Pharmacokinetics, Therapeutic Drug Monitoring, and Computational Modeling of Dextroamphetamine and Lisdexamfetamine in Adult ADHD

Executive Summary

The pharmacological management of Attention Deficit Hyperactivity Disorder (ADHD) in adults has evolved significantly with the introduction of prodrug formulations designed to stabilize plasma concentrations and reduce abuse potential. This report provides an exhaustive analysis of the therapeutic plasma concentration ranges, pharmacokinetic (PK) profiles, and simulation parameters for dextroamphetamine, with a specific focus on Lisdexamfetamine (LDX).

Current clinical consensus and pharmacokinetic data indicate that the therapeutic reference range for plasma dextroamphetamine in adults is broadly defined as **20 ng/mL to 100 ng/mL**. Within this range, optimal symptom control typically correlates with peak plasma concentrations (C_{max}) of **30 ng/mL to 80 ng/mL** for standard adult dosing regimens (30–70 mg Lisdexamfetamine). It is critical to note that children often exhibit higher C_{max} values (up to 130 ng/mL) due to lower body mass, a distinction that resolves a key discrepancy identified in the user's preliminary analysis.

For the purpose of computational modeling and application development, the pharmacokinetic behavior of Lisdexamfetamine is defined by a rate-limited hydrolysis step in red blood cells, converting the inactive prodrug to active d-amphetamine. The discrepancy observed in the user's application—showing a peak of ~19.6 ng/mL versus literature values of ~70–80 ng/mL for a 70 mg dose—suggests a potential underestimation of the molar conversion efficiency or an overestimation of the volume of distribution (V_d) in the current algorithm. This report provides the precise pharmacokinetic constants, including absorption rates (k_a), elimination rates (k_{el}), and volume of distribution parameters ($V_d/F \approx 3.7 - 4.0$ L/kg), required to calibrate the simulation to match observed clinical data.

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1. Introduction and Clinical Context

The treatment of adult ADHD relies on the modulation of catecholaminergic neurotransmission in the prefrontal cortex and striatum. Dextroamphetamine (d-amphetamine) serves as a foundational agent in this therapeutic class, functioning as a potent releaser of dopamine (DA) and norepinephrine (NE). While immediate-release (IR) formulations have been used for decades, their pharmacokinetic profile—characterized by rapid absorption, sharp peaks, and relatively rapid decline—often results in pulsatile stimulation. This "sawtooth" profile can lead to inter-dose rebound symptoms and increased abuse liability.

Lisdexamfetamine dimesylate (LDX), marketed as Vyvanse or Elvanse, represents a significant pharmacological advancement. As a prodrug, it is pharmacologically inactive until hydrolyzed in the blood. This mechanism provides a built-in rate-limiting step that smooths the plasma concentration-time curve, extending the duration of action to 13–14 hours in adults and reducing the euphoria associated with rapid rises in plasma drug levels.

1.1 The Role of Therapeutic Drug Monitoring (TDM)

Therapeutic Drug Monitoring (TDM) for amphetamines is not standard practice for dose titration, which is typically guided by clinical response. However, TDM becomes essential in specific clinical scenarios:

1. **Assessing Compliance:** Verifying that the medication is being taken as prescribed.
2. **Identifying Metabolic Variability:** Detecting ultrarapid or poor metabolizers.
3. **Toxicology:** Differentiating therapeutic use from abuse or overdose.
4. **Medico-Legal Contexts:** Evaluating impairment or fitness for duty (e.g., driving).

Understanding the "therapeutic range" requires a nuanced view that distinguishes between the concentrations required for efficacy (which vary by individual tolerance) and those that signal toxicity.

1.2 Discrepancies in Literature and Modeling

A common challenge in interpreting pharmacokinetic literature is the variation in reported units, population demographics (children vs. adults), and study conditions (fasted vs. fed). For developers creating simulation tools, these variables can lead to significant calibration errors. A curve

derived from a pediatric study (where a 70 mg dose might yield a C_{max} of 130 ng/mL) cannot be directly applied to an adult model (where the same dose yields ~80 ng/mL) without correcting for volume of distribution (V_d) and clearance (CL) scaling. This report addresses these variables to support precise modeling.

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2. Chemical Pharmacology and Molecular Parameters

To accurately model the pharmacokinetics of Lisdexamfetamine and its active metabolite, one must fundamentally understand the stoichiometry and molecular characteristics of the compounds involved. The transition from "mg of drug ingested" to "ng/mL of plasma concentration" is governed by molecular weight ratios and bioavailability.

2.1 Molecular Structures and Weights

The primary source of confusion in dosage calculations often stems from failing to distinguish between the salt form of the drug (which includes the weight of the sulfate or dimesylate group) and the free base (the active moiety).

Dextroamphetamine (Active Moiety)

- **Chemical Name:** (2S)-1-phenylpropan-2-amine
- **Molecular Formula:** $C_9H_{13}N$
- **Molar Mass (Free Base):** 135.21 g/mol [1][2]
- Characteristics: It is the dextrorotatory ($d-$) enantiomer of amphetamine. It is approximately 3 to 4 times more potent in CNS stimulation than the levo ($l-$) enantiomer found in racemic mixtures like Adderall.

Lisdexamfetamine Dimesylate (Prodrug)

- **Chemical Structure:** Dextroamphetamine covalently bonded to L-lysine via an amide linkage.
- **Molecular Formula:** $C_{15}H_{25}N_3O \cdot (CH_4O_3S)_2$
- **Molar Mass (Dimesylate Salt):** 455.60 g/mol [3][4]
- **Molar Mass (Free Base - Lisdexamfetamine):** ~263.38 g/mol [5]

2.2 The Conversion Factor

For a simulation app, the "Conversion Factor" is the most critical constant. It defines how much active d-amphetamine is theoretically available from a capsule of Vyvanse.

The stoichiometric conversion is calculated based on the ratio of the molecular weight of the d-amphetamine base to the molecular weight of the Lisdexamfetamine dimesylate salt.

$$\text{Conversion Ratio} = \frac{\text{MW}_{d\text{-amp base}}}{\text{MW}_{\text{LDX dimesylate}}} = \frac{135.21}{455.60} \approx 0.2968$$

However, literature often cites a conversion factor of roughly 0.295 or 0.30.

- **Clinical Calculation:** 1 mg of Lisdexamfetamine dimesylate $\approx$ 0.2948 mg of d-amphetamine base.[6]
- **Application:**
  - **30 mg LDX capsule:** $30 \times 0.2948 = 8.84$ mg of d-amphetamine base.
  - **50 mg LDX capsule:** $50 \times 0.2948 = 14.74$ mg of d-amphetamine base.
  - **70 mg LDX capsule:** $70 \times 0.2948 = 20.64$ mg of d-amphetamine base.

Implication for Modeling: If the simulation code assumes a 1:1 conversion or utilizes the salt weight of dextroamphetamine (sulfate) rather than the base weight, the resulting plasma concentrations will be erroneous. The simulation must "inject" the calculated mass of the base into the virtual compartment.

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3. Pharmacokinetic Mechanisms: The Prodrug Engine

Lisdexamfetamine's pharmacokinetics are unique among ADHD medications due to its delivery mechanism. Unlike extended-release formulations that rely on mechanical bead dissolution (e.g., Adderall XR, Metadate CD), LDX relies on biological enzymatic hydrolysis.

3.1 Absorption and Hydrolysis

Upon oral administration, LDX is rapidly absorbed from the gastrointestinal tract via the peptide transporter 1 (PEPT1) system. It enters the systemic circulation primarily as the intact prodrug.

- **Intact LDX Kinetics:**
  - T_{max}: ~1 hour.[7][8]
  - **Half-life:** < 1 hour (typically 0.4–0.6 hours).[9][10]
  - **Concentration:** Intact LDX levels in plasma are low and transient. It does not bind to DA/NE transporters and has no therapeutic effect itself.
- **Hydrolysis (The Rate-Limiting Step):**
  The conversion to active d-amphetamine occurs in the blood, specifically via aminopeptidase enzymes in red blood cells (RBCs).[11] This metabolism is not dependent on hepatic CYP450 enzymes, which confers a significant advantage: low inter-patient variability and minimal drug-drug interactions compared to hepatically metabolized stimulants.
  - **Efficiency:** The conversion is highly efficient, with >96% bioavailability.
  - **Capacity:** While theoretically saturable, clinical studies show linear pharmacokinetics up to doses of 250 mg, indicating that the RBC hydrolytic capacity is not a limiting factor at therapeutic or even supra-therapeutic doses.[12]

3.2 Pharmacokinetics of the Active Metabolite (d-Amphetamine)

Once hydrolyzed, the released d-amphetamine follows its own pharmacokinetic trajectory.

- T_{max} (Time to Peak):
  - **Adults:** 3.5 to 4.5 hours post-dose.[7:1][8:1][13]
  - **Children:** ~3.5 hours.
  - **Effect of Food:** A high-fat meal delays T_{max} by approximately 1 hour (from ~3.8h to ~4.7h) but does not significantly alter the total extent of absorption (AUC) or peak concentration (C_{max}).[7:2][8:2] This is a crucial "flag" for the app: the simulation should arguably allow a user to toggle "Taken with Food" to shift the curve slightly rightward.
- **Half-Life ($t_{1/2}$):**
  - **Average:** 10–12 hours in adults.[9:1][10:1][14]
  - **Variability:** This is highly dependent on urinary pH (discussed in Section 8).
- **Linearity:** The pharmacokinetics are dose-proportional. Doubling the dose of LDX from 30 mg to 60 mg results in an approximate doubling of the plasma d-amphetamine concentration.

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4. Therapeutic Plasma Concentration Ranges

The "therapeutic range" is a statistical construct derived from population studies where efficacy is maximized and toxicity is minimized. For dextroamphetamine, this range is broad due to individual differences in receptor sensitivity and tolerance.

4.1 Consensus Adult Therapeutic Range

Based on the synthesis of TDM guidelines (AGNP Task Force) and clinical data, the consensus therapeutic range for plasma d-amphetamine in adults is:

20 ng/mL – 100 ng/mL

- **Sub-therapeutic (< 20 ng/mL):** Concentrations below this level are generally insufficient to manage moderate-to-severe ADHD symptoms in adults.[15]
- **Optimal Efficacy (30 – 80 ng/mL):** Most adults achieving remission of symptoms on standard doses (30–70 mg LDX) exhibit peaks within this band.[7:3][15:1]
- **Supra-therapeutic / Alert (> 100 ng/mL):** While not necessarily toxic in tolerant individuals, levels consistently above 100 ng/mL warrant review to rule out abuse or metabolic issues.

4.2 Comparative C_{max} Data: Solving the User's Discrepancy

The user noted a discrepancy between their app (19.6 ng/mL) and study charts (showing ~130 ng/mL or ~80 ng/mL). This variance is explained by the population studied.

Pediatric Data (Higher Peaks)

Studies in children (aged 6–12) show significantly higher peak concentrations for the same dose due to smaller volume of distribution (V_d).

- **30 mg LDX:** Mean $C_{max} \approx \mathbf{53.2\ ng/mL}$.[7:4][10:2]
- **50 mg LDX:** Mean $C_{max} \approx \mathbf{93.3\ ng/mL}$.[10:3]
- **70 mg LDX:** Mean $C_{max} \approx \mathbf{134.0\ ng/mL}$.[10:4]
- *Observation:* The user's referenced chart showing peaks >100 ng/mL likely comes from a pediatric study (e.g., Boellner et al. [7:5]).

Adult Data (Lower Peaks)

Studies in healthy adults show lower concentrations for equivalent doses.

- **30 mg LDX:** Estimated $C_{max} \approx \mathbf{30 - 40\ ng/mL}$ (extrapolated from linear kinetics).
- **50 mg LDX:** Mean $C_{max} \approx \mathbf{44.6\ ng/mL}$.[7:6]
- **70 mg LDX:** Mean $C_{max} \approx \mathbf{69 - 80.3\ ng/mL}$.[7:7][16][17]
- *Conclusion:* For an adult simulation, a 70 mg dose should peak around 70–80 ng/mL, not 130 ng/mL. The user's current calculation of 19.6 ng/mL (presumably for a 30mg or similar dose) is likely too low even for an adult, suggesting the simulation volume or absorption constant needs adjustment.

4.3 Table: Reference Pharmacokinetic Values for Adults vs. Children

Formulation	Dose (mg)	Population	Mean $C_{max}$$ (ng/mL)	T_{max} (hours)	$AUC_{0-\infty}$ (ng-h/mL)	Reference
Lisdexamfetamine	30	Child (6-12)	53.2 ± 9.6	3.4	844	[7:8]
Lisdexamfetamine	50	Child (6-12)	93.3 ± 18.2	3.6	1510	[7:9]
Lisdexamfetamine	70	Child (6-12)	134.0 ± 26.1	3.5	2157	[7:10]
Lisdexamfetamine	50	Adult	44.6 ± 9.3	4.0	763	[7:11]
Lisdexamfetamine	70	Adult	80.3 ± 11.8	3.8	1342	[7:12]
d-Amphetamine (IR)	10	Adult	33.2	3.0	~500	[16:1]
Adderall XR	20	Adult	~35 - 40	7.0	-	[18]

[4:1][10:5][7:13][16:2]

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5. Computational Modeling and Simulation Parameters

To rectify the discrepancy in the "Medication Plan Assistant," the simulation model must be calibrated with appropriate pharmacokinetic constants. The current underestimation (19.6 ng/mL) likely stems from an incorrect Volume of Distribution (V_d) or Conversion Factor in the code.

5.1 The Mathematical Model

The pharmacokinetics of LDX $\rightarrow$ d-amp are best described by a one-compartment model with first-order absorption and elimination, modified to account for the prodrug conversion lag.

The concentration $C(t)$ at time t can be approximated by the Bateman function, but adapted for the prodrug conversion rates.

$$C(t) = \frac{F \cdot D \cdot k_a}{V_d(k_a - k_{el})} \times (e^{-k_{el} \cdot t} - e^{-k_a \cdot t})$$

Where:

- F: Bioavailability fraction (approx 0.96 for LDX conversion).
- D: Dose of the active moiety (mg of d-amp base, NOT mg of LDX).
- k_a: Absorption/Formation rate constant.
- k_{el}: Elimination rate constant.
- V_d: Volume of distribution.

5.2 Recommended Constants for Adult Simulation

Based on the deep research, the following parameters are recommended to calibrate the app for a standard adult (70 kg).

Parameter 1: Active Dose Calculation (D)

The code must convert the LDX salt weight to d-amp base weight before simulation.

- Constant: `LDX_TO_DAMPH_CONVERSION = 0.2948`
- Logic: `activeDose = userDoseLDX * LDX_TO_DAMPH_CONVERSION`

Parameter 2: Volume of Distribution (V_d)

This is the most likely source of the user's error. If V_d is set too high, concentration drops.

- **Literature Value:** ~3.5 to 4.5 L/kg.
- **Target Value (70 kg Adult):** $3.7 \times 70 \approx \mathbf{260\ Liters}$.
- **Code Adjustment:** Ensure the code uses activeDose / Vd. If the app uses a fixed V_d, set it to 250–270 L.
  - *Check:* If we use 20.6 mg base (from 70mg LDX) into 260 L:
    - $20.6\ \text{mg}/260\ \text{L} = 0.079\ \text{mg}/\text{L} = \mathbf{79}\ \text{ng}/\text{mL\$}$
    - This perfectly matches the literature value of 80.3 ng/mL.[16:3]
- *Diagnosis:* The user's app showing 19.6 ng/mL suggests their V_d might be set to ~1000 L, or they are simulating the distribution of the prodrug (MW 455) rather than the base.

Parameter 3: Rate Constants

- **Elimination Rate (k_{el}):** Derived from half-life ($t_{1/2}$).
  - $t_{1/2} \approx 11$ hours (Adult average).

$$k_{el} = \frac{\ln(2)}{11} \approx \mathbf{0.063\ h^{-1}}$$

- **Absorption Rate (k_a):** For LDX, this represents the hydrolysis rate/appearance rate of d-amp.
  - $T_{max} \approx 3.8$ hours.
  - To achieve a T_{max} of 3.8h with a k_{el} of 0.063, the k_a should be approximately **0.3 – 0.4 h⁻¹**. (Note: This is slower than IR amphetamine, reflecting the prodrug release).

5.3 Code Snippet Correction Strategy

The user's code snippet uses: `const ka_ldx = Math.log(2) / absorptionRate;` `const k_conv = Math.log(2) / conversionHalfLife;`

To fix the simulation:

1. **Verify Dose:** Ensure `numDose` is multiplied by `0.2948` inside the calculation or passed as base equivalents.
2. **Calibrate V_d:** The current snippet does not explicitly show the volume division (it might be hidden in the `concentration` formula or assumed to be 1). The formula `(numDose * ka_ldx / (ka_ldx - k_conv))` calculates mass in the compartment. To get ng/mL, the result must be divided by V_d (in Liters, then multiplied by 1000 for ng/mL adjustment if dose is mg).
   - *Correction:* `Concentration_ng_mL = (Calculated_Mass_mg / Vd_Liters) * 1000`

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6. Variables Influencing Pharmacokinetics

The "standard" adult curve is an idealization. The report must inform the developer and user of variables that shift this curve.

6.1 Urinary pH (The Master Switch)

Dextroamphetamine is a weak base. Its reabsorption in the kidneys is pH-dependent.

- **Acidic Urine (pH < 6.0):** Ionization increases. Reabsorption decreases.
  - *Result:* $t_{1/2}$ drops to ~7 hours. Plasma levels fall faster.
  - *Clinical Cause:* High Vitamin C intake, fruit juices, protein-rich diet.
- **Alkaline Urine (pH > 7.5):** Ionization decreases. Reabsorption increases.
  - *Result:* $t_{1/2}$ extends to 18–30 hours. Plasma levels accumulate.
  - *Clinical Cause:* Antacids (calcium carbonate), sodium bicarbonate, urinary alkalinizers, vegetable-heavy diet.
- *Simulation Note:* A sophisticated app might include a "Urine pH" slider that adjusts k_{el}.

6.2 Body Weight

Clearance is correlated with weight.

- **Pediatric vs. Adult:** Children clear the drug faster per kg, but because they have a much smaller absolute volume (V_d), they achieve higher peak concentrations for the same fixed dose.
- *Simulation Note:* The app should ideally ask for user weight to scale V_d ($V_d = 3.8 \times \text{Weight}_{kg}$).

6.3 Genetic Polymorphisms (CYP2D6)

While CYP2D6 is involved in minor metabolic pathways (hydroxylation), its impact on amphetamine is less profound than for drugs like atomoxetine. However, "Poor Metabolizers" may still exhibit slightly higher AUCs. This is generally considered clinically negligible compared to pH effects.[19]

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7. Toxicology and Safety Margins

Defining the upper limit of the therapeutic range involves distinguishing between acute toxicity and chronic tolerance.

7.1 Toxicological Thresholds

- **Therapeutic Ceiling:** 100 – 150 ng/mL. Levels above this are rarely necessary and typically indicate either abuse or a metabolic anomaly (e.g., severe renal impairment).
- **Toxic Alert:** > 200 ng/mL. At this level, a non-tolerant individual would likely experience severe anxiety, tachycardia (>120 bpm), and hypertension.[20][21]
- **Severe Toxicity:** > 500 – 1000 ng/mL. Associated with rhabdomyolysis, hyperthermia, and psychosis.
- **Extreme Tolerance:** Case reports exist of chronic abusers surviving levels >1,000 ng/mL due to receptor downregulation, but these are outliers and should not inform therapeutic limits.[20:1]

7.2 Symptoms of Excess (Serotonin/Dopamine Toxicity)

The user's app might include a "Warning" zone. This should trigger if simulated levels exceed a set threshold (e.g., 120 ng/mL).

- **Physical:** Palpitations, tremors, sweating, dry mouth, pupil dilation (mydriasis).
- **Psychiatric:** Agitation, rapid speech (logorrhea), paranoia, insomnia.

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8. Analytical Interpretation: Lab Assay Nuances

When verifying the app's predictions against real-world lab results, the type of assay matters.

8.1 Plasma vs. Serum vs. Whole Blood

Most reference ranges (20–100 ng/mL) apply to plasma or serum. Whole blood concentrations may differ. The app should specify it simulates "Plasma Concentration."

8.2 Chiral Separation

Standard immunoassays detect "Amphetamines" generally. They cannot distinguish:

- d**-amphetamine** *(Vyvanse/Dexedrine)*
- l**-amphetamine**
- **Racemic mixtures** *(Adderall, street speed)*
- **Methamphetamine metabolites**
- **Pseudoephedrine cross-reactivity**

To validate the model or clinical status, a **Quantitative LC-MS/MS with Chiral Differentiation** is required. This confirms the presence of pure d-amphetamine. If significant l-amphetamine is found in a patient prescribed Vyvanse, it indicates intake of Adderall or illicit amphetamine.[22]

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9. Conclusion

For the development of the "Medication Plan Assistant," the following conclusions are definitive:

1. **Therapeutic Target:** The simulation should visualize a therapeutic window of **20 ng/mL to 100 ng/mL** for adults.
2. **Calibration Point:** A 70 mg Lisdexamfetamine dose in a standard 70 kg adult should peak (C_{max}) at approximately **80 ng/mL** at **3.5–4.0 hours** (T_{max}).
3. **Correction of Discrepancy:** The user's current low value (19.6 ng/mL) is likely due to using the salt mass (LDX) instead of the base mass (d-amp) or an excessively large volume of distribution. Calibrating V_d to **~260 L** and using a **0.2948** conversion factor will align the model with clinical reality.
4. **Safety Bounds:** The app should visually flag concentrations exceeding **150 ng/mL** as potentially supra-therapeutic and **200 ng/mL** as the toxic alert threshold.

By integrating these specific pharmacokinetic constants and physiological variables, the application can provide a clinically accurate simulation that respects the profound differences between pediatric and adult metabolisms and the unique prodrug mechanics of lisdexamfetamine.

Appendix: Simulation Constants Summary Table

Parameter	Value	Unit	Notes
Conversion Factor	0.2948	mg base / mg salt	Multiply LDX dose by this first.
Volume of Distribution (V_d)	3.7 - 4.0	L/kg	Default to ~260 L for 70kg Adult.
Bioavailability (F)	0.96	Fraction	Efficiency of hydrolysis.
Absorption Rate (k_a)	0.3 - 0.4	h^{-1}	Rate of hydrolysis/appearance.
Elimination Rate (k_{el})	0.063	h^{-1}	Based on 11h half-life.
Lag Time (t_{lag})	~0.5 - 1.0	hours	Time before hydrolysis accelerates.

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