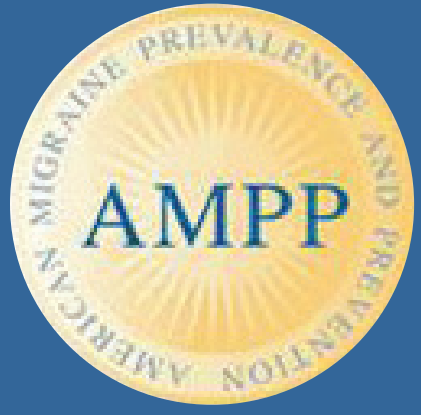


Examination of Unmet Treatment Needs Among Persons with Episodic Migraine: Results of the American Migraine Prevalence and Prevention Study (AMPP)



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BACKGROUND

- Despite the expanding therapeutic armamentarium, the minority of persons with migraine use migraine-specific agents as acute treatment
- In addition, satisfaction with migraine therapy is low to moderate, suggesting that at least a subset of persons with migraine have unmet treatment needs

STUDY AIMS

- To operationally define “unmet treatment needs” using conservative definitions
- To examine the prevalence of “unmet treatment needs” among persons with EM in the general US population

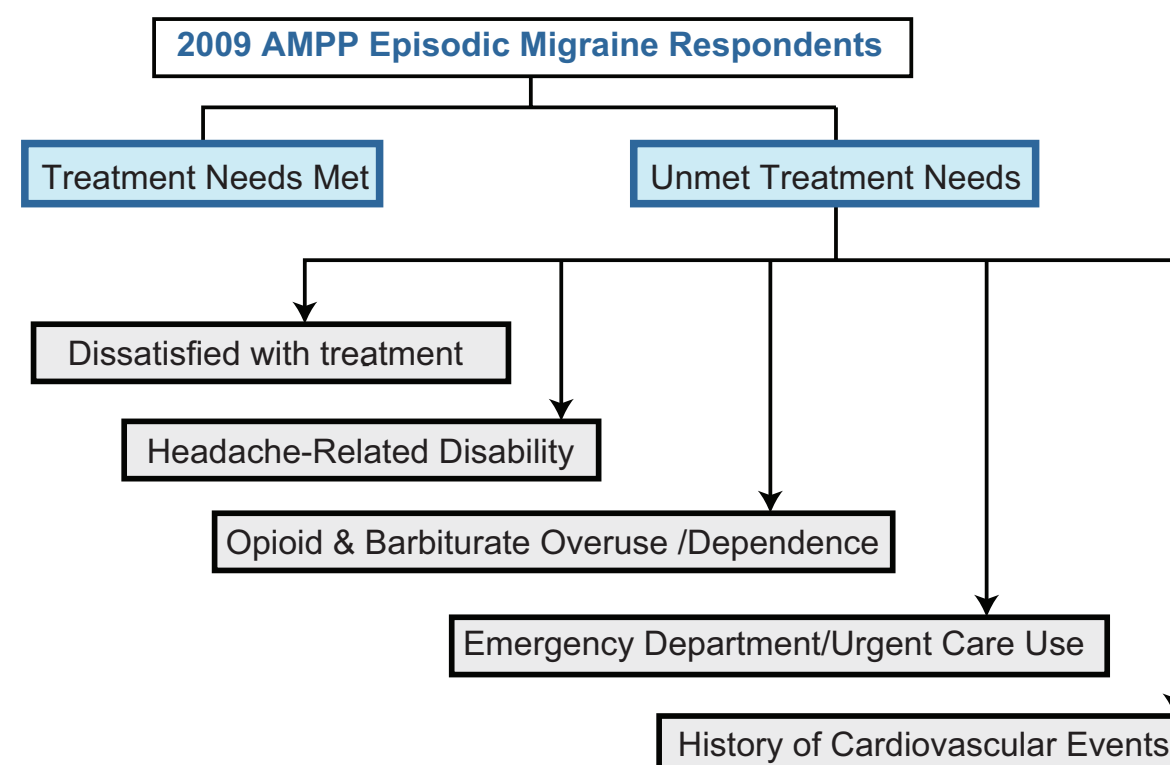
AMPP STUDY: DESIGN AND SAMPLING

- The American Migraine Prevalence and Prevention (AMPP) study is a longitudinal sample of persons with severe headache in the US population
- Sample was identified in a general-population screening study which netted 162,756 individual respondents in 2004
- A random sample of 24,000 with headache were entered into a longitudinal study
- In the baseline sample year (2005) there were 18,514 valid returns (77.1% return rate)
- Subsequent surveys were sent to the same sample in 2006, 2007, 2008 and 2009

CURRENT STUDY METHODS

- Examined 2009 AMPP EM sample
- Identified 5 candidate domains of unmet treatment need
- Developed a yet-to-be validated unmet need definition
- Contrasted unmet need definition categories on various outcomes of interest

Study Design



Categories of Unmet Treatment Needs

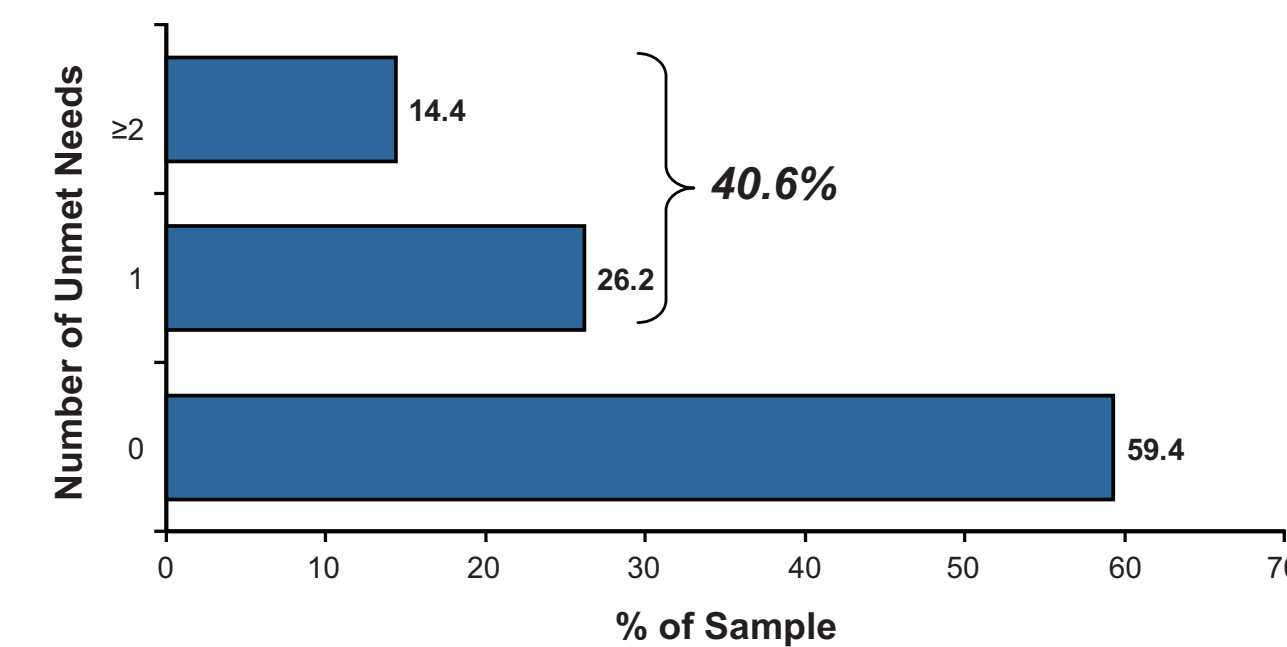
- Dissatisfaction with current acute treatment** was defined using the Patient Perception of Migraine Questionnaire (PPMQR)
- Moderate or severe headache-related disability** was defined by a MIDAS score ≥ 11
- Excessive use of opioids or barbiturates** was defined as use on ≥ 4 d/mo or by meeting DSM-IV criteria for dependence (based on criteria modified for inclusion in the AMPP)
- Excessive use of the emergency department (ED) or urgent care clinic (UCC) for headache** was defined by ≥ 2 visits in the preceding year
- History of cardiovascular (CVD) events** (including self report of MI, stroke angina, claudication, stent or CABG)

RESULTS

Sample

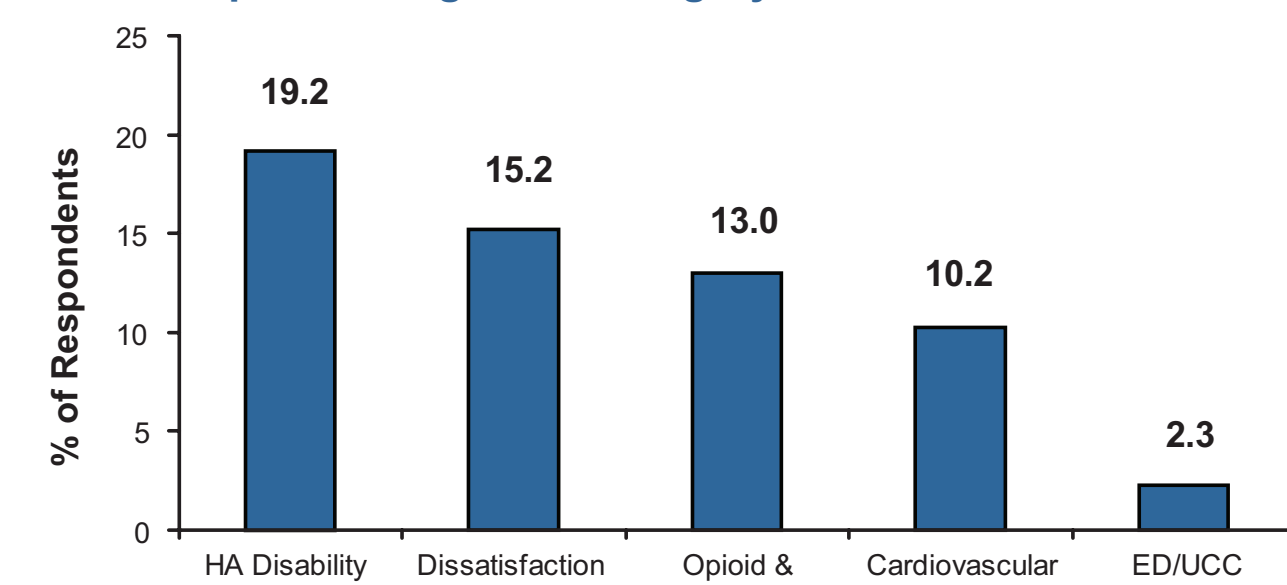
- In 2009, 20,107 total returns in AMPP
 - 11,792 were part of original AMPP cohort
 - 8,315 were part of a study resampling 2004 screening-phase respondents
- Of the 11,792 AMPP cohort members, 5,591 (47.4%) met ICHD-2 criteria for EM

Number of Unmet Needs



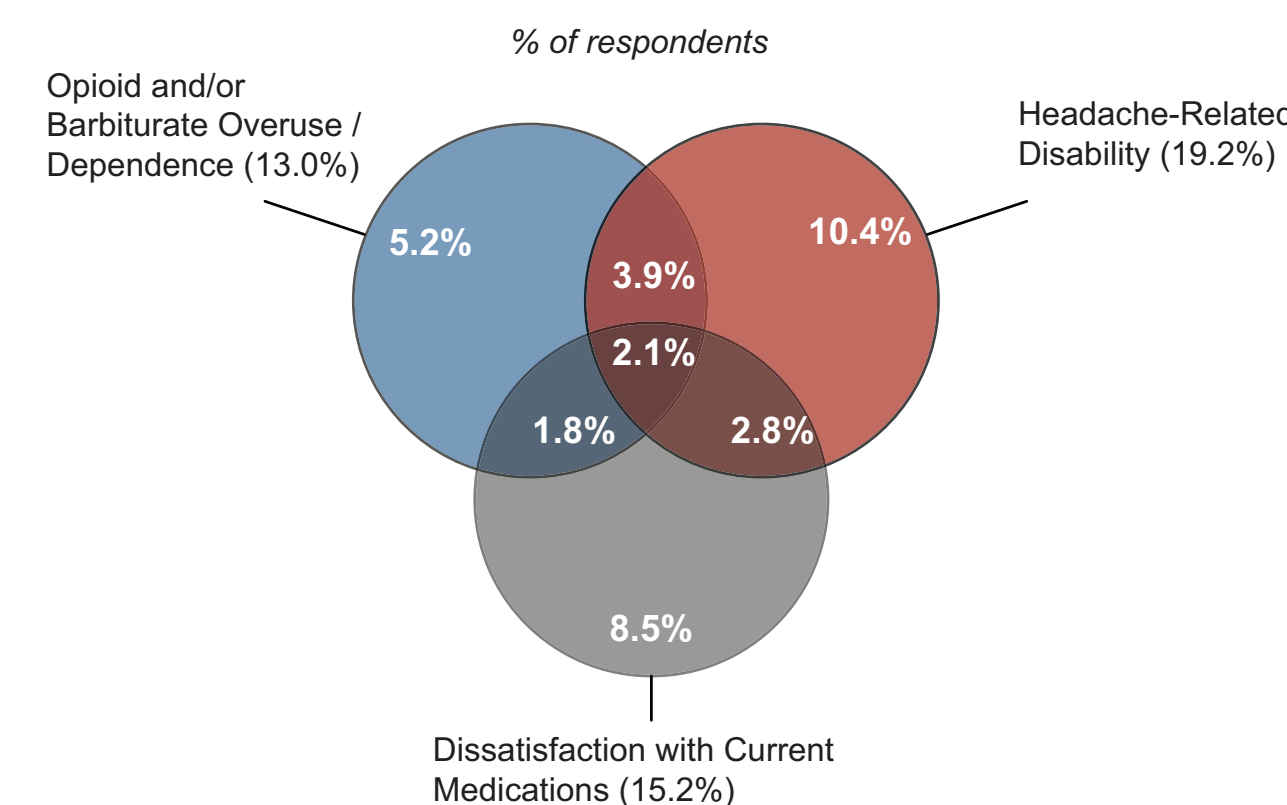
N=5,591

% of Sample Meeting Each Category of Unmet Need



N=5,591, *respondents may meet criteria for more than one unmet need type

3 Most Common Unmet Needs



N=5,591

Contrasting Unmet Need Groups

- Each unmet treatment need group was contrasted against those with no unmet needs on a series of univariate outcomes
- Normally distributed outcomes such as age and BMI were modeled using ANOVA
- Count outcomes, such as headache days/month were modeled using negative binomial regressions
- All other variables were binary and modeled via Logistic regressions

Sociodemographic Characteristics

	Number of Unmet Treatment Needs			Odds ratio/ Mean Differences (95% CI)	
	No unmet needs	1 unmet need	≥2 unmet needs	0 vs. 1	0 vs. ≥2
Female N(%)	2,675 (80.65)	1,198 (81.66)	660 (81.78)	Reference	Reference
Male N(%)	642 (19.35)	269 (18.34)	147 (18.22)	0.94 (0.80,1.10)	0.93 (0.76,1.13)
Age M(SD)	51.0 (12.36)	51.8 (12.72)	52.1 (12.46)	0.77 (0.01,1.54)*	1.07 (0.11,2.03)*
BMI M(SD)	29.4 (7.55)	30.3 (8.25)	30.8 (9.05)	0.93 (0.43,1.42)*	1.43 (0.80,2.05)*
Married N(%)	515 (15.53)	244 (16.63)	137 (16.98)	1.09 (0.92,1.28)	1.11 (0.91,1.37)
Headache d/mo M(SD)	1.9 (2.09)	3.3 (2.97)	4.6 (3.4)	1.72 (1.62,1.82)*	2.43 (2.27,2.60)*

*p<0.05, CI= confidence interval; test statistic for N(%)=odds ratio, for M(SD)= mean differences (ANOVA)

Medication Use

	Number of Unmet Treatment Needs			Odds ratio/ (95% CI)	
	No unmet needs N(%)	1 unmet need N(%)	≥2 unmet needs N(%)	0 vs. 1	0 vs. ≥2
NSAID use in preceding 3 months	1,355 (40.85)	634 (43.22)	343 (42.50)	1.10 (0.97,1.25)	1.07 (0.92,1.25)
Triptan use in preceding 3 months	272 (8.20)	172 (11.72)	133 (16.48)	1.49 (1.22,1.82)*	2.21 (1.77,2.76)*
Current preventive medication use	337 (10.16)	245 (16.70)	225 (27.88)	1.77 (1.48,2.12)*	3.42 (2.83,4.14)*

*significant at p<0.05, CI= confidence interval

Presence of Psychiatric Comorbidities

	Number of Unmet Treatment Needs			Odds ratio/ (95% CI)	
	No unmet needs N(%)	1 unmet need N(%)	≥2 unmet needs N(%)	0 vs. 1	0 vs. ≥2
Anxiety	154 (4.64)	158 (10.77)	170 (21.07)	2.48 (1.97,3.12)*	5.48 (4.34,6.93)*
Depression	320 (9.65)	329 (22.43)	331 (41.02)	2.71 (2.29,3.20)*	6.51 (5.43,7.81)*

*significant at p<0.05, CI= confidence interval
Depression measured using the PHQ-9
Anxiety measured using the anxiety module of the PRIME-MD

CONCLUSIONS

- We defined 5 indicators of “unmet treatment need” in this US population sample of persons with EM.
- 4 of the 5 areas of unmet need were endorsed by $\geq 10\%$ of the sample.
- Headache-related disability, overuse or dependence on opioids and barbiturates, and dissatisfaction with current medications for headache were the most common areas of unmet need.
- Of 5,591 survey respondents with EM, 40.6% had at least one unmet treatment need.
- Compared with respondents with no unmet needs, those with ≥ 1 were more likely to:
 - Meet criteria for depression and/or anxiety
 - Have more headache days per month
 - Be currently using triptans and preventive medications
- These results demonstrate that unmet needs exist among persons with EM in the population despite the use of currently available therapies.

Disclosures

Dawn C. Buse, PhD has received grant support and honoraria from Allergan Pharmaceuticals, Iroko Pharmaceuticals, MAP Pharmaceuticals, and Merck & Co., Inc.
Daniel Serrano, PhD has received grant support and honoraria from Allergan Pharmaceuticals, Endo Pharmaceuticals, GlaxoSmithKline, MAP Pharmaceuticals, Merck & Co., Inc., NuPathe, Novartis, Ortho-McNeil and the National Headache Foundation
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