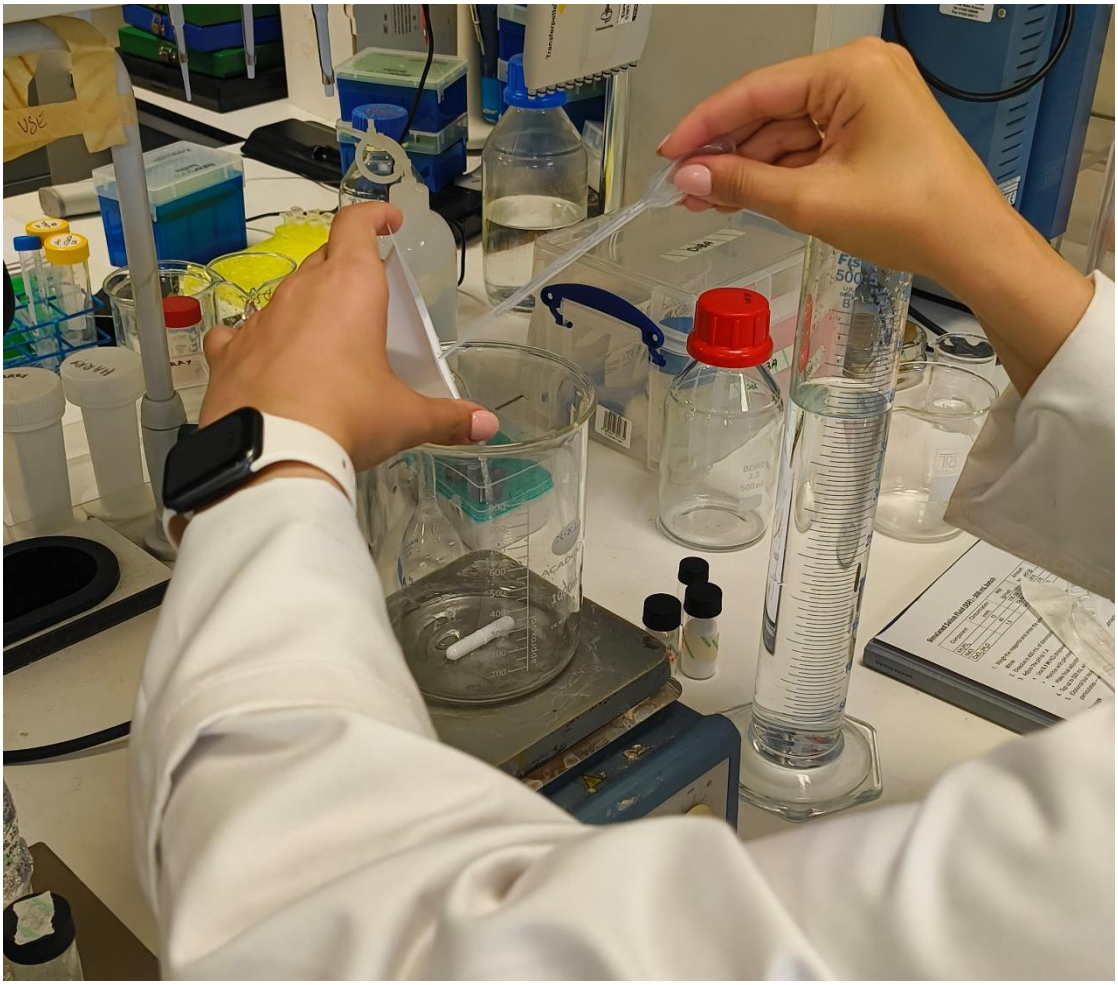
Faculty of Life Sciences
UCL School of Pharmacy

Laidlaw Undergraduate Research Programme

Research Report

From Bench to Bedside: The Development & Evaluation of Orodispersible Films for Paediatric Drug Delivery



Preparation of Simulated Saliva Fluid (SSF)

Ravleen Kaur Gujral

Supervisors: Dr Karolina Dziemidowicz & Dr Diba Keyhanfar

LAIDLAW SCHOLARS

Contents

Introduction

Research Problem

Even the most effective medication does not work if the patient refuses to take it. According to Milne and Bruss (2008), more than 90% of paediatricians reported that a drug's taste and palatability were "the biggest barriers to completing treatment". This makes dosing children a challenge. How can we improve medication adherence to enhance therapeutic outcomes in young patients?

The Dziemidowicz Lab at the UCL School of Pharmacy is a multidisciplinary team developing a novel drug delivery platform called Orodispersible Films (ODFs) that have been shown to be a child-friendly dosage form for young patients (Orlu *et al.*, 2017). As such, ODFs represent a breakthrough in paediatric drug delivery where the need for "personalised dosing" remains critical due to the lack of suitable commercial alternatives (Walsh *et al.*, 2021).

For my research project, I joined the Dziemidowicz Lab to explore the development of ODFs through hands-on laboratory research at the UCL School of Pharmacy and its evaluation as a child-friendly, palatable formulation at Great Ormond Street Hospital (GOSH) to manage and improve the treatment of chemotherapy-induced nausea and vomiting (CINV) in paediatric oncology patients.

In this research report, I will share the context behind this project and outline its objectives through various analytical techniques, interviews, and surveys. From this, I can reflect on any findings, next steps regarding ODF development, its wider significance in clinical settings, as well as the skills and insights I gained from this project.

Background Knowledge

Orodispersible Films

Child-friendly dosage forms are limited for antiemetics (Orlu *et al.*, 2017). Commonly prescribed antiemetics like Ondansetron can either be administrated orally (via a tablet or oral solution), by intravenous injection, or intravenous infusion (Paediatric Formulary Committee, 2025a), whereas Levomepromazine can only be administered to children via continuous intravenous infusion, or by subcutaneous infusion (Paediatric Formulary Committee, 2025b).

Typically, injections and infusions are the chosen method of administration due to several advantages, such as:

1. Emesis will not impact drug absorption.
2. Rapid onset of action.
3. The drug avoids metabolism in the liver, making it is less susceptible to degradation. This leads to greater bioavailability which allows:
    a. Minimal adverse effects.
    b. Minimal dose.

Despite these advantages, injections and infusions are invasive, can be painful, and require hospitalisation to be administered. Alternative dosage forms could simplify drug administration and allow drug delivery at home, which would be much more comfortable for the patient and their caregiver(s). This has motivated the development of ODFs.

ODFs are thin, polymeric sheets - similar in size and thickness to a postage stamp. They're designed to "dissolve rapidly upon contact with saliva" to release active pharmaceutical ingredients (APIs) that can be quickly absorbed through the oral mucosa (lining of the mouth), into the bloodstream (Dziemidowicz *et al.*, 2025). Administration of ODFs does not require any preparation or water, making them portable and efficient for children. They also require less taste masking than oral dosage forms, providing an opportunity to improve paediatric medication adherence.

ODFs are formulated using a polymer solution containing the API and excipients, like flavouring agents, that is "spun" into polymeric sheets of fibres (*Figure 1)* using electrospinning equipment.

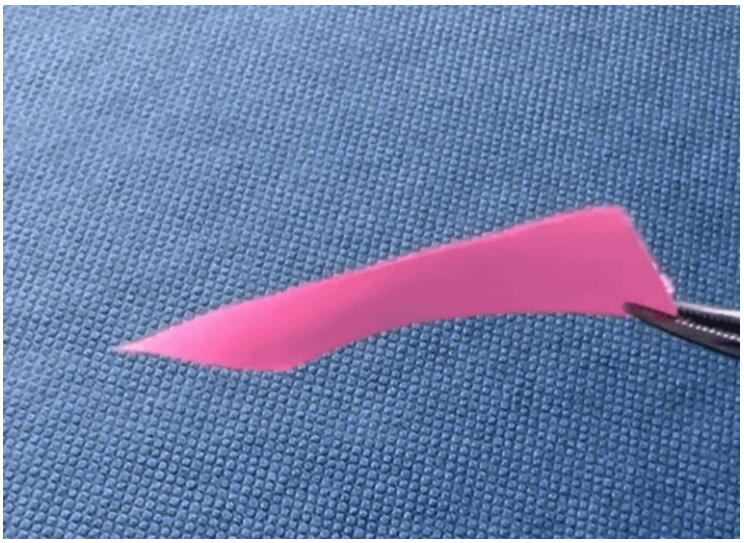


Figure 1: A thin polymetric film consisting of a polymer solution combined with rhodamine (an artificial dye).

Electrospinning

The Dziemidowicz Lab have been using electrospinning to create ODFs by “spinning” a polymer solution into ultrafine fibres by applying electricity *(Figure 2)*.

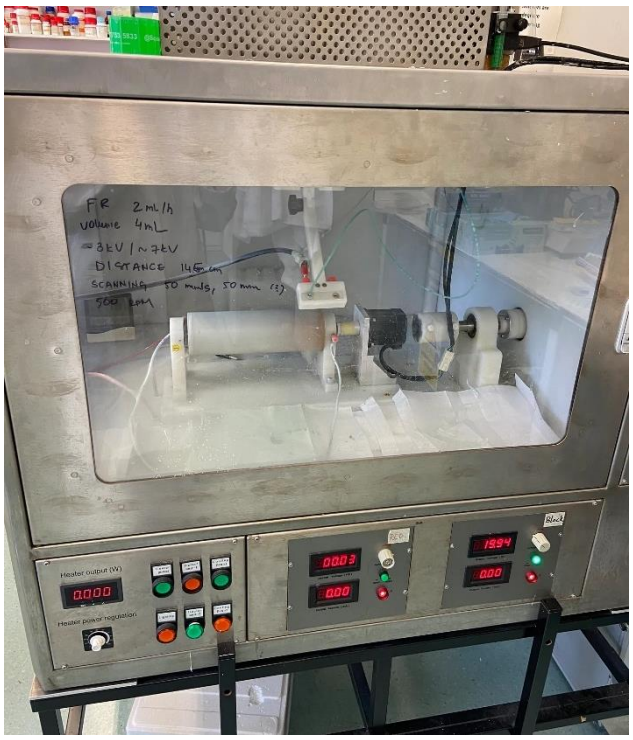


Figure 2: The Electrospinning machine at the UCL School of Pharmacy.

In this process *(Figure 3)*, the polymer solution is loaded into a syringe with a “spinneret” (a specialised nozzle to extrude a solution into thin fibres). Once a high voltage is applied, a “charged jet of solution at the Taylor Cone” (needle tip) is formed. As the jet travels through the air, the “solvent cools down and evaporates to form solid fibres on the grounded metal collector” (a flat, electrical ground), gradually building into a thin film *(Rana et al., 2017)*.

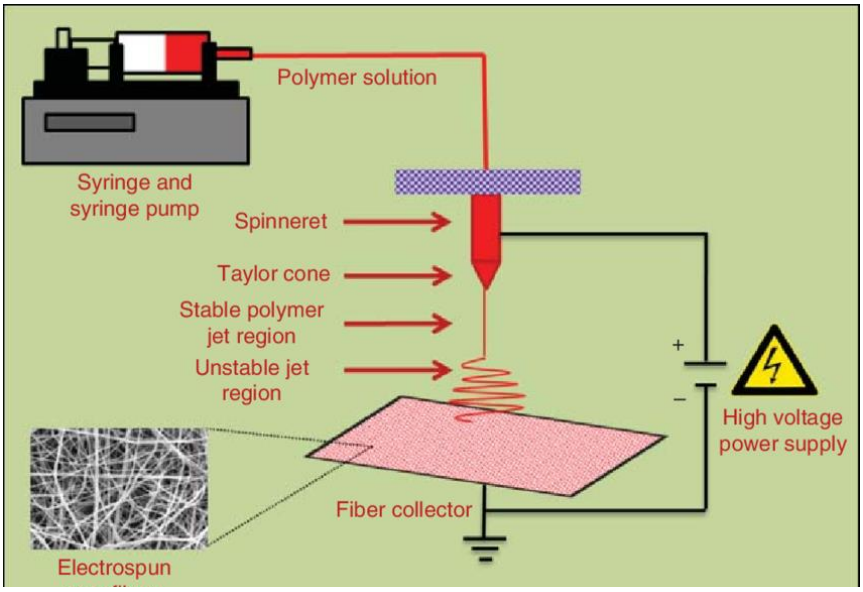


Figure 3: A schematic representation of electrospinning (Rana et al., 2017).

The API is evenly distributed throughout the network of fibres, ensuring consistent dosing, and each fibre is often thinner than a human hair, with a large surface area-to-volume ratio. This allows rapid disintegration upon contact with saliva, leading to fast drug release and absorption and a rapid onset of action according to Fick's First Law of Diffusion *(Equation 1).* This is ideal when paediatric patients require rapid relief from CINV.

$$\frac{dM}{dt} \propto -DA\frac{dC}{dx}$$

Equation 1: Fick's First Law of Diffusion where the rate of the diffusion of mass is proportional to the negative diffusion coefficient, surface area of the mass, and the concentration gradient.

Electrospinning can be compared to making candy floss: rather than using heat to stretch a sugar solution into strands, electrospinning stretches a polymer solution into fibres using electricity.

By adjusting parameters like the voltage, flow rate, and collector distance, properties like dissolution rate and film strength can be fine-tuned. For example, a high flow rate causes a greater volume of fluid being forced through the spinneret, causing the formation of thicker diameter fibres. However, a flow rate that is too high will cause the Taylor cone to become unstable due to the impact of gravitational forces. This can cause droplets to form instead of fibres. Additionally, low relative humidity in the lab environment is optimal as it allows the solvent to evaporate more quickly into the air during electrospinning, aiding the formation of dry, consistent fibres. Moreover, increasing the voltage and decreasing the distance between the capillary needle and collector created a stronger electric field, which was vital for overcoming the surface tension of the liquid formulation and forming consistent fibres.

Chemotherapy-Induced Nausea & Vomiting (CINV)

Chemotherapy is one of the most effective and widely used treatments for paediatric oncology; however, it comes with side effects like nausea and vomiting - referred to as chemotherapy-induced nausea and vomiting (CINV). According to Ruggiero *et al.* (2018), CINV affects up to 70-80% of patients receiving chemotherapy, making it a significant concern in paediatric cancer care due to its impact on patients' quality of life, treatment adherence, and overall clinical outcomes.

CINV can be classified into three main types depending on the timing of onset:

- Anticipatory CINV: occurs before treatment as a conditioned response to previous experiences of nausea or vomiting (Kamen *et al.*, 2013).
- Acute CINV: develops within the first 24 hours of chemotherapy administration.
- Delayed CINV: occurs after 24 hours and can persist for several days following treatment (Gupta *et al.,* 2021).

For paediatric oncology patients, CINV is more than just physical discomfort. Frequent nausea and vomiting can lead to dehydration and malnutrition, which compromises overall health. Resultingly, the anxiety and loss of appetite that's generated causes reduced adherence to medication (Han *et al.,* 2025), which delays recovery or could even convince caregivers and patients to discontinue chemotherapy (Woodgate *et al.,* 2013).

Aims & Objectives

Objective 1: Laboratory characterisation measures the physical composition and chemical properties of ODFs. This ensures drug quality, safety, and efficacy of ODFs as it provides an understanding of structure and stability that influence patient acceptability and medication adherence. In this project, ODFs were analysed using techniques including thermogravimetric analysis (TGA), differential scanning calorimetry (DSC), powder X-ray diffraction (PXRD), scanning electron microscopy (SEM), and ultraviolet-visible spectroscopy (UV-Vis).

Objective 2: I visited the Oncology and Haematology Department at GOSH to interview paediatric oncology patients and their caregivers regarding their experiences with CINV and current antiemetic treatments and management strategies. This gave me insight into their preferences with drug and non-drug advice, any effective approaches and limitations, and struggles with CINV. Hearing descriptions of how severe CINV can be and the extent that it inhibits the patient's ability to carry out daily activities emphasised the significance of personalised formulations to me – methods to administer APIs should always aim for the best therapeutic outcome and consistent medication adherence.

Objective 3: Evaluating the potential use of ODFs in a clinical setting for paediatric patients guarantees that ODFs are an acceptable alternative for paediatric patients, caregivers, and healthcare professionals. This allows me to explore opportunities to improve medication adherence and patient wellbeing through more child-friendly drug delivery systems.

Methodology

Laboratory Research

In this project, I used a range of analytical techniques to study ODFs, aiming to understand how these films are formed and structured, and how they might behave when used in a clinical setting in the real world.

Overview

1. Thermogravimetric Analysis (TGA)

   TGA involves heating a sample of material while continuously measuring its mass. Any changes (loss or gain) in mass are recorded as either a function of temperature (dynamic TGA) or time (isothermal TGA) – data is used to determine the temperature at which the material will decompose at. Overall, this tells me how stable ODFs are under heat and how they'll break down.

   Mass fluctuations in the data of a TGA curve correspond to different thermal events.
   - A quick drop at the beginning of heating represents drying of the sample.
   - Gradual or sharp weight loss represents polymer decomposition.
   - Further weight loss at higher temperatures symbolises complete degradation of the sample.

2. Powder X-Ray Diffractions (PXRD)

   PXRD works by directing x-rays via an X-ray tube at a powdered sample where its atoms diffract the X-rays. Analysing the pattern at which the x-rays scatter (the resulting diffraction pattern) allows me to analyse the composition of materials, purity, and crystallinity determination (if a material is crystalline or amorphous), which influences solubility and stability. PXRD showed whether the API in the films stayed crystalline or became amorphous after processing. This was important for predicting how quickly it might dissolve and for confirming that no impurities had been introduced during formulation.

   Sharp, well-defined peaks indicate a crystalline structure, whereas a broad hump shows an amorphous structure.

3. Differential Scanning Calorimetry (DSC)

   DSC is another thermal analysis technique that measures the heat absorbed or released by a sample (the sample's heat flow), compared to an inert control, as both are heated or cooled at a controlled rate. This provides information on physical and chemical changes, such as melting or crystallization.

4. Scanning Electron Microscopy (SEM)

   SEM creates high-resolution images of a sample's surface at a microscopic level. It uses an electron microscope to generate a focused beam of electrons that form signals from the sample's interactions with the electrons, in order to scan the surface of the sample. These signals provide information about the sample's surface topography, composition, structure, and particle size (distinguishing between single particles and aggregates), which gives me an idea about dissolution rate (which influences drug absorption and onset of action) and formulation performance (like the stability of dispersed systems).

5. Ultraviolet Visible Spectroscopy (UV-Vis)

UV-Vis measures the absorbance of ultraviolet and visible light by a sample to determine how much of a substance is present. I used UV-Vis to determine how much drug was in prototype ODFs and how quickly it was released when placed in liquid. A higher absorption reading indicates a greater concentration of the drug.

Clinical Research

Survey Design

To collect data, I used the survey that the previous Laidlaw Scholar designed *(Appendix 1)* that included closed-ended (Likert scale, multiple-choice, ranking) questions and open-ended questions. To gain further data, I edited and added more questions *(Appendix 2)*, building on the original survey, to gain a better understanding of 3 key areas:

1. Frequency and Severity of Nausea and Vomiting
2. Current Management Strategies
3. Treatment Experiences and Expectations

Caregivers of paediatric oncology patients in the Oncology and Haematology Department at GOSH were invited to complete the survey either independently or as an in-person, recorded, and transcribed interview. Where appropriate, young people were invited to share their own experiences directly.

Overall, 19 families participated and I was able to collect both quantitative and qualitative data that showed measurable trends and captured the experiences and struggles of patients and caregivers.

Ethical Considerations

Several key ethical principles were considered to protect participants and ensure research integrity.

1. I was introduced to eligible caregivers and patients by a member of GOSH staff, ensuring that I had permission to enter patient rooms, and I was adhering to occupational health and safety requirements, including the use of face masks and PPE.

2. I re-introduced myself to caregivers and patients, clearly explaining my role as a pharmacy student conducting research with the UCL School of Pharmacy. This helped to establish trust and transparency, reassuring participants of my identity and the purpose of my visit.

3. Providing clear information about the study and gaining consent from participants both verbally and written on the survey *(Appendix 2)*, including but not limited to:

    a. The purpose of the research and what participation involves.
    b. The duration of their involvement.
    c. The voluntary nature of participation – participants can withdraw at any time.
    d. How data will be collected, stored, used, and anonymised.
    e. Who has access to the data.

4. I removed all names and identifying details from transcripts and avoided collecting unnecessary personal information that was unrelated to my research to protect participants' identities.

5. I avoided influencing or leading participants' responses by using a neutral tone in both surveys and interviews.

Data Presentation & Findings

Laboratory Research

Scanning Electron Microscopy (SEM)

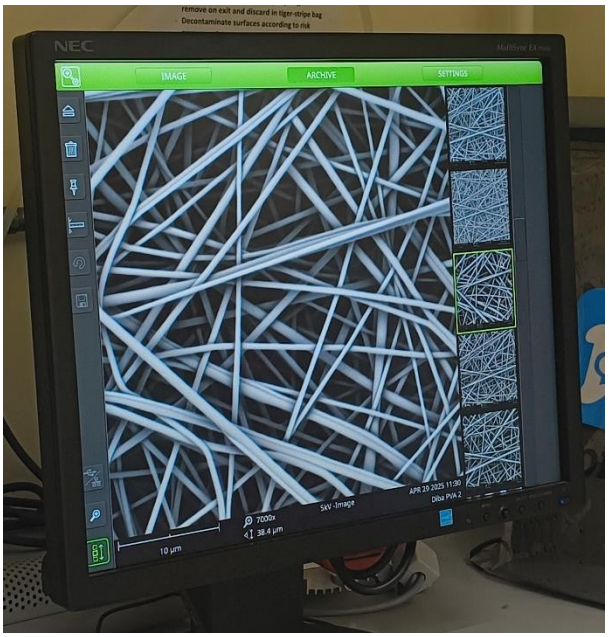


Figure 4: A scanning electron microscopy (SEM) image of crystalline structure found in a prototype ODF.

Figure 5: A scanning electron microscopy (SEM) image of amorphous structure found in a prototype ODF.

Figure 4 and *Figure 5* show SEM images showing the morphology and topography observed in two samples of prototype ODFs. SEM was used to examine the microstructural features of the ODFs to determine whether the API retained its crystalline structure or transitioned to an amorphous state after processing.

A crystalline structure can be seen in *Figure 4* – the particles have clear angles, edges, and planes, which is typical of an ordered lattice. This means the API maintained its crystallinity after formulation, which is desirable for an ODF due to improved physical stability. For these ODFs, this contributes to a longer shelf life and reduced susceptibility to crystallisation (Ochi *et al.*, 2015), which is ideal for the long-term management of CINV.

In contrast, *Figure 5* shows irregular, non-uniform shapes that indicate an amorphous structure. This suggests that the API used in this sample changed in crystalline structure during formulation.

Ultraviolet Visible Spectroscopy (UV-Vis)

Figure 6 demonstrates how absorbance of light changes with wavelength for each concentration (7–25 µg/mL), where there's an increase in absorbance with concentration – consistent with Beer-Lambert's Law *(Equation 2).*

$$A = \varepsilon l c$$

Equation 2: Beer-Lambert's Law where the absorbance of light by a solution is directly proportional to the concentration of the absorbing species and the path length the light travels through the solution.

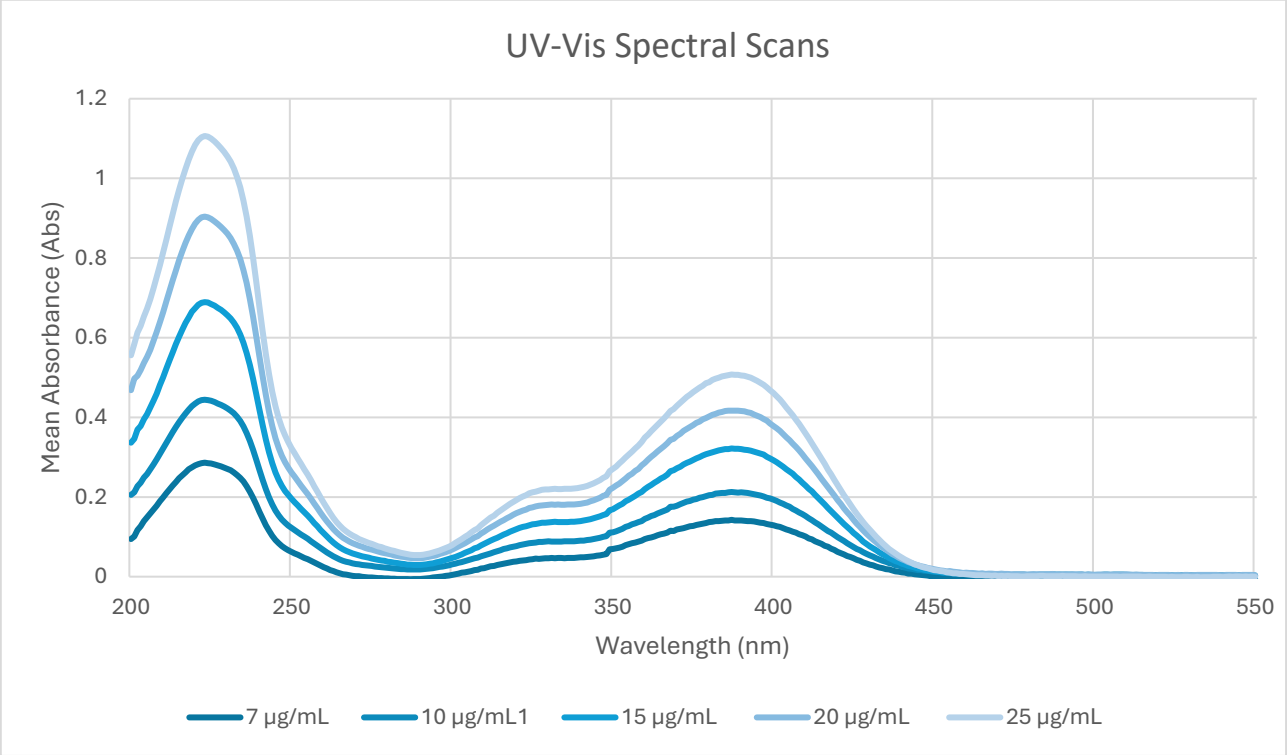


Figure 6: UV-Vis spectral scans.

The curves show two main peaks, with a pronounced λmax (maximum absorbance wavelength) at approximately 223 nm and a secondary shoulder at approximately 390 nm. λmax is the wavelength where my sample shows its maximum absorbance, as light absorption is strongest.

To calculate concentration, I plotted a calibration curve with absorbance (A) against concentration (C) *(Figure 7)*. As a result, Beer-Lambert's Law *(Equation 2)* becomes a straight-line relationship *(Equation 3)*.

$$A = mC + c$$

Equation 3: Straight-line relationship of Beer-Lambert's Law where: A = absorbance, m = slope (gradient) = εb (absorptivity × path length), C = concentration, and c = intercept.

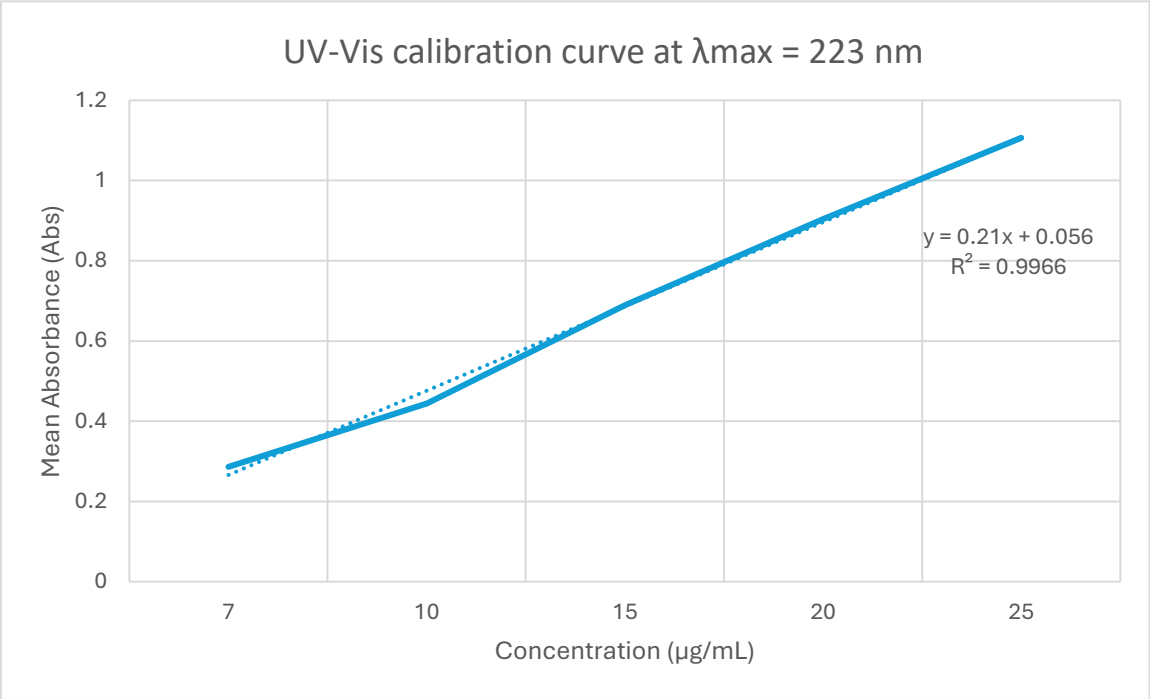


Figure 5: UV-Vis calibration curve at λmax.

There's a strong linear relationship between absorbance and concentration for the standard drug solutions ranging from 7–25 µg/mL in *Figure 7*, supported by the R^2 value of 0.997. This indicates a very low level of variance in the absorbance data set. *Figure 7* could be used to determine the concentration of drug released from ODFs during dissolution studies.

By measuring the absorbance of film samples at λmax = 223 nm and applying the regression equation, the amount of drug released at each time point could be quantified. This is significant as an accurate measurement of the amount and rate of API released from the ODFs allows the prediction of whether the formulation can achieve therapeutic concentrations rapidly enough to prevent or treat acute CINV, and whether sustained release characteristics may manage delayed CINV.

Frequency & Severity of CINV

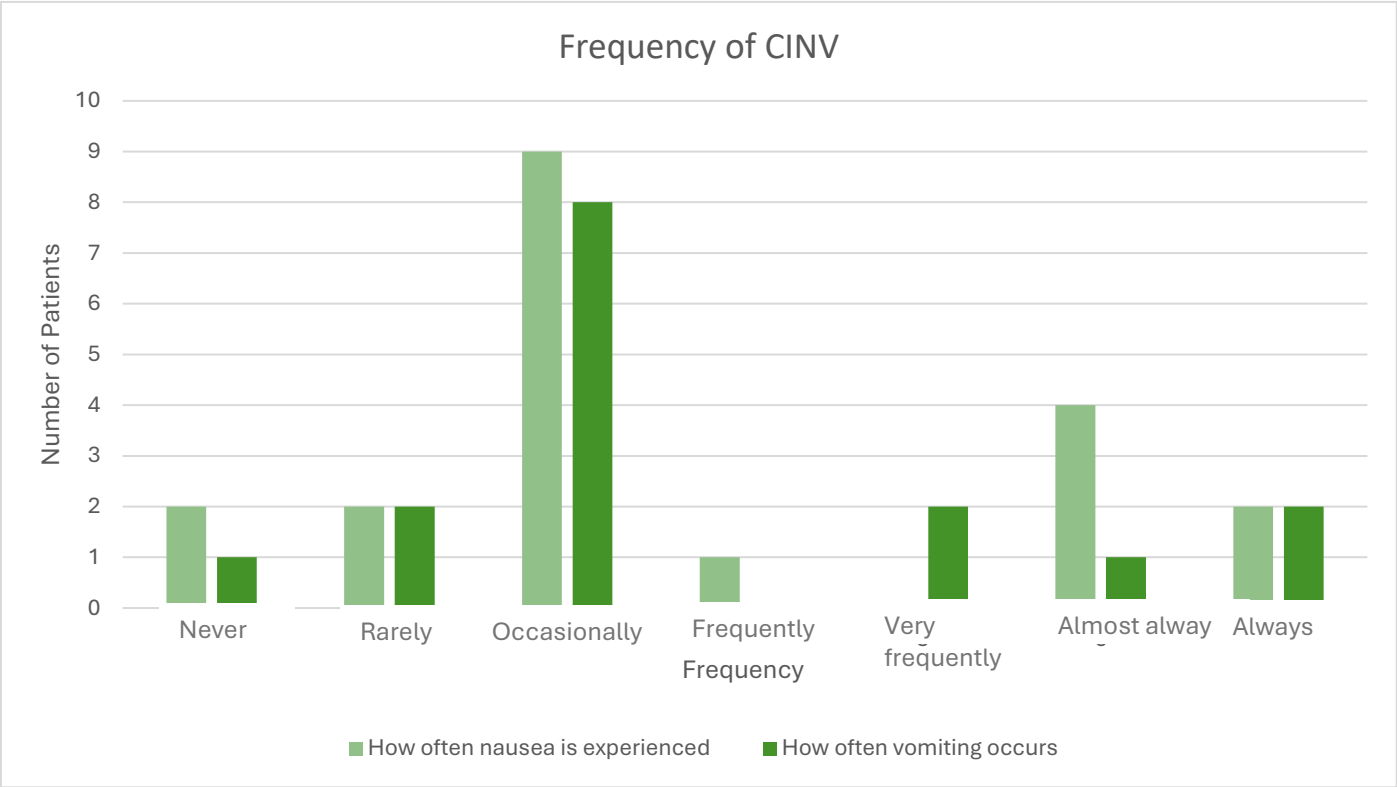


Figure 8: Bar chart displaying the reported frequency of CINV.

Frequency Key:

- Never
- Rarely (less than once a month)
- Occasionally (1-3 times a month)
- Frequently (1-3 times a week)
- Very frequently (more than 4 times a week)
- Almost always (almost daily)
- Always (daily or multiple times a day)

Figure 9: Key displaying what each Adverb of Time symbolise in terms of numbers.

In *Figure 8*¸ I've shown the responses I received from participants when I asked about the frequency of CINV to indicate how severely patients are affected, as more frequent episodes suggest ineffective antiemetic therapeutics, and the impact on daily life.

Half the participants (8 out of 19) reported that sickness occurred 1-3 times a month on average, typically after chemotherapy and/or cancer treatment – this was the most common response. This highlights acute and delayed CINV,

as discussed earlier. Most families gave different levels of frequency for nausea compared to vomiting, with nausea typically being experienced more than vomiting, with an anomaly being 2 families stating they experience vomiting "Very frequently" but no families reporting very frequent nausea.

In addition to the multiple-choice question, I asked an open-ended question for families to further comment on when they think CINV usually occurs. 3 families reported that CINV episodes followed food or dietary supplements, while 2 families reported that sickness seemed to happen all the time, regardless of triggers. Only one family said it occurred every few weeks, and another reported that it does not occur at all. These findings show that for most children, nausea and vomiting are strongly tied to the timing of chemotherapy, though other triggers like food can also play a role in worsening symptoms – a sign of anticipatory CINV.

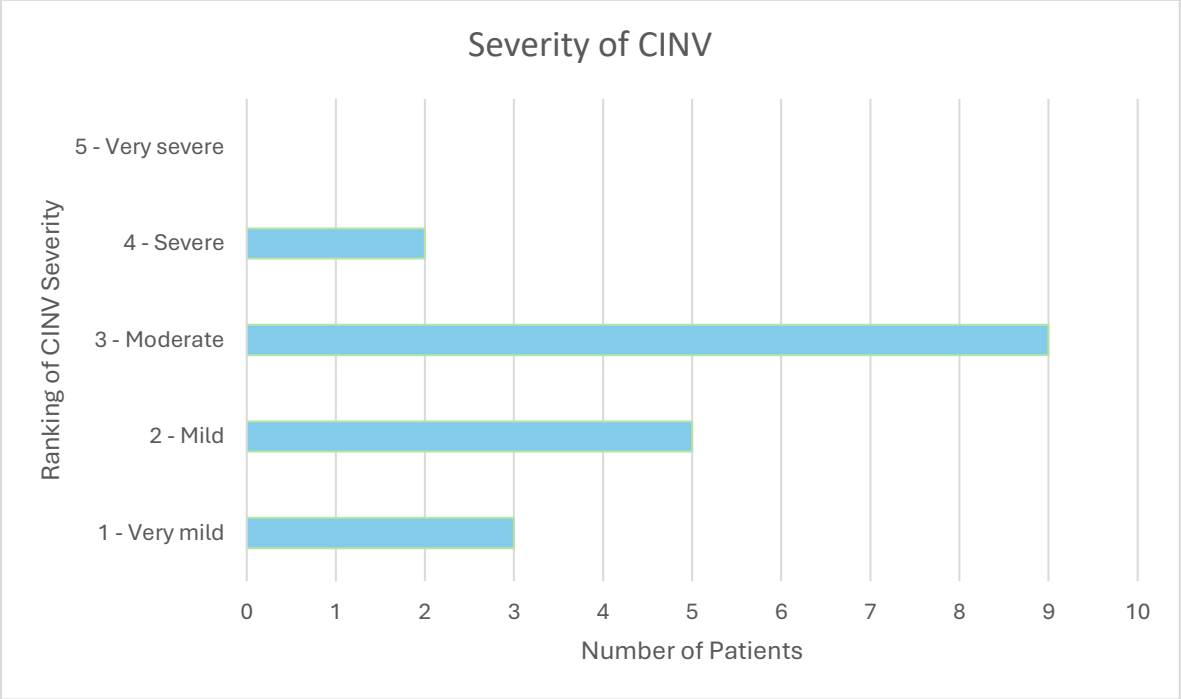


Figure 10: Clustered bar chart displaying the reported severity of CINV.

In *Figure 9*¸ I asked about the typical severity of CINV using a combination of a Likert scale and images for participants to select their answers from. This question further indicated how severely patients are affected and the impact on daily life. The majority of families reported that their CINV is "Moderate", with no families reporting "Very severe" CINV. A smaller but significant number of 2 families reported "Severe" CINV. This data set demonstrates that CINV is unique for each patient but remains a significant issue.

Participants found this question quite complex to answer, struggling to accurately correlate severity to a number (1-5), an adjective (like "Mild"), and to an image, asking for further clarification as to what each rank involved.

Question 6 in the first section of my survey *(Appendix 2)* asked about the duration of CINV – how long episodes of CINV lasted. There was a spread of data across three main categories. 6 families reported that sickness lasted less than 30 minutes usually, while another 6 families described episodes lasting 1-2 hours. 5 families reported CINV that lasts longer than 2 hours, with a few families mentioning that episodes can last for half a day or more. Only one family reported that their child never experienced CINV. These results further highlight how CINV is unique for each patient, with some recovering quickly while others feel discomfort for a large portion of their day. This impacts daily activities like eating and rest and shows the continuous burden CINV places on patients and caregivers, despite antiemetics being prescribed.

Question 9 *(Appendix 2)* was an open-ended question to better understand what physical, emotional, and social impacts patients feel from the CINV – responses further emphasised how extensive the discomfort can be. Many families described loss of appetite and dehydration as their child would feel unable to eat or drink during CINV episodes. Another common response was fatigue, which highlighted that patients were unable to carry out daily activities like attending school or spending time with friends and family - families often must reorganise daily life around episodes of vomiting. One parent mentioned that CINV made them worried about losing an NG tube during emesis, which would require replacement and cause further physical discomfort.

As a result of CINV, several families mentioned that their child felt anxiety before chemotherapy – some families went as far as to report that their child dreaded going to the treatment environment. One family stated that despite CINV stopping, the emotional toll of the nausea and emesis would remain; this made their child apprehensive to eat or drink for up to days on end. This insight helped me truly understand the critical need for better management strategies and child-friendly support for CINV.

Current Management Strategies

Participants were asked about what medicinal form their antiemetic medication are/was given in, so I could understand how antiemetics were administered in real life, especially as Ondansetron is already available as an ODF (Paediatric Formulary Committee, 2025a). This question also helps me identify which dosage forms are most accepted currently.

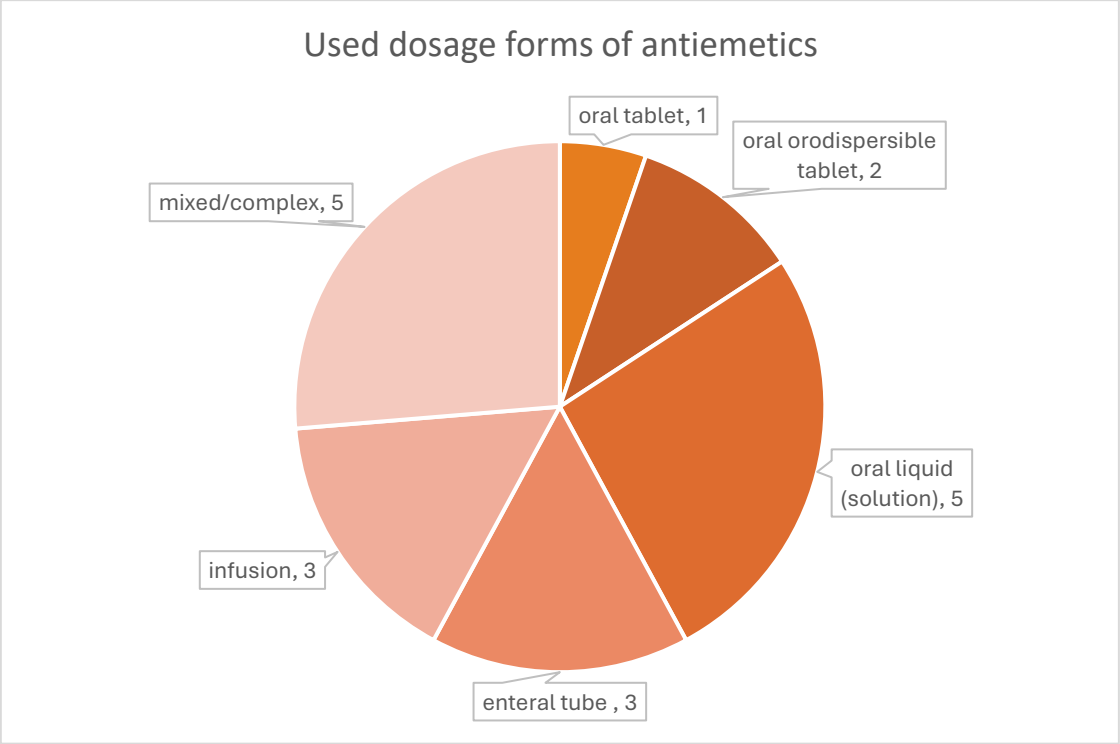


Figure 11: Pie chart displaying the dosage forms of antiemetics administrated to patients.

Oral liquids (solution) were the most used dosage form, followed by enteral tube administration (via NG or PEG), and infusions. Only one family reported using tablets, and another family uses orodispersible tablets. Several families stated that their medication comes in mixed or complex dosage forms, the reasons being:

1. Their child received a combination of medicinal forms depending on where the medication was being administered. For example, an oral solution would be taken at home while infusions would be given at the hospital.
2. Their child has recently changed dosage forms and is using both at the moment.
3. Their child used to use a particular dosage form but now uses another.

Overall, oral dosage forms are the most common method of administration of antiemetics – 8 families reported it as their child's main dosage form. Mixed/complex methods of administration were the second most frequent, with 5 families stating they use it. 3 families reported using enteral tube delivery, and another 3 families use infusion.

These results emphasised that oral administration, although most used, is often combined with other forms of administration like infusion, which indicates it must be a problematic dosage form. The fact that many families used mixed/complex administration indicates a need for child-friendly alternatives that aren't invasive or require hospitalisation but are still effective.
When asked about the biggest issues with current anti-sickness treatments, I received the same two answers from participants: poor palatability and difficulty swallowing. Families described poor taste and smell with syrups, making

many children unwilling to take them or vomiting immediately after administration. Tablets were widely reported as too large or uncomfortable to swallow, particularly for younger children or those already feeling nauseous. Even when medicines were successfully taken, parents found convincing their child very emotionally draining, and it often created anxiety around future doses for the child – this links to anticipatory CINV.

Several families also mentioned problems linked to infusions. Despite its rapid onset of action, patients found it invasive, were anxious about needles, and were uncomfortable with the continuous hospital visits. Overall, parents emphasised that antiemetics were essential, but the form they came in often added to the stress of managing CINV rather than relieving it.

When discussing non-drug management strategies, all participants were quick to report that they've not been recommended any advice by any healthcare professional and insinuated that this support would have been appreciated. As a result, most families did not have many non-drug management strategies aside from a couple of families that mentioned distractions like music or TV were helpful in reducing CINV symptoms. One family found that an aromatherapy bottle worked well in reducing CINV symptoms, making it very helpful when antiemetics weren't as effective.

Treatment Experiences & Expectations

At the end of the questionnaire, participants were given a table that listed and showed an image of a range of dosage forms *(Appendix 2)*. They were asked to give their general thoughts on the options shown and their reasons behind their opinion, as well as to rank the medicinal forms from most appealing to least appealing.

Participants were originally unaware of what ODFs were and asked for clarification. Once informed, they were among the most appealing formulations as many families stated they liked the idea of an oral medication that can quickly dissolve to be absorbed and doens't need to be swallowed. Families found many advantages in ODFs:

1. They suggested it had a low risk of being vomited.
2. Participants believed that their child would take an ODF even if they were reluctant to take any oral medication.
3. ODFs can be taken on the go, so families may not need to reorganise daily life around episodes of vomiting.

However, they also highlighted that taste masking would be essential for children to accept the films.

Oral solutions had a variety of results. Some families ranked them high in preference due to familiarity and ease of administration to their child, while other families ranked liquids low due to the bitter taste, foul smell, and need for large volumes of solution.

Tablets, crushed tablets, and dispersible tablets were consistently ranked lowest, which reflects many negative opinions. Often, patients would be reluctant to take tablets due to their CINV, and/or would vomit up the tablet, rendering them ineffective. Crushed tablets and dispersible tablets tasted bitter, were difficult and bothersome to crush, or struggled to disperse and were a nuisance to administer while on the go.

Infusions were typically rated somewhere between 3-5 (the middle). Families valued their effectiveness but disliked the invasiveness and need for frequent hospital visits that disrupted their daily lifestyle.

This ranking exercise provided a valuable quantitative picture of preferences that backed up the qualitative feedback from earlier questions. It showed that families are open to new formulations like ODFs, provided they are palatable and easy to use.

Conclusion

This project explored the development and evaluation of ODFs as a child-friendly formulation to manage CINV in paediatric oncology patients. Laboratory analyses confirmed that the prototype ODFs were of suitable quality, displaying desirable crystalline structure, stability, and consistent drug distribution. These properties are essential for reliable dissolution, medication adherence, and beneficial therapeutic outcomes.

Clinical data gathered from caregivers and young patients at GOSH highlighted that current antiemetic formulations, particularly syrups and tablets, are often poorly tolerated due to issues with taste, swallowing difficulty, and emotional distress. These findings reaffirm that the acceptability of a medicine's dosage form is central to adherence and treatment success.

When introduced to the concept of ODFs, most participants viewed them positively, appreciating their ease of use, portability, and suitability for children who struggle with oral or invasive dosage forms. Although effective taste masking remains a key consideration, overall, the results suggest that ODFs are an acceptable and promising alternative for paediatric antiemetic therapy.

This study therefore supports continued development and clinical evaluation of ODFs as a practical means of improving medication adherence, comfort, and therapeutic outcomes in children undergoing chemotherapy and experiencing CINV.

Evaluation & Next Steps

Both the laboratory and clinical components of this project provided valuable insights into the development and acceptability of ODFs for managing CINV. The lab results demonstrated that the electrospinning process successfully produced films with desirable structure and stability. However, I was unable to gain results for most of the laboratory research I carried out due to faulty equipment and time constraints. Limitations also include the small number of samples tested and the lack of drug-loaded prototypes, which makes me unable to assess solubility and drug release profiles. Future research should incorporate quantitative analyses such as in vitro disintegration and dissolution testing using medicated formulations.

The clinical results effectively captured the perspectives of patients and their caregivers. My survey revealed key challenges with existing antiemetic dosage forms and a strong inclination towards ODFs. If I had the opportunity to carry out this survey again, I would expand the survey to a larger, more diverse population across multiple hospitals to strengthen the validity of my results and limit bias. Carrying out a study of real ODF prototypes to assess palatability would truly determine their acceptability in the real world.

The insights I've gained can contribute to the development of ODFs for other patient groups, beyond paediatric oncology. Depertments like palliative care also administer antiemetics, and would benefit from ODFs where acceptability and ease of administration are equally important.

Personal Reflections

As a pharmacy student, this project has been one of the most rewarding and eye-opening experiences of my academic journey. It allowed me to bridge the gap between laboratory science and patient-centred care as per the GPhC standards - between understanding medicines as chemical formulations and seeing them as lifelines for real people.

Working in the lab taught me patience and analytical thinking, from understanding the variety of techniques I was being taught to use to interpreting results. Beyond the technical skills, it was the clinical side of this project that left the deepest impression. Listening to children and families speak about their experiences with CINV reminded me why I chose to study pharmacy in the first place: to help make treatments more tolerable, effective, and compassionate.

This project has strengthened my confidence as both a researcher and a future pharmacist. It has taught me that true innovation happens when science and empathy meet and has deepened my motivation to work on healthcare innovations that make a real difference to patients and families.

Bibliography

Dziemidowicz, K. *et al.* (2025) 'Characterisation and sensory evaluation of placebo OrPhyllo TM orodispersible films as a versatile paediatric drug delivery platform,' *Drug Development and Industrial Pharmacy*, pp. 1–15. https://doi.org/10.1080/03639045.2025.2521664.

Gupta, K., Walton, R. and Kataria, S.P. (2021). Chemotherapy-Induced Nausea and Vomiting: Pathogenesis, Recommendations, and New Trends. Cancer Treatment and Research Communications, [online] 26(100278), p.100278. https://doi.org/10.1016/j.ctarc.2020.100278.

Han, L. *et al.* (2025) 'Development and validation of the Pediatrics Functional Living Index—Emesis scale,' *Frontiers in Oncology*, 15. https://doi.org/10.3389/fonc.2025.1573996.

Kamen, C. *et al.* (2013) 'Anticipatory nausea and vomiting due to chemotherapy,' *European Journal of Pharmacology*, 722, pp. 172–179. https://doi.org/10.1016/j.ejphar.2013.09.071.

Milne, C.-P. and Bruss, J.B. (2008) 'The economics of pediatric formulation development for off-patent drugs,' *Clinical Therapeutics*, 30(11), pp. 2133–2145. https://doi.org/10.1016/j.clinthera.2008.11.019.

Ochi, M. *et al.* (2015) 'Physicochemical and Pharmacokinetic Characterization of Amorphous Solid Dispersion of Meloxicam with Enhanced Dissolution Property and Storage Stability,' *AAPS PharmSciTech*, 17(4), pp. 932–939. https://doi.org/10.1208/s12249-015-0422-x.

Orlu, M. *et al.* (2017) 'Acceptability of orodispersible films for delivery of medicines to infants and preschool children,' *Drug Delivery*, 24(1), pp. 1243–1248. https://doi.org/10.1080/10717544.2017.1370512.

Paediatric Formulary Committee (2025a) *Ondansetron*. https://bnfc.nice.org.uk/drugs/ondansetron/ (Accessed: September 15, 2025).

Paediatric Formulary Committee (2025b) *Levomepromazine*. https://bnfc.nice.org.uk/drugs/levomepromazine/ (Accessed: September 15, 2025).

Rana, D., Ramasamy, K., Samad Ahadian, Geetha Manivasagam, Wang, X. and Ramalingam, M. (2017). Polymeric Nanobiomaterials. pp.65–84. https://doi.org/10.1002/9783527698646.ch3.

Ruggiero, A. *et al.* (2018) 'Acute chemotherapy-induced nausea and vomiting in children with cancer: Still waiting for a common consensus on treatment,' *Journal of International Medical Research*, 46(6), pp. 2149–2156. https://doi.org/10.1177/0300060518765324.

Walsh, J. *et al.* (2021) 'Path towards efficient paediatric formulation development based on partnering with clinical pharmacologists and clinicians, a conect4children expert group white paper,' *British Journal of Clinical Pharmacology*, 88(12), pp. 5034–5051. https://doi.org/10.1111/bcp.14989.

Woodgate, R.L. and Degner, L.F. (2003). Expectations and Beliefs About Children's Cancer Symptoms: Perspectives of Children With Cancer and Their Families. Oncology Nursing Forum, 30(3), pp.479–491. https://doi.org/10.1188/03.onf.479-491.

Appendices

Appendix 1: Original survey used in 2024 to explore chemotherapy induced nausea and vomiting (CINV) in paediatric patients.

N&V HCP SURVEY – V2024 05 05

Nausea & Vomiting (Sickness) Survey

There is a knowledge gap in reporting incidence and experience of nausea & vomiting in paediatric cancer patients that needs addressing. We would therefore like to explore the appropriateness of improving treatment outcomes and patient wellbeing.

In this survey, we want to explore nausea & vomiting severity, current coping options, and treatment experiences & expectations.

Firstly, we would like to inform you that this questionnaire session will be recorded for accuracy of data collection, transcribing, and analysis. All responses are kept anonymous and confidential. You may choose to stop participating at any point during the questionnaire.

Do you give consent for this questionnaire session to be recorded?

Yes/No

Signature:

1. **Scoping for Nausea & Vomiting (Sickness) Severity and Frequency:**

a) Usually, how bad do you think the sickness is?

- 1 = Very mild
- 2 = Mild
- 3 = Moderate
- 4 = Severe
- 5 = Very severe

b) In your opinion, how often does the sickness usually happen?

- Never
- Rarely (less than once a month)
- Occasionally (1 - 3 times a month)
- Frequently (1 - 3 times a week)
- Very frequently (more than 4 times a week)
- Almost always (nearly every day or daily)

c) Please comment further on when you think the sickness usually happens.

d) In your opinion, how long does the feeling of sickness usually last for?

e) What would you say is the general physical, emotional, and social impact of the sickness? (*e.g. inability to move, emotional distress, inability to carry out daily activities, etc.)?*

2. **Current coping options:**

a) What non-medical advice is given when the child is feeling sick? *(For example, NHS advice includes: get plenty of fresh air / distract yourself – for example, listen to music or watch a film / take regular sips of a cold drink / drink ginger or peppermint tea / eat foods containing ginger – such as ginger biscuits / eat smaller, more frequent meals.)*

b) Are any medicines offered to treat the sickness?

If yes, then:

c) Which medicine(s) are suggested?

d) What is the usual medicinal form that is given i.e. is it a liquid medicine, pill, suspension, infusion, etc.?

3. **Treatment experiences & expectations:**

a) What do you think is the biggest issue experienced with the current anti-sickness treatments?

b) What is the usual reaction towards current anti-sickness treatments?

c) **For patients & families:** *Present the different medicinal forms. (explanations/images provided at the end for patients/families to read).*

Which forms of medicine appeal or don't appeal to your child? Could you comment on the available options and the reasons for your child's choices?

Tablet:	
Crushed tablet in water:	
Dispersible tablet:	
Liquid:	
Orodispersible film:	
Infusion:	

Explanations/images:

Tablet: a solid medicinal form that is swallowed by the patient.	
Crushed tablet in water: the tablet is physically crushed and then mixed with water before being given to the patient.	
Dispersible tablet: the tablet dissolves in water before being given to the patient.	
Liquid - commercial suspension/solution: a liquid medicine where the particles are either suspended or dissolved completely	
Orodispersible film: a thin paper-like film that dissolves on the tongue before being swallowed.	
Infusion: A needle is used to puncture the skin and insert a catheter that delivers medicines/nutrients.	

Appendix 2: Edited survey used in 2025 to explore chemotherapy induced nausea and vomiting (CINV) in paediatric patients.

Nausea & Vomiting (Sickness) Survey

In this survey, we want to explore the experience of nausea & vomiting and its severity in paediatric cancer patients, current management options, and treatment experiences & expectations in order to improve treatment outcomes and patient wellbeing.

We are inviting parents/carers of young people undergoing cancer treatment to complete this survey. Where appropriate, young people are invited to share their own experiences directly.

You will be asked to complete this survey individually or take part in an interview (depending on your preference) involving voice recording. The survey/interview should take no more than 30 minutes.

There are 3 sections to this survey:

1. Frequency and Severity of Nausea and Vomiting
2. Current Management Strategies
3. Treatment Experiences and Expectations

You may choose not to answer any questions and to stop participating at any point during the questionnaire.

All responses will be anonymised, confidential, and recorded for accuracy of data collection, transcribing, and analysis.

Please read and initial each box:

- ☐ I have read and understood the information above.
- ☐ I understand that my participation is voluntary and I can withdraw from the survey at any time.
- ☐ I give permission to be voice recorded during an interview.
- ☐ I consent to taking part in this survey.

Signature: _____

Date: _____

Please turn over to the next page to begin the survey.

Ravleen Kaur Gujral & Kimberly Gan
UCL, School of Pharmacy

Section 1: Frequency and Severity of Nausea and Vomiting

1. How often is **nausea** experienced?

   - ☐ Never
   - ☐ Rarely (less than once a month)
   - ☐ Occasionally (1-3 times a month)
   - ☐ Frequently (1-3 times a week)
   - ☐ Very frequently (more than 4 times a week)
   - ☐ Almost always (almost daily)
   - ☐ Always (daily or multiple times a day)

2. How often does **vomiting** occur?

   - ☐ Never
   - ☐ Rarely (less than once a month)
   - ☐ Occasionally (1-3 times a month)
   - ☐ Frequently (1-3 times a week)
   - ☐ Very frequently (more than 4 times a week)
   - ☐ Almost always (almost daily)
   - ☐ Always (daily or multiple times a day)

3. How often does **vomiting** occur once feeling nauseous?

   - ☐ Never
   - ☐ Occasionally (25% of the time)
   - ☐ Half the time
   - ☐ Almost always (75% of the time)
   - ☐ Always (100% of the time)

4. Please comment further on when you think the nausea and/or vomiting usually occurs:
   For example, before/after treatment sessions, after eating food, etc

   _____

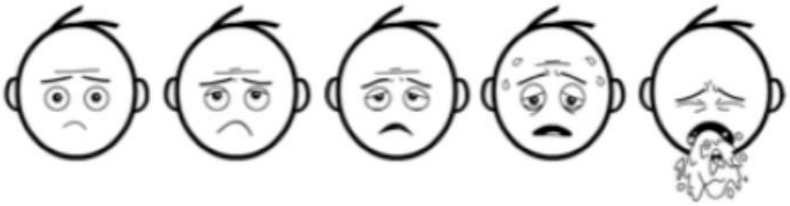
5. When did nausea/vomiting first start in relation to treatment?

   - ☐ Before treatment began
   - ☐ After the first session
   - ☐ After a few sessions
   - ☐ Other: _____

6. How long does each episode of nausea and vomiting usually last?

- ☐ Less than 30 minutes
- ☐ 30 minutes - 1 hour
- ☐ 1 hour - 2 hours
- ☐ More than 2 hours
- ☐ All day

7. On a scale from 1-5, how severe is the **nausea** and **vomiting** usually?



1 2 3 4 5

- ☐ 1 = Very mild
- ☐ 2 = Mild
- ☐ 3 = Moderate
- ☐ 4 = Severe
- ☐ 5 = Very severe

8. Is there anything that makes the nausea and/or vomiting better and/or worse?
For example, medication, distractions like music or TV, certain smells, eating food, etc.

_____

9. What physical, emotional, and social impacts are there from the nausea and vomiting?
For example, inability to carry out daily activities, emotional distress, etc.

_____

_____

Section 2: Current Management Strategies

1. What medications have been used to manage the nausea/vomiting? *If details like dosage and strength are known, please list them.*

_____

2. What is the medicinal form that the medicine(s) are/were given in?
For example, tablet, liquid for oral administration, infusion, etc.

_____

3. How effective are/were the medications in reducing symptoms of nausea/vomiting?

- ☐ Never effective
- ☐ Occasionally effective (25% of the time)
- ☐ Half the time effective
- ☐ Almost always effective (75% of the time)
- ☐ Always effective (100% of the time)

4. Are there any issues you've faced with the medications?
For example, the smell, the taste, storage, etc.

_____

5. Have you been recommended any non-drug advice to manage the nausea/vomiting?
For example, the NHS recommends getting fresh air and taking regular sips of cold water.

_____

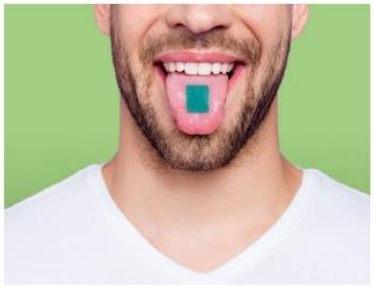
   a. How effective are the non-drug advice in reducing symptoms of nausea and vomiting?

- ☐ Never effective
- ☐ Occasionally effective (25% of the time)
- ☐ Half the time effective
- ☐ Almost always effective (75% of the time)
- ☐ Always effective (100% of the time)

Section 3: Treatment Experiences and Expectation

1. What forms of medicine appeal or don't appeal to your child? Please comment on the available options, the reasons for your opinions, and rank the medicinal forms from 1-8 (most appealing to least appealing):
   If you have any questions or need further clarification regarding the medicinal forms below, let us know!

Medicinal Forms		**Comments**	**Rank**
Tablet: a solid medicinal form that is swallowed by the patient.			
Crushed tablet in water: a tablet that is physically crushed then mixed with water before being given to the patient.			
Dispersible tablet: a tablet that dissolves in water before being given to the patient.			
Liquid: a liquid medicine (the particles are either suspended or dissolved completely) that the patient swallows.			

Orodispersible film: a thin paper-like film that dissolves on the tongue before being swallowed.			
Infusion: a needle is used to puncture the skin and insert a catheter that delivers a medicine.			
Injections: a needle and syringe are used to puncture the skin or a vein to deliver a medicine.			
Rectal pills (suppositories): solid medications inserted into the rectum where they dissolve to release medicine into the bloodstream.