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Abstract

Objectives: *To create easy to understand, antidepressant medication decision making aids and describe the process used to develop the aids for patients diagnosed with depression.* ***Methods:*** *In collaboration with the Institute for Clinical Systems Improvement (ICSI), antidepressant medication decision making aids were developed to enhance patient and physician communication about medication selection. The final versions of the aids were based on design methods created by Dr. Victor M. Montori (Mayo Clinic) and discussions with patients and providers. Five physicians used prototype aids in their outpatient clinics to assess their usefulness.* ***Results:*** *Six prototype antidepressant medication decision making aids were created to review potential side-effects of antidepressant medications. The side effects included were those patients feel are most bothersome or may contribute to premature discontinuation of antidepressant treatment, including: weight changes, sexual dysfunction, sedation, and other unique side effects. The decision aids underwent several revisions before they were distributed to physicians. Physicians reported patients enjoyed using the decision aids and found them useful. The sexual dysfunction card was considered the most useful while the daily administration schedule card was felt to be the least useful.* ***Conclusions:*** *Physicians found the antidepressant decision making aids helpful and felt they improved their usual interactions with patients. The aids may lead to more patient-centered treatment choices and empower patients to become more directly involved in their treatment. Whether the aids improve patient's medication adherence needs to be addressed in future studies.*

Introduction

Approximately 14.8 million adults, or 6.7% of the United States (U.S.) population, suffer from depression annually.[1,2] Depression is often a chronic or recurrent disorder and may require patients to adhere to life-long treatment.[3,4] The symptoms of depression are treatable, but depression is only detected in one-third to one-half of patients suffering from the illness.[5] About one half of patients with depression are treated in the primary care setting and only 20-40% show significant improvement after one year.[1,6,7]

The American Psychiatric Association's (APA), Practice Guideline for the Treatment of Patients with Major Depressive Disorder (Third Edition),[4] outlines three phases for the treatment of depression: acute, continuation, and maintenance phases. The goal of the acute phase is to achieve complete remission of the patient's depressive symptoms. The acute phase lasts a minimum of six to twelve weeks. The goal of the continuation phase is to preserve remission and prevent symptom relapse. The same antidepressant medication and dose should be used during both the acute and continuation treatment phases. The maintenance phase should be considered for patients at risk of recurrence of depressive episodes.

Effective treatment of depression requires patients actively participate in, and adhere to, treatment plans, despite side effects or burdensome treatment requirements.[4,8,9] Patients may have strong preferences for medications based on previous experiences of family and friends.[4] Considering these preferences during treatment decision making may improve adherence to treatment.[4,8,9] Successful treatment of depression should also include the patient and their family actively participating in their care and ongoing education.[4]

Antidepressant medications exhibit similar antidepressant efficacy between and within classes. The initial selection of an antidepressant medication should be based on anticipated side effects. The tolerability and safety of antidepressant side effects should be assessed for each individual patient. Selective Serotonin Reuptake Inhibitors (SSRIs), venlafaxine, duloxetine, mirtazapine, and bupropion are all first-line options for the treatment of depression. These agents have more tolerable side effects than tricyclic antidepressants (TCAs) or mono-amine oxidase inhibitors (MAOIs).[4,8,9]

Side effects complicate treatment because they often occur before benefit from the medication is recognized.[4] Patients need to take an antidepressant for at least 6 to 12 months

after symptom remission to reduce the risk of symptom recurrence.[4,8] Discontinuing the medication too early is associated with a 77% increase in recurrence of symptoms.[10] Untreated symptoms of depression, such as feelings of pessimism, low motivation, low energy, isolation, and guilt may also lead to patients stopping treatment prematurely.[4]

Patient's attitudes may also impact compliance. A study evaluating the reasons why patients stop their antidepressants found 55 percent stopped treatment when they started to feel better, 23 percent due to side effects, 10 percent due to fear of becoming dependent on antidepressant medication, and 10 percent because of lack of efficacy. Many patients believe their depression will resolve without intervention. Patients may also adjust the dose of their antidepressant without discussing these changes with their prescriber.[11]

Current guidelines for the treatment of depression strongly suggest incorporating patient specific preferences when selecting an antidepressant medication.[4,8,9] Unfortunately, patients' personal experience or preferences are not explicitly incorporated into the decision-making process of these guidelines. Education on the potential side effects of antidepressant medications may help patients make informed decisions and adhere to treatment. Research suggests the physician-patient relationship is critical in influencing medication adherence. Patients who believe their physicians understand how they feel are more likely to tell them if they have been non-compliant.[11]

Dr. Victor M. Montori (Mayo Clinic) has developed diabetes medication decision aids for antihyperglycemic medications. Implementation of the decision aids encouraged patients to ask their physicians questions and voice concerns.[12] Dr. Montori and his team have also created decision aids to assist patients with type 2 diabetes select an appropriate statin to treat hypercholesterolemia. This set of aids increased the proportion of patients who adhered to statins at three months and assisted in improved dialogue between patients and their providers.[13] Decision making aids for osteoporosis in the primary care setting are currently being evaluated.[14]

The goal of the current study was to create similarly designed decision making aids for depression. These aids would assist patients and providers in the selection of a suitable antidepressant medication by initiating conversations about side effects, costs, and effective treatment of depression. The long-term goal is to evaluate the effectiveness of the aids and the process of shared decision making on overall patient compliance with antidepressant medication and treatment outcomes.

Methods

Antidepressant medication decision making aids were developed in collaboration with the Institute for Clinical Systems Improvement (ICSI). Dr. Montori previously reviewed the process for developing diabetes decision making aids.[12] The overall design of the antidepressant aids built on the fourth, and final prototype used in his study.

The development of the antidepressant medication decision-making aids started with selecting potential topics. We consulted psychiatrists, primary care physicians, and members of ICSI to identify key areas patients and providers felt were important when selecting an antidepressant medication. We also used accumulated, direct patient experience to further refine our themes and the overall content for the initial topics. We reviewed commonly asked questions during patient-focused medication groups on inpatient units and during patient interviews as part of physician-requested pharmacy consults. We initially came up with twelve potential topics.

The primary resources for card content were Micromedex and standard, psychopharmacology reference books. The symbols and layouts of the cards changed several times before they were distributed to physicians to help make them more patient-friendly (Fig. 1). The final version of the aids was provided to five primary care physicians or psychiatrists in the Minneapolis/St. Paul Metropolitan area.

This study did not require University of Minnesota, Institutional Review Board (IRB) approval because it was not considered human subjects research.

Results

The number of card topics was reduced from twelve to six based on physician feedback and to ensure patients would have time to evaluate the aids during a typical appointment. Decision aids were designed to address cost, daily administration schedule, and potential side effects like weight gain and sexual dysfunction (Fig. 2). The aids took the form of 9 inch x 3.5 inch paper, laminated cards. Each card addressed one issue, such as sexual dysfunction, and then represented how it is affected by each of the first-line antidepressants. Symbols and pictures on the cards help minimize text and made the cards more useful for people who have difficulty reading.

The medications selected to be included in the antidepressant medication decision-making aids included all commercially available SSRIs and mixed-reuptake inhibitors (e.g., venlafaxine, bupropion, mirtazapine, and duloxetine) indicated for the treatment of major depression. These

medications comprise approximately 98 percent of prescriptions commonly used during the initial treatment of a major depressive episode in our practices. Monoamine oxidase inhibitors (MAOIs) are rarely seen until a patient has failed numerous other antidepressant treatment options. Tricyclic antidepressants (TCAs) are primarily used for neuropathic pain or for the treatment of insomnia, rather than depression. We excluded both the MAOIs and TCAs for simplicity, their rare use as a first or second-line antidepressant treatment options, and because we already had multiple agents included in the aids.

Physicians reported patients found the decision aids interesting and enjoyed using them. The aids facilitated conversations and changed the normal interaction between the provider and patient. The sexual dysfunction card was considered the most useful while the administration schedule card was least useful. While the sexual dysfunction card was most useful, it was also the most confusing for patients because of the positive and negative symbols indicating the potential risk of each agent causing sexual side effects. Physicians suggested cards addressing dosing range, pregnancy category, breast feeding compatibility, mechanism of action, drug-drug interactions, and co-morbidities treated by each drug would also be useful for patients in the future.

Discussion

Six aids were designed to allow physicians enough time to discuss all topics with the patient. Paper, rather than electronic, cards were developed so patients and physicians could easily use them in an exam room and to minimize technical difficulties. Many patients used the cards but few were willing to provide direct feedback regarding their experience with the decision aids. The decision aids likely influenced the content of the conversations and the questions asked by patients.

Physicians are clinical experts and can provide a wealth of knowledge and clinical practice experience to a patient consultation. However, physicians occasionally develop a short-list of first-choice antidepressant medications which may not be appropriate for all patients. Patients are experts on how they feel and may be better able to define their overall level of depression and the degree to which it interferes with their day-to-day activities. By providing details about their daily lifestyle (i.e., what time they wake up, when they eat meals, when they return from work, and the type of work they do), patients are providing important information necessary for the success of their antidepressant treatment.[12]

The aids were not meant to replace education provided by the physician but should encourage patients to ask questions and voice concerns. The usefulness of the aids relies on the physician's communication skills and clinical knowledge. These attributes are variable among physicians and could affect the overall experience the patient has with the decision aids. Physicians in this study were provided with a user guide but were ultimately allowed to use the decision aids however they deemed appropriate.

The design of the "administration schedule" card changed prior to distributing it to physicians to help minimize confusion (Fig. 1). Team members from ICSI felt the sun and moon symbols would be easier for patients to understand, rather than the multiple capsules used on the first design. The cards contain all the necessary information but some of the symbols, such as the pluses and minuses on the sexual dysfunction card, were confusing to some patients. Dr. Montori's study incorporated a design team to assist with card layout and design. Future studies of the depression aids would benefit from the assistance of a graphics artist or design consultant.

The topics of the six prototype cards were found to be relevant by patients and physicians. However, there are other important issues that were not addressed by the cards, such as medication dose ranges or pregnancy safety category. Topics like pregnancy category would be useful for a smaller subset of patients, but would be extremely helpful when discussing the risks and benefits of treating depression during pregnancy.

Physicians reported some patients were hesitant to use the decision making aids because they did not want to be part of a study. Therefore, we had to rely on the physician's interpretation of the patient interaction and could not analyze information directly provided by patients. In the future, some type of incentive may need to be offered to patients to motivate them to provide feedback in the form of surveys or short-answer questions. Dr. Montori offered patients 15 dollars for participating in his study with the osteoporosis decision aids but we did not have such funds available.[14]

There are several potential barriers to the shared decision making process for mental health patients. Patient insight regarding the need for treatment and their symptom severity, fears about social stigma if professional help is sought, attitudes about treatment, changes in symptom severity, and confusion about the many different treatment options can impact the shared decision making process. While many patients with depression report they would like to receive

more time consulting with their physician and more information about their illness and treatment options, other patients prefer the physician to take action and make decisions. The latter is generally true for patients who are too ill to take part in the process or make decisions about difficult situations.[15]

Barriers exist for physicians as well. Shared decision making is a time consuming practice and physicians must be able to integrate patient preference, clinical judgment, and expanding scientific knowledge.[16,17] Despite these barriers, simple and easy-to-understand decision making aids could greatly enhance mental health patients' understanding of depression and the treatments available.

While it appears the decision aids were easy to understand and changed the normal interaction between the provider and patient, more data is necessary to reach a conclusion. Dr. Montori has already shown that decision making aids for patients with diabetes are helpful for selecting diabetes medications and/or statins. They help create conversations and patients ask more questions. The decision making aids for statins increased adherence rates at three months but the aids for diabetes medications did not improve adherence.[13,18] The current study allowed for the successful design of six antidepressant decision aids and helped determine which of the aids need more work. The development of additional cards can also begin based on feedback from physicians and patients. Another study assessing the design of the cards and their usefulness is necessary before adherence and shared decision making can be addressed. In the future, an electronic version of the cards could also be developed.

Dr. Montori and his team went through the design process for their diabetes decision aids and determined which design best facilitated a conversation between the clinician and patient about diabetes medication options. The prototypes were evaluated in two ways. They were used in actual clinical encounters and researchers recorded observations and later looked for patterns. The second method involved a patient advisory group, in which participants role-played using the prototypes and then reflected on their experience. Researchers again looked for patterns and compared their reflections with the behaviors in the clinical encounters. They used pattern recognition to identify problems and challenges and used these as opportunities to experiment with the prototypes.[12] We relied on feedback from ICSI team members, physicians, and patients but did not have access to advisory or research teams.

Dr. Montori's first prototype provided bullet-form, quantitative information about the pros and cons of each medication (Fig. 3). Each card described one medication or drug class and focused on numerical information. This prototype did not prompt patients to ask questions or talk about the cards. Patients found the information interesting but wanted the aids to provide a direct comparison across treatment options. The second prototype was a narrative explanatory form and allowed patients to compare across medications (Fig. 4). Patients understood the information on the cards but it did not change the interaction with the provider much. The cards included too much text and patients still found it difficult to compare medication options. The third prototype listed medication options along the top of the card and categories along the left. Velcro was affixed to the back of the cards and the patients and clinicians could arrange them on a decision board. These cards generated more conversation but were cumbersome and still contained too much text.[12] Our cards also underwent several revisions but we did not have access to a design team and did not have the funding to pay for a graphic artist.

The final version of Dr. Montori's aids focused on using pictures and symbols rather than words. Instead of each medication having its own card, the cards described how each medication could affect the issue of interest (Fig. 5). This design generated conversation and changed the type of questions patients asked.[12] Based on this success, the design for the antidepressant aids built on the final prototype used in his study. There are some key differences, however.

The medication classes on Dr. Montori's aids are always listed in the same order (i.e. metformin, followed by insulin, followed by glitazones, etc.) to help patients easily compare the medications. We were not able to replicate this with the antidepressant aids because there were more medications to compare and they did not fit nicely onto one card. This may have made it more difficult for patients to locate a specific medication on each card and compare across treatment options. Another difference is the choice of topics addressed by the aids. For example, Dr. Montori did not address the cost associated with each agent because of the variety of medication benefits available.[12] Another limitation to including cost data on a decision aid is the information outdates quickly and needs to be updated frequently. Despite these issues, we chose to address cost because we found it was a large concern for patients in our medication groups. Many of our patients do not have insurance and cannot afford the more expensive, brand name products.

In the future, we plan to assess the feasibility of the decision making aids through use of surveys that will be provided to physicians and patients. We would also like to include pharmacists who are following mental health patients in

ambulatory care clinics and helping make treatment decisions. This may be accomplished through collaboration with the College of Psychiatric and Neurologic Pharmacists (CPNP), which would allow us to disseminate the decision aids to other mental health pharmacists who could help assess and evaluate them in their practice settings. The surveys will be used to further evaluate the graphics on the aids, their readability, and ease of use. Based on the results of this development study, we plan to create two more versions of the sexual dysfunction card so providers and patients can help determine which card is easiest to understand and has the most useful graphics. Along with providing the user-manual we created for physicians, we plan to host in-services at participating sites to teach providers how to appropriately use the decision aids in practice. We may also create an on-line link to the decision aids to assess the feasibility of using an electronic form versus hard copies in the provider's office. The final goal will be to evaluate the effectiveness of the aids and the process of shared decision making on overall patient compliance with antidepressant medication and treatment outcomes.

Conclusion

Antidepressant decision making aids appear to be useful for helping patients choose an initial antidepressant and increased discussion between the physician and patient. The design of the cards plays an important role in how the patient interacts with the physicians and the type of questions asked. More studies are necessary to determine if the aids can shift the clinical visit from a disease-centered approach to a patient-centered approach. Involving patients more in the decision making process may ultimately improve compliance and invest them more in their own health.

References

1. Kessler R, Chiu W, Demler O, Walters E. Prevalence, severity and comorbidity of 12- month DSM-IV disorders in the national comorbidity survey replication. *Arch Gen Psychiatry* 2005; 62:617-27.
2. The Numbers Count: Mental Disorders in America. 2008. National Institute of Mental Health. 25 July August 2011 <http://www.nimh.nih.gov>
3. Depression. 2008. Mayo Clinic. 25 July 2011 <http://www.mayoclinic.com>
4. American Psychiatric Association. Practice guideline for the treatment of patients with Major Depressive Disorder (third edition). 2010. <http://www.psychiatryonline.com>
5. Schonfeld M, Verboncoeur C, Fifer S, et al. The functioning and well-being of patients with unrecognized anxiety disorders and major depressive disorder. *J Affect Disord* 1997; 43: 105-19.
6. Katon W, Von Korff M, Lin E, et al. Stepped collaborative care for primary care patients with persistent symptoms of depression: a randomized trial. *Arch Gen Psychiatry* 1999; 56: 1109-15.
7. Unutzer J, Katon W, Callahan C, et al. Collaborative care management of late-life depression in the primary care setting: a randomized control trial. *JAMA* 2002; 288:2836-45.
8. Lam R, Kennedy S, Grigoriadis S, et al. Canadian network for mood and anxiety treatments (CANMAT) clinical guidelines for the management of major depressive disorder in adults. *J Affect Disord* 2009; 117: 26-43.
9. Qaseem A, Snow V, Denbert T, et al. Using second-generation antidepressants to treat depressive disorders: a clinical practice guideline from the american college of physicians. *Ann Intern Med* 2008; 149: 725-733.
10. Melfi C, Chawla A, Croghan T, et al. The effects of adherence to antidepressant treatment guidelines on relapse and recurrence of depression. *Arch Gen Psychiatry* 1998; 55:1128-32.
11. Demyttenaere K. Compliance and acceptance in antidepressant treatment. *Int J Psych Clin Pract*2001; 5(1): 29-35.
12. Breslin M, Mullan R, Montori V. The design of a decision aid about diabetes medications for use during the consultation with patients with type 2 diabetes. *Patient Ed and Counseling* 2008; 73: 465-472.
13. Weymiller A, Montori V, Jones L, et al. Helping patients with type 2 diabetes make treatment decisions: statin choice randomized trial. *Arch Intern Med* 2007; 167: 1076-1082.
14. Pencille L, Campbell M, Van Houten H, et al. Protocol for the osteoporosis choice trial. A pilot randomized trial of a decision aid in primary care practice. *Trials* 2009; 10: 113-121.
15. Simon Dipl Psych D, Loh Dipl Psych A, Wills C, et al. Depressed patients' perceptions of depression treatment decision-making. *Ltd Health Expectations* 2006; 10: 62-74.
16. Torrey W, Drake R. Practicing shared decision making in the outpatient psychiatric care of adults with severe mental illnesses: redesigning care for the future. *Community Ment Health J* 2010; 46: 433-440.
17. Drake R, Cimpean D, Torrey W. Shared decision making in mental health: prospects for personalized medicine.
18. Mullan R, Montori V, Shah N, et al. The diabetes mellitus medication choice decision aid. *Arch Intern Med* 2009; 169(17): 1560-1568.

Figure 1: The aid on the right depicts the original version of the "Schedule" card and the aid on the left represents the final prototype used in the study.

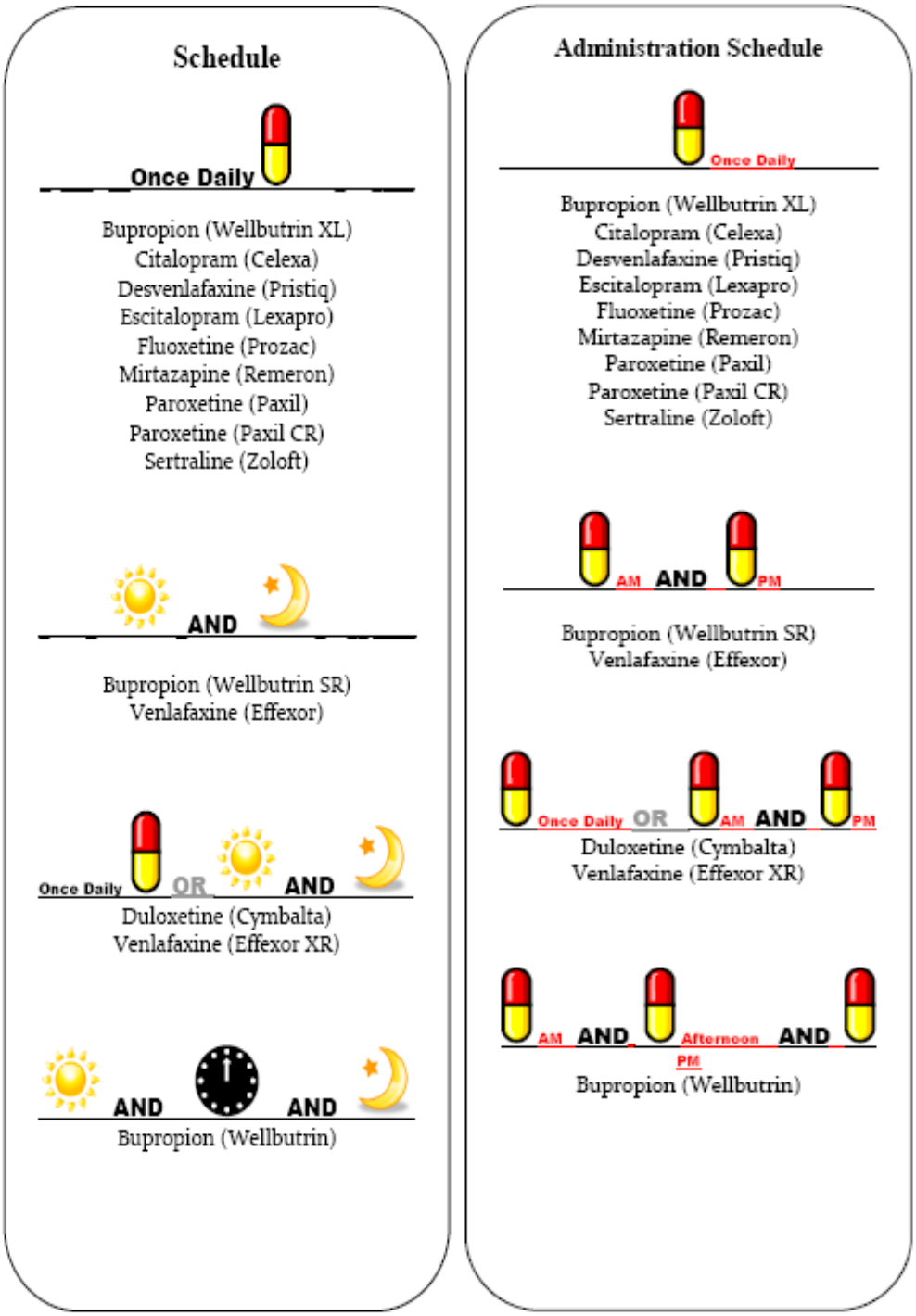

Figure 2: The six prototype cards used in the study.

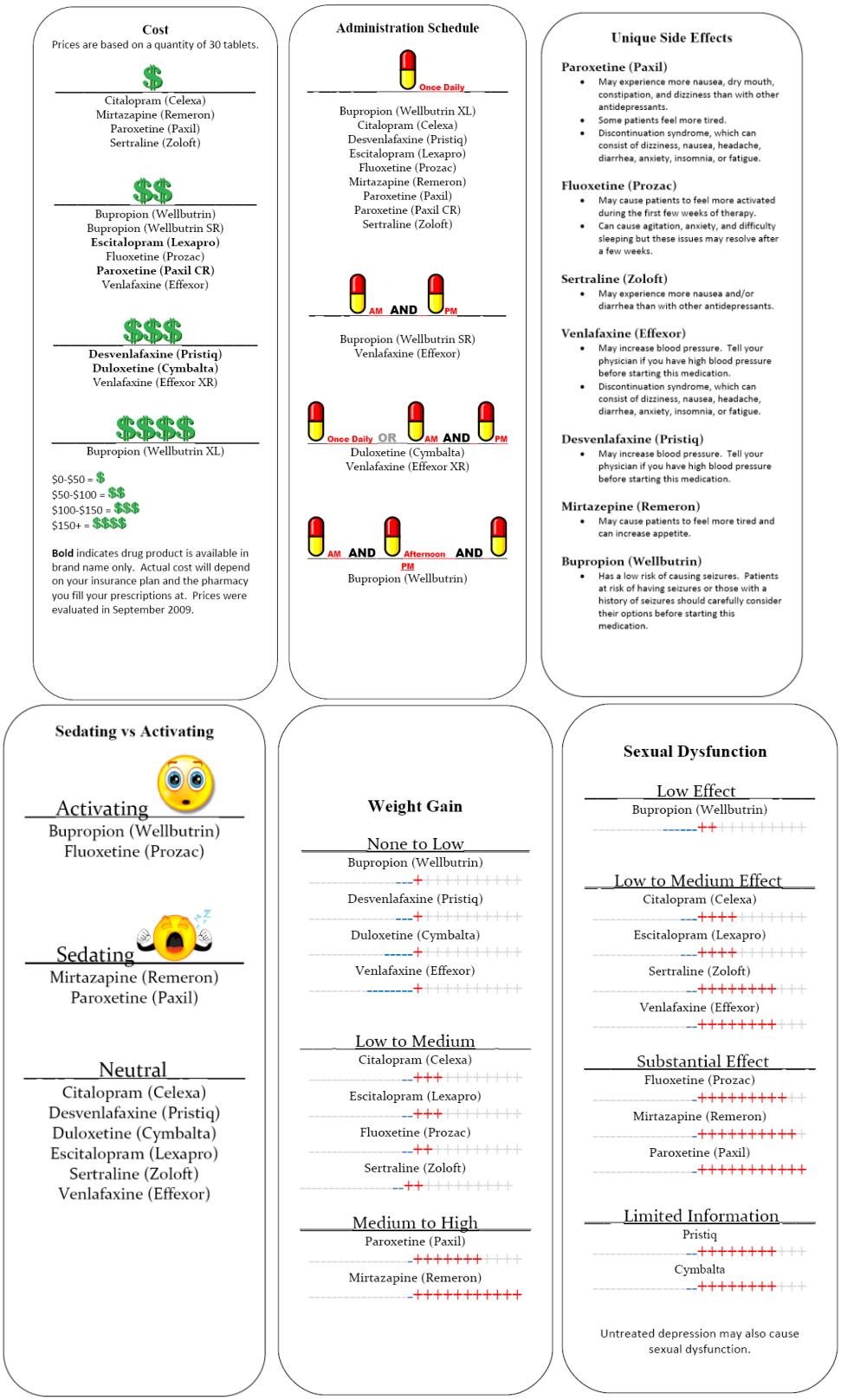

Figure 3: An example of Dr. Montori's first prototype. Reprinted with permission from reference 12.

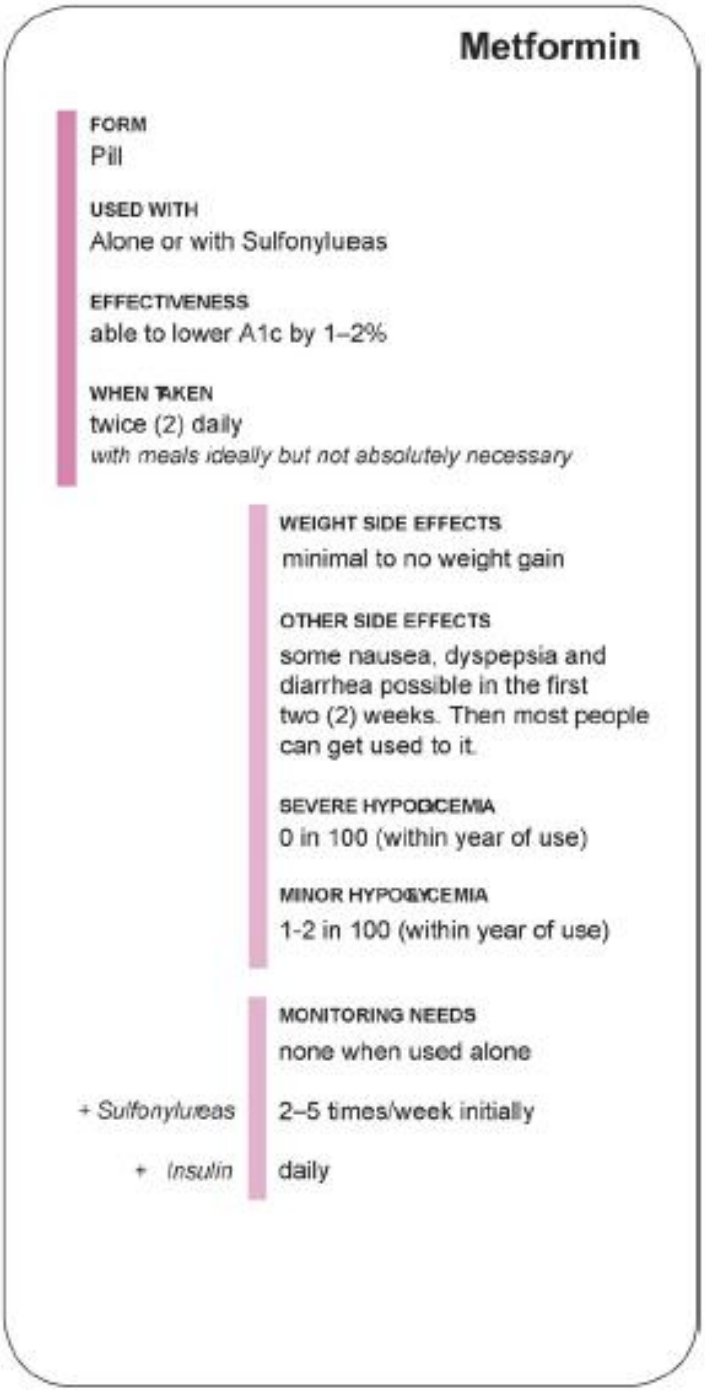

Figure 4: An example of Dr. Montori's second prototype. Reprinted with permission from reference 12.

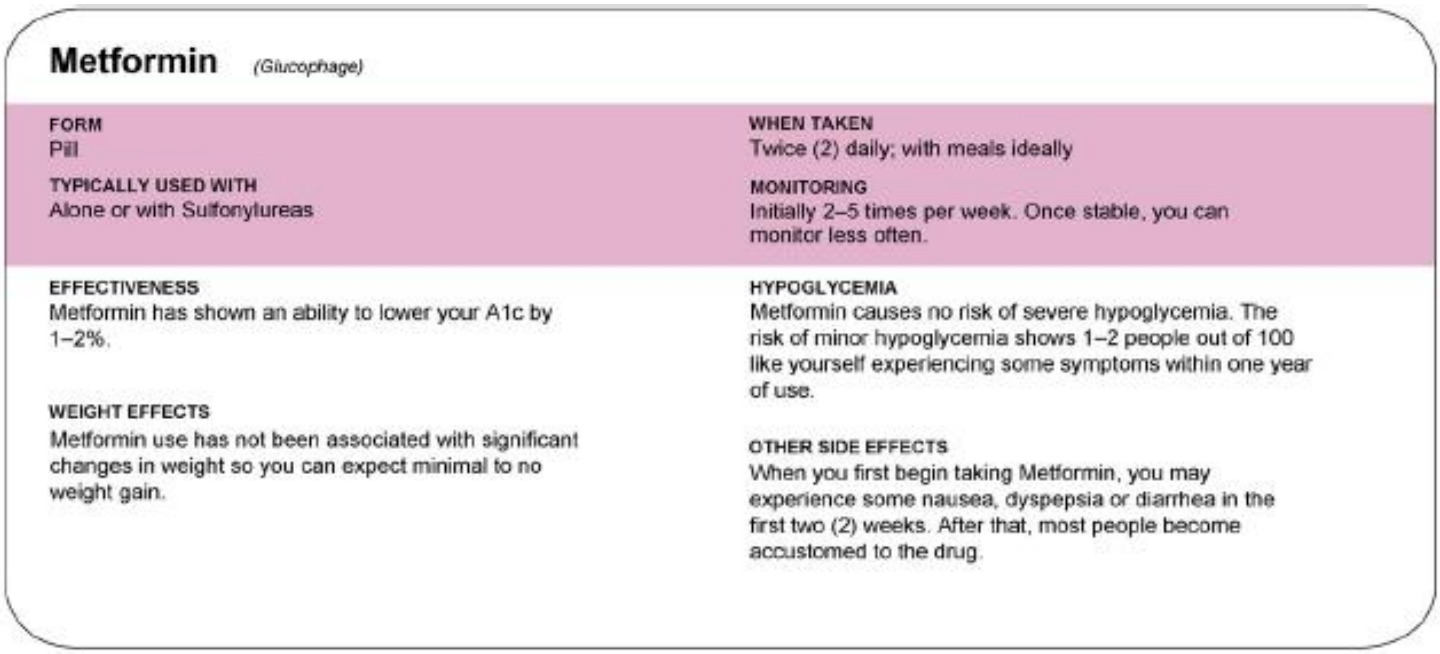

Figure 5: Dr. Montori's final prototype set. Reprinted with permission from reference 12.