

Supplemental Information: The mouse as a model for neuropsychiatric drug development

James R. Howe VI, Mark F. Bear, Peyman Golshani, Eric Klann, Stuart A. Lipton, Lennart Mucke, Mustafa Sahin, and Alcino J. Silva

Supplemental Table Legend

Table S1. Confidence in back-translatibility of selected neuropsychiatric drugs from humans back to mice in specific behavioral assays for selected neuropsychiatric indications. Bold denotes the indication for the drugs listed below the indication and italics indicate that the drug was used as an adjunct rather than a primary treatment.

SSRI: Selective serotonin reuptake inhibitor; SARI: Serotonin antagonist and reuptake inhibitor; SNRI: Selective serotonin-norepinephrine reuptake inhibitor; NDRI: Norepinephrine-dopamine reuptake inhibitor; FST: forced swim test; TST: tail suspension test; EPM: elevated plus maze; PTZ: pentylenetetrazole test; MES: maximal electroshock seizure test; PPI: prepulse inhibition; ADHD: attention deficit hyperactivity disorder; OCD: obsessive-compulsive disorder; NMDA: *N*-methyl-D-aspartate; GABA: γ -aminobutyric acid; AChE: acetylcholinesterase

Supplemental Methods

Review Details

To generate the initial list of neuropsychiatric drugs for review, we consulted a list of the 200 most-prescribed branded drugs from 2014, the most recent year for which

this data was available (Symphony Health Solutions, unpublished data, 2015). We selected all compounds indicated for neuropsychiatric indications, using this set of compounds as a nonexhaustive, generally representative sample of common neuropsychiatric drugs. We considered drugs to be clinically effective if they could gain and maintain FDA approval for a given indication. A drug was considered indicated for neuropsychiatric disease if its FDA-approved label indicated it for treatment of a neurological or psychiatric disease (as either a primary or adjunct therapy), and the listed indications were the only ones considered for review in the drug's efficacy in mouse behavioral assays. We excluded prodrugs metabolized into active drugs found elsewhere on the list (e.g., codeine and lisdexamfetamine) and combination drugs (e.g., hydrocodone-acetamenophen) to ensure we examined only single compounds with more circumscribed effects.

We considered each indication for each drug independently, using the drug-indication combination as the general unit of analysis in this review. All listed neuropsychiatric indications were investigated for each drug, with the exception of two (promethazine for sedation and methylphenidate for narcolepsy) for which no relevant studies could be identified for review. To determine whether a drug was originally developed for a given indication using mouse behavioral assays, we examined each drug's original patent. If the application mentioned a behavioral assay for a given indication performed in mice, we classified the drug as developed using mice for that indication. If the patent did not contain either proprietary information or a reference to a prior study with that information, we assumed mouse behavioral assays were not used to develop the drug for that indication.

We conducted a systematic review for studies testing the selected drugs using mouse behavioral assays for the FDA-indicated neuropsychiatric disorders by electronic search of the Reuters Web of Science database (July-August 2016) using the search terms “[name of drug] + [indication of interest],” sorting by citation count in descending order. We used the 25 most-cited qualifying studies for each drug-indication combination, and if our search returned fewer than 25 studies for the combination, we used all qualifying studies. If a drug was indicated for multiple neuropsychiatric indications and a study included for one indication contained experiments applicable to other approved indications for that drug, but it was outside the top 25 most-cited for that indication, it was also reviewed for the drug’s other indication. As a result, more than 25 studies were reviewed in a subset of drug-indication combinations.

A study qualified for inclusion in this review if it contained one or more experiments utilizing (1) a mouse model of a neuropsychiatric disorder for which the drug of interest was indicated and (2) a widely-accepted behavioral assay relevant to the neuropsychiatric disorder, and if at least one of the treatments was administration of the drug of interest (alone if approved for the indication as a primary therapy or in combination with an FDA-approved primary therapy if approved as an adjunct). We included mouse neuropsychiatric disease models if the investigator claimed it modeled either the indication of interest or a closely related indication with similar symptoms, due to the relative etiological uncertainty of neuropsychiatric disease. No studies were excluded or differentially weighted on the basis of the method used to model the indication of interest, dosage or route of administration of the drug, mouse genetic background, journal of publication, date of publication, authorship or any

features/associations of the authors, rationale for the experiment, or any other aspects of the study unrelated to the methodology of the experiment(s) of interest. No reviews, conference abstracts, books, or meta-analyses were considered for inclusion.

Quantification and Statistical Analysis

For each drug-indication combination, we divided experiments into groups based on the mouse behavioral assay used. If the drug was approved as an adjunct, we further subdivided these groups based on the primary therapy it modified. In all experiments, we classified a successful back-translation as a result where administration of the drug produced a statistically significant result in the expected direction based on its use in humans and a failed back-translation as a result where administration of the drug failed to yield such a result (i.e., either statistically nonsignificant or significant in an unexpected direction). If the FDA approved the compound only as an adjunct to enhance another neuropsychiatric drug, we assessed it based only on its enhancement of the primary compound's behavioral effect. We took statistical significance statements made in reviewed studies at face value. In light of the diversity of treatments, models and statistical methods used and variations in how different groups presented data even for the same behavioral assay, we did not attempt to assign different weights to different experimental designs or independently estimate effect sizes or degrees of efficacy.

To avoid overestimating significance as a result of publication bias, including selection of the most impactful papers, we used conservative estimations of confidence to assess back-translatibility. We divided our estimates of confidence in back-translatibility into four general tiers: high, moderate, low, and ineffective. To reach a determination of

“high confidence,” a drug had to succeed in a behavioral assay in at least 90% of replications, with a minimum of 3 replicates. For the purposes of this study, we defined a replicate as an experiment utilizing a given compound in a given behavioral assay in an independent publication. A “moderate confidence” determination required between a 67-90% replication success rate in a minimum of 3 replicates. All combinations with success rates sufficient to qualify as high or moderate confidence but with fewer than 3 replicates were classified as “low confidence.” Any combination with a replication success rate below 67% was classified as “ineffective,” regardless of the number of replicates.

Simple determinations of back-translatibility were made based on the highest level of confidence that a single behavioral assay could qualify for in a given drug-indication combination. If at least one behavioral assay replicated at high confidence or moderate confidence, general confidence in back-translation of the combination was classified as “high” or “moderate,” respectively. Due to the relatively high standard for a drug to pass even the “moderate” threshold for efficacy in a given behavioral assay, we considered this sufficient evidence to support classification as a successful back-translation to mice. If all assays were ineffective, then we classified the drug-indication combination as a “failure” to back-translate. If the drug-indication combination showed efficacy, but only in behavioral assays where less than three studies had been conducted under the given conditions, then general confidence was classified as “inconclusive.” We used this classification because these combinations did not meet the standards to support a determination of efficacy or lack thereof. We could not classify the compound as ineffective in the given behavioral assay for the given indication, because its success rate would otherwise be sufficient to give us moderate or high confidence in its efficacy.

However, we cannot classify it as efficacious with any degree of confidence, as it has not been validated to a sufficient degree. Hence, more information is needed; the current literature is “inconclusive.”

References for each drug/indication combination

Alprazolam (anxiety): [S1-S25].

Amitriptyline (depression): [S26-S50].

Amphetamine:

Attention deficit/hyperactivity disorder (ADHD): [S51-S75].

Narcolepsy: [S76-S81].

Aripiprazole:

Depression: [S82-S87].

Bipolar disorder: [S82-S105].

Schizophrenia: [S86-S108].

Tourette's disease: [S87, S94-S95, S97-S98, S106, S108]

Baclofen (myorelaxation): [S109-S126].

Bupropion:

Depression: [S40, S44, S127-S148].

Smoking cessation: [S127, S149-S164].

Buspirone (anxiety): [S20-S21, S25, S42, S165-S185].

Citalopram (depression): [S85, S129, S145, S186-S207].

Clonazepam:

Anxiety: [S14, S208-S214].

Seizures: [S214-S238].

Clonidine (ADHD): [S239-S250].

Diazepam:

Anxiety: [S12, S169, S181-S182, S251-S280].

Seizures: [S12, S234, S253, S259, S265-S266, S268, S273, S275, S281-S302].

Myorelaxation: [S12, S123, S253, S255, S259-262, S266-S267, S268, S275, S277, S279, S283, S291-S292, S300, S304-S309].

Donepezil (Alzheimer's disease): [S310-S331].

Duloxetine:

Depression: [S332-S347].

Anxiety: [S247, S343, S347-S350].

Pain: [S342, S351-S360].

Escitalopram:

Depression: [S44, S143, S337, S344, S361-S378].

Anxiety: [S362, S374, S377-S386].

Fentanyl (pain): [S387-S411].

Fluoxetine:

Depression: [S129, S193, S195, S197, S200, S412-S441].

Anxiety: [S200, S414-S416, S418-S422, S424, S426, S427, S433-S436, S442-S454].

Obsessive-compulsive disorder (OCD): [S195, S434, S444, S447-S448, S451-S452, S455-S472].

Gabapentin:

Pain: [S342, S352, S473-S498].

Seizures: [S236, S288, S290, S299, S499-S518].

Lamotrigine:

Seizures: [S236, S285, S287-S288, S290, S299, S499-S500, S502, S504, S513, S517, S519-S533].

Bipolar disorder: [S520, S523, S533-S544].

Levetiracetam (seizures): [S232, S290, S299, S501, S512-S513, S521, S527, S533, S545-S558].

Lidocaine (anaesthesia): [S559-S583].

Lorazepam:

Anxiety: [S2, S14, S211-S212, S309, S584-S595].

Seizures: [S590-S592, S596-S601].

Methocarbamol (myorelaxation): [S123, S602].

Methylphenidate (ADHD): [S51, S60-S61, S69-S70, S74, S603-S621].

Mirtazapine (depression): [S622-S624].

Morphine (pain): [S409, S625-S648].

Oxycodone (pain): [S391, S396, S399, S403, S410, S649-S668].

Paroxetine:

Depression: [S36, S45, S129, S131-S132, S145, S188, S192, S199-S200, S429, S669-S688].

Anxiety: [S36, S200, S349, S384 S671-S673, S677, S679-S680, S686-S687, S689-S702].

OCD: [S467, S471, S672, S678-S679, S681, S703-S707].

Pregabalin:

Pain: [S342, S351, S358, S476, S487, S496, S708-S727].

Seizures: [S299, S511, S515, S728-S736].

Promethazine (pain): [S737-S740].

Quetiapine:

Depression: [S86, S741-S744].

Bipolar disorder: [S86, S93, S107, S741-S750].

Schizophrenia: [S86, S93, S107, S741, S743, S745, S747-S751].

Risperidone:

Bipolar disorder: [S91, S93, S97, S748, S752-S774].

Schizophrenia: [S91, S93, S97, S106, S748, S752-S759, S761-S778].

Ropinirole (Parkinson's disease): [S779-S787].

Sertraline:

Depression: [S31, S49, S82, S129, S192-S193, S199-S200, S670, S678, S788-S802].

Anxiety: [S31, S49, S200, S680, S789, S795, S797, S801-S808].

OCD: [S678, S809].

Sumatriptan (pain): [S810-S818].

Temazepam (sedation): [S819].

Topiramate (seizures): [S223, S236, S286, S290, S299, S309, S504, S513, S519, S521, S524-S529, S533, S820-S827].

Tramadol (pain): [S639, S666, S828-S849].

Trazodone (depression): [S47, S850-S857].

Venlafaxine:

Depression: [S44, S82, S134, S137-S138, S143, S334-S337, S790, S796, S852, S858-S869].

Anxiety: [S143, S349, S384, S680, S690, S692, S695, S697, S862, S865-S872].

Zolpidem (sedation): [S258, S265, S591, S684, S873-S895].

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