Disease-Monitoring Devices

Introduction

According to the U.S. Food and Drug Administration (FDA), a *medical device* is any product or equipment that is used to diagnose, cure, treat, or prevent a disease or other health condition. A *home healthcare medical device* is any product or equipment used in the home environment by persons who are ill or disabled. Examples of some home healthcare devices are ventilators and nebulizers (to help breathing), wheelchairs, infusion pumps, blood glucose meters, and apnea monitors. (Home Healthcare Medical Devices, 2003.) This section of the paper will focus on disease-related *home* medical devices that are used to *monitor* a condition and which have a *digital interface*. Although there are several devices for *monitoring* diseases, few are intended for *home use*, and even fewer have a chip or *computerized/digital interface*. In actuality, the home digital market is dominated by diabetes- and asthma-related devices. Mention will be made of cancer and Alzheimer "devices", but only briefly, as these do not really meet the definition of home digital devices.

Although these devices have come a long way, they all seem to face portability, data-analysis, and data-manipulation shortcomings. There is a long-standing battle in the computer interface world between the portability vs. limited screen size of portable devices, and the immobility vs. data-presentation flexibility of full-screen PC applications. Medical devices are no exception. However, few of the devices examined here present all the information a user would want on one visualization screen (e.g. graph or chart).

Useful sources for this section of the paper were the Food and Drug Administration (FDA) website, commercial device sites, and academic and industrial research centers. It is perhaps worth noting that the FDA Center for Devices and Radiological Health regulates medical devices to ensure that they meet reasonable safety and effectiveness standards, and FDA approval must be obtained for any device entering the U.S. market. The Administration monitors the quality of these products even after market-entry by inspecting manufacturing facilities, gathering information from the manufacturers, and accepting consumer complaints through the MedWatch system. The FDA also conducts user/usability tests for some devices, and sometimes issues specific interface guidelines. (FDA website, 2002.) All of these facts make the FDA a good starting point for examining home medical devices. Usability and interface issues can also be researched through various online support groups and expert websites, where readers candidly critique existing devices' functional and design-related problems. Commercial sites are useful for understanding current device capabilities and features, but, being essentially advertising vehicles, they prove less helpful for judging a device's (or its interface's)

strengths and weaknesses. Industrial and academic initiatives provide the bulk of research in this field.

Diabetes

Background

Diabetes is a chronic disease that affects 6% of the American population (McDonald et. al.). Simply described, diabetes impairs the pancreas' ability to produce or properly use insulin, which the body needs to control the amount of sugar (glucose) in the blood. This causes one's blood sugar level to increase to dangerous levels. Left untreated, this condition can cause blindness, heart attack, poor circulation, loss of feet or legs to gangrene and amputation, kidney dysfunction, and even death. Interestingly, glucose-monitoring has become the fastest-growing segment of the diagnostic testing market (Waynant, 1998), and it seems to boast the greatest number and variety of home devices.

There are three types of diabetes: Type-1, Type-2, and gestational. In Type-1 diabetes, the pancreas produces little or no insulin. This tends to affect people under the age of 30, and requires insulin injections and constant monitoring of blood glucose levels. In Type-2 diabetes, the body produces either insufficient levels of insulin, or cannot process the insulin that is produced. This form typically affects adults over the age of 40, and does not require insulin injections for control. It does still require constant monitoring of the diabetic's insulin level. Gestational diabetes affects some women during pregnancy; these women are at greater risk of Type-2 diabetes later in life. (McDonald et. al.)

There is no cure for this disease, but there are a number of things a patient can do to control it. The National Institutes of Health's Diabetes Care and Complications Trial (DCCT), conducted from 1983-1993, demonstrated that frequent monitoring of blood glucose and insulin levels could prevent many of diabetes' long-term complications, especially for Type-1 patients (Auxter, 1996). Some of the more common, current ways of detecting and monitoring diabetes are by checking the blood glucose level, the urine glucose (ketone) level, and the A1c hemoglobin level. Related tests check for kidney dysfunction, a condition sometimes caused by diabetes.

Commercial Devices

Blood Glucose monitoring

Meters Currently on the Market
Most current devices require that the diabetic collect a small blood sample, by pricking various body parts and smudging the blood onto a disposable "test strip", to determine the level of glucose in the body. The test strips are coated with chemicals (glucose oxidase, dehydrogenase, or hexokinase) that combine with the glucose in the patient's

blood. The strips are inserted into a meter, which typically determines the patient's glucose level by measuring the amount of electricity or light that passes through the sample. This is a prolific market: there are at least 25 different meters available commercially. (FDA website, 2002.)

These meters vary in many ways, but the attributes to look for are:

- Testing speed
- Where the blood can be collected
- How much blood must be collected
- Ability to store test results in memory
- Whether high and low glucose values are displayed
- Size of meter
- Cost of meter
- Cost of test strips; whether generic or brand-specific strips can be bought

One highly-touted marketing point is whether the project requires only 2 microliters of blood per test, as opposed to the formerly common 3-4 microliters. This would clearly be of interest to the patient, as less blood-drawing means less pain. The finger is the most common area from which to draw blood, but that becomes quite painful with repeated testing. Hence, many diabetics test their glucose levels less than twice a day, although 4-7 times per day is recommended (Waynant, 1998). There is also the problem that the user is more likely to become infected with other diseases, such as Hepatitus B, from reusing or improperly using the lancet device that is currently common for drawing blood (Polish et. al, 1992). Newer devices allow the user to prick less sensitive body parts, such as the forearm, upper arm, abdomen, thigh, calf, and fleshy part of the hand. The FDA, however, warns that blood in the fingertips shows glucose changes more quickly than blood in other parts of the body, and that further research is needed to determine if other locations provide adequately correct readings. (FDA website, 2002.)

Some products offer software programs that allow results to be downloaded onto a computer or PDA, save as many as the last 450 results, and/or calculate one's 14/30-day or monthly average. Many link to record-keeping systems, as discussed later. Interestingly, few seem to offer the ability to save a personal high or low, or alert the patient when those thresholds have been passed. None seem to marry the glucose readings with other data points that might prove interesting to the diabetic.

Non-Invasive and Minimally Invasive Monitors

As recently as 2002, a new breed of glucose monitor – the "non-invasive" monitor - hit the commercial market. GlucoWatch by Cygnus is a wristwatch device that continuously, non-invasively, and automatically monitors the user's glucose level without drawing blood. It can save up to 8,500 glucose readings, which can then be downloaded to a personal computer, emailed to one's doctor, or printed onto graphs, charts, and statistics. It also allows the user to set high- and low-glucose alerts (issued as an alarm), and enter event markers such as MEAL, EXER (for exercise), etc. to explain why a given reading is high or low. The "Children with Diabetes" website claims that 95% of the

Biographer readings are clinically acceptable. However, the manufacturer warns that GlucoWatch is intended to supplement, not replace, blood readings, and that GlucoWatch readings must be compared to finger-stick blood tests to ensure proper calibration. Interestingly, the manufacturer does not indicate what technology is used to take these measurements.

One competitor to the GlucoWatch (in that it is minimally invasive) is Medtronic's MiniMed Continuous Glucose Monitoring System (CGMS). This device is actually quite invasive, however, as it requires that a physician insert a sensor (catheter) under the patient's abdominal skin. The sensor reads glucose levels in the interstitial fluid, although it is unclear how that data is collected. This sensor remains under the skin for up to 72 hours, at which point the physician must remove it. Although there is a "monitor" interface into which the patient can enter related information (e.g. the time of meals, medication, and exercise), the patient cannot read the CGMS glucose readings proper – only the physician can. Furthermore, the patient must conduct finger-pricks four times a day, to keep the sensor calibrated. Since the average diabetic is advised to take four finger-pricks per day anyway, it is unclear what added benefit the CGMS provides. There is the added question of how "continuous" or "current" the CGMS readings truly are. Medtronic's website states that:

> "…blood glucose and interstitial fluid glucose levels are essentially equal when blood glucose is not changing rapidly. However, since glucose must enter the central blood supply, pass into peripheral circulation and cross a capillary boundary prior to entering the interstitial fluid, rapidly changing glucose levels create a lag between blood and interstitial fluid measurements. This means that when glucose concentrations are rising in the blood, they are lower in interstitial fluid throughout the lag. Overall, the differences between blood and interstitial fluid glucose levels do not affect the clinical utility of the Glucose Sensor data because they are minor (lags in glucose levels last usually less than 10 minutes) and because the data is analyzed in such a way that minor differences are negligible." (Medtronic: CGMS FAQ.)

However, if continuous tracking of current glucose levels is the goal, then measuring interstitial fluid seems to be a less than perfect way to do that.

Biocontrol also develops and sells a non-invasive device, the Diasensor. This product was being sold in the European Union as of 2003, but had not yet been approved by the FDA for sale in the U.S. The user takes his readings by placing his arm in the printer-sized device for 2 minutes; the device reads the glucose level using infrared light. Results are evaluated by the doctor, however, not the patient; so, Diasensor is evidently intended for professional more than personal use.

Urine Glucose (Ketone) Monitoring

Ketone-measuring devices are not technically personal devices with digital interfaces, so they are somewhat beyond the scope of this paper. However, they are worth mentioning at least in passing, because they measure another common aspect of diabetes: ketones.

Ketones are chemicals that the body produces when there is a shortage of insulin in the blood. This shortage causes the body to break down body fat for energy, and ketones are a by-product of burning fat. (FDA website, 2002.) High levels of ketones can lead to diabetic ketoacidosis (high levels of ketones and acid, leading to nausea and abdominal pain and possibly death) and coma. Although ketones are always present in urine, their concentration is usually so low as to be undetectable by routine tests. They are generally present enough to be detected in the urine of Type-1 diabetics, fasting individuals, and some pregnant women in the morning. Hence their use in diabetes testing. Blood ketone tests are generally preferred over urine tests, however. (Goldstein et. al., 1995.) The disadvantages of urine glucose tests include: 1) they will not indicate low glucose levels (below 180 mg/dl), since low levels of glucose are undetectable, 2) the readings change with the volume of urine, and 3) this measurement is more of an average than a precise-in-time reading. (FDA website, 2002.) Home testing kits do exist, however. They generally require dipping a dipstick into the urine to measure the ketone level, and sending the test to the physician for analysis. Blood (serum) ketone level can be assessed in the same manner. No true user interfaces have been developed as yet for this test. (FDA website, 2002.)

A1C Monitoring

Daily blood glucose testing indicates one's blood sugar level at the time of testing. Since blood glucose levels vary widely during the day, however, a single measurement of blood glucose is a limited indicator of overall diabetes control. The hemoglobin A1c test, by comparison, measures the average blood sugar for the past several months. This test works as follows. In the human body, sugar in the bloodstream attaches itself to the hemoglobin (the part of the cell that carries oxygen) in red blood cells. The sugar remains there for the life of the blood cell (approximately 120 days). The higher the level of blood sugar, the more sugar is attached to red blood cells. The hemoglobin A1c test measures the amount of sugar attached to the hemoglobin, so that it shows the amount accumulated over the life of the blood cell. Hence, it is used to measure the average blood sugar level for the past 2-3 months. A 1% reduction in A1c level is associated with a significant 35% decrease in the likelihood of damage to a diabetic's eyes, kidney, and nerves, and a 25% decrease in the likelihood of death (McDonald et. al.).

HbA1c testing is typically done in the doctor's office, or by sending a blood sample to a commercial lab for analysis. The author could find only one meter (Metrika's A1cNow Monitor) that allows the user to conduct this test at home. However, its value to the user is dubious. It is a disposable, one-use-only device, and it requires refrigeration. It also displays only the current reading in the display window, keeping no history of past readings and making no attempt to interpret the data. This seems like a very small step above sending results to the lab.

Assistive Devices

There are a few devices that cater to the visually impaired of manually disabled. These have magnifiers over the syringe-loading accessory, larger numbers on the insulin

syringe, and positioning aids for the syringe and insulin bottle.

Record-Keeping

Although this section of the paper is intended to cover the medical devices themselves, it is worth venturing out into the world of diabetes record-keeping, as that is a fairly well-developed interface arena. There are numerous record-keeping systems for the diabetic to choose from, ranging from downloadable log sheets/spreadsheets, web-based logs, commercial Windows software, freeware Windows software, to the old-fashioned hand-logging system. (Mendosa, 2003.) The log sheets and spreadsheets require manual data-entry, as would be expected. Most of the Web logs and commercial Windows software programs accept downloads of diabetic readings from commercial meters. The most commonly accepted meters were of the Roche, Therasense, LifeScan, and Bayer lines; logically, many of these websites were created and maintained by the parent company (e.g. Roche) as part of their marketing program. The freeware programs tend to require manual data-entry of glucose levels, insulin injections, etc, but there are several that download the patient's glucose readings from certain meters. Most of the latter accommodate the LifeScan One Touch and Roche Accu-Check meters, with some others covering Abbot's MediSense meter, and various meters by Bayer and Therasense.

Regardless of their type or source, most of the software programs allow the user to enter (or upload) glucose readings, medication, insulin, exercise, meals, test results, and personal notes in one session. Some allow for the planning and recording of meals; these often hook up to USDA sites to provide nutritional information online. Only a few run on hand-held devices (PDA's, Pocket PC's), and these capture only blood glucose readings. (Pocket DiabetiCare, 2004; Accu-Chek Pocket Compass, 2004; Healthmate, 2004.)

Notably, most devices focus only on reproducing one's measurements in log, chart, or graphical form; very few attempt to do analysis thereon. One system, WinglucoFacts boasts its ability to analyze the diabetic's data using statistical "pattern recognition" tests. (WinglucoFacts, 2004.) The few other systems that do analysis merely state that they provide statistical and/or graphical analyses of the users' blood glucose levels and/or insulin dosages, without providing more details. (Diabetes HomeCare, 2004; DIABASS, 2004; HealthDesk OnLine for Diabetes, 2004.)

User Interface Issues

Since 1984, the Food and Drug Administration (FDA) has received many reports of problems with blood glucose meters. A large number of these problems have been attributed to users' failure to maintain the meter properly, use of incorrect operating procedures, or failure to follow the instructions for meter use. (FDA website, 2002.) This suggests that many of the meters' problems do not involve user interface issues at all, except to ensure that an adequate Help and Tutorial are provided with the meter. This assertion is somewhat contradicted by other FDA studies and by online communities' device assessments, however.

The FDA suggests that the character size on glucose monitor displays be 5mm, so that diabetics with uncorrected eyesight problems can read the display's values. (FDA website, 2002.) It is difficult to tell how many meters live up to this expectation without purchasing and examining each one individually, however. The FDA also conducted a human factors study that revealed that blood sampling, which depends on test strips and the user's ability to draw and place blood thereon, has the greatest potential for error. (FDA website, 2002.) This problem is echoed in one online diabetic community's assessment of current monitors. One community member observed that individually wrapped strips are so hard to open, that the device often turns itself off before user can unwrap the strip. There were also complaints that the strips are so small, that they tend to get lost in all manner of places in the house. (Road Testing Blood Glucose Meters.) This was further complicated by the fact that wet or residue-laden fingers, room humidity, or air/light-exposure on the strips can cause faulty readings. (FDA website, 2002.) Taken together with the blood-drawing problems mentioned under "Current Devices", this would seem to indicate that test strips and the blood-drawing technique in general fail the usability test. No amount of interface changes (e.g. displaying test results) can overcome the strips' poor functionality. Other methods should be refined and marketed.

Web communities with users' critiques of glucose monitors offer insight into these devices' user interface issues. Looking at one such community website, users clearly hold that "smaller and faster" is good. Apparently many meters take 2 minutes to do their calculations, and this was deemed too long. There was also the obvious preference to draw less blood, and to not need to wipe the testing strip after each use. Almost all users were pleased to have the option of pricking some body part other than the finger (despite FDA reservations). Providing a countdown while the meter takes a reading was suggested – the kind of audio-visual feedback that interface-design theories encourage. And a few users noted that they would like the meters to measure more than just discrete glucose levels – for example, the meters should also measure ketones, or show average glucose readings. (Road Testing Blood Glucose Meters.)

Current Research

Two MIT students have done research into marrying up glucose test readings with photographs of diabetics' daily lives, to help the diabetics identify poor health habits. Their web-based tool consolidates these images and tests, color-codes them (warm colors indicate high, blues low, and yellow normal blood sugar levels), and allows the user to pick a day/hour to see the information visualized. (Frost and Smith, 2001.) Although interesting in concept, this may prove too time-consuming for the average person to actually use.

Similar to the MiniMed CGMS meter, researchers at the University of Pittsburgh have developed a tiny glucose sensor for implantation just underneath the skin. The sensor is a half-inch-long plastic tube about the diameter of a piece of thread, and is filled with particles that fluoresce according to blood sugar levels. A monitor fitted with a

photometer, which sits atop the skin and above the sensor, measures the light intensity of the fluorescence; this in turn reflects the glucose concentration. (Wong, 2000.) Like the CGMS, this is a very invasive and perhaps unappealing way to monitor diabetes.

Looking forward yet further, there are some very interesting "non-invasive" glucose-monitoring techniques that are being researched. Few of these appear to have made it from the drawing board to the commercial market, but they may have a role to play in the diabetic's future. Some alternatives to drawing blood are to investigate interstitial fluid (the fluid that surrounds the individual cells in the body), ocular (eye) fluids, and sweat. (Medtronic's MiniMed CGMS currently monitors interstitial fluid, actually.) Alternate data-gathering techniques include microdialysis, infrared spectroscopy, near infrared spectroscopy, fluid-extraction, and optical methods. The optical methods alone have several subcategories, most of which measure the wavelength, polarization, or intensity of light that is passed through the patient's skin. The results of these methods still need to be validated, and the instruments calibrated, however, before they can leave the research laboratory and enter the marketplace. (FDA, 2003; Waynant, 1998.)

Directions for Future Research

One question is outstanding: do these meters actually improve the diabetics' management of their disease? The American Diabetes Association points out:

> Although a number of SMBG (self-monitoring of blood glucose) methods store test results and with a computer interface can provide sophisticated analyses of blood glucose data, it is not known whether use of these data management systems yields better glucose control than patient review of results recorded in a logbook. (Goldstein et. al., 1995.)

One could readily argue that the monitors do help, in that they automatically store the results of many months of tests, saving hours of manual data entry. However, none of the monitors appears to go beyond this very simple data-gathering exercise. A worthy goal would be to superimpose the various measurements (e.g. glucose readings, insulin dosages, exercise, ketones, A1c tests) and their averages onto one screen. Of course, the PDA devices face the challenge of how to project data onto small screens – as do all PDA-based devices. However, such multi-valued graphs could be plotted on a PC, but no one appears to have taken this initiative.

In a similar vein, surprisingly few of the meters (or their fellow record-keeping systems) perform analysis of the data collected; instead, they simply mirror the information in another format (bar charts, graphs, etc.). As a matter of fact, *none* of the portable devices appears to perform analysis on the data, although this may be due to the limitations of a small PDA/Pocket PC screen.

Current research into combining photography with record-keeping to illuminate poor patient habits is provocative (Frost and Smith, 2001), but user studies should be conducted to see whether patients would actually spend the requisite time to enter all

these photos and data. At the least, such projects should consider creating a joint monitoring/record-keeping/photographing device that would perform all the functions at once, rather than requiring the user to carry so many individual pieces of equipment.

Of course, the ideal meter would do everything at once: measure the patient's glucose levels, show the patient's glucose history (juxtaposed against other relevant data, and supporting multi-data manipulation and analysis), and pump insulin into the patient's bloodstream when a reading was dangerously low. (Insulin idea is from Wong, 2000.) And, of course, to have this all bundled up in a portable, fast, reliable interface. That is asking for quite a lot, however, and might give rise to lawsuits if the insulin-injection function ever failed. So, such a device is probably decades away.

Asthma

Background

Asthma is a disease of the respiratory system (lungs, and airways) that affects an estimated 20.3 million Americans, of which approximately 70% are adults over the age of 18. (Asthma Statistics, 2004.) People with asthma have very sensitive airways, which react by narrowing when irritated. This narrowing makes it difficult for air to move in and out of their system, which causes difficulty in breathing, coughing, wheezing, chest tightness, and shortness of breath. Asthma can be allergic (extrinsic) and non-allergic (intrinsic). Extrinsic asthma is the more common form and is usually developed during childhood. In addition to the environment, those who have extrinsic asthma usually have a family history of allergies. Intrinsic asthma, which represents about 10 percent of all asthma cases, usually develops after the age of 30 and is not related to allergies. Those who develop intrinsic asthma usually have an infected respiratory tract.

Often described as an asthma attack, asthmatics sometimes have great difficulty in breathing and must gasp for air. In general, anything that will irritate the already sensitive airways of an asthmatic will result in an asthma attack. Environments plentiful in dust, smoke, high humidity, and/or extreme temperatures are common causes of irritation. Allergies from animal dander, pollen, molds and certain foods can also give asthmatics an attack. In addition to that, stress and emotional upset can also lead to difficulty in breathing and a narrowing of airways. Knowing one's personal triggers to these attacks can prevent many attacks, however.

Research has shown that by regularly measuring airflow in the lungs with a device called a Peak Flow Meter (or a similar product), trends in breathing problems can be identified and attacks sometimes anticipated (Jansen, 2003; The Lung Association website, 2004). These respiratory tests usually measure two things: the patient's PEF (Peak Expiratory Flow) and FEV (Forced Expiratory Volume), both measured in liters per minute. The PEF shows the volume of air that the patient can exhale when completely emptying the lungs. The FEV shows the volume of air that the patient can exhale over a given amount

of time, usually 1 second. (A digit after the FEV acronym indicates the number of seconds, e.g. FEV1, FEV6.)

The PEF/FEV measurements establish an asthmatic's best/worst measurements and personal safe/mediocre/dangerous (green/yellow/red) zones. Doctors may compare the patient's personal best/worst measurements with national averages (which are based on a person's age, gender, and height) as a way to measure the severity of the patient's symptoms. Zones are used to track patients' progress in managing their asthma, or to indicate impending attacks. The Green Zone indicates that the user's lungs are performing at 80-100% of his/her 'normal' Peak-Flow rate. This usually means that the individual's asthma is under control and that breathing is not very difficult. The Yellow Zone indicates that the lungs are operating at 50-80% of 'normal' capacity – i.e., the airways are narrowing and the patient should perhaps use an inhaler or take medication to avoid an attack. The Red Zone indicates a Peak Flow reading of less than 50% of the 'normal' reading, and that signals the patient to take immediate action to avoid an attack, and also contact to a doctor. Tracking patients' entries into these zones, their actual attacks, the presence of their triggers, and their medications over time can also help determine what aggravates or alleviates their asthma symptoms the most.

Commercial Devices

The original Peak Flow meter was a simple analog system with no digitized interface. The patient exhaled breath into an empty tube, whose marker rose to the corresponding level to indicate the volume of exhaled air. Measurements were read from the markings on tube's side, and had to be manually logged by the patient in order to track trends. (A.D.A.M., 2002; The Peak Flow Meter, 2004; Peak Flow Meters, 2002.)

Now there are a number of digital versions of the old Peak Flow meter on the market, many of which save the last 100 or more readings, and create graphs, emailed files, and bar charts of the results. Some allow results to be downloaded to an Internet page, where the user can see and track trends. A few allow the user to input doctor's appointments, regular medication refill dates, etc., which the interface uses to remind the user of important dates. Most of the digital models interface with a personal computer (PC) via an infrared (IR) port. PC-based systems, however, have the disadvantage of being largely immobile. Hence, a few portable (PocketPC or PDA) devices have now hit the market, but these tend to have more limited capabilities, probably due to the problems associated with displaying large data sets on small screens.

Interestingly, recent FDA research shows that asthmatics exhale more nitric oxide (a marker of inflammation) than non-asthmatics, and that this level decreases when an asthmatic receives steroid treatments. This method contrasts sharply with lung function tests (e.g. Peak Flow), as the latter measure lung constriction, not the underlying inflammation. Aerocrine has developed the NIOX device to fill this market niche, by measuring the concentration of nitric oxide in exhaled breath. It is used in physician's offices, primarily as a way of measuring the asthmatic's responsiveness to anti-

inflammatory therapy. It is not intended for home use, and so cannot be considered a true personal medical device, but its unique methodology is worth noting. (U.S. Oks breath test for monitoring asthma, 2003.)

User Interface Issues

Research has shown that most Peak Flow users tend to stop taking their measurements on a regular basis as time goes on, and that they will sometimes even make up data to fill in the missing gaps. (Modern Medicine, 1998.) This problem may have been alleviated by the arrival of digital meters that keep track of past readings. Nonetheless, it does mean that meters should have a way to deal with missing or incomplete data. There are mathematical models for dealing with incomplete data sets; it is unclear (and doubtful) that any of the meters currently use such algorithms for figuring out the patient's average readings, etc.

There do not appear to be any (or at not least many) asthma meters that cater to the older user. Although most asthmatics are children (who lose their symptoms upon entering adolescence), there is still a significant adult population. Intrinsic asthma hits mostly adults (see Background), and this alone accounts for 10% of all asthmatics. Meter interfaces should therefore accommodate these older users through larger font sizes on both the meter and any logging/charting software that uses the meter's test results.

Current Research

One Yale project (PalmAsthma) combines various data points in an attempt to present a fuller picture of the asthmatic's condition. The patient enters PEF readings and symptoms, and the doctor enters diagnoses and recommended medications. All entries are done manually via a pen-like stylus. The device is designed for use on various Palm devices, such as Freestyle, Cassiopia, and Clio. Although both patient and physician enter data, the intended beneficiary/user is the clinician, so this is only marginally a personal medical device. (Karras, 1999.)

The Slovak University of Technology developed the Amadia system, which maps PEF/FEV and blood pressure readings, weather conditions, and the presence of common allergens (e.g. pollen) in the environment. The PEF/FEV and blood-pressure readings must be manually entered by the user; the weather and allergens can be downloaded from the Internet. However, each of those variables is plotted on a separate graph, making it difficult for the user to get a true overview of what caused an asthma attack when. (Hercek et. al., 2002.)

The University of Maryland developed the AccuLung system, which plots manually-entered or digitally-uploaded PEF/FEV readings onto a chart, and shows Internet-provided weather and allergen information for the user's home or visited area. However, it suffers from the same data-integration issues that Amadia does, in that it does not plot these individual data sets against each other on one graph. The Maryland project uses a

small PDA screen as its interface, however, which hampers attempts to show multiple pieces of information simultaneously. (Bartow et. al., 2004.)

Various research efforts indicate that certain chemicals' presence in the throat, lungs and nose 1) indicates that unhealthy bacteria are at work and 2) can allow the detection of diseases such as liver failure, renal failure, diabetes, and asthma. Scientists at Imperial College of Science, Technology and Medicine, London, linked up with the joint venture company BodiTech in 1998 to develop a breathalyzer that detects these chemicals. (Health, 1998.) This research apparently has not led to any outcomes as yet, however.

Directions for Future Research

As with diabetes, there is an unmet need to plot all relevant asthma information one screen, to permit manipulation of that data, and also to analyze that data. Two devices come close (Amadia and AccuLung), but both are academic research projects that were not designed for commercial use. Although the Amadia system handles PEF/FEV readings, weather conditions, and the presence of common allergens (e.g. pollen) in the environment, it displays each of those variables on a separate graph, making it difficult for the user to get a true overview of what caused an asthma attack when. Similarly, AccuLung plots PEF/FEV readings on a chart, and shows weather and allergen information for the user's home or visited area, and records current medications, but it does not plot these values against each other. AccuLung's interface is a small PDA screen, however, which hampers its ability to show multiple pieces of information simultaneously. The result is the same, however: the user is left to figure out the correlation between poor expiratory readings/attacks, possible asthma triggers, and medications.

Other Diseases

Cognitive Diseases/Alzheimer's Disease

Several research projects are tackling the problems associated with Alzheimer's Disease and similar cognitive diseases that adversely affect one's memory. Most of these are geared towards short-term memory losses, that affect one's daily living. Some of these focus on pillboxes that "remember" and permit only those doses that a patient should take, or alarms that ring when a patient is supposed to take a medication (Gough et. al., 2004). Others track the patient's movement about the house, to make sure the bodily movements are normal, or to assist the patient in everyday tasks about the house. The tracking is done through cameras stationed throughout the house, smart furniture that recognizes human motion, or smart appliances that handle daily routines for the patient automatically. (Proactive Health Case Study, 2004.) There are even projects to include digital photographs in digital address books, cell phone lists, landline phones with LED displays, etc., in an effort to help the forgetful marry up an image with a name or number.

(Adewuyi et. al., 2004.) These are varied and sometimes have rich interfaces, but their functions vary so broadly that they will not be discussed in detail. More information can be gleaned from the sites listed in the References section.

Cancer

Most personal cancer devices have no digital interface; rather, they display test results on a material test strip directly (color-coded to indicate the results), or they require the sample be shipped to a lab for analysis. The few home bladder cancer tests require the patient to submerge a test strip in urine; test results are indicated by color changes on the strip. Otherwise, a professional must take the reading. Colon cancer, which can be detected by stool blood left from irritated polyps along the colon walls, require the patient either to smear fecal matter onto a test strip or to drop the test strip in the toilet bowl after a stool. The strip indicates positive/negative results by changing color. Home tests for prostate cancer measure the amount of prostate-specific antigen (PSA) in the blood, but these tests also either show results with no digital interface, or must also be sent to a laboratory for analysis. Clearly, there is an untouched market here for home medical devices to detect the various forms of cancer, but technology evidently has not progressed far enough to allow users to view or analyze their results at home. As such, they do not fall into the category of a personal medical device with a digital interface.

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