



## A Review on Therapeutic Drug Monitoring in Pediatric Oncology

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### Abstract

Therapeutic drug monitoring (TDM) is advised to guarantee children's safe and efficient dosage. The objective of the study was to create and assess an external population pharmacokinetic, pathophysiological, and pharmacological underpinning for TDM in pediatric oncology. This reflects both organ-specific diseases and common pediatric cases. Methotrexate, busulfan, and asparaginase are important medications under observation. Since children's metabolisms differ, TDM helps modify the course of treatment. Finger pricks are important tactics for decreasing blood loss and predicting drug behavior in various age groups. Therapeutic Drug Monitoring in Pediatric Oncology Supports Individualized Chemotherapy Through Analysis of Pharmacokinetic Differences and Genetic Factors.

**Keywords:** Therapeutic drug monitoring, Pediatric, Oncology, Chemotherapy, Pharmacokinetic, Genetic Factors

### Introduction

#### Definition of Therapeutic Drug Monitoring in Pediatric Oncology

Measuring medicine amounts in body fluids - often blood plasma or serum - forms the core of Therapeutic Drug Monitoring. Its purpose? To adjust doses so that therapy works better, yet causes fewer harmful reactions. When drugs have limited safe ranges, differ widely in patient absorption, or show strong ties between concentration and effect - or harm - the practice gains importance [1][2].

Because children's bodies change rapidly during growth, medicine behaves differently at each stage of development. Since organs process drugs in ways that shift with age, standard doses may miss the mark even when adjusted for size. When tumors damage liver or kidney function, drug handling becomes harder to predict. On top of that, therapies often interact, altering effectiveness without clear patterns. Genetic makeup further adds variation, making responses differ widely across patients. Given these layers, measuring drug levels directly helps tailor treatments more closely to individual needs. Instead of guessing, clinicians gain clearer insight into what dose works. This approach adjusts for complications introduced by disease or prior interventions. While weight-based dosing remains common, it rarely accounts for such complexity. Monitoring blood concentrations will close the gaps and provide us with smarter decision.

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## Classification of Therapeutic Drug Monitoring in Pediatric Oncology

When looking at TDM here, classification often follows what the treatment aims to achieve, which pharmacokinetic measure is applied, or the category of medication involved.

### 1. Classification by Treatment Goal

#### a. Safety-focused TDM

This approach focuses on preventing harmful reactions through strict control of medication concentrations under recognized safe limits. Busulfan illustrates the point well - too much raises chances of severe liver injury, known as sinusoidal obstruction syndrome, along with brain-related complications and greater death rates post-transplant.

#### b. Efficacy-focused TDM

Keeping drug levels steady matters most - this helps therapy work well while lowering chances of setbacks or weak results. When chemo doses fall too low, transplants might fail after blood stem cell replacement, or tumors could keep growing unchecked.

#### c. Integrated efficacy–toxicity TDM

Some current methods mix these aims, focusing on a particular dose window where tumor control works well without severe side effects. While aiming at cancer cells precisely, treatment also limits harm to healthy tissues.

### 2. Pharmacokinetic Classification

#### a. Trough concentration ( $C_{min}$ )-guided TDM

Measured right before the following dose, this approach captures drug concentration at its lowest point. Simple to apply, yet these trough levels sometimes fail to represent overall exposure in pediatric patients. For numerous anticancer agents, their link to actual treatment results remains weak .

#### b. AUC-guided TDM

AUC tracking captures total drug presence more precisely than other methods. Because too little or too much busulfan can lead to severe outcomes, dose adjustments guided by AUC are now routine in children's cancer care.

#### c. Model-informed precision dosing (MIPD)

Starting with sparse data, modern approaches apply population-based pharmacokinetic modeling combined with Bayesian predictions to estimate ideal dosing. If we talk about pediatric cases, especially, if blood draws are regular, there might be high risks and difficulties.

## Pathophysiological and Pharmacological Basis for TDM in Pediatric Oncology

This is why it is important to determine drug levels in the case of treating cancer in children. Effects of the disease, adverse effects of treatment, and metabolism changes resulting from growing are the key factors affecting the properties of drugs. Growing fast tumours cause tissue dynamics changes, affect protein binding mechanisms and clearance. Inflammation appears throughout the body, leading to unexpected changes in distribution.

The younger patients are, the less effective the clearance of some drugs is because they have not developed all liver enzymes yet. For instance, busulfan clearance depends on the age-specific metabolic pathway. It mostly occurs in the liver. This is why there may be differences in the way children receiving chemotherapy respond to treatment. Other factors affecting the disposition of a drug include increased load on some organs, particularly the kidneys, In the complicated courses of therapeutic procedures, such as bone marrow transplantations. In pediatric oncology, each child have a unique response to the drugs used. As such, personalisation of dosage in line with biological factors is crucial. This can be achieved through the measurement of blood levels.

## **Common Oncological cases related to pediatric:**

### **1. Carcinoma:**

Small cell lung carcinoma (SCLC) is a highly aggressive neuroendocrine tumour typically diagnosed in adults and the presentation of the condition in the pediatric population is extremely uncommon. The incidence of a primary lung cancer in children is very low and SCLC makes up a very small proportion of these cancers thus, restricting clinical experience and preventing the establishment of standardized management guidelines. The clinical and radiologic presentation of the disease is nonspecific, and therefore, diagnosis is traditionally made in an integrated fashion, using the combination of the histopathological assessment, immunohistochemical profiling, and molecular characterization. In the absence of pediatric-specific treatment regimens, therapeutic regimens are extrapolated directly from adult SCLC regimens, most of which include platinum-based treatment along with etoposide; the available evidence points to the fact that these regimens can also produce significant therapeutic responses, but their results are still variable because of the aggressiveness of the disease. The paucity of SCLC among the young population highlights the necessity of increased clinical awareness, systematic reporting, and additional studies that would enhance the quality of diagnosis and the best treatment approaches in the unusual clinical scenario.

### **2. Neuroblastoma:**

The primary complaints of boy admitted to the pediatric critical care unit were pain in both lower limbs, agitation, and trouble in walking. According to the patient's current history, he appeared to be asymptomatic before experiencing acute, progressively worsening pain in both lower limbs that was accompanied by a burning sensation. No history of headache, fever, vomiting, light-headedness, coughing, breathing difficulties, trauma, or lack of limb movement. However, there is a history of hospital stays. The patient received treatment for bronchopneumonia, was released, and had no prior history of tuberculosis exposure.

### **3. Wilm's Tumor:**

The belly lump in young kids, most often it's Wilms tumor – shows up fast, usually hits before age five. Picture this: a boy aged three, no pain but his left side swells slowly, month after month, along with fevers now and then. Pee stays normal, no blood, no burning when going. He isn't losing weight or skipping meals either. There is nothing odd in how the development was earlier, nor did any relatives have gene-linked conditions of kidney tumours. Out of nowhere case – which fits perfectly, since these things rarely run in families.

A belly exam often shows uneven swelling, one side bigger than the other. A solid lump can sometimes be felt near the side part of the abdomen, though it does not hurt when touched. The skin veins on the stomach might stand out more than usual because the growth pushes nearby structures. Most people have steady breathing, blood pressure, and temperature, but the heart may beat slightly faster. Blood counts, kidney values, and urine checks come back normal in many cases, which means pictures of the inside – like scans – are key to finding what is going on.

Imaging shows clear signs, depending on the method used. Belly X-rays might reveal swelling, along with shifted intestines, hinting at a growth inside. With ultrasound, one often sees a bigger-than-normal kidney, where a mixed-type lump takes up space in the middle and bottom parts. The usual layout of kidney tissue looks bent out of shape, usually alongside swollen drainage areas. Blood flow within the abnormal area can appear stronger when checked using color Doppler views; calcium spots hardly ever show up. A key clue pointing toward Wilms tumor? Nearby big blood pipes like the aorta or vena cava get pushed aside instead of being wrapped around – a detail that helps tell it apart from neuroblastoma.

A scan using contrast shows more detail about the growth, revealing a big uneven area in the kidney made of both solid and fluid-filled parts, each reacting differently to the dye. What remains of healthy kidney tissue can still exist, usually found toward the top part. The urine-collecting system might stretch from pressure, yet signs like cancer spreading into blood vessels or forming clots inside major veins near the kidney do not always

show up. Nearby lymph nodes could stay clear, so might faraway organs when first checked, while the opposite kidney typically looks fine except for slight shifts that help it take on extra work.

A single-sided Wilms tumor along with kidney swelling shows up clearly through scans and exam findings. Treatment usually lines up with standard children's cancer guidelines using several methods at once. In some cases, medicine given before surgery – often vincristine, actinomycin-D, and doxorubicin – helps shrink the growth so removal goes smoother. After full kidney removal, more treatment follows depending on how risky the case looks.

#### 4. Lymphoma:

##### *Childhood Peripheral T Cell Lymphoma Example:*

One year old girl shows signs after weeks of ongoing fever plus belly swelling that keeps getting worse. These kinds of lymphoma show up hardly ever in kids, making up just about 1 percent of non-Hodgkin cases during childhood. Swollen glands everywhere along with enlarged liver and spleen turned up on exam, pointing toward illness spread through much of the body. Such broad impact often appears when this particular cancer reaches later stages.

Something odd shows up in blood tests – white cells high, especially lymphocytes, plus lactate dehydrogenase ticking upward. Normal ranges? Blood counts, kidney, liver stuff – they might still sit okay

Even though kids' PTCL is rare and often resists standard treatments, stronger approaches built for childhood lymphomas sometimes work better. A tough chemo plan packed with several drugs brought full recovery here, even with widespread illness at first. This outcome suggests serious therapy might turn things around when odds seem low.

From time to time, a case like this one shows up – matching what doctors usually see in young patients with PTCL when they check symptoms, scans, or tissue samples. Though uncommon, such tumors often leave teams puzzled about the right call on diagnosis and next steps in care. Treatment paths can feel uncertain, yet stronger approaches meant for younger bodies may still have a place – for some kids, under strict review.

#### Organ Specific Conditions:

##### 1. Pediatric Lung Cancer

One child in every two million could develop primary lung cancer - such rarity means it accounts for merely 0.2 percent of pediatric tumor diagnoses. While smoking links strongly to adult forms, youth cases rarely connect to known risks such as environmental contact or lifestyle patterns. Signs often lack clarity; diagnosis then emerges unexpectedly, sometimes only once illness has advanced further.

Most children develop distinct lung tumor patterns compared to adults. Under WHO classification, cancers arising from airway lining fall into categories such as non-small cell carcinoma - this includes glandular, squamous, and large-cell variants - as well as small-cell disease and select neuroendocrine growths. Gland-based tumors occur more frequently among younger individuals. Rarely seen is the small-cell type, accounting for roughly 4 to 5 percent of pediatric instances.

Not many symptoms stand out early in children who develop lung cancer - shortness of breath, discomfort in the chest, or frequent respiratory flare-ups may come and go without clear warning. Because imaging results sometimes mirror those seen in common infections or inherited conditions, telling them apart takes extra care. Often, diagnosis waits until later stages simply because signals are too mild at first. By then, spread has likely begun, giving less room for effective response. When cancers grow quickly - as some small-cell forms do - the path forward turns steep: survival beyond twenty-four months hovers near five percent.

Rare cases mean guidelines focused on kids do not exist. For lack of a set path, medical teams borrow strategies from adult care. Therapy tends to mix approaches - radiation or chemotherapy - while cutting out tissue happens only if required. The choice among paths rests mostly on tumor type and its reach across the body. A few new studies suggest that chemotherapy strategies, adapted from adult treatments, may reduce symptoms and delay

disease progression in some children. What emerges is a broader insight - collaboration across fields and tailored advice are becoming essential when tackling this rare form of cancer.

## **2. Pediatric Brain Cancer.**

Brain cancers in children rank highest among solid tumors affecting youth, contributing significantly to fatalities linked to pediatric malignancies. Every year, about 5.7 per 100,000 youngsters receive a diagnosis of primary brain or central nervous system tumors. Though grouped together, these conditions differ widely - location, biological behavior, and individual progression patterns shape their impact. Among them, astrocytomas, medulloblastomas, ependymomas, and brainstem lesions appear frequently but present distinct features. Because symptoms depend heavily on tumor placement and growth rate, they range broadly: some experience persistent headaches, others face nausea, fits, unsteady motion, mental fog, or changes in emotions and daily conduct.

Children's brain tumors usually belong to one group: either they arise from glial cells or come from immature neurons. More than half of all childhood CNS masses are gliomas. Even if rarer, medulloblastoma and AT/RT tend to appear in severe cases. Thanks to sharper imaging, improved surgical methods, targeted radiation, along with newer medications, survival rates for young patients have gone up lately. Even so, every situation presents challenges due to how uniquely tumors appear across children. Reaching the tumor site is tough - often stopped by the protective layer separating blood from brain matter. Once therapy finishes, certain kids deal with long-term changes in memory or slower physical development. Lately, researchers have turned attention toward DNA signals within these abnormal growths. Efforts likewise go toward drugs designed to hit distinct features of childhood cancers. Just as critical is delivering proper dose levels beyond bodily barriers. For younger individuals, treatment adjustments often follow extended healing phases. What influences care plans hinges on these prolonged timelines.

## **3. Pediatric gastric cancer**

A small number of stomach cancer cases occur in children, with nearly all falling under adenocarcinoma - making up roughly 0.05 percent of gastrointestinal tumors in younger people, meaning clinicians encounter it much less frequently than adult forms. Symptoms like ongoing belly pain, vomiting, reduced red blood cells, dark bowel movements, or weight loss appear early; since such signs match many common illnesses, diagnosis tends to drag on. Often, the disease has advanced before detection. When examined closely, young individuals show a distinct spread of cancer cells featuring curved nuclei - a trait linked to harder recovery paths. A single faulty gene can shift the odds - errors in the CDH1 code raise chances of inherited stomach cancer. Still, forces beyond DNA join in, such as *Helicobacter pylori* and environmental nudges. Childhood stomach troubles fueled by lingering *H. pylori* may set off changes in tissues that echo into adult risks. Yet actual tumors rarely emerge during youth. Clearing the bug early might reverse certain alterations, possibly cutting future harm. Because pediatric instances stay rare, medical teams tend to adapt adult protocols when shaping choices about detection and treatment. Options - from surgery to mixtures of medicines - are shaped more by disease depth than age alone.

## **Common Oncological Issues Found in the Pediatric Population**

### **Pediatric Malignancies:**

One child at a time, cancer reshapes lives across households and communities globally. Though science advances steadily, the fight against childhood tumors stays deeply difficult. Leukemia strikes some, brain growths others - each case unfolding without warning. Young bodies bear heavy reactions when exposed to radiation or strong drugs meant to heal. Diagnosis often comes too late, tangled in subtle signs mistaken for common illness. Complexity grows because developing tissues respond differently than mature ones. Unexpected hurdles emerge where treatment itself risks long-term harm. Behind every number is a daily reality shaped by uncertainty. What drives progress here is fresh approaches to treatment, along with a clearer view

of what makes childhood cancers so different. Shifting attention now toward this collection, the piece opens up a closer look at work centered on young patients facing cancer.

One child in four diagnosed with cancer has acute leukemia - it leads among pediatric cases. Though less common than some illnesses, it spreads fast when present. Most young patients face either AML or its close relative, acute lymphocytic type. Looking at nearly seven hundred cases, researchers spotted extremely high white blood cell counts in roughly one out of six kids overall. For those carrying AML alone, that number crept higher - about every fifth patient showed this sign. Such intense levels often go hand-in-hand with more complications during treatment. Outcomes tend to be tougher too; survival dips where these markers rise. This research suggests improving surveillance during initial phases along with adjustments in therapeutic strategies. Tumors outside the bone marrow linked to acute myeloid leukemia, called myeloid sarcomas or chloromas, differ widely in how often they occur and their clinical effects.

More than one in four childhood cancers involve the brain or spinal cord, placing them just behind leukemias in frequency. These growths differ widely, each shaped by distinct biological behaviors and therapy paths. A synthesis by Thorbinson and Kilday outlines current understanding of molecular features, outcomes, standard care, and emerging approaches for medulloblastoma, high-grade gliomas, and ependymoma - the trio most often seen in young patients. Among these, DIPG makes up 10 to 15 percent of cases; despite being a glial origin tumor, it resists existing medical interventions. Because options remain limited, attention turns toward novel immune-based therapies that may shift results. Ependymoma, occupying third place in incidence among pediatric central nervous system tumors, shows wide variation across genetic profiles and patient presentations. Despite being the third most frequent childhood cancer, neuroblastoma leads to more than 15% of pediatric cancer fatalities, with fewer than half surviving five years. Because of this, fresh treatment approaches are needed - ones focused on the specific molecular mechanisms driving tumor growth.

Kidney tumors in kids often point to one main type - nephroblastoma, sometimes called Wilms tumor - which appears in roughly 5% of childhood cancer cases. Because inherited patterns matter, findings from a look back at 2927 patients hint that genetic roots should shape how families get advice and treatment. Among rare growths, pediatric sarcomas take up close to 13% of all youth cancers, blending unusual forms across bones and soft tissues. While rhabdomyosarcoma dominates among soft tissue origins, bone-related types mostly include osteosarcoma and Ewing's sarcoma.

While scientists still do not fully understand what triggers pediatric cancer, possible contributors include changes in genes, family history passed from close relatives, or outside influences like surroundings and exposures. Rather than inherited patterns alone, some cases appear tied to new gene errors formed at conception, or even influenced by the mother's genetics. Often, early-life cancers connect with built-in conditions - examples being below-average birth size, having older mothers or fathers, or physical traits present at birth. Exposure to strong radiation, along with prior medical therapies, has clearly shown links to higher chances of developing these cancers in children. Other suspected elements involve what parents eat, medicines taken during pregnancy, or intake of caffeine and alcohol by the mother.

### **TDM Drugs Utilized In Oncological Issues**

Nowhere more critical than in cancer care does tracking medicine levels become vital, especially when dealing with treatments that work only within narrow limits and show wide variation between patients. Even slight differences in how much drug reaches the system may trigger harmful reactions or result in failure to treat the disease. Through checking substance amounts in body liquids, dosage adjustments fit each person improve both safety and real-world outcomes. This approach gains extra importance in children's cancer therapy due to growth-linked shifts affecting how medicines enter, move through, break down, and leave the body. (Smita et al., 2022).

## **Methotrexate**

The medication has an immunosuppressant effect as well. This happens regardless of the medication being taken in recommended dosages. Some signs of brain poisoning from the use of methotrexate appear hours, even years later after the treatment – in unpredictable degrees. While there are people who experience nothing more than a mild reaction to the medication, there are those who experience severe effects unpredictably. The application of radiation therapy at the same time as methotrexate causes increased susceptibility for specific individuals. Genes can influence the way the drug impacts the nervous system.

## **Busulfan**

Busulfan is a bifunctional anticancer drug that alkylates DNA and operates without regard to cell cycle. Following systemic absorption, carbonium ions are quickly produced. These ions then undergo a nucleophilic substitution process (SN<sub>2</sub>) with DNA guanine molecules to form intra- and interstrand crosslinks. This causes the DNA molecule to split and the twin strands to crosslink, which interferes with DNA replication, RNA transcription, and ultimately cell proliferation.

## **Tacrolimus**

Used mainly in children receiving stem cell transplants, tacrolimus helps avoid complications tied to immune response. A small shift in blood levels can push the drug into ranges where it either stops working well or causes serious harm, particularly to kidneys and nerves - this reflects its narrow safety window. Routine checks become essential then, simply because unpredictability shapes nearly every step of treatment. Monitoring turns standard practice under these conditions.

## **Vincristine**

Vincristine plays a central role in combination chemo plans targeting kids' cancers, including Wilms tumor. Yet despite frequent nerve-related side effects tied to dosage and wide differences in how patients process it, tracking blood levels remains rare in everyday care. Even so, newer insights into how the body handles the drug - alongside clearer links between concentration and harm - are reviving interest in dose adjustments based on measured exposure. Right now, studying its movement through the body takes priority over using those measurements routinely in clinics.

## **Preferred Medication in Cancer Treatment**

### **Methotrexate:**

Although effective against tumors, methotrexate (MTX) disrupts folic acid processes through inhibition of dihydrofolate reductase, impairing DNA formation. This agent, used in oncology, reaches the body via routes like intravenous or intrathecal delivery. Despite targeting malignant cells, it may trigger issues such as bone marrow suppression, liver damage, kidney dysfunction, mouth sores, or nervous system effects. Originally designed to hinder cell replication, MTX also dampens immune responses. Unwanted reactions occur even when dosing follows standard protocols. Hours or even years following exposure, signs of MTX-related brain toxicity can emerge - varying widely in intensity. Though some cases stay mild, others grow serious without clear warning. Radiation given at the same time increases vulnerability in certain patients. A person's genes may also play a role in how the drug affects nervous tissue. When medicines mix, unintended effects on the brain sometimes follow. Kidney problems slow toxin removal, raising risks further.

Though taken by mouth, skin application, vein infusion, or spinal injection, MTX remains a standard chemotherapy option. Because it carries strong charge and resists fat, crossing into brain tissue through blood becomes nearly impossible - making the spinal method key when cancer spreads to nervous areas like in leukemia or lymphoma. Hours after treatment, sometimes weeks or much later, signs of nerve harm might emerge; these effects differ greatly in shape and intensity. Timing matters - not just how often but when doses arrive shapes what damage could follow. Not everyone responds alike: people on identical plans show varied reactions, likely due to personal biological differences despite shared risk factors tied to such nerve-related

side effects. This paper looks at different types of brain damage caused by methotrexate, exploring what increases the chance of harm while also considering ways to prevent or treat it. Monitoring blood levels matters during treatment since methotrexate's effects can vary widely among patients

1. Limited therapeutic index
2. Serious toxicity risk (myelosuppression, nephrotoxicity, mucositis)
3. Timing of leucovorin rescue depends on therapeutic drug monitoring. Dosing adjusts according to measured levels. How much is given ties directly to patient-specific data. When it's administered follows concentration trends. Decisions rely on real-time pharmacokinetic feedback.

### **Busulfan:**

This work follows a five-year observation period focused on identifying factors that shape busulfan pharmacokinetics within therapeutic drug monitoring. What drives variation in exposure levels becomes clearer when patient-specific patterns are examined closely. A main goal involves refining how conditioning treatments are tailored before transplantation. By studying individually adjusted dosing strategies, insights emerge about their impact on outcomes. Success in pediatric hematopoietic stem cell transplantation gains clarity through such targeted evaluation. How doses behave in young cancer patients reveals critical links to treatment effectiveness. One outcome shows how fine-tuning influences overall survival trends. Attention shifts toward practical adjustments informed by real-world data.

### **Applications of TDM**

Sometimes, it may be quite difficult to achieve proper medication due to monitoring. Monitoring the response in cancer cases is very significant when medication is considered. Increasing of doses of specific drugs leads to negative responses. However, low doses can lead to ineffective therapy. That is why monitoring of such drugs is required in some cases. It should be emphasized that individuals respond differently to different medications, because the human body processes medication differently. From practical perspective, it can be stated that monitoring of medication concentrations within a bloodstream or another body fluid is the definition of TDM. Such management is useful for achieving the desirable goals without causing side effects. In cases when chemotherapy or long-term anticancer medications are used, TDM can play an important role. Maintaining of medication levels within zones corresponding to effective results enhances the precision of therapy. Nowadays, there have been many developments that facilitate the process of TDM application at hospitals. For instance, functioning of vital organs, as well as the usage of other medications and presence of preexisting conditions influence on dosage of therapy. As far as nowadays personalized therapy is applied for cancer cases more often, it becomes even more important. New advances in lab methods and modeling now allow hospitals to apply TDM more smoothly than before. The way a patient's organs work, along with any additional medications and existing health conditions, guides how physicians adjust treatment amounts. With growing reliance on tailored approaches in cancer therapy, monitoring drug levels has gained prominence. This method supports customized care while reducing risks.

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