of patients completing all, some or none of the appropriate follow-up ÷ Number of eligible patients enrolled	54
Follow-up rate	Number of patients with at least one additional test ÷ Number of eligible patients enrolled	33
Follow-up rate	Number of patients with a diagnostic resolution ÷ Number of eligible patients enrolled	6
Timely follow-up rate	Number of patients completing follow-up at different time-points ÷Number of eligible patients enrolled	2
Multiple calculations	Compared measurements by external chart review, internal chart audit, administrative data review and a combination of chart review and administrative data review	1

Table 2: Factors associated with AFU.

Major Category	Subcategory	Studies
1. Individual Patient Characteristics	Socioeconomic status	5
	Difficult access to care	5
	Lack of insurance	3
	Race	5
	Age	21
	Gender	14
	Education level	11
	Marital status	8
	Functional impairment	3
	Lack of transportation and child care	6
	Knowledge and understanding of the research (fear and coping)	6
	Health status (pregnancy, HIV status, addiction, domestic violence, cognitive performance, verbal intelligence and comorbidities)	4
Total		54
2. Social Support	Family support	8
	Friend support	4
	Healthcare provider support	5
Total		12
3. Medical Staff Characteristics	Physician-patient communication (regarding risk, medication choice, results and necessary follow-up)	13
	Communication among providers	8
	Transparency of the informed consent document	1
	Relationship among the study coordinator, care providers and participants	9
	Consistency in protocols for maintaining contact with participants	2
	Failure to refer for further testing	3
	Physician's lack of adherence to guidelines	1
Total		28
4. Research Design and Practice Setting	"Control group" attrition	1
	Therapy-related factors (route of administration, complexity of treatment, duration of treatment period, side effects of medication, degree of required behavioral change, taste of medication and requirements for drug storage)	26
	Reminder system	39
	Organizational structural characteristics (waiting times, on-site specialists and technology options)	7
	Case managers or navigators	3
Total		76
5. Public Health Care Policy	Professional norms	2
	Evidence-based guidelines for follow-up diagnosis	1
	Quality expectations and benchmarks	1
Total		4

Table 3: Intervention strategies to promote AFU.

Major Category	Interventions	Studies
1. Patient and Family Support Management	Patient education (workshops, informational materials and telephone and in-person counseling)	12
	Support network enhancement	9
	Transportation assistance	5
	Case management	2
Total		28
2. Information System and Interaction Improvement	Improve clinician reminders (short message service, electronic mail, telephone and paper record)	39
	Delivery system design	8
	Promote positive collaborative relationships	9
Total		56
3. Research Design Enhancement	Pre-randomization ("run in" and "testing")	2
	Active control strategy	2
	Develop a reasonable regimen protocol	11
Total		15

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or outcome. Lin Ailing [22], conducted a trial to analyze AFU and factors that influence AFU in elderly arrhythmic patients implanted with a cardiac pacemaker. Each enrolled patient received a follow-up evaluation by a questionnaire composed of the following 4 questions: (1) Can you attend regular clinic visits according to the follow-up plan? (2) Can you make self-surveillance on your pulse under medical instructions? (3) Can you come back to the clinic on the occurrence of an abnormal pulse rhythm? And (4) Can you accept long-term follow-up by medical staff? "Good compliance" was only reported when 4 answers of "completely yes" were received; otherwise, the patient was considered to be in "bad compliance". Another trial investigated clinical AFU after endoscopic sinus surgery in patients with chronic rhinosinusitis [23]; the postoperative effect "good compliance" referred to the postoperative patients who adhered to clinical follow-up for at least 6 months and 5 times; otherwise, the patients were considered to be in "bad compliance".

Improved awareness of the five factors associated with AFU will aid in the selection of priority objectives and will guide interventions. In addition to improving AFU, this knowledge will eventually improve the quality of clinical research. The first factor, the relationship between individual patient characteristics and AFU, has received increased attention and is the most important. In the subcategory analysis, a representative study concerning follow-up for abnormal Papanicolaou tests indicated that young age, minority race and low socioeconomic status were risk factors for non-adherence to recommendations [24]. The second major factor was social support, which helps patients reduce negative attitudes toward treatment and motivates patients to remember to implement the treatment. Studies also showed that patients who had emotional support and help from family members, friends or healthcare providers were more likely to comply with the treatment [25]. Interestingly, issues of cultural context, social support (instrumental and emotional) and related social network factors have also been found to enhance and to reduce Papanicolaou and mammography test AFU among African American and Hispanic women [26-28]. However, inconsistent evidence may reflect differences in measurement or personal preferences that affect the appointment scheduling decision. Studies have also explored selected physician factors and their relationship to follow-up after abnormal results. The importance of communication between patients and physicians regarding risk, medication choice, results and necessary follow-up was frequently noted [29]. Wolf illustrated the complexity of communication tasks, such as describing the procedure, advance preparation, benefits and risks, and demonstrated that physician self-reporting of the completion of these tasks was significantly higher than was observed in a separate video sample [30]. However, few studies have actually assessed the completion of communication regarding the discrete steps that are necessary for follow-up. The complexity of this communication, not only with the patient but also between providers at other locations, reinforces the importance of focusing on steps that would enhance a successful transition. These steps include transparency of the informed consent document; a strong relationship among the study coordinator, care providers and participants; and consistency in protocols for maintaining contact with participants to decrease patient attrition [31]. Physician decision-making and failure to refer for further testing can contribute to follow-up failure [32,33]. This failure may be due to a physician being unaware of an abnormal test result or choosing not to refer. Physicians' lack of adherence to follow-up guidelines has also been described and has been noted in diagnostic follow-up after fecal occult blood test screening in the elderly [34]. Other provider-related characteristics include board certification, years in practice, specialty, perceptions of severity gender and staff sensitivity [26,27]. Additional factors that may increase the likelihood of attrition include a large number of follow-up tests and study designs with control groups that receive no perceived benefit. Some participants have withdrawn from studies following the intervention phase because they are no longer provided with therapies even though study visits continue to occur [17]. Reminder systems for providers and for patients (mail and phone) have been frequently and consistently cited as being significantly beneficial, as have other information tracking systems [35]. In several studies, organizational structural characteristics, such as waiting times and the presence of on-site specialists and tracking technology, have demonstrated a positive relationship with AFU [35]. Several studies discussed a growing interest in the relationship between case managers or navigators and adherence, including the impact on the prevalence of follow-up after abnormal tests. Navigators may essentially tailor intervention [36]. Another important factor in relation to AFU is public policy and federal initiatives [37]. Given the importance of insurance, including the benefit structure within insurance policies [38], public policies impact follow-up by enabling patients to access and receive testing. Professional norms have been influenced by the promulgation of evidence-based guidelines for breast, cervical and colorectal cancer screening [39]. These norms include evidence-based guidelines for follow-up diagnosis [40,41]. Quality expectations and benchmarks, such as the Healthcare Effectiveness Data and Information Set, have been shown to influence health plan and provider performance in screening [42].

A comprehensive understanding of the multiple related factors of AFU and their associated interfaces provides a foundation for improving interventions. The present study has also shown that three intervention strategies can improve follow-up, although the mechanisms of action are unclear. The first category of strategies is patient and family support management. Studies addressing patient self-management emphasized the importance of patient education in various ways [26,35]. Several of these studies reported a guiding theoretical model or framework. The interventions were usually designed to address several patient-level characteristics that were mentioned above, including knowledge deficits, fears, forgetfulness, family member support and other support networks that promote patient involvement in research; family therapy referral was also considered [43]. The second category of strategies, which is the most important, is information system and interaction improvement. Studies of interventions to improve clinician reminders have shown significant and consistent effectiveness for almost all of the study types. Reminders can especially be used to modify the behavior of unintentionally non-adherent patients [44]. Such systems can cue the physician and remind the patients about the recommended follow-up visits and abnormal test or diagnostic evaluations. Additionally, reminder systems can provide positive feedback for the regimen and AFU. Delivery system design strategies have been shown to directly affect the performance of follow-up testing and include the implementation of same-day and same-site testing, as these

strategies eliminate interfaces with other organizations, repeat visits to the study site and the process of appointment scheduling [45]. To promote positive, collaborative relationships between subjects and members of the research team, one person can be chosen as the primary contact for the study participants; this contact can cross-train all of the personnel so that they will be knowledgeable about the ongoing trials and properly respond to participant needs [14]. The last category of strategies was research design enhancement. A preventative approach for promoting adherence in effectiveness studies is recruitment screening to identify potential subjects at risk for compromised adherence. Recruitment screening requires excluding subjects who are at-risk for non-adherence by identifying histories of poor treatment adherence, inconsistencies with medical care (e.g., lateness or missed appointments) and problems with communication or ambivalence about participating. This preventative approach also includes effective communication about trial participation (e.g., explanation of informed consent, acceptance of random allocation and importance of adherence) [46]. For the "active control" strategy, a Neuro rehabilitation trial provided an alternative to participant remuneration; the alternative provided participants with the potential to derive a perceived benefit from study participation, even if they were not in the experimental group [14]. It must be emphasized that to develop a reasonable regimen protocol, the following 4 steps should be considered [16]: 1. Set goals with clear and realistic expectations; 2. Streamline the protocol to consider the minimum dosing frequency, number of pills and risk of side effects, as well as available materials and convenient packaging; 3. Develop a regimen that can be realistically integrated with patients' other daily activities; and 4. Enhance healthcare access by promoting comorbid condition treatment and addressing psychosocial factors.

The interpretation of the current study must be understood within the context of its strengths and limitations. The strengths of the study included that the broad range of content concerning the AFU spectrum gave a comprehensive understanding of measurement methods, associated factors and intervention strategies. Meanwhile, despite the descriptive character of the study, the relative strict eligible criteria requiring clear calculation method for measurement, specific data to indicate direction and magnitude of associated factors or intervention strategies improved methodological rigor and validity of this study. The weaknesses of the study must also be acknowledged. The huge variety in study design and multifold complexity made it impossible for a meta-analysis to quantitatively analyze the direction and magnitude of intervention effects. Despite these limitations, this study remains the first ever study to systematically assess the AFU in clinical research spectrum, evaluating the measurement methods used in previous studies, identifying influencing factors associated with AFU and exploring effective intervention improvements.

In conclusion, our study has demonstrated that the number of published studies regarding the measurement, associated factors and intervention strategies of AFU is increasing. The aim of these studies is to illuminate the nature of patient adherence to clinical research across a broad spectrum of patient conditions and improvement interventions. We also found that the majority of studies used different FURs to calculate AFU, that individual patient characteristics were the most important AFU-associated factor and that information system and interaction improvement was the most studied intervention strategy to improve AFU. Therefore, individual patient-centered information system and interaction improvement would be the most important direction of development to improve patient AFU, while, multiaspect environment factors and research design enhancement should be paid more attention. A full understanding of the measurements, associated factors and intervention strategies of AFU is an important step toward improving the quality of clinical research.

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