Draft Final Report: Med Assist (March 24, 2016)
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We describe herein the final report of the Med Assist Program. Three manuscripts are still in preparation and will be forwarded to Pfizer when submitted for publication. Our work can be described in three parts:

1. **Design and Implementation of a Patient-Centered Navigator Program to Improve Adherence to Disease-Modifying Antirheumatic Drugs**
2. **Barriers to Adherence and Actions of DMARD Navigators to Improve Adherence**
3. **Results of a Pilot Study to Improve DMARD Adherence through Patient-Centered Navigators: Med Assist**

1. Design and Implementation.
    a. **Background**: We developed a patient-centered intervention using navigators, college-educated individuals trained to provide education, advocacy, mental health support and care coordination services tailored to each patient's needs, to understand and improve adherence to disease modifying antirheumatic drugs (DMARDs).
    b. **Methods:** Two board-certified rheumatologists designed a training curriculum for the navigators that included education about systemic rheumatic diseases. Collaborating with a pharmacist, materials were developed on DMARD pharmacokinetics, administration, drug interactions, monitoring, and adverse effects. The drug and disease-specific training consisted of three two-hour modules. A health behavior epidemiologist provided a two-day motivational interviewing training. To familiarize the navigators with available resources, meetings were arranged with a social worker, psychiatry department leadership, a financial counselor, clinic administrators and outpatient pharmacists. Individual structured interviews were conducted between the navigators and four rheumatologists to better understand the needs and perspectives of providers. The navigators also shadowed nurse practitioners during medication education sessions and rheumatologists during clinic visits (**see Attachment for complete materials**).
    c. **Results:** We identified and trained three patient navigators, one of whom is fluent in Spanish. Patients receiving care at an academic medical center with a rheumatic disease who recently started an oral DMARD were eligible. Patients could self-refer, be referred by their rheumatologist, or be identified by electronic medical record review and were contacted after approval from their rheumatologist. 25 of the 32 practicing rheumatologists referred patients. We sent letters to 553 patients, 313 of whom were reached by a navigator. Of these, 114 enrolled and 102 completed baseline surveys. During the ongoing two-year study, patients are followed for a 6-month period. There have been 360 patient encounters (phone calls or in person meetings) and 20 patients have completed the 6-month intervention. Navigators have established a rapport with rheumatologists and opened a channel of communication between patients and providers. They have identified medication errors, recognized and addressed mental health issues and adverse events, and coordinated care across providers to facilitate adherence to rheumatologists' recommendations. They developed a system with the psychiatry department to expedite referrals based on needs they uncover and routinely work with pharmacies, insurance companies and the financial counselor to ensure that patients obtain their prescribed medications.

d. **Conclusions:** A patient navigator program is a feasible strategy to facilitate care coordination and promote adherence to oral DMARDs. Next steps include evaluation of the impact of rheumatology-specific navigators on clinical outcomes and long-term adherence.

2. Barriers to Adherence and Actions of DMARD Navigators to Improve Adherence.
   a. **Background:** Poor adherence to medications is a common problem among rheumatology patients that can lead to irreversible negative outcomes. We piloted an intervention using patient navigators- laypeople trained in care coordination, basic rheumatology, and relevant pharmacology- to improve adherence to oral disease-modifying antirheumatic drugs (DMARDs). Navigators aimed to identify and understand barriers to adherence to DMARDs that may be missed during clinical encounters and to work with patients to develop personalized strategies to overcome these barriers.

   b. **Methods:** We recruited patients ≥18 years-old from a large academic Arthritis Center. Eligibility included a rheumatic disease diagnosis by a board certified rheumatologist and initiation of an oral DMARD within the prior 6 months. Navigators conducted baseline interviews to assess patients' understanding of their rheumatic disease and their adherence to DMARDs. Then, depending on need, navigators contacted patients once every 1-4 weeks by phone or in person, and these conversations were thoroughly documented. Navigators connected patients with hospital resources, provided education about diagnoses and medications, and developed individually tailored strategies to circumvent barriers. Five team members independently reviewed the documentation from patient call notes to categorize issues raised by participants and subsequent navigator actions. Multiple issues and actions could be recorded per patient but each was counted only one time per patient. Differences in coding were adjudicated by the team.
   c. **Results:** Two navigators followed 92 patients for up to six months. At baseline (see **attached Table 1**), mean age was 54 years (SD 17) and 92% were female. 81% had inflammatory arthritis, 10% had lupus or mixed connective tissue disease, and 9% had other rheumatic diseases. Seven main categories of patient issues relevant to adherence were identified: adverse events (45%), challenges with medication acquisition (31%), concerns about medication effectiveness (30%), lack of knowledge about medications or diagnosis (20%), need for social support (14%), financial/insurance difficulties (11%), and interruptions in medication use (9%) (see **attached Figure 1**). 19% of patients raised no issues, 25% discussed one, and 56% ≥ 2 issues. The most common navigator actions included: facilitation of patient-doctor communication (33%), medication and diagnosis education (30%), development of individualized strategies to improve adherence (18%), and assistance with financial/insurance issues (11%).
   d. **Conclusion:** Most patients described one or more issues related to their oral DMARD adherence or to their rheumatic disease. Navigators played a key role uncovering and addressing concerns not identified by routine clinical care. Further analyses will assess the impact of navigators on DMARD adherence and rheumatic disease-related outcomes.

3. Results of a Pilot Study to Improve DMARD Adherence through Patient-Centered Navigators: Med Assist
    a. **Background:** Medication nonadherence accounts for more than $100 billion in preventable healthcare costs annually in the US. Nonadherence to disease-modifying antirheumatic drugs (DMARDs) among patients with rheumatic diseases likely results in significant morbidity. We pilot tested a DMARD navigator program (Med Assist) to determine if one on one patient-centered attention could reduce medication non-adherence for DMARDs.
    b. **Methods:** English or Spanish-speaking patients ≥18 years old who recently started an oral DMARD for a systemic rheumatic disease were invited to participate. The study took place between 2013 and 2015 at an academic medical center. We identified patients using electronic medical record review and obtained permission to contact the patients from the treating rheumatologist. Medications and demographic factors were ascertained using electronic medical record queries. Trained bilingual research assistants administered baseline surveys by phone or in person. We measured self-reported adherence to oral DMARDs using the eight-item Morisky Medication Adherence Scale (MMAS). We determined disease activity for rheumatoid arthritis (RA) and other inflammatory arthritis with the Rheumatoid Arthritis Disease Activity Index (RADAI). Anxiety and depression were assessed with the Mental Health Inventory (MHI-5) and perceived illness severity using the Brief Illness Perception Questionnaire. Trained DMARD navigators interacted with patients over the course of six months. We examined the change over time in the MMAS and correlates of change.
    c. **Results:** We administered surveys to 92 patients. The mean age was 56.1 years (SD 16.2) (see **Table 2**), 95% were female, 72.8% were White, 5.4% Black, 2.2% Asian and 19.6% not reported;17.4% identified as Hispanic. 80.4% had RA or other inflammatory arthritis, 7.6% lupus, and 4.3% other systemic rheumatic diseases. In terms of medication use, 52.2% recently started methotrexate, 20.7% hydroxychloroquine, 10.9% sulfasalazine, 6.5% leflunomide, 3.3% azathioprine, and 3.3% tofacitinib. The mean RADAI was 14.7 (SD 9.1). 89.8% of patients had depressive symptoms (MHI-5<70). The mean adherence score was 6.6 (SD 1.4); 23.9% reported poor adherence to their prescribed DMARD (MMAS <6), 53.3% borderline (MMAS 6 to <8) and 22.8% high (MMAS=8). Patients with poor adherence were more likely to be younger (p=0.01), have more active RA (p=0.05), and more depressive symptoms (p=0.02) . Examining the MMAS and MHI-5 over time showed slight improvement that was not statistically significant (see **Table 2**).
    d. **Conclusion:** In this single arm open label pilot study, the majority of patients who recently started an oral DMARD had borderline or poor adherence and a significant burden of depressive symptoms at baseline. After a six month DMARD navigator program, there was no statistically significant improvement.

Table 1:

	Overall	Poor Adherence (MMAS<6)	Borderline Adherence (MMAS 6 to <8)	High Adherence (MMAS=8)	P-Value
Age, mean years (±SD)	56.1 (±16.0)	48 (±14.6)	57.1 (±15.7)	62.4 (±16.1)	0.01
Gender					
Female	87 (95%)	19 (22%)	47 (54%)	21 (24%)	0.71
Male	5 (5%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	
Ethnicity					
Hispanic	16 (17%)	6 (37.5%)	9 (56.3%)	1 (6.3%)	0.17
Non-Hispanic	72 (78.2%)	15 (20.8%)	39 (42.4%)	18 (25.0%)	
Not-reported	4 (4.3%)	1 (25.0%)	1 (25.0%)	2 (50.0%)	
Race					
White	67 (72.8%)	12 (17.9%)	36 (53.7%)	19 (28.4%)	
Black	5 (5.4%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	
Asian	2 (2.2%)	1 (50.0%)	1 (50.0%)	0 (0.0%)	0.14
Not Reported	18 (19.6%)	7 (38.9%)	10 (55.6%)	1 (5.6%)	

RADAI, mean (±SD) N = 73	15 (±9)	16 (11)	16 (9)	10 (6)	0.05
MHI-5, mean (±SD)* N = 88	61 (±10)	58 (±10)	62 (±10)	62 (±9)	0.02
Illness Perception, mean (±SD)** N = 91	45 (±10)	42 (±12)	45 (±9)	46 (±10)	0.46

Figure 1a:

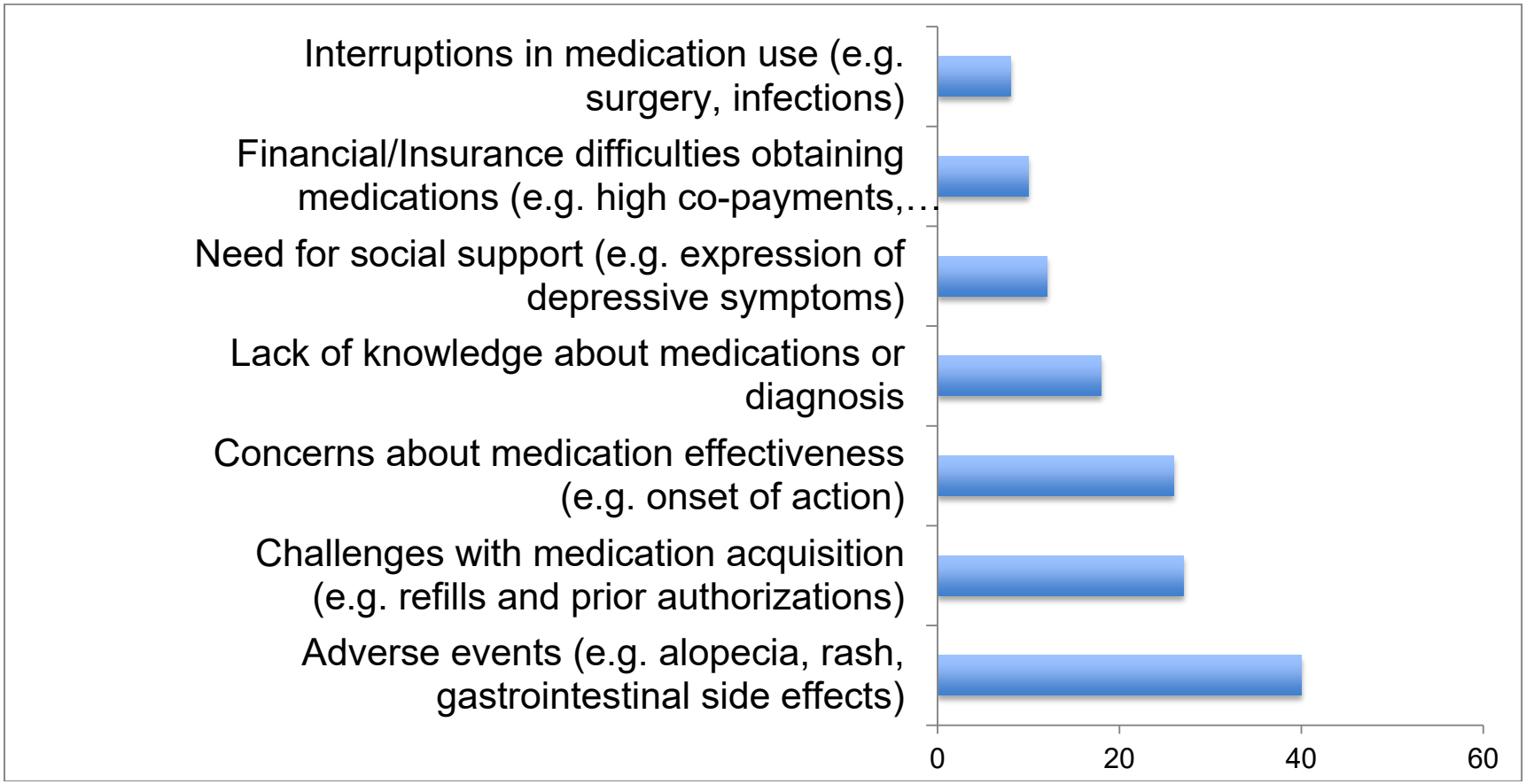
Interruptions in medication use (e.g. surgery, infections)
Financial/Insurance difficulties obtaining medications (e.g. high co-payments,…
Need for social support (e.g. expression of depressive symptoms)
Lack of knowledge about medications or diagnosis
Concerns about medication effectiveness (e.g. onset of action)
Challenges with medication acquisition (e.g. refills and prior authorizations)
Adverse events (e.g. alopecia, rash, gastrointestinal side effects)
0
20
40
60

Figure 1b

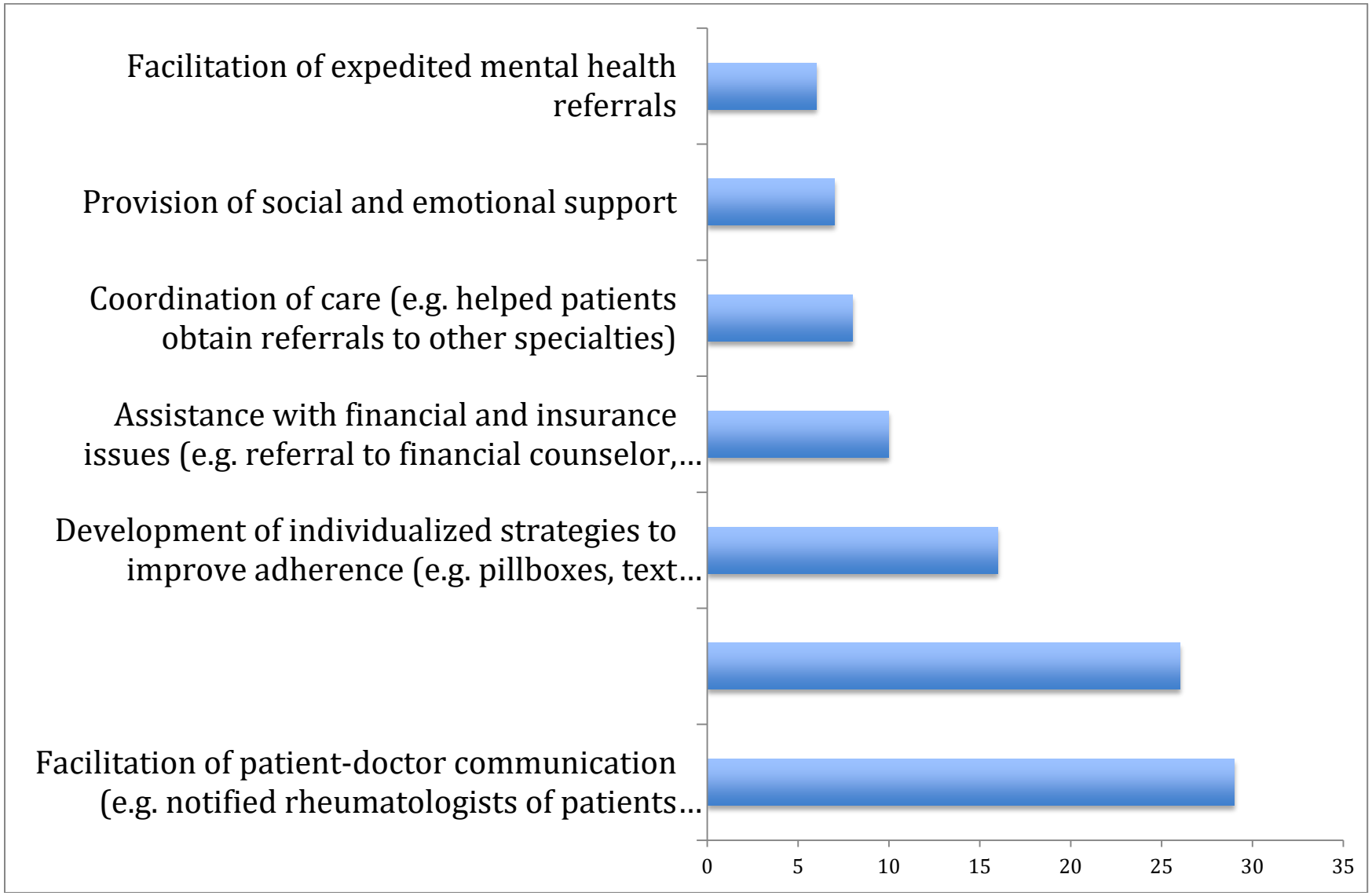
Facilitation of expedited mental health referrals
Provision of social and emotional support
Coordination of care (e.g. helped patients obtain referrals to other specialties)
Assistance with financial and insurance issues (e.g. referral to financial counselor,...
Development of individualized strategies to improve adherence (e.g. pillboxes, text...
Facilitation of patient-doctor communication (e.g. notified rheumatologists of patients...
0
5
10
15
20
25
30
35

Table 2:

Morisky

```
. ttest MoriskyFollowupScore==MoriskyBaselineScore

Paired t test
```

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
M~pScore	67	6.492537	.1902153	1.55698	6.11276	6.872315
M~eScore	67	6.626866	.1603307	1.312363	6.306755	6.946976
diff	67	-.1343284	.1598854	1.308718	-.4535498	.1848931

```
     mean(diff) = mean(MoriskyFollowu~e - MoriskyBaselin~e)       t =  -0.8402
 Ho: mean(diff) = 0                                 degrees of freedom =       66

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.2019         Pr(|T| > |t|) = 0.4039          Pr(T > t) = 0.7981
```

Mental Health (MHI-5):
MHI0=baseline
MHI1 = 6 month
Lower score = increased depressive symptoms

```
. ttest MHI1==MHI0

Paired t test
```

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
MHI1	48	74.5	2.575457	17.84329	69.31885	79.68115
MHI0	48	71.25	2.986153	20.68868	65.24263	77.25737
diff	48	3.25	1.966587	13.62491	-.7062628	7.206263

```
     mean(diff) = mean(MHI1 - MHI0)                                t =   1.6526
 Ho: mean(diff) = 0                             degrees of freedom =       47

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 0.9475         Pr(|T| > |t|) = 0.1051          Pr(T > t) = 0.0525
```