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Design of a handheld electronic pain, treatment and activity diary

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ABSTRACT

Effective tools for recording and analyzing data on patients' pain experience, use of pain treatments, and physical function are needed to improve communication between providers and patients with noncancer chronic pain. A handheld electronic diary (HED) that can be used throughout the day may provide more useful and accurate information about pain, treatments, and function than available paper and on-line diaries that are designed to be used once daily, weekly or less often. Based on user-specified requirements we designed and built a prototype HED with 7 modules. Diary queries are followed by multiple choice responses customized to the patients' expected responses. Usability testing confirmed user comprehension and acceptability of the queries, response sets, and interface.

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1. Project goals and design requirements

More than 50 million American adults suffer from noncancer chronic pain (NCCP) associated with spine disorders, osteoarthritis, neuropathy, trauma, headache, fibromyalgia, and other conditions [1–4]. Treatment of NCCP may include medication, injections, surgery, physical therapy, psychotherapy, meditation, and other complementary therapies. Primary care providers (PCP) and pain specialists play central roles in the management of adults with NCCP, including monitoring patients' pain and response to therapies.

Both adult patients with NCCP and their medical providers are dissatisfied with current management of NCCP and outcomes of treatment [5–8]. Patients report that providers do not appreciate the severity of their pain and its impact on their function and mental health. Providers report that they do not get enough credible information about patients' symptoms and function to make confident decisions about pain management. Regular monitoring of pain, pain triggers, treatment responses, and physical function is central to effective pain management [9–11]. But there are many barriers to gathering, analyzing, and communicating pain and activity data. Patients have a limited capacity for accurate recall of their pain and activities and have difficulty summarizing and communicating the salient details of the experiences they are able to recall.

Paper-based tools and on-line electronic diaries with limited reporting function are available and are usually designed to be completed daily or less often, so they do not capture hourly variation in pain and function and may overestimate the amount and intensity of pain [12,13] compared to immediate reports. Available pain reporting tools also are not widely used.

In theory a handheld electronic diary (HED) should be more accessible than an Internet diary that requires a personal computer (PC) for access and could be easier to use than a paper diary. In fact, there is substantial evidence that users favor HEDs over paper and on-line diaries. For many years HEDs have been successfully used in research studies on chronic pain and other conditions, and subjects' compliance with protocols calling for frequent data input has been excellent [14–18]. However, most published studies on chronic pain involving HEDs have used the Ecological Momentary Assessment (EMA) method, which calls for sampling, often randomly, a subject's waking moments [19–21]. The HED sounds an alarm when a moment is to be sampled, and the subject enters data about his/her pain experience at that moment. The objective is usually to explore associations between pain and other subject characteristics in data aggregated across many subjects. Creating an accurate daily profile of a single patient's pain with this method is possible only if there is little minute to minute and hour to hour variation in pain because immediate momentary pain is usually sampled every 2 h or less frequently. The alternative to EMA is to rely on subject recall, and this is the approach used by currently available individual pain diaries. Potentially significant limitations of the recall method are that patients must use idiosyncratic and poorly characterized cognitive processes to generate summary measures of pain over long periods of time and that average pain intensity may be overestimated compared to ratings obtained by EMA [22]. We are aware of only one published report of the use of a handheld electronic pain diary designed for clinical use by individual patients [23,24]. Most patients made only one entry each day. The authors provide some evidence that pain diary information when shared with a patient's medical provider sometimes lead to a change in therapy.

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Given evidence that many people are willing and able to use HEDs and, given the limitations of existing paper and electronic pain diaries, we sought to develop a handheld, electronic pain/treatment/activity diary (EPTAD) and an associated data analysis system that could effectively meet the needs of NCCP patients and their providers for information about pain, treatment, and activity. Because of concerns about the applicability of EMA methods to individual patients and the evidence for bias in long-term pain recall, we elected to rely on short-term recall of lowest, highest and average pain intensity over short periods (e.g. 2 h), based on an assumption that short-term recall may be more accurate than long-term (e.g. daily) recall. We decided to include physical activity and treatment modules in the diary, because pain experts emphasize improved physical function as the central outcome of successful pain management, and because knowledge of patients' actual use of prescribed treatments is key to judging treatment effectiveness. We hypothesized that recall for use of treatments and physical activity over a 2 h period may be reasonably accurate because the number of treatments and of basic activities for an individual patient is small. To facilitate rapid response to diary queries and to allow patients to track multiple pains and treatments, we also proposed to tailor patient response options to their usual pains, treatments and activities. Finally, we proposed to include utilities for reporting on acute pain experiences and antecedents, sleep and an overall comparative assessment of the pain experience over an entire day. The use of short-term recall, and the integration of treatment, activity, sleep and acute pain assessments into our diary are advances over both research and clinical pain dairies reported in the literature or available today.

Based on patient focus groups and early usability testing we identified key design requirements: (1) A touch screen interface at least 2 inches by 3 inches with 12 point or greater font and large buttons, (2) diary query sets consisting of multiple choice options that could be completed within 1–2 min, (3) Automated skip patterns so all queries presented are relevant to the context, (4) Query responses customized to the user's usual types of pain, treatments, and activities to reduce response time. (See Fig. 1 for screen shots.)

2. Prototype description

With funding from the Robert Wood Johnson Foundation (RWJF) through Project HealthDesign, and with input from patients/users, we developed the content, interface and navigation schema for 7 EPDAT modules. We also developed an outline of diary data analysis plans and some prototype data displays (See Fig. 2).

The Routine Pain, Activity, Medication and Non-Medication Treatment, modules are designed for use every 2–4 waking hours for one or more days to capture information about the preceding 2–4 h. The Acute Pain, Sleep, and End of Day Reports are completed at the time of acute pain, upon awakening, and before retiring, respectively. The pain, medication, and activity response sets are tailored to each user, who identifies his/her pains in his/her own language, types and strengths of medications, other types of treatments used, and locations and types of usual activities. These responses are entered into EPTAD software so only the custom responses are displayed for each query. Table 1 summarizes the content of the modules, and Table 2 shows queries and response sets for selected modules

3. Testing/evaluation results

We developed a functioning prototype of all the modules except for the Activity module. Prototype software was installed on a Hewlett Packard iPAq handheld device with a Windows Mobile operating system. Four users with NCCP participated in usability testing with a device that had response sets tailored to the user's profile. A consultant experienced in usability testing used a formal protocol and scenarios in the tests, which were videotaped and took about one hour each. The consultant reviewed the video tapes, took notes on user behaviors and dialogue that he deemed significant, then summarized the findings. Users received training in entering responses by touching the desired response on the screen, in scrolling down the screen to access longer lists of responses, and in using a "Next" button to move to the next screen. They read a scenario about a patient's recent pain experience and completed a Routine Pain Report on the device based on the scenario. Next they were asked to complete a Routine Pain Report based on their own experiences over the two previous hours. They then reviewed other scenarios and completed related End of Day, Acute Pain, and Sleep reports. They were asked to discuss the meaning of comfort levels, pain levels and "average" pain, and finally to provide general comments on their experience using the device.

Users reported that screen and font size were acceptable. They sometimes failed to review all response options because they did not see the prompt to scroll down for more responses. They also wanted a "back" button to return to earlier screens to revise answers. Some users had difficulty with number selection boxes that required tapping an arrow to change the number in the box. Users reported no difficulty in interpreting the comfort and pain scales or in selecting items from other response sets.

Users agreed that the device was easy to use and could help their doctors better understand their experiences. Most subjects reported that the device and related reports would probably be most useful for patients with new onset of NCCP and for themselves and others when there was a need for a change in treatment. Users did not spontaneously identify ways the device could help them personally improve pain management and were not queried about this.

Fig. 1. Screen shots of selected screens from the Routine Pain Report and the Routine Activity Report modules.

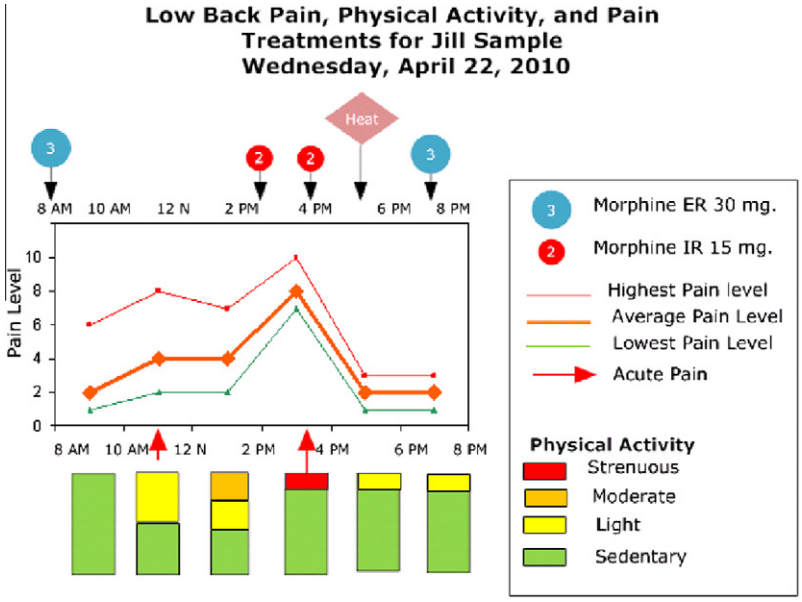

Fig. 2. Proposed design of graphical output developed from analysis of EPTAD data. The graphic combines data from the Routine Pain, Acute Pain Episode, Routine Medication and Non-Medication Treatment Reports to show the time course of one pain and associated treatments, activities and acute pains. The figure is designed to allow viewers access to basic summaries of each dimension (pain, treatment, activity) and also to explore complex pain patterns and their relationships to treatments and activities. The stacked bar graphs below the *x* axis depict physical activity for each 2 h period marked on the *x* axis above the bars. The amount of each bar occupied by a given color is an estimate of the proportion of the 2 h period occupied by the type of activity keyed to the color.

Table 1
Description of EPTAD modules.

Module	Data collected	Response sets tailored to patient
Routine Pain Report	*For each 2 h waking period:* • Overall comfort level over period (very uncomfortable to very comfortable) *For each reported pain experienced in period:* • Pain intensity score (0–10) (lowest, highest, average) • Duration of pain	Pains
Routine Medication Treatment Report	*For each reported use of medication* • Frequency of use during the previous period • Number of medication units used • Response to medication (if used for acute pain)	Medication name, strength
Routine Non-Medication Treatment Report	*For each treatment:* • Name of treatment • Response to treatment	Treatments
Routine Activity Report	*For each location and related activity:* • Duration of activity	Locations Activities
Acute Pain Episode Report	*For each pain episode:* • Type of pain • Peak intensity of pain (0–10) • Antecedent event/s (selected from list of common causes of acute pain) • Duration	Pain/s
Sleep Report	*For each daily sleep period:* • Use of medication at bedtime • Use of medication during the sleep period • Number of sleep interruptions • Overall quality of sleep • Duration of actual sleep	Medications
End of Day Report	*For each day:* • Overall comparative assessment of pain experience • Overall comparative assessment of activity • Overall assessment of mood	No tailoring

To test the interoperability of the EPTAD application with the Project HealthDesign prototype of a personal health record (PHR) database, we developed an application to synchronize EPTAD data on the iPAQ with the PHR database via an Internet connection and demonstrated successful data transfer of all data types, confirming the adequacy of the PHR data structures for storing all data types needed for a complex diary application. It should be straightforward to develop a web-based application to access EPTAD data from the PHR along with PHR data from other sources and to explore associations of pain, treatment and activity with diet, mood, blood pressure, and other health measures.

4. Discussion and implications

Field testing of the EPTAD is needed to determine whether users will reliably enter data every 2–4 h as envisioned. Before field test-

ing we will: (1) revise the application to present all response options for a query on one screen to avoid the need for scrolling, (2) add a "Back" button, (3) replace the number selection box with a pop-up number pad, (4) and attempt to identify design features that older adults may need to use the device effectively. Data displays and analyses need to be developed and evaluated for comprehension and utility by patients and providers. We can envision a role for the EPTAD in the routine care of patients with NCCP. For example, a PCP or pain specialist could recommend a patient use the EPTAD in preparation for an initial visit or as part of an assessment of the use and effectiveness of recommended treatments. The patient would complete an online or paper-based inventory of his/her types of pain, pain treatments, and physical activities. A technician would use the inventory to customize EPTAD response sets. With the aid of software yet to be developed, patients themselves might customize the EPTAD software directly. Patients would obtain a device loaded with the customized software from a healthcare facility. In the future EPTAD software could be developed that would allow patients to use their own Smart Phones or Personal Digital Assistants as pain diaries. The patient would then use the device for a prescribed period and upload the data to a central web-based repository on his/her own at home or with the help of a technician at a healthcare facility. Patients, providers, or technicians would use a web-based analytic tool to produce data displays, which could be printed if desired. Clinicians could review the data analyses with patients (on paper or on a PC), and could also receive automated messages (decision support) recommending changes to treatment based on the automated application of guidelines to the patient's data.

5. Conclusion

We developed and user tested a handheld EPTAD, and demonstrated basic interoperability with a prototype PHR. If field tests of the EPTAD and related data analyses are promising, we will need to study their use in clinical settings, and to compare their effects on pain treatment outcomes with usual care and with the use of other pain reporting tools that provide less detail than the EPTAD.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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Table A1
Examples of Queries and Responses for 3 EPTAD Modules.

Routine Pain Report
1. What was your BEST overall comfort level over the last 2 h?
[] Very comfortable [] Comfortable [] Uncomfortable
[] Very uncomfortable
2. What was your WORST overall comfort level over the last 2 h?
[] Very comfortable [] Comfortable [] Uncomfortable
[] Very Uncomfortable
3. What was your AVERAGE overall comfort level over the last 2 h?
[] Very comfortable [] Comfortable [] Uncomfortable
[] Very uncomfortable
4. Check one or more short duration pains you had over the last 2 h
[] Custom short pain (1) [] Custom short pain (*n*) [] Other short pain [] None à 7
5. How many times did you have <custom pain> in the last 2 h?
[] 1 [] 2 [] 3 [] 4 [] 5 [] 6 or more
6. What was the highest level of <custom pain>?
[] 0 [] 1–2 [] 3–4 [] 5–6 [] 7–8 [] 9–10
7. What factor/s do you think brought on the pain?
[] Not used to activity [] Activity too long or intense
[] Lifting, pushing, pulling [] Bending, reaching, twisting
[] Slipping, tripping, falling [] Other (keyboard entry)
[] Nothing I did
(Loop for up to 5 custom pains)
8. Check one or more long duration pains you had over the last 2 h
Custom long pain (1) [] Custom long pain (*n*) [] Other long pain
[] None → medication treatment module
9. What was the HIGHEST level of this pain over the last 2 h?
[] 1–2 [] 3–4 [] 5–6 [] 7–8 [] 9–10
10. What was the AVERAGE level of this pain over the last 2 h?
[] 0 [] 1–2 [] 3–4 [] 5–6 [] 7–8 [] 9–10
11. What was the LOWEST level of this pain over the last 2 hours?
[] 0 [] 1–2 [] 3–4 [] 5–6 [] 7–8 [] 9–10
12. How much of the time did you have this pain in the last 2 h?
[] All [] Most [] Some [] Not much
13. Was this pain worse or longer lasting than usual?
[] Yes [ ] No → medication treatment module
14. What factor/s do you think made this pain worse than usual or longer lasting? → Medication treatment module
[] Not used to activity [] Activity too long or intense
[] Sitting or standing too long [] Custom factor A
[] Custom factor B [] Custom factor C
[] Other (keyboard entry)
(Loop for up to 5 custom pains)

Activity Report
1. Where were you over the last 2 h? (select all that apply)
[] Inside [] Outside [] Traveling in a vehicle
[] Traveling NOT in a vehicle
a. Where were you inside?
[] Home [] Work [] Other
b. Where were you outside?
[] Home [] Work [] Other
2. What were you doing while <selected location>?
[] Custom activity (1) (Keyed to location)
[] Custom activity (*n*) (keyed to location)
[] Other
3. How long were you doing <custom activity > over the last 2 h?
[] Less that 30 min [] 30–59 min [] 60–89 min [] 90–120 min
(Loop up to 8 times for each location)

Routine Medication Treatment Report
1. Did you take any regularly scheduled doses of any medication over the last 2 h?
[] Yes [] No → 4
2. Which regularly scheduled medication/s did you take?
[] Custom medication 1 [] Custom medication (*n*)
3. How many pills or patches did you use?
(Number pad)
(Loop through 1–7 scheduled medications)

4. Did you take any breakthrough medication for any pain in the last 2 h?
[] Yes []No → END
5. Which breakthrough medication/s did you take?
[] Custom medication 1 [] Custom medication (*n*)
6. How many pills did you use?
(Number pad)
7. Which pain/s did you need to take (custom medication) for?
[] Custom pains 1 [] Custom pain (n)
8. How much relief did you get with <custom non-drug treatment 1–7> ? → END
[]None [] 10–19% [] 20–39% [] 40–59% [] 60–79%
[] 80–100%

(Loop up to 7 for custom medications)

Appendix A

See Table A1.

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