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FINAL REPORT

Utilising novel nutritional biomarkers in oesophago-gastric cancer to trigger standardised pre-operative nutritional surveillance and intervention in high-risk patients across partnered health care services.

The 'NuBio Care Pathway' Project

Alfred Health
Department of Oesophago-Gastric and Bariatric Surgery
Department of Nutrition and Dietetics

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The Southern Melbourne Integrated Cancer Service (SMICS) is supported by the Victorian Government.

SMICS acknowledge Aboriginal and Torres Strait Islander people as the Traditional Custodians of the land. We acknowledge and pay respect to their Elders, past and present.

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Executive Summary

Background

Malnutrition, low skeletal muscle mass and poor muscle quality are associated with an increased risk of surgical complications and reduced overall survival in patients undergoing resection of oesophagogastric (OG) cancer. Identifying patients with low muscle mass, irrespective of body weight or weight loss, increases malnutrition detection rates. Ensuring timely and comprehensive assessment of malnutrition and muscle health is required to reduce risks associated with the curative treatment pathway for oesophagogastric cancer.

Problem Identification

The nutrition management of patients with OG cancer has lacked an objective assessment of skeletal muscle mass and muscle quality. Computed tomography (CT) body composition analysis has been used in local research projects but has not been translated into clinical practice. Additionally, patients receive oncological treatment at multiple sites throughout Victoria, often contributing to delays in identifying malnutrition and variations in nutrition management.

Project Aim

The project aimed to develop a *comprehensive framework* involving *early identification* of *malnutrition* and nutritionally high-risk patients and formulate a *standardised nutrition care pathway* to be *shared* with *partnered healthcare services* for patients undergoing potentially curable OG cancer surgery.

Key Results

1. *The early identification of malnutrition at diagnosis.*
   Novel nutritional biomarkers, specifically skeletal muscle mass and muscle quality, were assessed using routine clinical CT images with automated body composition software. Muscle parameters and nutrition status were confirmed at diagnosis and re-staging (preoperatively).
2. *Development of a feasible and standardised nutrition care pathway.*
   The pathway targets the prevention and treatment of malnutrition, specifically focusing on monitoring body composition and functional changes during treatment.
3. *Establishing mechanisms for communicating a patient's nutrition status and muscle assessment to all relevant treating clinicians, regardless of geographical location.*
   Nutrition status and muscle health were included in all multidisciplinary meeting documentation, with individual patient reports sent to treating clinicians and patients.

Clinical applicability

The improved pathway of care will a) provide timely and effective nutrition interventions aimed to maintain or optimise nutrition status before surgery, b) ensure all patients have an individualised nutrition care plan before surgery, irrespective of their treatment location, c) utilise nutrition biomarkers to identify nutritionally compromised patients and recommend interventions that aim to mitigate the risk of adverse surgical outcomes.

Contents

1. Introduction

1.1 Problem definition

We identified that the surgical management for patients with oesophagogastric (OG) cancer at Alfred Health lacked a standardised, patient-centred, and streamlined pathway to provide up-to-date and evidence-based nutrition care, especially to nutritionally high-risk patients.

A major complexity to the problem is that surgery occurs at one centre with multiple sites administering neoadjuvant therapy delivered by entities functioning largely independently of the surgical centre. Presently, nutritionally high-risk patients are not accurately identified early, and nutrition surveillance and intervention are highly variable across centres.

The individual components required to improve the nutrition management of this patient group are available but are not consistently applied routinely in clinical practice. They are:

- Simple nutritional biomarkers specifically measure muscle health (poor muscle quantity or quality) via body composition assessment using computed tomography (CT) images taken routinely for diagnostic and restaging purposes. These nutritional biomarkers markers stratify markedly increased surgical risk, and we can measure those.
- Dietary interventions focused on managing patients with poor muscle health, malnutrition, or at high risk of developing these conditions.
- Committed dietitians and clinicians who can undertake these interventions.
- Platforms for documenting and disseminating nutrition information to treating clinicians.

A health service-centric approach is potentially a barrier to optimal, patient-centred care. Therefore, we aim to improve that aspect of care for this nutritionally high-risk patient group.

In essence, we identified the need to accurately detect nutritionally high-risk patients early in their treatment pathway and translate these findings into routine practice to enable high-quality nutrition care when and where it is most needed.

1.2 Background

Curative treatment pathways for oesophago-gastric (OG) cancer usually involve multiple modalities, are rigorous and associated with significant morbidity risk (1). Improvements in neoadjuvant therapy have led to higher survival rates following surgical resection, with tumours frequently able to be downstaged (2). The potential for cure mandates closer assessments of baseline physiological function to assess the patient's ability to complete all therapies, avoid severe complications, and recover their quality of life.

Malnutrition impairs the patient's capacity to tolerate neoadjuvant treatment (3), can increase hospital length of stay (LOS) (4, 5), and is associated with reduced overall survival and a limited capacity to withstand invasive treatments and recovery from severe postoperative complications for those undergoing surgical resection (6, 7). However, the conventional malnourished patient is less commonly observed as the global prevalence of overweight and obesity rises. More recent definitions of malnutrition include assessment of skeletal muscle mass, body mass index (BMI), and weight loss to improve the detection of malnourished and physically compromised patients (8).

Body composition analysis using diagnostic computed tomography (CT) can precisely and accurately assess skeletal muscle mass and quality and adipose tissue stores (9). Low skeletal muscle mass and poor muscle quality are known consequences of ageing and malignant disease (10) and negatively impact chemotherapy tolerance, postoperative outcomes and long-term survival in various gastrointestinal cancers (11). Assessment of muscularity may provide a powerful physiological staging adjunct able to predict the risk of postoperative complications.

1.2.1 Alfred Health data

A comprehensive study, including 108 patients who underwent resection of OG cancer with curative intent, at The Alfred Hospital was conducted between 2010-2018. CT images assessed preoperative body composition, specifically skeletal mass, and poor muscle quality. Additionally, along with baseline nutrition parameters such as body mass index (BMI, kg/m^2) and preoperative weight loss, skeletal muscle was incorporated into the diagnosis of malnutrition.

The study aimed to assess the preoperative prevalence of patients with low skeletal muscle, poor muscle quality, and malnutrition and determine whether they were associated with postoperative complications and outcomes. The key findings of this study are summarised below.

Low skeletal muscle

Low skeletal muscle mass, measured as skeletal muscle index (SMI), was prevalent and occurred irrespective of BMI (Figure 1.1).

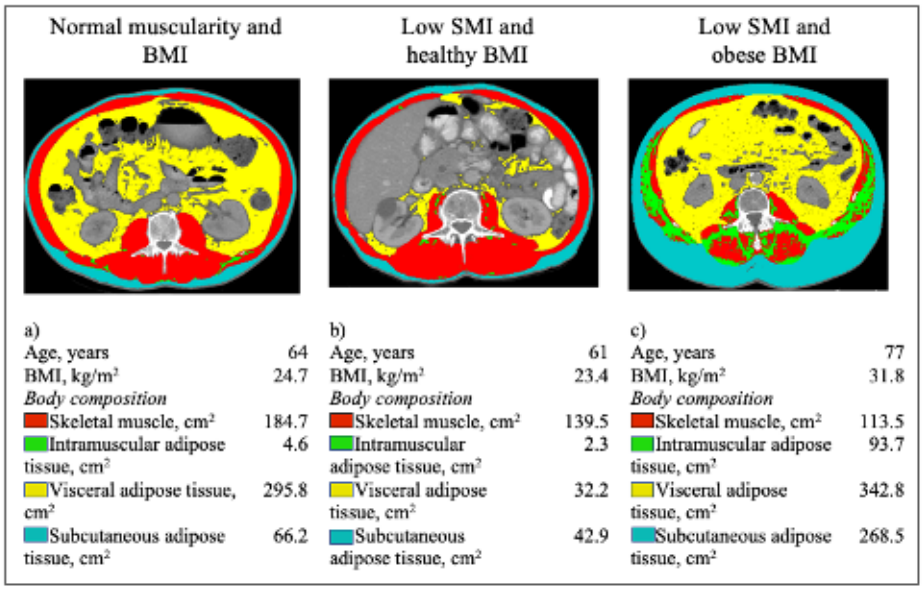

Figure 1.1. Body composition analysis using preoperative CT images demonstrates varied muscularity and BMI profiles.

Low muscle mass (SMI) was associated with an increased risk of postoperative complications and delayed recovery if a complication occurred (12). More specifically:

- Low muscle mass was identified in 61% of patients; 40% had a BMI in the overweight or obese category.
- Low muscle mass was associated with lower body weight ($p = 0.042$) and BMI ($p = 0.002$) and greater preoperative weight loss ($p = 0.037$).
- Patients with low muscle mass had a higher postoperative pneumonia rate (30 vs. 7% normal muscularity, $p = 0.004$).

- Postoperative length of stay (LOS) was higher in patients with low muscle mass if they had any complication (19.5 vs. 14 days, $p = 0.026$) or pneumonia (21 vs. 13 days, $p = 0.018$).

Poor muscle quality

Poor muscle quality is defined as low skeletal muscle density due to increased intramuscular adipose tissue infiltration (termed 'myosteatosis'). Myosteatosis was also prevalent (56%) and was associated with an increased risk of complications, including anastomotic leaks (Figure 1.2) (13).

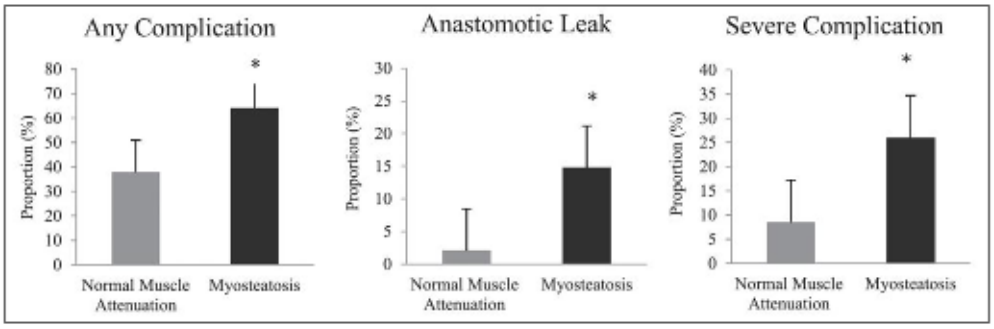

Figure 1.2 The proportion of patients with any complication (p = 0.014), anastomotic leak (p = 0.041), and severe complications (p = 0.013) were higher in patients with myosteatosis compared to those with normal muscle quality.

Malnutrition

Malnutrition defined by the Global Leadership Initiative on Malnutrition (GLIM) incorporates three phenotypic criteria based on low BMI, the percentage loss of weight (LOW) and low skeletal muscle mass, and the presence of one aetiologic criterion of reduced dietary intake or inflammation (8). According to the GLIM criteria, 69.4% ($n = 75$) of patients were malnourished before surgery, including 30.6% ($n = 33$) who had severe malnutrition (14). Malnutrition was an independent predictor of postoperative pneumonia (OR 5.7, 95% CI 1.1-1.29, $p = 0.038$). Severe malnutrition, stage 4 disease, and higher age were associated with poorer 5-year overall survival after multivariate analysis (OR 2.39, 95% CI 1.12-5.11, $p = 0.025$) (Figure 1.3).

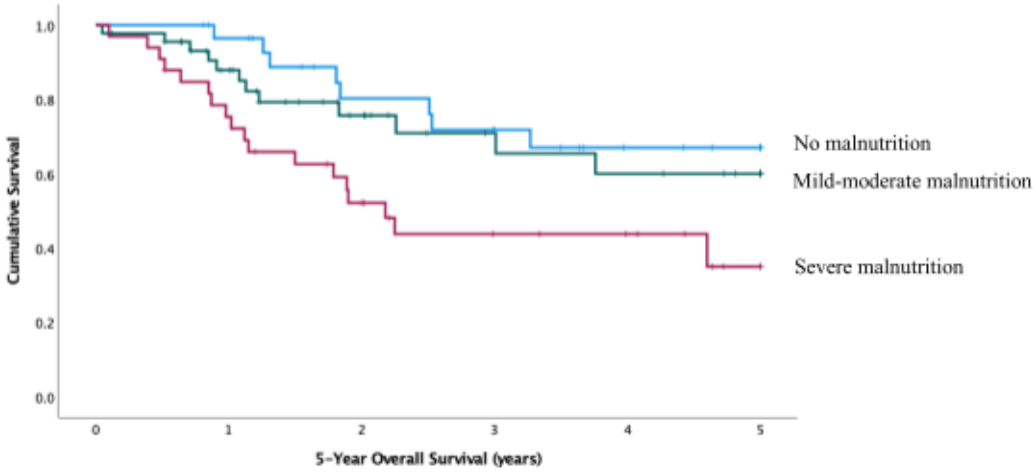

Figure 1.3 Kaplan-Meier survival analysis. Patients with severe malnutrition had poorer 5-year overall survival (45.5%) compared to patients with mild-moderate malnutrition (73.3%) and patients without malnutrition (69.7%) (Log-rank, p = 0.022).

Changes during neoadjuvant treatment – body composition and malnutrition

A prospective study of 50 patients who had OG cancer resection with curative intent at the Alfred Hospital was conducted. CT images were taken routinely at diagnosis (before neoadjuvant treatment) and restaging (after neoadjuvant therapy) to assess body composition. Body weight was also measured at these time points. Forty-three patients had a CT scan taken at diagnosis and restaging.

Preliminary data (unpublished) show a significant reduction in body weight (Figure 1.4a) and skeletal muscle Figure 1.4b) between the diagnostic and restaging CT scan. Pre-defined cut-points determined the proportion of patients with low muscle mass. There was a significant increase in patients with low muscle mass after neoadjuvant treatment (Figure 1.4).

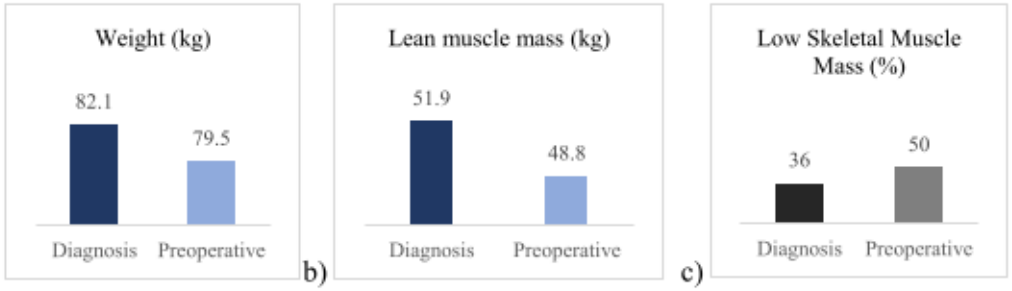

Figure 1.4 a) A significant reduction in the mean body weight ($p = 0.006$) during neoadjuvant therapy; b) a significant reduction in lean muscle mass ($p < 0.001$) during neoadjuvant therapy; c) the proportion of patients with low skeletal muscle mass increased significantly during neoadjuvant therapy ($p = 0.045$).

1.2.2 Interventions aimed at mitigating the risk of poor muscularity and malnutrition.

Early identification and management of malnutrition

Optimal nutrition care pathways include early nutrition risk screening to identify malnourished patients and those at high risk of developing malnutrition based on their tumour type, location, and proposed treatment plan (15). All patients with upper gastrointestinal cancer are at high risk of malnutrition, irrespective of baseline nutrition status or BMI (including obesity) (16). Early identification of nutrition deficits can reduce adverse outcomes and prevent weight and muscle mass deterioration before surgery.

Intensive dietitian monitoring and intervention

Gastrointestinal symptoms and dietary intake vary considerably throughout the multimodal curative treatment pathway. Dietitian consultations monitor changes in nutrition status and provide specialised dietary advice and targeted interventions. More intensive dietetic consultations (≥ 3 appointments) are associated with significantly less preoperative weight loss compared to patients who receive 0-2 consultations (17). Dietitian-delivered intensive nutrition support at all stages of the treatment pathway may also decrease severe complications after oesophageal cancer surgery (18). Measures to assess change in muscle mass, quality, and function are needed to understand their impact on recovery.

Timely and adequate provision of nutrition support

Nutritional interventions for treating muscle loss in cancer patients include meeting adequate energy requirements and higher protein needs, along with consideration of specific supplements and amino acids (19). Clinical Nutrition in Surgery practice guidelines state that all patients undergoing upper gastrointestinal surgery should receive oral nutrition support, regardless of their nutrition status (15). The benefit of preoperative oral nutrition support (ONS) showed that patients who had >2 weeks of ONS lost less weight than patients who had ONS for 0-2 weeks and was associated with reduced length of stay in malnourished patients (17).

Postoperatively, dietary counselling and ONS after gastrectomy significantly reduce weight loss and are associated with higher muscle mass (20). Meeting the recommended nutrient needs for upper gastrointestinal cancer patients is challenging, particularly due to the high rate of obstructive symptoms and gastrointestinal intolerance after eating postoperatively. Pathways to identify patients who require nutrition support and aim to mitigate excessive weight loss should form part of intensive nutrition interventions.

Specialist and centralised care coordination

Structured care pathways can guide clinicians, reduce variations in care, and improve access to dietetics services (21). Data from a national multicentre point prevalence study showed that patients from metropolitan areas were more likely to receive preoperative nutrition support than those in rural or regional locations (22). Traditional models of care disadvantage patients who cannot frequently attend outpatient appointments in person at specialised centres. Since the COVID-19 pandemic, telehealth application has significantly increased, showing improved access and efficiency of services (23).

1.2.3 Service delivery gap

Practice guidelines recommend pre-operative nutrition risk screening and timely nutrition support in upper gastrointestinal cancer surgery patients (15, 24). Nutritional therapy should be started as early as possible to maximise outcomes for surgery, and intervention should continue post-discharge (15, 24, 25). Formal nutrition management pathways can also improve neoadjuvant treatment tolerance (26).

Data from the Department of Oesophagogastric and Bariatric Surgery unit OG cancer audit so that 43% of patients who have surgery at The Alfred have neoadjuvant treatment at centres other than Alfred Health (Figure 1.6). This can lead to inconsistent, uncoordinated, and untimely nutrition assessments and interventions. Most of the preoperative nutrition intervention is provided at the Alfred Hospital (20%), Frankston Hospital (15%), followed by Cabrini Health (8%).

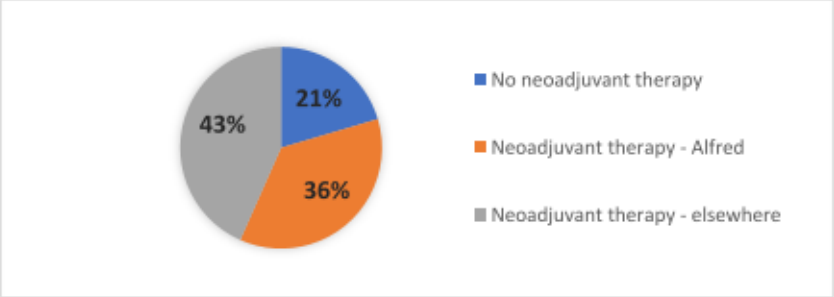

Figure 1.5 Location of neoadjuvant therapy before OG cancer surgery at Alfred Health (n = 196).

1.2.4 Summary

Our local data show that malnutrition and poor muscle health are highly prevalent in patients who undergo OG cancer surgery and have a negative prognostic impact on surgical and oncological outcomes. Routine clinical CT images can identify low muscle mass and poor muscle quality, nutritional biomarkers that may represent an opportunity for targeted intervention.

There is a significant need to improve the early and more accurate identification of nutritionally compromised patients to assist in timely and effective dietetic intervention. Assessing body composition is a key component of a detailed nutrition assessment. Poor muscularity cannot be accurately identified using standard anthropometric measures, and malnutrition may be under-recognised in patients who are overweight or obese. Dietary interventions, delivered via intensive dietitian consultations and nutrition support, can prevent, or treat malnutrition and aim to play a role in attenuating muscle loss.

2. Aims and Objectives

The project aims to develop a *comprehensive framework* involving *early identification* of *malnutrition* and nutritionally high-risk patients and formulate a *standardised nutrition care pathway* to be *shared* with *partnered healthcare services* for patients undergoing potentially curable OG cancer surgery.

We propose to develop a coordinated nutrition intervention pathway of care to identify malnutrition, including low muscle mass, and to ensure that healthcare providers are given information and strategies to provide equitable and patient-centric nutrition care.

At diagnosis, all patients will receive a comprehensive nutrition assessment by a specialised dietitian, including objective body composition techniques and novel nutritional biomarkers. Ongoing nutrition care will be triaged to existing services where the patient undergoes neoadjuvant treatment or preoperative care.

The improved pathway of care will a) provide timely and effective nutrition interventions aimed to maintain or optimise nutrition status before surgery, b) ensure all patients have an individualised nutrition care plan before surgery, irrespective of their treatment location, c) utilise nutrition biomarkers to identify nutritionally compromised patients and recommendation interventions that aim to mitigate the risk of adverse surgical outcomes.

Table 2.1 The project aims and objectives.

Aim	Objective
1. To initiate the early identification of malnutrition and nutritionally high-risk patients at diagnosis.	1. Complete body composition assessment to quantify nutritional biomarkers (muscle mass and quality) using diagnostic and restaging CT imaging.
	2. Implement screening for malnutrition, incorporating CT muscle results, before the patient is first presented at the MDM.
2. Develop a feasible standardised nutrition care pathway aiming to prevent and treat malnutrition, specifically targeting monitoring of body composition and functional changes.	3. To assess the level of understanding that oncology and surgical dietitians have regarding the importance of assessing skeletal muscle mass and strength and enhancing the utilisation of these measures in clinical practice.
	4. Understand the current clinical evidence to identify the optimal nutrition management for OG cancer patients, specifically those with malnutrition or low muscle mass.
	5. Identify the components required to address the project aims and incorporate them into a standardised care pathway.
3. Establish mechanisms for communicating a patient's nutrition status and muscle assessment to all relevant treating clinicians, regardless of geographical location.	6. Improve the level of nutrition information on the OG oncology MDM agenda, meeting summary documentation, and patient summary reports.
	7. Develop resources for clinicians and the patient that summarises the patient's muscle assessment, nutrition status, and recommended nutrition management plan.

3. Methods

3.1 Project scope

This project focused on developing a new and comprehensive framework to enhance the overall nutrition management of patients undergoing treatment for potentially curable OG cancer, regardless of their neoadjuvant treatment site. The pathway is centred around utilising CT images to assess muscularity and more accurately identify malnourished or high-risk patients, followed by providing an optimal nutrition care pathway and communication to patients and treating clinicians.

It is not within the project's scope to show a decrease in malnutrition rates, a reduction in muscle loss, or an improvement in oncological, surgical, or quality-of-life outcomes. Rather, the project serves as a foundation to imbed assessment of important nutritional biomarkers into clinical practice so that future projects can focus on interventions to address key outcomes.

This project consisted of three phases for developing, implementing, and evaluating the project, as outlined in Figure 3.1 and described further below.

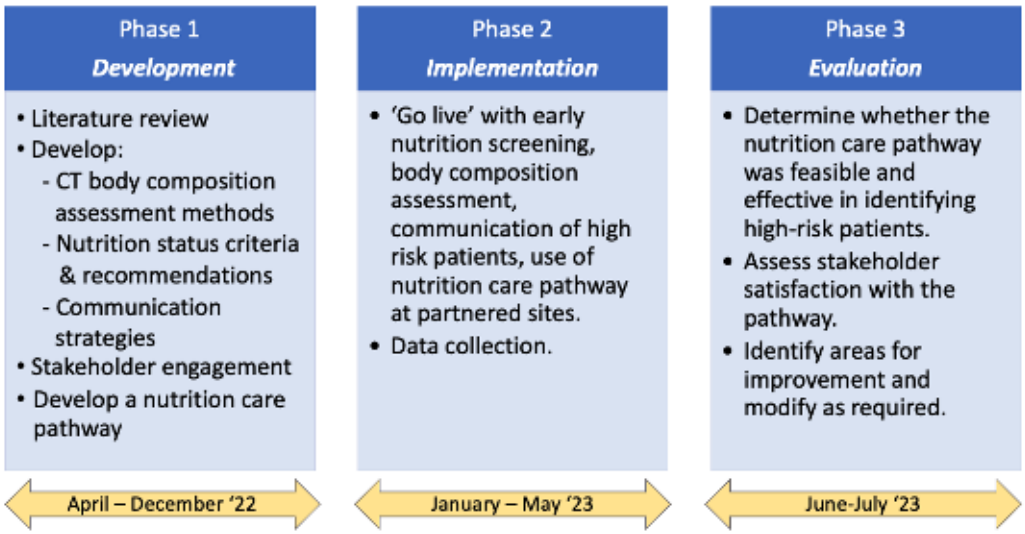

Figure 3.1 Processes and timeline involved in each NuBio Care Pathway project phase.

3.1.1 Inclusion criteria

- All patients diagnosed with OG carcinoma and deemed eligible by participating oesophago-gastric surgeons to undertake a curative multimodal treatment pathway with surgical resection.
- Eligible patients will be identified at The Alfred OG cancer multidisciplinary meeting.

3.1.2 Exclusion criteria

- Patients who were not curative and proceeded to palliative treatment,
- Patients who had endoscopic mucosal resection (EMR) for superficial lesions,
- Patients who had a gastrointestinal stromal tumour (GIST),
- Patients who received definitive radiotherapy.

3.1.3 Included health services

- Alfred Health
- Cabrini Health
- Peninsula Health

- Peninsular Private hospital
- Bendigo Health
- Other centres where patients with oesophago-gastric cancer from Alfred Health may undertake chemotherapy or radiotherapy.

3.2 Outcomes

The expected outcomes of this project address each of the aims and objectives outlined in ***Table 2.1***

Objective 1. Complete body composition assessment to quantify nutritional biomarkers (muscle mass and quality) using diagnostic and restaging CT imaging.

Outcome 1: Identify an accurate and efficient computer software program to assess body composition using diagnostic CT images.

Outcome 2: All patients presented at MDM who are potentially curable have a body composition assessment completed at the time of the first MDM presentation.

Objective 2. Implement screening for malnutrition, incorporating CT muscle results, before the patient is presented at the MDM.

Outcome 3: All patients are to have their nutrition status assessed prior to the first presentation at MDM, using CT body composition results to identify low muscle mass or poor muscle quality.

Objective 3. To assess the level of understanding that oncology and surgical dietitians have regarding the importance of assessing skeletal muscle mass and function and enhancing the utilisation of these measures in clinical practice.

Outcome 4: Undertake benchmarking with dietitians from partnered healthcare services to determine current practices concerning body composition and functional assessment in clinical practice.

Outcome 5: Improve the dietitian's understanding of skeletal muscle's role in the patient's overall health and nutrition management.

Outcome 6: Increase the proportion of patients who have an assessment of muscle mass or strength throughout their cancer treatment pathway.

Objective 4. Understand the current clinical evidence to identify the optimal nutrition management for OG cancer patients, specifically those with malnutrition or low muscle mass.

Outcome 7: Review the relevant clinical nutrition literature to identify optimal nutrition management recommendations and develop a resource to be shared with treating dietitians.

Objective 5. Identify the components required to address the project aims and incorporate them into a standardised care pathway.

Outcome 8: Develop a nutrition care pathway, including the assessments required at each stage of the patient's treatment, responsibilities, and recommendations.

Objective 6: Improve the amount of nutrition information on the OG oncology MDM agenda, meeting summary documentation, and patient summary reports.

Outcome 9: Incorporate nutrition status information, including anthropometry, muscle assessment results, and overall nutrition status on all MDM correspondence.

Objective 7: Communicate the patient's muscle assessment results and overall nutrition status with patients and clinicians at diagnosis and restaging.

Outcome 10: Develop resources for clinicians and patients that summarise the patient's muscle assessment, nutrition status, and recommended nutrition care pathway to enhance patient management.

3.3 Phase 1: Project development

The project development phase was the most extensive component, running from April to December 2022 (in a part-time capacity). The methods undertaken in the development phase are described below.

3.3.1 CT body composition assessment processes

A literate search was undertaken to identify key research papers using modern, efficient, accurate, and validated computer software programs for CT body composition analysis. National and international experts in body composition assessment techniques were contacted to discuss their experience using various software programs, and recommendations for the optimal program were sought.

Several meetings were held with members of the Department of Radiology as key stakeholders of this project, including a consultant radiologist, the CT nurse supervisor, the radiology and nuclear medicine imaging systems manager, and the radiology research lead. The purpose of the meeting was to a) understand the radiologist's workflow in assessing CT images for the OG cancer MDM, b) determine the existing resources available in terms of the computers to house the CT body composition software, c) approval to access CT images, d) requirements to conduct a project in conjunction with the Department of Radiology. The governance requirements related to introducing new computer software to Alfred Health and accessing CT images from a confidentiality and patient consent perspective are described further in section 3.6.

3.3.2 Nutrition status assessment and interventions

Benchmarking was undertaken through structured interviews via Microsoft Teams with surgical oncology dietitians from Frankston and Cabrini Hospital. The interview questions sought to determine a) the current dietetic resources available to treat these patients, b) the dietitian's current involvement in their OG cancer MDM, c) whether formal nutrition care pathways already exist, and d) which components of nutrition status or body composition assessment are already part of routine clinical care.

A comprehensive literature review was undertaken to examine various aspects of the projects. This involved searching for research papers that discussed OG cancer surgery nutrition management pathways or clinics, best practice guidelines or consensus statements for identifying and managing malnutrition or sarcopenia in oncology and surgical patients, as well as identifying the most accurate and feasible bedside methods for measuring muscle mass and strength and confirming valid thresholds for categorising patients with low muscle or strength measures.

3.3.3 Communication strategies

Meetings were held with the Alfred OGB data manager (Kalai Shaw) and cancer nurse coordinator (Courtney Regan) to discuss the inclusion of nutrition information on the MDM agenda, the MDM summary, and the more detailed individual patient MDM summary reports that are added to the patient's electronic medical record. Kalai created new fields in the MDM reporting computer program, conducted several trials, and made amendments. Feedback on and approval to implement the proposed changes to the MDM documentation were obtained from OGB consultant and project clinical lead Paul Burton and the Head of Unit, Wendy Brown.

Stakeholder engagement included several meetings with oncology and surgical dietitians from the Alfred Hospital, Cabrini Hospital and Frankston Hospital, having spoken to their managers previously to obtain support for the project. Communication pathways for patient handover processes were created. Discussions with key stakeholders were undertaken to identify the type of information required to successfully implement this new pathway of care.

3.3.4 NuBio Care Pathway Development

A draft nutrition care pathway was developed based on the information described in sections 3.3.1 to 3.3.3 (above). Feedback was sought from the dietitian group, data manager, cancer nurse coordinator, and clinical project lead. Subsequently, the Nutritional Biomarkers in the Management of Oesophagogastric Cancer Care Pathway (NuBio Care Pathway) was developed. The NuBio Care Pathway was presented to key stakeholders (detailed in section 3.6) to update them on the project's progress and obtain further feedback. In addition to conducting meetings, a presentation was made to the Alfred OG Cancer MDM team providing an overview of the NuBio Care Pathway, allowing for discussion and feedback.

3.4 Phase 3: Implementation

The implementation phase or project pilot commenced in January 2023. All processes were followed as outlined in the NuBio Care Pathway and Figure 3.2.

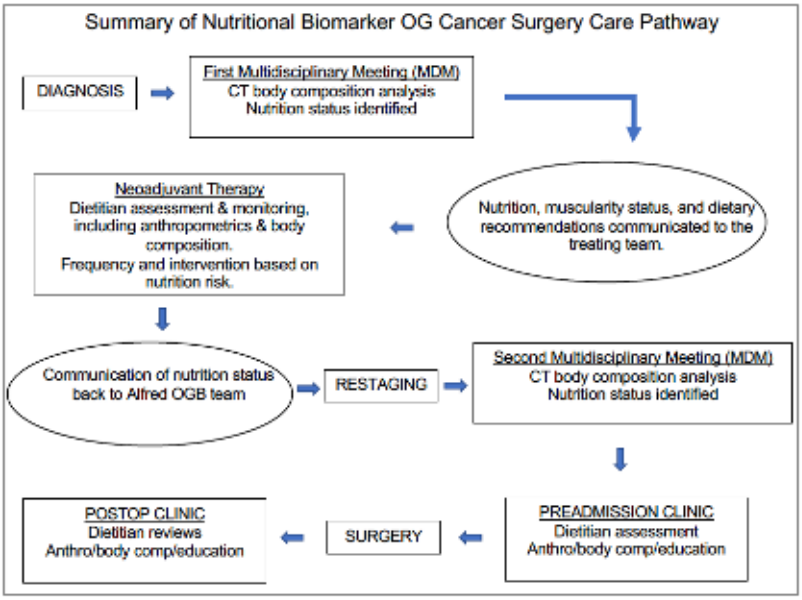

Figure 3.2 Summary of the Nutritional Biomarker OG Cancer Surgery Care Pathway. This pathway follows the usual care pathway for patients with OG cancer, with the addition of CT body composition assessment and communicating the patient's nutrition and muscularity status to treating clinicians early in the care pathway.

Additional in-person meetings were held with dietitians at Alfred Health, Peninsular Health, and Bendigo Health (video conference) as patients who were part of the project were undertaking neoadjuvant treatment at their centres. Where required, these meetings included training and demonstrations of how to conduct bedside body composition assessments to ensure that dietitians were confident with doing so independently.

Regular discussions with dietitians, nurse coordinator and data manager were held to identify and address any issues with the proposed pathway and make amendments when required.

The data manager developed a database housed by the Alfred Health REDCap platform. The database allowed for centralised storage of deidentified information on patient demographics, CT image body composition analysis results and nutrition status data. Data were entered prospectively throughout the implementation phase.

3.5 Phase 4: Evaluation

Satisfaction surveys were designed to address the key framework components by Sekhon et al (2017), who describe the acceptability of healthcare interventions (27). This theoretical framework of acceptability incorporates several domains, including perceived burden, affective attitude, opportunity costs, ethical considerations, participant or user experience, and intention.

Patient satisfaction surveys were administered via semi-structured interviews via video conferencing, and clinician surveys were distributed via email using an online survey.

Meetings with the relevant department managers, specifically nutrition and dietetics, surgery, and radiology, were undertaken to discuss the project outcomes and sustainability plan.

3.6 Governance structure

3.6.1 Stakeholder engagement

A meeting with all key stakeholders was conducted via Microsoft Teams to introduce the proposed pathway and obtain feedback or suggestions for improvement. Phone discussions were held with those who were unable to attend. The clinicians who attended this meeting or had follow-up discussions were:

- Wendy Brown – Head of Unit, Oesophagogastric Surgeon, Alfred Health.
- Paul Burton – Oesophagogastric surgeon, Alfred Health, and Cabrini Health.
- Richard Chen - Oesophagogastric surgeon, Alfred Health, and Cabrini Health.
- Ali Andrabi - Oesophagogastric surgeon, Peninsular Health.
- Ben Markman – Medical Oncologist, Alfred Health, and Cabrini Health.
- Ian Porter – Radiation Oncologist, Cabrini Health.
- Zee Wan Wong – Head of Oncology, Peninsular Health
- Courtney Regan – Oesophagogastric Cancer Nurse Coordinator, Alfred Health.
- Nicole Vaughn – Senior oncology dietitian, Alfred Health (Alfred dietitian representative)
- Bree Voegt – Oncology dietitian, Cabrini Health
- Janet Tam – Oncology dietitian, Frankston Hospital.
- David Quinn – patient/consumer.
- Sascha Bandelli – patient/consumer.

Subsequent conversations were had with consumers to obtain feedback on the nutrition summary document for patients and sections of the NuBio Care Pathway that involved direct patient contact.

3.6.2 Ethical Considerations and Consent

A full research ethics application was submitted to the Alfred Human Research and Ethics Committee (HREC) on 29.09.2022 and approved on 01.11.2022 (HREC number 496/22).

Approximately 27 documents were submitted for the ethics approval process, including a detailed project description, Victorian HREC-specific forms, medical physicist report and risk assessment, patient information and consent form, Alfred Health IT system architecture assessment and a research IT security clearance form.

Furthermore, due to recently updated Alfred Health research IT security clearance requirements, any computer software programs used in the clinical management of patients must be approved by the Australian Government Therapeutic Goods Administration (TGA). To apply for a TGA Clinical Trail Notification (CTN), HREC approval has been obtained first. The CTN application was submitted on 09.11.2022 and approved on 06.12.2022.

4. Results

Table 4.1 Summary of the results, addressing each of the project outcomes.

Project outcomes	Summary of results
1. Identify an accurate and efficient computer software program to assess body composition using diagnostic CT images.	The Data Analysis and Facilitation Suite (DAFS) body composition program was chosen for use in this project. Overview of literature and rationale for selection of software in Section 4.1.
2. Body composition was assessed for all curable patients before the MDM.	90% of eligible patients had body composition assessed using CT images before their first MDM presentation (**Table *4.2***).
3. Assess nutrition status of all eligible patients before MDM, using CT body composition to identify low muscle mass or poor muscle quality.	90% of eligible patients had their nutrition status assessed, including muscle assessment before their first MDM presentation (**Table *4.2***).
4. Benchmark body composition and functional assessment practices being undertaken at partnered healthcare services.	Benchmarking identified that no centres were measuring muscle mass or strength in routine clinical practice. Findings are summarised in section 4.3.1.
5. Improve the dietitian's understanding of the role that skeletal muscle plays in the patient's overall health and nutrition management.	Satisfaction survey results show that all dietitians reported an improved understanding of the importance of skeletal muscle in the patient's overall health after participating in the NuBio Care Pathway (section 4.6).
6. Increase the proportion of patients who have an assessment of muscle mass or strength throughout their cancer treatment pathway.	There was a >80% increase in the proportion of patients who had muscle mass and strength assessment completed (**Table *4.2***).
7. Review clinical nutrition literature to identify optimal nutrition recommendations and develop a resource to be shared with treating dietitians.	A literature review was conducted. The results of the literature review formed the NuBio Care Pathway Supporting Document for Clinicians (Attachment 1), summarising the evidence used to support specific pathway components.
8. Develop a nutrition care pathway, including the assessments required at each stage of the patient's treatment, responsibilities, and recommendations.	The Nutritional Biomarker in the Oesophagogastric Cancer Care Pathway was developed (Appendix 2).
9. Incorporate nutrition status information, including anthropometry, muscle assessment results, and overall nutrition status on all MDM correspondence.	Nutrition status data has been added to all MDM documents (Appendix 3).
10. Create resources for patients and clinicians to summarise muscle assessment results, nutrition status, and recommended care pathways.	Nutrition summary information resources were created for patients and clinicians (Appendix 4).

4.1 CT body composition assessment

4.1.1 Summary of literature review

Body composition is increasingly recognised as an important prognostic factor for health outcomes in patients with cancer. Computed tomography (CT) scans, when taken as part of routine care, provide an excellent opportunity to precisely measure the quantity and quality of skeletal muscle and adipose tissue. However, manual analysis of CT scans is costly and time-intensive, limiting the widespread adoption of CT-based body composition measurements.

Our previous research has utilised SliceOmatic (TomoVision, Canada) to assess CT-body composition. SliceOMatic requires the user to manually landmark L3, transfer the L3 slice to SliceOmatic, set standardised Hounsfield Unit (tissue density) thresholds to measure skeletal muscle and adipose tissue, semi-automatically segment each body compartment, and precisely trace skeletal muscle borders before exporting results. While retrospective CT analysis has been instrumental in understanding the relationships between body composition and clinical outcomes, analysis requires manual segmentation of a single scan, may require 15 to 20 minutes to complete analysis, and may become time and cost-prohibitive when applied to the clinical setting.

Recent advances in artificial intelligence (AI) technology, specifically deep learning, have demonstrated success in biomedical image segmentation. As described by Paris et al. (2020), 'deep learning is a subfield of machine learning which utilises deep neural networks to make predictions (e.g., segmentation maps) based on input data (e.g., CT scans)' (28). Many validation studies demonstrate that deep-learning neural networks accurately assess body composition (29-31). However, despite the generalizability of their neural networks for body composition analysis of CT scans, neither the networks nor training data have been made publicly available, limiting the implementation and reproducibility of these approaches.

4.1.2 Selected body composition software

The Data Analysis and Facilitation Suite (DAFS) by Voronoi Health Analytics (Canada) was selected as this project's body composition software program. DAFS is a platform that allows efficient AI-assisted medical image analysis using radiological images, including CT. CT images are entered into DAFS in DICOM format (axial abdomen series), then processing (data curation, segmentation, and annotation), and results generation occurs automatically. The results are exported in a detailed data file and a patient summary report (included in the clinician summary information document, Appendix 4). Using DAFS, a CT series for multiple patients can be analysed simultaneously, taking the user approximately 5-10 minutes (other work can be done during the processing time) to export results.

The DAFS software met the key requirements of the project (efficient, accurate), Alfred HREC (anonymisation), and Alfred IT security clearance review (on-premises deployment without the use of cloud-based systems, all of which supported our successful TGA CTN application. All other available AI-based body composition technology did not meet these requirements.

4.2 Participation in the pilot phase

The preliminary MDM agenda was used to screen patients who were considered potential candidates for surgical resection with curative intent. The below flowchart outlines the outcome of patient selection.

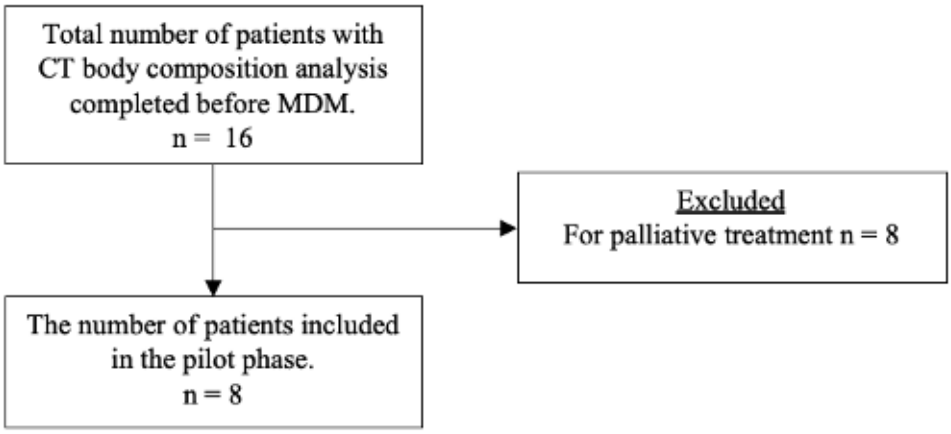

Figure 4.1 Flow chart of patient inclusion.

4.3 Nutrition assessment and recommendations

4.3.1 Benchmarking

Benchmarking was undertaken to understand the dietitians' current involvement in the MDM, to identify whether nutrition care pathways already exist and, if so, which elements they include, and whether body composition assessment is undertaken as part of the nutrition assessment.

Discussions with oncology and surgical dietitians at Alfred Health, Peninsular Health and Cabrini Health showed that:

- Dietitians already attend the MDM at each healthcare service;
- The nutrition status of patients is not routinely reported or discussed at any MDM but may be raised by the dietitian as required;
- There are no pre-existing nutrition care pathways in place for the management of patients with oesophageal or gastric cancer;
- In two services, referral to a dietitian is initiated from the Malnutrition Screening Tool (MST) in the oncology outpatient unit.
- Anthropometric measures (excluding weight), function (strength) or body composition were not assessed at any site, despite the required equipment, such as a hand grip strength dynamometer, being available at each site.

4.3.2 Literature review and dietitian resources

A literature review was conducted to identify the key components of a nutrition care pathway in the surgical management of patients with oesophageal and gastric cancer. The literature review results formed the basis of the *NuBio Care Pathway Supporting Document for Clinicians (Attachment 1)*, which was developed to provide additional information on the rationale for the project and each element included in the NuBio Care Pathway. Specifically, the supporting document includes current evidence to support the recommended body composition assessment methods, identification of Malnutrition, components of dietitian interventions and pre-and postoperative nutrition management. This document also served as a tool for dietitians to refer to when conducting anthropometric, strength and body composition assessments.

4.4 NuBio Care Pathway

The NuBio Care Pathway, as shown in Appendix 2, was developed and shared with the relevant stakeholders at the project's implementation phase.

The pathway summarises the steps undertaken at several time points in the patient's treatment journey. They are:

1. *Before the initial MDM*: CT body composition analysis, nutrition information, and malnutrition diagnosis.
2. *During the MDM*: Reporting of nutrition status and nutrition recommendations.
3. *After the MDM*: Communication of nutrition status to the clinicians and patient
4. *During neoadjuvant treatment*: Dietitian assessment and monitoring recommendation, dietary recommendations for malnutrition and low muscle mass.
5. *Restaging MDM*: As per points 1-3 above.
6. *Before surgery*: Recommendations for nutrition assessment at Preadmission Clinic (PAC)
7. Pos*toperatively*: A summary of inpatient nutrition management and flow chart to streamline outpatient nutrition management.

The success of the pathway implementation was measured against key performance indicators (KPI) that focus on improving the assessment of body composition and malnutrition, monitoring of patients, and reducing deterioration of nutrition status during neoadjuvant treatment. The KPIs and the results are outlined in Table 4.2.

Table 4.2 Results for the key performance indicators that address project outcomes.

Performance indicator	Usual care	Pilot phase	Result
The proportion of patients who had *CT body composition analysis* completed before the MDM.	0%	90%	Substantial improvement - project aim met. One patient did not have these measures taken before the MDM, but the results were available before the completion of the final MDM reports.
The proportion of patients who had a *nutrition assessment*, including muscle measurements, completed before the MDM.	0%	90%	Substantial improvement - project aim met. One patient did not have these measures taken before the MDM, but the results were available before the completion of the final MDM reports.
The proportion of patients who had an assessment of muscle mass or strength during their treatment pathway.	0%	90%	Substantial improvement - project aim met. One patient did not have theses assessments taken

			due to dietitian leave cover arrangements.
Number of patients with nutrition information included in their final MDM documentation.	0%	100%	Substantial improvement - project aim met.
Average change in body weight (kg) from diagnosis to re-staging.	-2.6kg	-1.8kg	Less weight loss occurred during the pilot phase compared with usual care*.
Average change in CT-lean muscle mass (kg) from diagnosis to re-staging.	-3.1kg	-2.4kg	Less muscle loss occurred during the pilot phase compared with usual care*.
Proportion of patients diagnosed with malnutrition at re-staging using the GLIM definition.	72.2%	50%	Fewer patients were diagnosis with malnutrition during the pilot phase compared with usual care*.

*The statistical and clinical significance of the between-group differences could not be quantified due to the low number of patients in the pilot group.

4.5 Communication strategies

The communication strategies implemented during the pilot phase address outcomes 9 and 10 (detailed in section 3.2).

The first step in communicating the patient's muscle mass and nutrition status results was including this information in all MDM documentation (Appendix 3). The second step was to provide patient-specific information directly to the treating team (oncologists, dietitians, and surgeons) and the patient (Appendix 4).

As mentioned in the method section, communication strategies also included liaisons with stakeholders throughout the project's development phase.

4.6 Project evaluation

Evaluation surveys were sent to dietitians, oncologists, surgeons, and patients after the pilot phase. The evaluation surveys aimed to assess the *acceptability* and *satisfaction* with the NuBio Care Pathway. The survey questions were based on a theoretical framework of healthcare interventions' acceptability, as Sekhon et al. (2017) described (27), and considered attitudes, burden, intervention coherence, perceived effectiveness, and self-efficacy. The responses for each survey are summarised below and described in detail in Appendix 5.

4.6.1 Dietitian evaluation results

Summary of results

- Six dietitians completed the survey, including four who managed patients during the pilot phase. The other two dieticians were consulted during the project's development but did not have patients undergo treatment during the pilot phase.

- All dietitians reported an improved understanding of skeletal muscle's role in the patient's overall health and nutrition management after implementing the NuBio Care Pathway.
- Most dietitians reported a low burden when undertaking functional and anthropometric measures in the outpatient setting.
- All dietitians reported a positive experience with undertaking functional and anthropometric measures, specifically, understanding the rationale, instructions and being able to interpret results.
- There were positive attitudes toward the effectiveness of the 'Nutrition Summary - Information for Healthcare Professionals' document; however, including images of CT body composition may need further consideration.
- 100% of respondents agree that the NuBio Care Pathway processes should continue in routine clinical practice.

Comments and feedback
Positive

- "I don't believe the measurements were burdensome. I think they assisted in illustrating the importance of adequate nutrition before surgery and the possible detriment of poor intake."
- "The pathway was most valuable in identifying patients early for dietetic intervention and assisted immensely in understanding a patients nutrition risk at the time of the MDM. Often nutrition is not discussed as part of MDM, and patients are not known to The Alfred before the MDM so it's difficult to know which patients need to be seen. The pathway definitely helped with this."
- "I would be happy to continue with this pathway for oesophageal and gastric cancer patients. I was only involved with one patient however I feel it motivated my patient in trying to optimise his nutrition and protein intake."
- "I found the supporting clinical documentation really helpful in terms of summarising the literature and providing references for further reading."

Potential areas for improvement

- Measurements taken in the preadmission clinic:
  "The patients have a lot of appointments that day, and sometimes the session for dietitian education can be a lot for the patients, so it was hard to prioritise the measurements when the patients were anxious and had a lot of questions."
- Postoperative measurements:
  "It was difficult to complete the measurements in the post-op phase as most appointments are now telehealth or telephone, and often patients prefer not to return to clinic, especially as we service a large area and patients need to travel long distances to attend clinic."
- Documenting anthropometric and functional measurements:
  "A central place to document results on Electronic Medical Records would be beneficial".

4.6.2 Oncologist and surgeon evaluation results

Summary of results

- Three of the five doctors directly involved in the NuBio Care pathway during the pilot phase responded to the survey.
- All respondents agree with nutrition information's inclusion and clinical relevance on MDM documentation.

- All respondents strongly agreed that the nutrition summary document enhanced their understanding of the patient's overall health status and wish to continue to receive it in the future.
- All clinicians agree that the NuBio Care Pathway should continue in routine clinical practice.

Comments

- Nutrition data on the MDM documentation:
  "It is very helpful but a little unclear about what action we should take. That would be the next step in this project."
- Nutrition Summary - Information for Healthcare Professionals document:
  "I think it is excellent and should be distributed widely".
  "Including CT images makes the document more visually appealing and increases the impact, but the CT images don't carry any substantial meaning".

4.6.3 Patient evaluation results

Summary of results

- Three patients were contacted to provide feedback and complete the evaluation survey.
- All patients understood the reason for pre-MDM nutrition screening and did not find the conversation burdensome.
- Most patients understood the nutrition summary document and found the information useful.
- All patients reported an improved understanding of skeletal muscle in their overall health.

Comments

- Pre-MDM nutrition screening questions:
  "I felt the phone call helped me bring more information to the story. It added some details to an area the surgeons had already touched on".
  "I had no issues being called at this time; I knew what it was about".
- Nutrition Summary – Information for Patients' documents.
  "I didn't know that I was malnourished because I thought my weight was higher than it should have been. But knowing this made me more conscious about keeping up with the nutrients via the feeding tube".
  "This information should always be given in person. It would have been very stressful if the information was sent to me, but it wasn't as bad because malnutrition was explained to me immediately (in person)".
  "The document really helped my partner in understanding nutrition".
  "We get a lot of information at once, so I didn't get to reading all of the information".

4.6.4 Challenges and solutions

Table 4.3 below describes challenges that arose during the development or pilot phase of the NuBio Care Pathway. The solutions refer to those that have already been implemented or will be considered in the future.

Table 4.3 Challenges identified during the pilot phase and solutions that were implemented.

Challenge	Solution
Alfred Health ITS security guidelines recommend that all new software programs involved in assessing	A Clinical Trial Notification (CTN), requesting use of the selected CT body composition software program, was

patients' clinical condition are approved by the Therapeutic Goods Administration (TGA).	approved by the TGA, facilitated by the Alfred HREC committee.
The time required to obtain ethics and TGA approval was longer than expected.	The pilot phase of the project commenced later than initially intended. However, it was still possible to conduct a 6-month pilot which was sufficient time to implement and evaluate the new care pathway and meet the projects aims and objectives.
Computers in the Department of Radiology did not meet the minimum software requirements for installing and running the CT body composition program. Also, the software did not integrate with PACS, meaning that the radiologist's workflow would be negatively impacted by accessing body composition programs on a separate computer.	The computers in the Nutrition Department meet the specifications of the body composition software program. It was deemed to be feasible for this to be undertaken by the Dietitian who is already trained in CT body composition analysis.
Assessing the feasibility of the Radiology Registrar to undertaken CT body composition analysis as part of their routine MDM preparations indicated that a) there was not capacity to include this task in their current workflow, and b) registrar rotations increased the need for regular training.	It was deemed to be feasible for this to be undertaken by the Dietitian who is already trained in CT body composition analysis. Additional dietitians will undergo training in CT body composition analysis to ensure the sustainability of this pathway.
Nutrition information was intended to be included on the MDM documentation for patients who were planned for curative resection. However, omitting this information for other patients (e.g., patients for palliative management) was considered inequitable.	It was decided that all patients will have had nutrition data included on the MDM documentation. However, only those intended for curative Tx had CT muscle assessment results during the pilot. Expansion of the inclusion criteria will be considered in the future.
There were occasions where the CT body composition results were not available for analysis before the MDM.	The OG cancer nurse coordinator requested that CT images taken external to Alfred Health were uploaded to the Alfred radiology imaging systems at the first available notice. This allowed for more timely CT body composition assessment.
The dietitian's access to body composition assessment tools varied between hospital sites.	The body composition tools recommended in the Supporting Document for Clinicians document include readily available beside assessment measures.

4.6.5 Risk assessment

There were no adverse events throughout the project's implementation phase. The safety monitoring plan outlined in the Alfred HREC application stated:

- *There was negligible risk to the patient.* Additional CT images were not required, therefore, not exposing the patient to further radiation.
- *There were minimal data security risks.* CT images and patient information were deidentified and stored with Alfred Health approved IT systems.

- *There was a low risk of software dysfunction.* Any issues with the DAFS software were resolved directly via the vendor.

Potential risks before the commencement of the project were managed accordingly. They were:

- *Reduction in the diagnosis of oesophago-gastric cancer due to the COVID-19 pandemic.* COVID-19 restrictions did not impact patient management during the project's timeline.
- *Delays in implementing routine reporting of radiology biomarkers.* This occurred on one occasion (as per Table 4.3) but was mitigated by implementing process changes.
- *Lack of agreement of all sites to participate.* All sites that were approached agreed to participate in the project.
- *Difficulty in obtaining agreement on standardised nutritional pathways and triage plan.* An agreement was obtained by all stakeholders.

5. Discussion

The funding obtained to develop the NuBio Care Pathway has enabled the implementation of a new and evidence-based care pathway for the nutritional management of patients undergoing surgical resection of oesophageal and gastric cancer at Alfred Health.

Using CT body composition software to measure muscle health and incorporate skeletal muscle mass in diagnosing malnutrition is a novel example of translating research into clinical practice. As body composition features emerge as important clinical metrics in the prognosis of patients with cancer, it is necessary to use automated analysis software, such as DAFS, to encourage integration into usual practice and improve patient outcomes. However, attempts to integrate CT body composition assessment into the standard workflow of the radiologist when preparing for the MDM proved to be more challenging than expected. For reasons related to IT requirements and the radiologist's workflow, it was deemed more suitable for an appropriately trained dietitian to undertake CT body composition analysis. During the implementation phase, it became evident that the dietitian is best positioned to undertake this task, especially when other dietitians may utilise this skill and apply it to other oncology patient cohorts.

Communication of the patient's nutrition status and muscle health by way of adding it to the MDM documentation and direct communication with clinicians and the patients has shown a substantial improvement in the awareness of the importance of muscle mass in the overall patient's health. All clinicians have indicated they would like to continue to receive a summary of the patient's muscle health and nutrition status. Documentation of the patient's overall nutrition status on the MDM agenda allows for collaborative and timely decision-making regarding a patient's nutrition management plan. This may include confirming the need for an enteral feeding tube before neoadjuvant treatment or arranging a dietitian assessment in the clinic immediately after the MDM for high-risk patients. Previously, without knowing the patient's nutrition status before the MDM, there was potential for delays in identifying malnutrition and initiating the required treatment.

The Supporting Document for Clinicians resource provides dietitians with a summary of the evidence related to body composition assessment, the methods, and tools to estimate skeletal muscle mass in clinical practice, and the key nutrition recommendations used to target the treatment of malnutrition or poor muscle health. The supporting document has led to greater use of anthropometric or bedside body composition measures and may be used in the ongoing management of patients with cancer.

The NuBio Care Pathway has also served as a tool that clearly defines roles and responsibilities, specifically those of the dietitian and cancer nurse coordinator, in the patient's nutrition management. This has been particularly important for patients who had neoadjuvant or adjuvant treatment at centres outside of the Alfred as it provides a central point of contact and nutrition recommendations based on individualised nutrition assessment that aims to reduce variability in nutrition care.

6. Conclusion

Through the successful implementation of the NuBio Care Pathway project, significant improvements have been made in the nutrition management of patients. This innovative approach has resulted in the early identification of patients at high risk of malnutrition, who then received evidence-based nutritional management throughout their treatment pathway. By integrating CT body composition assessment and providing a comprehensive nutrition care pathway, patients' nutrition status, including measures of muscle mass and strength, has been closely monitored and coordinated.

All stakeholders have endorsed this new care pathway for implementation into routine clinical practice. The NuBio Care Pathway project is a model for advancing nutritional care and improving patient outcomes.

7. Recommendations

The outcome of this project is that all elements of the NuBio Care Pathway are to be implemented into routine clinical practice.

The key components that will require a change in current practice and are supported by the relevant stakeholders are:

1. The OG surgery dietitian, currently trained in CT body composition assessment, will measure muscle mass and quality before the patient is discussed at the MDM using diagnostic and restating CT images and automated analysis software.

2. The OG surgery cancer nurse coordinator will call the patients before the MDM to obtain current nutrition information (weight, weight loss, changes in eating, and food texture).

3. The nutrition information, muscle results, overall nutrition status and recommendations will be included in all MDM documentation.

4. In addition, the patient's nutrition status will be included in the verbal overview of the patient's medical history, read by the surgical registrar or resident, when the patient is discussed at the MDM.

5. The patient's nutrition summary and recommended nutrition management will be provided to the treating clinicians after the MDM and to the patient at their next dietitian consultation.

6. The nutrition and body composition data obtained during the project will continue as standard care and align with the prospectively maintained OG cancer surgery database. The database

will serve as an avenue to evaluate clinical practice and may be used to link nutrition and body composition parameters with oncological and surgical outcomes in future endeavours.

7.1 Sustainability

To implement the outcomes of this project into practice, the sustainability of each pathway component was considered during the development and implementation phase. The areas of sustainability that have been addressed are:

1. Since the commencement of the project, additional ongoing funding for clinical care and service delivery by the OG cancer surgery dietitian was obtained. This will allow for additional tasks such as CT body composition and overall nutrition care coordination to continue.

2. There are plans for more dietitians to undergo CT body composition assessment training to a) assist in implementing this nutrition care pathway into other oncology and surgery areas, and b) account for dietitian turnover and succession planning.

3. Ongoing data collection, specifically the reporting of nutritional biomarkers, will allow for ongoing assessment of the impact of these biomarkers on patient outcomes and encourage ongoing dissemination of results to maintain interest in and recognition of these important nutrition measures.

8. Future directions

Implementing the NuBio Care Pathway into clinical practice will enhance the nutrition management of patients with oesophagogastric cancer at Alfred Health. Although this project focused on patients eligible to undergo potentially curative surgery, the body composition components of this pathway should be transferred to the management of patients undergoing palliative management or surgical treatment in other clinical areas. For this to occur, we will plan for more dietitians to undergo training in CT body composition assessment so they can utilise CT images of their patients at various stages of the treatment pathway.

We endeavour to increase consumer engagement and feedback, leading to improved patient education resources designed specifically to increase their awareness about the importance of muscle and nutrition in their overall health status.

As we continue with the NuBio Care Pathway in clinical practice, continued prospective data collection will allow for future service and clinical evaluation. Understanding how changes in nutrition status and CT body composition parameters during neoadjuvant treatment or preoperatively impact surgical outcomes will inform future research or quality improvement endeavours aimed at preventing the development of poor muscle health and malnutrition.

Dissemination plans for the project include presenting at surgical and nutrition forums or conferences, and as the number of patients involved in the NuBio Care Pathway grows, there is potential for research publications.

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11. Appendix 1: Glossary

Abbreviation	
BMI	Body mass index
CT	Computed tomography
DAFS	Data Analysis Facilitation Suite
DH/Department	Victorian Government Department of Health
GLIM	Global Leadership Initiative on Malnutrition
HREC	Human Research Ethics Committee
ICS	Integrated Cancer Service (an individual part of VICS)
LOS	Length of stay
LOW	Loss of weight
MDM	Multidisciplinary Meeting
OG	Oesophagogastric
OGB	Oesophago-Gastric and Bariatric
ONS	Oral nutrition support
PACS	Patient Archiving Communication System
SMI	Skeletal muscle index
SMICS	Southern Melbourne Integrated Cancer Service
TGA	Therapeutic Goods Administration
VICS	Victorian Integrated Cancer Services (network of 9 ICS)

12. Appendix 2: Nutritional Biomarkers in the Oesophagogastric Cancer Care Pathway.

MALNUTRITION & BODY COMPOSITION:

Nutritional Biomarkers in the

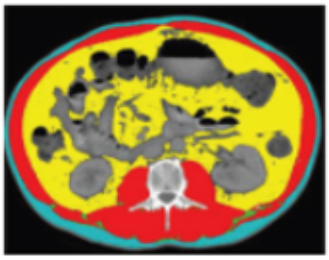
Oesophagogastric Cancer Care Pathway

The following steps outline the processes of the *NuBio Care Pathway* that will be completed at *diagnosis and restaging* for all patients eligible for *resection of oesophagogastric (OG) cancer*.

BEFORE INITIAL MDM

1. CT BODY COMPOSITION ANALYSIS

Muscle mass, muscle quality, and adipose tissue stores are assessed using routine diagnostic CT images and specific body composition software.



Body composition parameters to be reported

Tissue	Cross-sectional area	Mean density
Skeletal muscle	_____ cm^2	_____ HU
Subcutaneous adipose tissue	_____ cm^2	_____ HU
Visceral adipose tissue	_____ cm^2	_____ HU
Intramuscular adipose tissue	_____ cm^2	_____ HU

2. NUTRITION STATUS

Anthropometrics and dietary

The OG cancer nurse coordinator will obtain the following information from the patient via telephone, before the MDM.

Anthropometrics	
Body weight	_____ kg
Height	_____ m
Body Mass Index (BMI)	_____ kg/m^2
Weight loss	_____ kg
Percentage weight loss	_____ %
Timeframe of weight loss	_____

Dietary information	
Reduced food intake ≤ 50% usual for >1wk OR any reduction of intake for > 2 wks.	☐ Yes ☐ No
Texture of food (normal/soft/pureed/liquids)	_____

Muscle assessment

The OG cancer nurse coordinator will use the CT body composition parameters to complete the below fields and determine whether patients are below the cut-points for muscle quantity and quality.

Skeletal muscle QUANTITY	
Skeletal muscle index (SMI)*	_____ cm^2/m^2
Low SMI cut points:	
Male	< 52.4 cm^2/m^2
Female	< 38.5 cm^2/m^2
Low SMI	☐ Yes ☐ No

*Skeletal muscle index (cm^2/m^2) is calculated using skeletal muscle cross-sectional area and height data.

Skeletal muscle QUALITY	
Skeletal muscle attenuation	_____ HU
Myosteatosis* cut points:	
BMI ≤ 24.9 kg/m^2	< 41 HU
BMI ≥ 25 kg/m^2	< 38.5 HU
Myosteatosis	☐ Yes ☐ No

*Myosteatosis is determined by the skeletal muscle attenuation (HU) measure. Low muscle HU indicates poor muscle quality.

MALNUTRITION & BODY COMPOSITION:
Nutritional Biomarkers in the
Oesophagogastric Cancer Care Pathway

BEFORE INITIAL MDM

3. MALNUTRITION DIAGNOSTIC CRITERIA

Anthropometrics & Body Composition

- The table below contains information obtained in steps 1 and 2.
- Each measure (BMI, weight loss, and SMI) will fall into one of the three categories based on the cut-points.
- *Nutrition status is determined by selecting the highest category.*

	Well-nourished	Moderate malnutrition	Severe malnutrition
BMI (kg/m²)	>20 if < 70 yrs OR >22 if > 70 yrs	<20 if < 70 yrs OR <22 if 70 yrs	<18.5 if < 70 yrs OR <20 if 70 yrs
Weight loss (%)	<5% within 6 mths OR <10% beyond 6 mths	5-10% within 6 mths OR 10-20% beyond 6 mths	>10% within 6 mths OR or >20% beyond 6 mths
Skeletal muscle index (SMI)	Men ≥ 52.4 cm²/m² Women ≥ 38.5 cm²/m²	Men ≥ 39.1-52.3 cm²/m² Women ≥ 34.2-38.4 cm²/m²	Men < 39.1 cm²/m² Women < 34.2 cm²/m²

Dietary information

- Dietary intake and food texture cannot be used to diagnose malnutrition in isolation.
- Dietary information supports the diagnosis of malnutrition and identifies patients at high risk of developing malnutrition.
- The response in the highest category indicates the most appropriate malnutrition category.

	Well-nourished	Moderate malnutrition	Severe malnutrition
Reduced food intake	No	Yes	Yes
Food texture	Unchanged	Soft	Pureed or fluids

MDM

4. REPORTED NUTRITION & BODY COMPOSITION PARAMETERS

The following parameters will be reported at the MDM and recommendations will be included in the patient's MDM summary.

Anthropometrics	
BMI (kg/m²)	_____
Weight loss (%)	_____

Muscle Assessment	Yes	No
Low SMI	☐	☐
Myosteatosis	☐	☐

NUTRITION STATUS	
Well nourished	☐
Moderate malnutrition	☐
Severe malnutrition	☐

Dietary Reduced food intake: ☐Yes ☐No Food texture: _____

NuBio Care Pathway recommendations*

☐ **Well nourished**	Brief education by Dietitian at the commencement of neoadjuvant treatment. Regular monitoring by treating team.
☐ **Moderate malnutrition**	Dietitian assessment at commencement neoadjuvant therapy or preadmission clinic if proceeding directly to surgery.
☐ **SEVERE MALNUTRITION**	Immediate dietitian assessment, prior to planned treatment (neoadjuvant therapy or surgery).

*More detailed information regarding the recommendations can be found in the treatment phase of the nutrition care pathway.

MALNUTRITION & BODY COMPOSITION:
Nutritional Biomarkers in the
Oesophagogastric Cancer Care Pathway

AFTER MDM

5. COMMUNICATION OF NUTRITION STATUS

The primary treating team, including the medical oncologist, radiation oncologist, surgeon, dietitian, and cancer nurse coordinators, and the patient will be provided with written information regarding:

1. The impact of malnutrition and impaired muscle health on patient outcomes.
2. The patient's overall nutrition risk.
3. Nutrition care pathway recommendations regarding the timing of initial dietitian intervention.
4. The type and frequency of monitoring parameters for the reassessment of nutrition risk.

DIETITIAN ASSESSMENT & MONITORING

6. DIETITIAN ASSESSMENT and MONITORING

Below is an overview of the nutrition care pathway dietitians will implement at the patients' initial assessment. Dietitians and doctors are required to monitor changes in nutrition status.

WELL NOURISHED	MODERATE MALNUTRITION	SEVERE MALNUTRITION
Initial Assessment		
Start of neoadjuvant treatment	Start of neoadjuvant treatment	Immediately after MDM
• Baseline anthropometry measured & nutrition status confirmed. • Measure muscle mass & strength (if able). • Dietary education.	• Full assessment & confirm nutrition status. • Measure muscle mass & strength (if able). • Dietary education + ONS.	• Full assessment & confirm nutrition status. • Muscle mass & strength measured (if able). • Dietary education + ONS • *Assess need for EN.*
Monitoring during neoadjuvant treatment		
• Patient, oncologist & dietitian to monitor for changes in weight/diet. • Repeat muscle mass & strength measures half-way through treatment.	• Review every 2-3 weeks, or as required. • Repeat muscle mass & strength measures half-way through treatment.	• Review weekly – twice weekly, or as required. • Repeat muscle mass & strength measures halfway through treatment.

EN: enteral nutrition; ONS: oral nutrition support.

7. DIETARY RECOMMENDATIONS FOR MALNUTRITION and LOW MUSCLE MASS

The dietitian provides individualised medical nutrition therapy, taking into consideration the below nutrient recommendations and therapeutic targets to minimise muscle mass loss.

Energy 105-125kJ/kg/d **Protein** 1.2-1.5g/kg/d* *distribute evenly across meals	**ONS** Provide ONS to malnourished/high-risk patients or any patient with inadequate dietary intake from food.	**Enteral Nutrition** Consider EN if total oral intake is insufficient. Commence early if malnourished.	**Parenteral Nutrition** PN may be required if malnourished or severe nutrition risk when EN provision is inadequate.

EN: enteral nutrition; ONS: oral nutrition support; PN: parenteral nutrition.

3

MALNUTRITION & BODY COMPOSITION:
Nutritional Biomarkers in the
Oesophagogastric Cancer Care Pathway

BEFORE MDM

8. RESTAGING MDM

- Steps 1-4 will be repeated before the second or re-staging MDM discussion.
- The dietitian providing nutrition care during neoadjuvant treatment or in the lead-up to surgery will give a nutrition handover to the Alfred OG cancer surgery dietitian.
- The Alfred OG cancer dietitian will then complete step 2 (nutrition status), step 3 (references ranges to determine nutrition risk), and provide the information in step 4 to the Alfred OG cancer nurse coordinator before the MDM.
- If a patient requires further dietitian intervention or nutrition support before surgery, this will be discussed at the MDM and managed by Alfred OG cancer surgery dietitian.

BEFORE SURGERY

9. PREADMISSION CLINIC (PAC)

- All patients will be seen by the dietitian in person in PAC.
- The nutrition assessment includes:
  - Body composition assessment – bedside methods, if available
  - Muscle strength – hand grip dynamometer
  - Malnutrition diagnosis
  - Request for baseline nutrition biochemistry
- The dietitian will also educate the patient on dietary requirements and progression to eating after surgery.

INPATIENT

10. SURGERY

- The Alfred OG surgery inpatient dietitian will:
  - manage nutrition care for the duration of the inpatient stay,
  - maintain a record of cumulative dietary intake through admission,
  - record weight and dietary intake (including nutrition support) upon discharge,
  - handover to outpatient OG surgery dietitian for follow-up.

POSTOPERATIVE

11. POSTOPERATIVE NUTRITION MANAGEMENT

All patients will be reviewed by the OG surgery dietitian within 1-2 weeks after discharge.

Surgical follow-up

- Dietitian review consultations will occur every 2-4 weeks for the first 3 months, then every 3-6 months for the first year (at the dietitian's discretion).
- Anthropometrics, body composition analysis and functional assessment will be done within the first 3 months postoperatively, if possible.

Adjuvant therapy

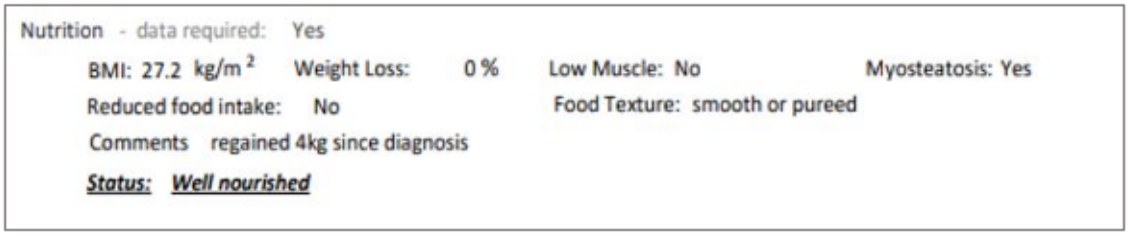
Handover to outpatient oncology dietitian at commencement of chemotherapy

Outpatient oncology dietitian will hand patient back to OG surgery dietitian at completion of adjuvant therapy

13. Appendix 3: Multidisciplinary Meeting (MDM) Documentation – Nutrition Parameters.

1. MDM Agenda

The MDM agenda, sent to all clinicians attending before the meeting, now includes the nutrition information below and the usual information on the patient's clinical background and imaging results.



Nutrition - data required: Yes

BMI: 27.2 kg/m ^{2} Weight Loss: 0 % Low Muscle: No Myosteatosis: Yes

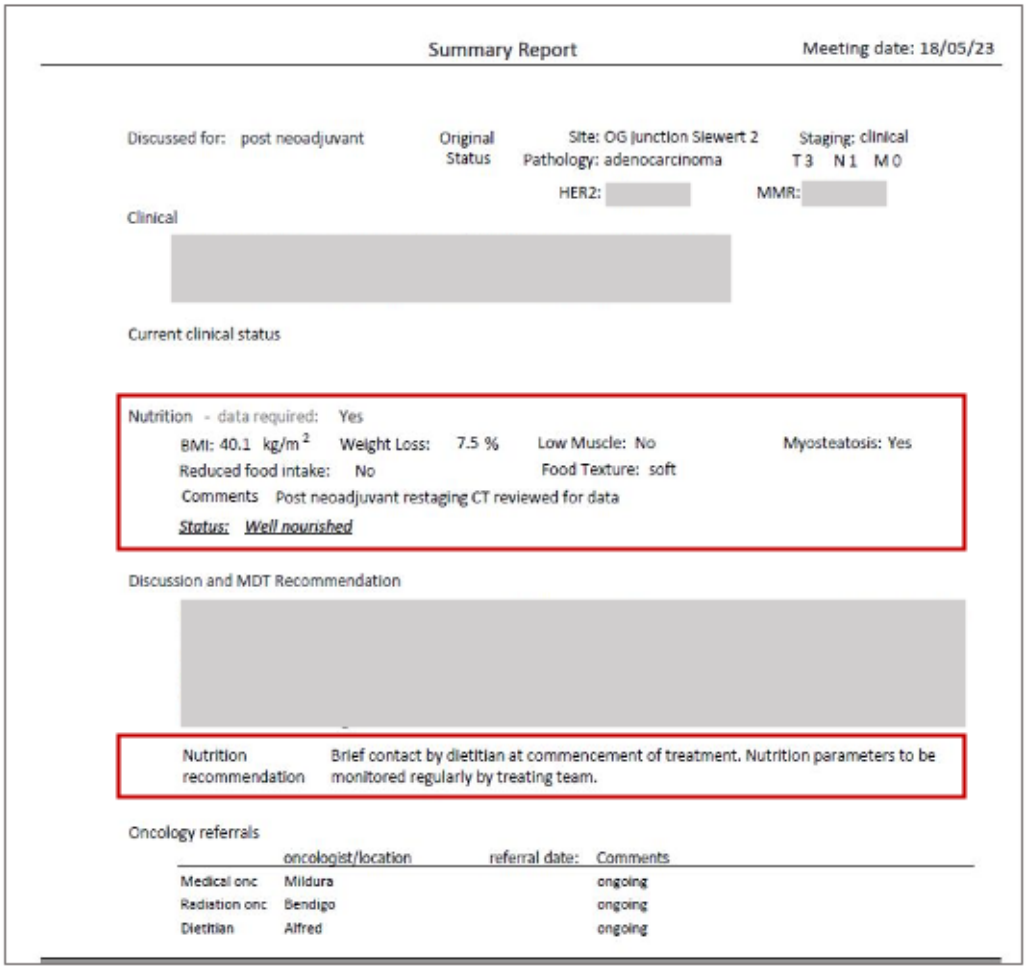
Reduced food intake: No Food Texture: smooth or pureed

Comments regained 4kg since diagnosis

Status: ***Well nourished***

1. MDM summary report and individual patient reports

The MDM summary report forms the individual patient summary reports and outlines the discussion undertaken during the MDM and the subsequent management plan. In addition to the nutrition information and nutrition status (shown above), the summary report also includes nutrition recommendations automatically generated when selecting the relevant nutrition status category.



Summary Report Meeting date: 18/05/23

Discussed for: post neoadjuvant Original Status Site: OG Junction Siewert 2 Staging: clinical

Pathology: adenocarcinoma T 3 N 1 M 0

HER2: MMR:

Clinical

Current clinical status

Nutrition - data required: Yes

BMI: 40.1 kg/m ^{2} Weight Loss: 7.5 % Low Muscle: No Myosteatosis: Yes

Reduced food intake: No Food Texture: soft

Comments Post neoadjuvant restaging CT reviewed for data

Status: ***Well nourished***

Discussion and MDT Recommendation

Nutrition recommendation: Brief contact by dietitian at commencement of treatment. Nutrition parameters to be monitored regularly by treating team.

Oncology referrals

	oncologist/location	referral date:	Comments
Medical onc	Mildura		ongoing
Radiation onc	Bendigo		ongoing
Dietitian	Alfred		ongoing

14. Appendix 4: Nutrition summary documents for patients and clinicians.

After the MDM, the Patient Nutrition Summary for Health Care Professionals (example below) was sent to the treating oncologist, surgeon, and dietitian.

NUTRITIONAL BIOMARKERS CARE PATHWAY

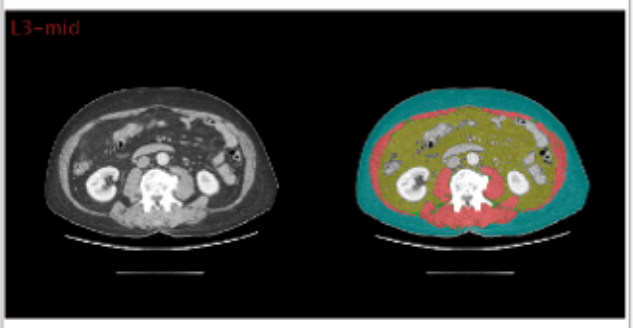
Information for Health Care Professionals

- Malnutrition, low muscle mass, and poor muscle quality (myosteatosis) are highly prevalent, can occur irrespective of body mass index (BMI), and increase the risk of negative outcomes for patients who have upper gastrointestinal cancer surgery.
- CT scans, taken routinely for clinical purposes, can be used to assess body composition and identify patients with low skeletal muscle index (cm^2/m^2, SMI).
- Integrating muscle mass and malnutrition assessment into clinical practice across the continuum of care is required for the early identification of at-risk patients.

The below information is to inform you on:
a) your patient's current *nutrition status*, and
b) their recommended nutrition *management plan*.

Patient Information			
Name:	**DOB:**	**Alfred UR:**	**MDM date:**

Voronoi Health Analytics



Tissue	Cross sectional Area	Mean HU	Index
Skeletal Muscle	134.33 cm^2	31.11 HU	
Subcutaneous Adipose Tissue	229.03 cm^2	-105.41 HU	
Visceral Adipose Tissue	210.98 cm^2	-87.37 HU	
Intramuscular Adipose Tissue	10.39 cm^2	-41.88 HU	

Anthropometrics

BMI (kg/m^2): _____

BMI category: _____

Weight loss (%): _____

Muscle Assessment

	Yes	No
Low SMI	☐	☐
Myosteatosis	☐	☐

Dietary Information

	Yes	No
Reduced food intake	☐	☐

Food texture: _____

Overall nutrition status: SEVERE MALNUTRITION

NuBio Care Pathway recommendations*

ASSESS

- Dietitian assessment immediately after MDM.
- Confirm nutrition status.
- Assess muscle mass and strength (if able).
- Dietary education & oral nutrition support (ONS) +/- *enteral nutrition (EN).*

MONITOR

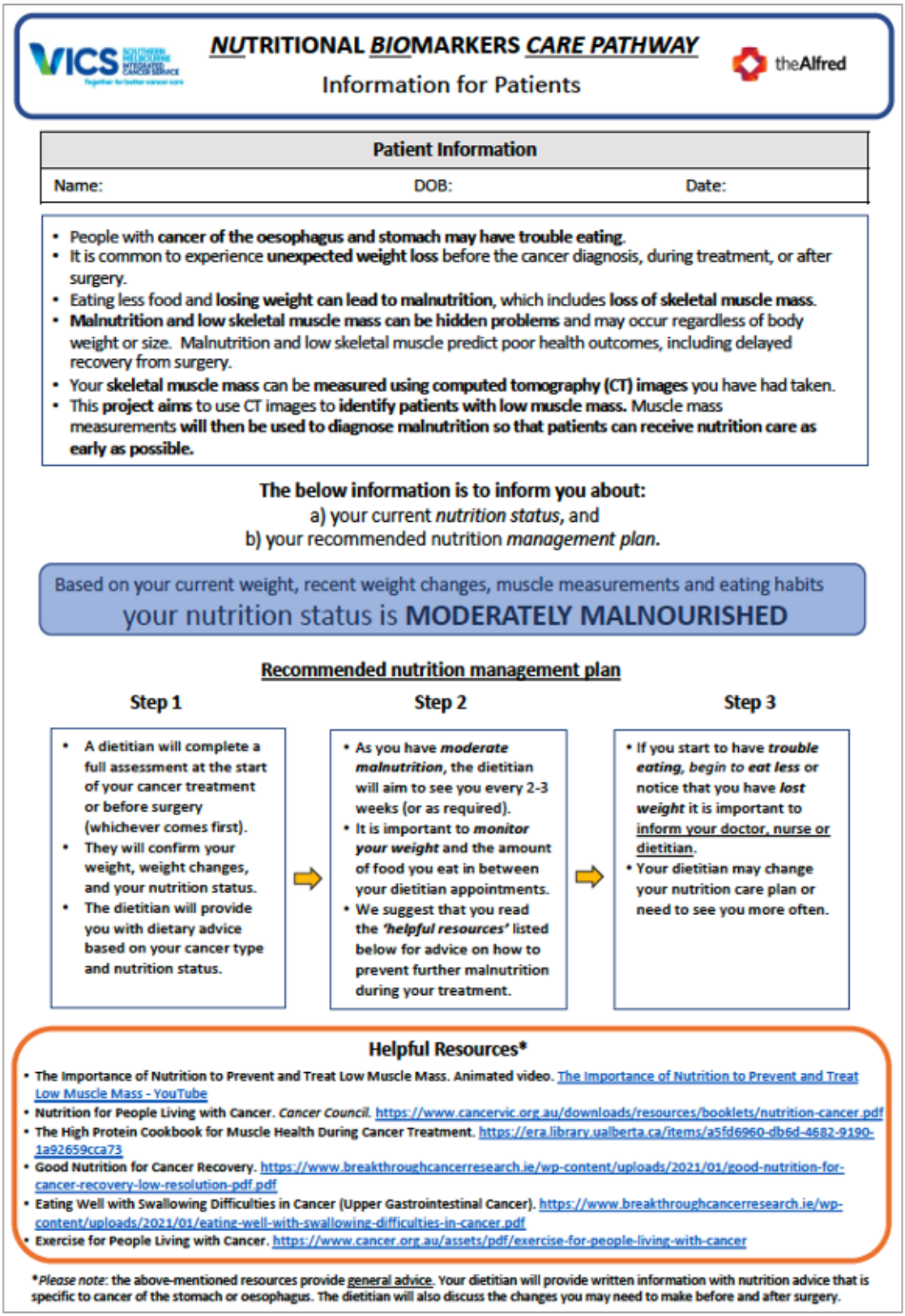
- Dietitian reviews weekly-twice weekly (as required).
- Monitor changes in weight, & food/ONS/EN intake.
- Re-assess muscle mass and strength halfway through neoadjuvant treatment (if able).

RE-ASSESS & ESCALATE

- If further weight loss occurs reassess nutrition requirements and increase provision.
- Commence EN (if not already) & ensure adequate nutrition provision prior to surgery.

*Refer to NuBio Care Pathway supportive document for Dietitians for more detailed information.

The Patient Nutrition Summary – Information for Patients document (example below) was given to patients during their first interaction with a dietitian after the MDM.



NUTRITIONAL BIOMARKERS CARE PATHWAY

Information for Patients

Patient Information		
Name:	DOB:	Date:

- People with **cancer of the oesophagus and stomach may have trouble eating**.
- It is common to experience **unexpected weight loss** before the cancer diagnosis, during treatment, or after surgery.
- Eating less food and **losing weight can lead to malnutrition**, which includes **loss of skeletal muscle mass**.
- **Malnutrition and low skeletal muscle mass can be hidden problems** and may occur regardless of body weight or size. Malnutrition and low skeletal muscle predict poor health outcomes, including delayed recovery from surgery.
- Your **skeletal muscle mass** can be **measured using computed tomography (CT) images** you have had taken.
- This **project aims** to use CT images to **identify patients with low muscle mass.** Muscle mass measurements **will then be used to diagnose malnutrition so that patients can receive nutrition care as early as possible.**

The below information is to inform you about:

a) your current *nutrition status*, and

b) your recommended nutrition *management plan*.

Based on your current weight, recent weight changes, muscle measurements and eating habits your nutrition status is **MODERATELY MALNOURISHED**

Recommended nutrition management plan

Step 1

- A dietitian will complete a full assessment at the start of your cancer treatment or before surgery (whichever comes first).
- They will confirm your weight, weight changes, and your nutrition status.
- The dietitian will provide you with dietary advice based on your cancer type and nutrition status.

Step 2

- As you have ***moderate malnutrition***, the dietitian will aim to see you every 2-3 weeks (or as required).
- It is important to ***monitor your weight*** and the amount of food you eat in between your dietitian appointments.
- We suggest that you read the ***'helpful resources'*** listed below for advice on how to prevent further malnutrition during your treatment.

Step 3

- If you start to have ***trouble eating***, ***begin to eat less*** or notice that you have ***lost weight*** it is important to inform your doctor, nurse or dietitian.
- Your dietitian may change your nutrition care plan or need to see you more often.

Helpful Resources*

- **The Importance of Nutrition to Prevent and Treat Low Muscle Mass. Animated video.** The Importance of Nutrition to Prevent and Treat Low Muscle Mass - YouTube
- **Nutrition for People Living with Cancer.** *Cancer Council.* https://www.cancervic.org.au/downloads/resources/booklets/nutrition-cancer.pdf
- **The High Protein Cookbook for Muscle Health During Cancer Treatment.** https://era.library.ualberta.ca/items/a5fd6960-db6d-4682-9190-1a92659cca73
- **Good Nutrition for Cancer Recovery.** https://www.breakthroughcancerresearch.ie/wp-content/uploads/2021/01/good-nutrition-for-cancer-recovery-low-resolution-pdf.pdf
- **Eating Well with Swallowing Difficulties in Cancer (Upper Gastrointestinal Cancer).** https://www.breakthroughcancerresearch.ie/wp-content/uploads/2021/01/eating-well-with-swallowing-difficulties-in-cancer.pdf
- **Exercise for People Living with Cancer.** https://www.cancer.org.au/assets/pdf/exercise-for-people-living-with-cancer

**Please note*: the above-mentioned resources provide general advice. Your dietitian will provide written information with nutrition advice that is specific to cancer of the stomach or oesophagus. The dietitian will also discuss the changes you may need to make before and after surgery.

15. Appendix 5: Evaluation Survey Responses

DIETITIAN Survey Responses

1. Reported *understanding* of skeletal muscle's role in overall health and nutrition management of patients with cancer.

	None	Little	Some	Good	Very good
Usual care		33%	33%	17%	17%
Post-pilot phase			33%	33%	33%

2. Perceived *burden* related to undertaking hand grip strength and/or calf circumference measure in clinical practice.

Degree of burden scale									
None				Neutral					Significant
1	2	3	4	5	6	7	8	9	10
	50%	25%			25%				

3. Level of agreement with statements related to the *experience* of undertaking hand grip strength and/or calf circumference measurements.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Unsure
I understood the rationale for completing the measures.				75%	25%	
Instructions for undertaking measurements were clear and easy to understand.					100%	
The process for documenting measures was efficient.				50%	50%	
I was able to interpret the measurement results.				100%		
I felt confident communicating the results with the patient.			25%	75%		

4. Level of agreement with statements related to their *attitude* toward and the *effectiveness* of the 'Nutrition Summary - Information for Healthcare Professionals' document.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Unsure
The information was clear and used terminology that I understood.				50%	50%	
The visual image of CT body composition analysis added value to the document.		25%	25%	50%		
The timing of receiving this document was appropriate.				75%		25%

Information in this document enhanced my management of the patient.		25%	50%	25%	

5. Overall *agreement* with the continuation of the NuBio Care Pathway.

	No	Yes
Do you recommend that the NuBio Care Pathway continues in clinical practice?		100%

ONCOLOGIST and SURGEON Survey responses

1. Level of agreement with statements related to their *attitudes* toward and *acceptance* of nutrition information included in the MDM documentation.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Unsure
I am aware that nutrition data is included in all MDM documentation.					100%	
The nutrition data is relevant and clinically meaningful					100%	
The nutrition data should be discussed during the MDM				100%		
Nutrition data on the MDM influences my clinical decision making.			33%	33%	33%	

2. Level of agreement with statements related to their *attitude* toward and the *effectiveness* of the 'Nutrition Summary - Information for Healthcare Professionals' document.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Unsure
The document enhanced my understanding of the patient's overall health status.					100%	
The document contained too much information	33%	66%				
The visual image of CT body composition analysis added value to the document.			66%	33%		
I would like to continue receiving this document in the future.				100%		

3. Overall *agreement* with the continuation of the NuBio Care Pathway.

	No	Yes
Do you recommend that the NuBio Care Pathway continues in clinical practice?		100%

PATIENT Survey Responses

1. Level of agreement with statements related to the *understanding* and *burden* of pre-MDM nutrition screening questions.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Unsure
I understood why I was asked about my weight and recent eating habits.				100%		
The timing of the conversation was appropriate.				66%	33%	
The conversation required little effort or time				66%	33%	

2. Perceived level of *burden* associated with having anthropometric and functional measures taken during treatment.

Degree of burden scale									
None				Neutral					Significant
1	2	3	4	5	6	7	8	9	10
33%	66%								

3. Level of agreement with statements related to their *understanding of* and the *effectiveness* of the 'Nutrition Summary – Information for Patients' document.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Unsure
I understood why the information was given to me.				66%	33%	
The information was clear and used language that I understood.				66%	33%	
The list of additional resources was useful and informative.			33%	66%		

4. Reported *understanding* of skeletal muscle's role in overall health and nutrition management of patients with cancer.

	None	Little	Some	Good	Very good
Pre-treatment	66%		33%		
Post-treatment		66%			33%

16. Acknowledgements

We would like to thank Kalai Shaw, data manager for the Department of Oesophago-Gastric and Bariatric Surgery, who implemented changes to the MDM agenda and patient reports by adjusting data reporting programs to include nutrition information. Kalai also developed the database that housed all relevant data collection parameters for the project.

Courtney Regan and Anna Hutton, who were both in the role of OG cancer nurse coordinator at different stages during the project development and implementation phase, helped to brainstorm the flow of the care pathway, accepted additional tasks to their usual role, trailed the pathway and provided valuable feedback and suggested improvements along the way.

Several members from The Alfred Department of Radiology supported the project's aims and assisted in overcoming several hurdles when investigating how CT body composition assessment could be implemented into routine practice.

The Alfred nutrition management team supported the secondment of the project lead from her usual clinical role for the duration of the project.

All dietitians involved showed interest and enthusiasm for trailing a new pathway of care, undertaking measures not usually applied in clinical practice, and providing valuable feedback throughout the project.