The increasing public health burden associated with stroke-related disability\(^1\) and the current emphasis on cost reduction in health care have resulted in decreased inpatient rehabilitation length of stay.\(^2\) These factors are driving a search for more cost-effective methods for post-stroke neurorehabilitation, including robotic devices that provide movement therapy. As new tools for therapists, robotic stroke therapy devices have the potential to alleviate the labor-intensive aspects of physical rehabilitation and to enable novel modes of exercise not currently available. In addition, automated stroke therapy systems might provide a cost-effective means for individuals with chronic stroke to maintain movement ability after receiving standard inpatient and outpatient rehabilitation.

Successful automation of stroke therapy will ultimately depend upon four criteria. First, and most important, the device must provide quantifiable, functional benefits to the patient. Second, the device should improve the efficiency of therapists’ current practice. Third, the device should be affordable for clinics yet profitable for manufacturers. Finally, the device should not increase the cost of health care.

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In this article, we first review evidence that therapy techniques amenable to automation can have significant benefits after stroke. We then present results from three research laboratories in which devices for upper limb movement therapy are undergoing clinical testing with poststroke patients. Finally, we describe a project to develop a commercial device and discuss how this device can satisfy the four criteria listed earlier.

**Justification for Use of Robotics Technology in Stroke Therapy**

There are several treatment philosophies that provide different recommendations for the progression of treatment, type of movements to use, and the context of the activities. Nevertheless, the interaction between the therapist and patient can be classified into three broad categories. Much of the work in this field has focused on replicating these categories with devices.

1. **Passive (or externally imposed)** movement involves movement of the patient’s joints by the therapist as the patient remains relaxed. This is used to maintain range of motion at joints and flexibility in muscle and connective tissue. It can also be used to temporarily reduce hypertonia or resistance to passive movement. It may also serve to help the patient retain or reestablish important proprioceptive information about the achievable workspace that the impaired limb should be able to reach as recovery progresses.

2. **Active-assisted movement** is used when the patient cannot complete a desired movement independently. During attempts by the patient to move a joint or limb, external assisting forces are applied as needed. These forces can be in the form of manual manipulation from a therapist, from the patient’s contralateral limb, or from constraints placed in the environment to guide and assist the movement. For example, the forearm can be placed on a skateboard that rides on a tabletop. The tabletop serves as a constraint that assists the movement by eliminating or reducing the effects of gravity. The tabletop can then be tilted so that more difficult movements are partially assisted by gravity.

3. **Active-resisted movement** is used by higher level patients and involves completing movements against resistance from gravity, additional weights, an elastic band, or the therapist. It has been difficult to demonstrate convincingly the value of therapy for rehabilitation of motor function after neurologic injury. This is due to the fact that therapy is delivered to patients while spontaneous recovery is occurring, and it ethically cannot be withheld from patients to allow for a controlled trial. However, there is evidence in animal models that active practice is critical to the recovery process. In rats, amphetamine accelerates recovery from unilateral ablation of the motor cortex only if the animals are allowed to practice repetitive activities. In squirrel monkeys that were allowed to spontaneously recover after a focal ischemic infarct in the motor cortex, there was a loss of hand territory in adjacent undamaged cortex. In monkeys that actively retrained the affected limb, this loss of hand territory was prevented.
representations expanded into what were previously elbow and shoulder areas. Although the link between restoration of cortical maps and functional recovery is not entirely clear, it is likely that reestablishment of cortical maps for muscle activation is an important component of functional recovery.

In clinical trials with moderately or mildly impaired human stroke participants, there is evidence that simple repetitive exercise may be superior to other types of therapy. In chronic patients, Constraint-Induced therapy has been shown to result in substantial increases in the use of the more-affected limb in activities of daily living (ADLs). This treatment involves intensive repetitive exercise of the more-affected limb coupled with constraint of the opposite less-affected limb. Recent studies have shown that Constraint-Induced therapy results in positive motor cortex reorganization and has advantages relative to Neuro-Developmental treatment of equal intensity. Other studies have reported that repetitive practice of hand and finger movements against loads resulted in greater improvements in motor performance and functional scales than Bobath-based treatment, transcutaneous electrical nerve stimulation, and suprathreshold electrical stimulation of hand and wrist muscles. Parry et al. reported that in mildly impaired patients, additional treatment with a trained assistant was more effective than additional conventional treatment from a physical therapist. The assistant focused on repetitive practice of movements and functional activities, whereas the therapist focused on teaching techniques and encouraging self-practice. Significantly, this study also reported that neither of these additional treatments was effective in severely impaired patients.

Even though unassisted movement may be the most effective technique in patients with mild to moderate impairments, active-assisted movement may be beneficial in more severely impaired patients. Active-assisted movement may be especially effective in the acute and subacute phases when patients are experiencing spontaneous recovery. If significant movement has yet to return, repeated attempts to use the limb could lead to “learned nonuse,” because the patients are discouraged by the poor performance of the limb. In this case, active-assisted movement may be superior to unassisted movement. The negative conditioning associated with poor performance is avoided, because the attempted movements are completed with external assistance. The strongest clinical evidence for active assistance is a study of 100 acute stroke participants that found significant decreases in arm impairment with an intervention of stereotyped active-assisted movement. This treatment was most effective in participants with severe motor deficit.

All of the aforementioned therapies rely on repetition as a primary contributor to functional recovery. One of the primary benefits of robotic technology is the ability to automate repetitive motions. In this way, the robot becomes a tool for the therapist. The therapist can perform an initial assessment of the patient’s functional level and determine the movement patterns that would be beneficial to practice. The skill of the therapist is then augmented with a device that can repeatedly replicate the movement patterns and free the therapist from this time-consuming activity. Thus, a potential role for robotic devices is to facil-
itate highly repetitive, active-assisted movement training for more severely impaired patients, especially in the acute and subacute phases of recovery.

**Clinical Trials of Three Devices**

In the following sections, we review three research projects that are testing the efficacy of robotic devices that implement passive, active-assisted, and active-resisted movement. In each case, the focus is impaired shoulder and elbow movement after stroke. Although the devices are different in design and operation, the clinical results from these studies all support the hypothesis that movement therapy assisted by robotic devices has therapeutic benefits.

**MIT-MANUS**

The first robotic system to receive extensive clinical testing was the MIT-MANUS, a two degree of freedom robotic manipulator that assists shoulder and elbow movement by moving the hand and forearm of the patient in the horizontal plane. A unique design feature is low intrinsic endpoint impedance (i.e., back-driveability), which allows the device to simulate free movements and to guide a weak limb in “hand-over-hand” therapy. For more than 5 years, clinical testing has been underway predominantly at the Burke Rehabilitation Hospital (White Plains, NY). A complete description of this project is included in the Krebs et al. article in this issue (“Robot-Aided Neurorehabilitation: From Evidence-Based to Science-Based Rehabilitation”).

Their testing protocol is guided by how the device could be used clinically, as an adjunct to regular therapy, to provide patients with extra sensorimotor stimulation that they would not normally receive if the device was not available. A recent report covered 56 subacute patients who completed the study. In addition to their regular therapy, experimental participants received five 1-hour sessions a week (25 total sessions) with MIT-MANUS beginning 23 days after stroke onset. Control participants received 1 hour of “sham” therapy a week, for which the participants used the less-impaired limb in the robot or the robot interacted passively with the more-affected limb. When compared to controls, the experimental participants had greater gains in proximal arm strength (Motor Power score), reduced motor impairment at the shoulder and elbow (Motor Status Scale score), and greater recovery of functional independence (FIM™ Instrument; FIM™ is a trademark of the Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.). The two groups were still statistically different in terms of motor impairment at a 3-year follow-up.

The MIT-MANUS testing demonstrated that subacute patients who received robotic therapy in addition to their regular therapy improved more than patients who did not receive this added robot therapy. However, several meta-analyses have concluded that greater intensity of conventional therapy is also effective for reducing levels of impairment, disability, and mortality. Without a comparison to conventional treatment, it may be difficult to convince clinicians that similar or better therapeutic effects could not be achieved with other devices or techniques. Clinical acceptance will depend upon whether the device offers benefits not easily achieved by additional conventional
treatment from therapists, PT or OT aides, caregivers, or even a well-designed self-exercise program. At a minimum, the device should be able to take over some aspects of conventional treatment without loss of effectiveness.

**MIME**

In an effort to demonstrate the advantages of robotic stroke therapy and to ultimately support its clinical acceptance, the MIME project at the Veterans Affairs Palo Alto Rehabilitation Research & Development Center has focused on measuring the therapeutic effects of robotic therapy compared to conventional techniques.²⁵ The MIME system consists of a robot manipulator (PUMA 560) which applies forces to the paretic limb through a customized forearm and hand splint (Fig. 1). The robot’s six degrees of freedom allow the forearm to be moved within a large range of positions and orientations in three-dimensional space. A six-axis sensor measures the forces and torque between the robot and the paretic limb. Four modes of robot-assisted movement have been developed. In passive mode, the participant relaxes as the robot moves the paretic limb toward a target with a predetermined trajectory. In active-assisted mode, the participant triggers initiation of the movement with volitional force toward the target and “works with the robot” as it moves the limb. In active resisted mode, the robot provides a viscous resistance in the direction of the desired movement and spring-like forces in all other directions as the participant attempts to reach toward the target. In bimanual mode, the participant attempts bimanual mirror-image movements while the robot assists

*Figure 1.* A participant attempting bimanual mirror-image movements toward a target (ball) in MIME. Movement of the participant’s right, less-affected forearm is measured by a six degree of freedom digitizer. The left, more-affected limb is assisted by a PUMA 560 robot that continuously moves to the right arm’s mirror-image position with minimal delay. To perform unilateral movements, the right arm is removed from the digitizer. Interposed between the left arm splint and the robot is a six-axis force/torque sensor and a pneumatic safety device that collapses and cuts power to the robot when a predetermined critical torque level is exceeded. Straps limit the robot to a safe range of motion.
the more-affected limb by continuously moving that forearm to the contralateral forearm’s mirror-image position and orientation. During bimanual mode, the two forearms are kept in mirror symmetry by a position digitizer that measures the movement of the contralateral forearm and provides coordinates for the robot motion controller.

The goal of the initial clinical testing was to compare the effectiveness of a therapy program of robotic manipulation with an equally intensive program of conventional therapy techniques. Twenty-seven chronic stroke patients received 24 one-hour sessions over 2 months. Participants in the robot group practiced shoulder and elbow movements while assisted by MIME. Emphasis was placed on targeted reaching movements that started close to the body and ended further away. Participants in the control group received Neuro-Developmental therapy-based treatment targeting proximal upper limb function and received 5 minutes of exposure to the robot in each session.

When compared to conventional treatment, robot therapy had advantages in terms of clinical and biomechanical measures. The robot group had statistically larger improvements in a clinical motor impairment scale (Fugl-Meyer) after 1 month of treatment and also after 2 months of treatment. After 2 months of treatment, the robot group had significantly greater strength improvements in joint actions that received focused training (shoulder flexion, abduction, adduction, and elbow extension). Analysis of the kinematics of free reaching movements found that the robot group had larger increases in reach extent in six of the eight movements tested. At the 6-month follow-up, the groups were no longer different in terms of the motor impairment scale. However, the robot group had larger improvements in the FIM at the 6-month follow-up.

These results are evidence that this regimented program of robot-assisted movement has significant advantages compared to an equally intensive program of conventional treatment. While proximal upper limb function was the focus of treatment in both groups, there was no attempt to match the content in terms of movement type or number. Thus, the advantages of the robot treatment could have been due to this disparity in content. It remains to be determined if similar results would have been attained if a human therapist performed the actions of the robot. However, this would have required the therapist to support the paretic limb against gravity and apply assistance or resistance to the limb for nearly an hour. Thus, the argument can be made that the robotic device provides an effective program of exercise that cannot easily be replicated by a human therapist.

Although both groups eventually reached the same level of improvement in the Fugl-Meyer motor impairment scale at the 6-month follow-up, the pattern of improvement was clearly different. The rate of improvement in the first month of treatment was four times greater in the robot group. In contrast, the controls continued to improve in the 6-month period after the end of treatment, whereas the robot group showed minimal improvements in this period. This suggests that the mechanism of improvement was different in the two groups. Significant group differences in the biomechanical measures of strength and reaching extent also support this theory. For example, it
may be that participants in the robot group improved in their ability to activate paretic muscles, which resulted in improvement in the strength measures. Participants in the control group might have had improvements in skill acquisition that carried over to home exercise programs and provided the basis for improvements during the follow-up period. Because both treatments appear to have therapeutic value, but with different mechanisms, the best overall coarse may be to integrate robotic devices into conventional treatment.

Ongoing clinical testing is comparing the effectiveness of MIME treatment with conventional methods in acute and subacute stroke patients (1 week to 5 months post-stroke). The subacute testing will also evaluate the effectiveness of the bimanual mode compared to unilateral modes. A dosage effect will be sought by comparing acute patients who receive 2 hours of treatment with MIME to patients who receive 1 hour per day.

**ARM Guide**

The MIT-MANUS and MIME studies provide evidence that robotic therapy is useful as an adjunct to or even as a replacement for some conventional therapy techniques, but they leave open the question of which elements of the robotic therapy are essential. For example, it may be that the repetitive movement attempts by the patient, rather than the mechanical assistance provided by the robotic device, are the primary stimuli to recovery. This question is being addressed using a device called the ARM Guide in a study at the Rehabilitation Institute of Chicago in collaboration with the University of California at Irvine.

The ARM Guide is a trombone-like device designed to mechanically assist in reaching movements (Fig. 2). Because reaching movements typically follow straight-line trajectories, the device uses a linear slide to guide reaches by the participant. The linear slide can be oriented at different yaw and pitch angles to allow reaching to different workspace regions. Like MIT-MANUS and MIME, the device can assist or resist movement and can measure hand movement and force generation. The device is statically counterbalanced so that it does not gravitationally load the arm. Patients receive visual feedback on a computer screen about their movement as sensed by position and force sensors on the device.

In an ongoing clinical evaluation of the device, 16 chronic stroke patients have received 24 therapy sessions over 2 months. The first group, termed the “robot group,” participated in 24 exercise sessions that lasted approximately 1 hour each. During each session, the participant performed reaching movements with the ARM Guide toward five targets distributed at different reach heights and directions. The participant initiated movement, and the ARM Guide sensed that movement had started and then moved the handle at a desired speed through the arm’s full passive range. The participant was instructed to follow along with the handle. If the participant moved at the desired speed, the device did not assist or resist in the arm movement. If the participant was unable to complete the reach or moved too slowly, the device assisted through the end of the reach, with the firmness of assistance increasing exponentially throughout the movement. If the participant’s movement was too fast, the
device resisted movement. Visual feedback of the amount of assistance or resistance provided by the device was given on the monitor in front of the participant (Fig. 2).

The second group, or “free-reaching group,” performed a matched amount of non-robotic exercise. Participants sat in front of a black screen with numbered targets that were located identically to the targets used with the ARM Guide. The participants were instructed to reach as far as they could toward the target at a comfortable pace. No mechanical assistance or constraint was provided to the movement. An electromagnetic motion analysis system (Ascension Technologies, Inc., Burlington, VT) was used to record the hand motion throughout the reach.

All participants were evaluated before and after therapy using a set of biomechanical measures of arm movement, including measures of range, speed, smoothness, and muscle tone. In addition, two clinical measures, the Chedoke-McMaster Scale and the Rancho Functional Test of the Upper Extremity, were used to evaluate arm function. So far, participants in both the ARM Guide and free-reaching groups have shown significant improvement in both the biomechanical and clinical measures.\textsuperscript{30,31}

Although there are apparent differences in the patterns of voluntary motion in the ARM Guide population, the amount of functional improvement in the two groups has been comparable.
One interpretation of these preliminary results is that the action of repetitively attempting to move, rather than the mechanical assistance provided by the ARM Guide, is the primary stimulus to arm movement recovery. Participants in both the ARM Guide and the free-reaching groups tried to activate damaged descending pathways for a matched amount of repetitions, and this volitional effort may have been the stimulus for motor recovery. This hypothesis is consistent with other repetitive movement exercise paradigms that improve upper extremity movement ability after brain injury.\textsuperscript{8,12,14}

Another possible explanation for these preliminary results is that the particular form of robotic therapy provided by the ARM Guide is suboptimal and that other forms of robotic therapy may demonstrate a benefit over unassisted exercise. For example, the MIME device provides bimanual therapy, and this feature may be therapeutically beneficial. A third possible explanation is that mechanically assisted movement will eventually be found to benefit particular subsets of stroke patients. For example, severely impaired participants may have an increase in motivation and may benefit from the proprioceptive stimulation and soft tissue effects provided by the mechanical assistance. The participant population in the ARM Guide study spanned a range of impairment levels and stroke types; further analysis is needed to determine if patients with particular clinical profiles benefit uniquely from the mechanical assistance.

\textbf{ARC-MIME: Commercialization}

The ARC-MIME project at the Rehabilitation Technologies Division of Applied Resources Corp. (Westmont, NJ) is an attempt to develop a clinically viable, commercial device that merges concepts from MIME and ARM Guide\textsuperscript{13} (Fig. 3). Because many of the movement patterns used in the MIME therapy are based on straight-line reaching movements, a linear slide such as the ARM Guide could accommodate a significant portion of the movement patterns used in the MIME treatment. In addition, since a linear guide has only one degree of freedom, safety of limb manipulation and a reduction in manufacturing costs may be more easily achieved. With NIH Small Business Innovation Research (SBIR) Phase I support, a prototype one degree of freedom device (ARC-MIME) was built that emulates many of the MIME therapy tasks. The MIME software was ported to ARC-MIME, making available all of the MIME control modes.

In initial testing of ARC-MIME at the Veterans Affairs Palo Alto Rehabilitation Research & Development Center, four chronic stroke patients exercised in both MIME and ARC-MIME in the same session. Participants were first seated in ARC-MIME, and the slides were positioned to perform forward-tabletop and forward-upward reaches. Participants performed 10 trials of each mode for each trajectory. A goniometer measured the angles of the elbow and shoulder at the start and end positions of each trajectory. Participants then moved to the MIME system, and matching trajectories were programmed into the robot. Ten trials were performed at each mode. When the movement patterns were matched in this way, the force directed toward the targets by the paretic limb in the two devices was not significantly different. Thus, it was concluded that participants
interact in ARC-MIME in a similar fashion to MIME, and the clinical gains seen in the MIME training could possibly be reproducible with ARC-MIME. Furthermore, because the slide is functionally similar to the ARM Guide, the benefits of training with the ARM Guide could translate to this device if the ARM Guide exercise modes are implemented. With NIH SBIR Phase II funding, a second design iteration is currently underway, and clinical testing is expected to begin in 2002.

One issue to be resolved by the ARC-MIME project is whether effective yet affordable systems can be developed. Because the cost of the investigational devices described earlier is prohibitive, it becomes paramount to identify the essential therapeutic features. For example, much of the expense of ARC-MIME lies in the six-axis force sensor used to measure off-axis forces from the paretic arm. Measurement of these forces may not be critical to the therapeutic effectiveness of the device, so this expensive sensor may not be necessary. In addition, the effects of bimanual therapy in MIME are currently being evaluated in a clinical trial. If the value of the bimanual mode is equivocal, implementing only the unilateral exercises can further reduce the cost. Cost reduction will have to be balanced with the potential for quantitative feedback and novel sensorimotor stimulation. For example, an automated system with sensors can provide immediate, continuous, quantitative performance information on the progress and status of the user.

Figure 3. Photos of the ARC-MIME system. (A) A right hemiparetic participant is performing bimanual mirror-image movements in the system. The slides can be tilted and rotated to align with different directions. A six-axis sensor measures forces between the participant’s left arm and the slide. A single-axis force sensor measures the forces applied along the slide by the participant’s right arm. (B) A close-up view of the slide and the attachments with the splint. The splint is free to rotate about all axes. A quick-release mechanism allows for easy detachment from the system.
This information can be integrated into the exercises, providing feedback and motivation to the patient and creating a dynamic therapy program that automatically responds to the patient.

Critical to the commercial success of any device such as ARC-MIME is the determination of how the device could be used to benefit both patients and therapists. For those patients who could tolerate additional exercise, a robotic therapy device could be used relatively unsupervised as an adjunct to regular therapy. Also, therapists could integrate the device into their regular therapy. This could improve the efficiency of therapists by providing a tool that alleviates the manual manipulation aspects of their treatment, thereby allowing them to focus on other aspects of therapy. The device could allow more effective group therapy, allowing the therapist to give one-on-one attention to one patient while another worked in the device with intermittent supervision. Finally, if the device can be made portable, a home version could facilitate more effective home-based exercise programs.

In addition to improving the efficiency and intensity of current rehabilitation practice, an effective therapeutic device could actually decrease the cost of health care. A device that facilitates faster functional recovery could reduce the duration of one-on-one therapy required in both inpatient and outpatient settings. If patients achieved a higher level of functional independence by using the device, the cost of long-term care might also be reduced by decreasing or delaying the need for assisted living or paid caregivers.

Even though most stroke survivors regain the ability to ambulate at some level, recovery of use of the more-affected arm is generally poorer. This in part may be due to the historic emphasis on ambulation and mobility in rehabilitation, with upper limb movement ability often of secondary importance. With the emphasis on cost reduction in health care, an effective device could fill a need that is unlikely to be addressed by additional one-on-one treatment from therapists. Even if the device does not significantly decrease the cost of health care, it may still be economically viable if it improves the quality of life after stroke. For example, if the device helps individuals with stroke improve or maintain their arm movement ability, they may elect to purchase the device or pay for its use out-of-pocket.

From a market entry standpoint, the overwhelming demographic shifts toward aging populations in many western countries speak to the opportunity for alternatives and supplements to existing therapy. The population at risk for a stroke will increase sharply in this century. Modest market share can result in a successful product. A successful product will lead to its widespread use and inevitably drive advances in this technology. In addition, it is expected that the uniform, systematic therapy techniques facilitated by ARC-MIME will lead to advances in the understanding of the effects of therapy on recovery from stroke and eventually to new improved therapy techniques.

**Future Areas**

Although all the work reviewed in this article is directed at shoulder and elbow movement, recovery of hand function is an area that also deserves attention. Given the
integral role of the hand in upper limb function, devices for hand movement therapy are likely to be targets of future research. However, with the large number of degrees of freedom involved with hand movement, the engineering challenges are considerable if all degrees of freedom are to be actuated. Instead, a device that assists a limited set of hand movements may be the only cost-effective design. For example, a device that assists cylindrical grasp, thumb-index finger pinch, and three-jaw chuck may be sufficient to provide functional benefits.

Researchers are also developing robotic devices for gait training. Efforts in this area are motivated by evidence that body-weight–supported locomotion training in humans improves stepping after spinal cord injuries and other neurological disorders.\textsuperscript{34–38} This training involves partial unloading of the patients’ lower limbs with a harness suspended overhead while therapists assist with the patients’ leg movements during stepping on a treadmill. The treatment is highly labor-intensive, and devices that automate this type of training could have a large impact. To date, several robotic devices have been developed for automating body-weight–supported locomotion training in humans.\textsuperscript{39,40} However, results of patient testing with these devices are limited.

**Conclusion**

Clinical results from three research labs provide evidence that robotic devices for upper limb movement therapy have therapeutic value. Results from MIT-MANUS support its use as an adjunct to regular therapy, and the results from MIME suggest that robotic devices can provide benefits not currently provided by conventional techniques. The ARM Guide results show that a simpler one degree of freedom device can also have measurable benefits, but they also illustrate the importance of identifying the critical therapeutic aspects of the device. After completion of clinical trials of ARM Guide, MIME, ARC-MIME, and MIT-MANUS, a clearer picture will emerge of the essential therapeutic aspects of robotic devices and the populations that will benefit most from them. This in turn will ultimately determine how a cost-effective commercial device can be produced.

Although selective benefits from specific types of robotic interventions may emerge, we believe that a key factor in promoting recovery with the aid of a robotic device is intensive, repetitive practice. The influence of duration, intensity, and frequency of treatment may ultimately outweigh the specific benefits that result from different types of robotic therapy. It is the ability of robotic devices to cost-effectively provide such therapy that may ultimately offer the greatest advantage.

It is important to emphasize that robotic technology is not intended to replace the therapist. No robot can replicate the knowledge and experience of the therapist in assessing the needs of the patient and the outcomes of the therapy program. Instead, robotic technology can be used to carry out the repetitive practice that is needed to facilitate functional gains. In this way, the therapist can leverage her or his time by treating more patients, while robotic devices facilitate more repetitive practice for each patient. This can result in functional recovery that is potentially greater than what is currently being achieved.
Acknowledgments

The MIME project was funded by the Department of Veterans Affairs, Veterans Health Administration, Rehabilitation Research and Development Service. The ARM Guide project was funded by the Whitaker Foundation and the National Institute for Disability and Rehabilitation Research. The ARC-MIME project was supported by a National Institutes of Health Small Business Innovation Research grant.

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