Nutrition Guidelines for Cystic Fibrosis in Australia and New Zealand

Administration Report

Prepared by Nicole Saxby and Susannah King January 2017





Introduction

After five years of hard work by a group of volunteers, the '2017 'Nutrition Guidelines for Cystic Fibrosis in Australia and New Zealand' (herein referred to as the '2017 guidelines') are now complete and ready for use. The '2017 Guidelines' provides an up-to-date resource that addresses the many aspects of nutrition management in cystic fibrosis (CF). It aims to facilitate optimal outcomes for all individuals with CF by informing best practice in clinical nutrition, and to promote consistency and equity of healthcare and evidence based practice throughout Australia and New Zealand.

The creation of the '2017 guidelines' was overseen by the Thoracic Society of Australia and New Zealand (TSANZ). The initial project proposal put forward to the TSANZ Clinical Care and Resource Subcommittee was based on the domains of the Appraisal of Guidelines for Resource & Evaluation (AGREE II) framework which helped to ensure a structured and rigorous development methodology, as well as transparency.

This administration report contains non-technical information relating to the processes of guideline development including:

- information about the chief custodian of the project and other stakeholders,
- lists of contributors and PICO questions covered,
- the role of consumers in the development of the guidelines,
- the communication strategy used,
- guideline quality controls, and
- conflict of interest declarations and funding arrangements.

Governance and Stakeholder Involvement

The primary custodian of the '2017 Guidelines' is the:

Thoracic Society of Australia and New Zealand Clinical Care and Resource Sub-Committee Suite 405, Level 4, 5 Hunter Street, Sydney NSW 2000 Phone +61 (2) 9222 6200

The following professional organisations were collaborators in the creation of this document:

- Dietitians Association of Australia (DAA)
- Dietitians New Zealand (DNZ)
- Cystic Fibrosis Australia (CFA)
- Cystic Fibrosis Association of New Zealand (CFANZ)

A copy of the memorandum of understanding between all stakeholders can be found in appendix A of this administration report.

Funding

These guidelines were created by a volunteer workforce. Limited funding through professional associations was used for teleconference meetings, \$5000 in total (i.e. TSANZ \$2000 (40%), DAA \$2000 (40%), DNZ \$1000 (20%). For these above mentioned reasons, any risk of bias from funders is minimal.

Educational up-skilling events

In 2012, two unrestricted educational grants were obtained independently of this guideline project through Abbott Medical (Australia) and Boehringer (New Zealand) to up-skill dietitians in evidence based practice. To ensure independence, a protective barrier between the funding sources and the guideline

project, CFA acted as the custodian of grant monies. CFA officials ensured that the money was only utilised for professional development proposes.

Funds were used to support guest speakers, room hire and subsidised airfares/travel to four evidence based practice professional development events in 2012-2013. The guideline project was not discussed at any of these events, and participating dietitians received no direct funding from any pharmaceutical sponsor. These events were advertised to all CF dietitians in Australia and New Zealand via the DAA, CFA and CFNZ websites. It is likely that some of the membership of dietitian steering group will have attended all or some of these events. If so, this will be openly declared in declaration of interest in appendix C.

Clinical questions covered

Chapter	Section	PICO question	Aetiology	Assessment	intervention	Monitoring
1 Introduction		Nil				
2 Methods		Nil				
3 Role of nutrition		Nil				
4 Service Delivery	4.2	What is the level of dietetic service required for people with CF?				
5 Assessment		Nil				
6 Nutrition interventions	6.1.1	Compared to standard nutritional care, do behavioural interventions around food and mealtimes improve behaviours, diet variety, and weight or nutrition status in children with CF?			✓	
	6.1.2	When should behavioural interventions around food and mealtimes be considered for children with CF?			✓	
	6.1.3	Do appetite stimulants, megesterol acetate and cyproheptadine, improve nutritional status in CF?			✓	
	6.1.4	Does the use of recombinant growth hormone improve nutritional status in prepubertal people with CF?			✓	
	6.1.5	Is there any rationale for the use of commercial oral nutritional supplements over food or mealtime strategies to improve nutritional intake, weight or pulmonary function in CF?			✓	
	6.1.6	Should enteral feeding be considered to improve nutrition outcomes for people with CF?			✓	
	6.1.7	Should enteral feeding be considered to improve pulmonary status in people with CF?			✓	
	6.1.8	When should enteral feeding be introduced for someone with CF?			✓	
	6.1.9	What is the ideal enteral feeding regimen for someone with CF?			✓	
	6.1.10	What are the risks associated with enteral feeding in CF compared to the general population?			✓	
7 Macronutrients	7.1.1	Are energy requirements elevated in the CF population compared to the general population?			✓	
	7.1.2	Are protein requirements elevated in the CF population compared to the general population?			✓	
	7.1.3	What is the evidence to support the routine recommendation of a high fat diet for people with CF?			✓	
	7.1.4	What are the recommendations for fibre in people with CF?			✓	

Chapter	Section	PICO question	Aetiology	Assessment	intervention	Monitoring
	7.2.1	Does dietary supplementation with omega-3 essential fatty acids improve health outcomes in people with CF?			✓	
8 Fat soluble vitamins	8.1.1	How should vitamin A be assessed for people with CF?			✓	
	8.1.2	What is the role for routine supplementation of vitamin A in people with CF and pancreatic insufficiency?			✓	
	8.1.3	What vitamin A supplementation dose should be prescribed to treat vitamin A deficiency in people with CF?			✓	
	8.1.4	What is the safe upper limit for vitamin A supplementation in people with CF?			✓	
	8.1.5	How often should vitamin A levels be measured in people with CF?				✓
	8.2.1	Is vitamin D status associated with measures of respiratory health (lung function, pulmonary exacerbations, markers of inflammation) in people with CF?		✓		
	8.2.2	Is there an ideal serum 25-hydroxyvitamin D level to aim for in people with CF?		✓		
	8.2.3	Is the time of year, specifically the season, important when measuring and interpreting an individual's serum vitamin D level?		✓		
	8.2.4	Should supplemental vitamin D be given to individuals with pancreatic sufficient cystic fibrosis as part of routine care?			✓	
	8.2.5	What doses of vitamin D are needed to prevent deficiency in people with CF?			√	
	8.2.6	What doses of vitamin D are needed to correct deficiency in people with CF?			✓	
	8.3.1	How should vitamin E levels be assessed for people with CF?		✓		
	8.3.2	What is the role for supplementation of Vitamin E in people with CF?			✓	
	8.3.3	What is the safe upper limit for vitamin supplementation for people with CF?			✓	
	8.3.4	How often should vitamin E levels be measured in people with CF?				✓
	8.4.1	How should vitamin K status be assessed for people with CF?		✓		
	8.4.2	Should vitamin K supplementation be recommended for all pancreatic insufficient people with CF?			✓	
	8.4.3	How often should vitamin K levels be measured in people with CF?				✓
9 Minerals	9.1.1	How should iron status be assessed in people with CF?		✓		
	9.1.2	How should iron deficiency be treated in people with CF?			✓	
	9.1.3	Is iron supplementation contraindicated in people with CF who are chronically colonised with pseudomonas aeruginosa?			✓	
	9.2.1	Does supplementing magnesium above the RDI improve nutrition and/or respiratory outcomes in people with CF?			✓	

Chapter	Section	PICO question	Aetiology	Assessment	intervention	Monitoring
	9.3	Nil				
	9.4.1	How do environmental factors and exercise impact on sodium requirements for people with CF compared to those without CF?			✓	
	9.4.2	What is the recommended daily sodium requirement for people with CF compared to those without CF?			✓	
	9.5.1	How should Zinc status be assessed for people with CF?		✓		
	9.5.2	What are the recommendations for zinc supplementation in people with CF?			✓	
	9.5.3	What is the safe upper limit for zinc supplementation in CF?			✓	
10 Pancreatic enzyme replacement therapy	10.1.1	Does gastric emptying rate impact PERT efficacy in people with CF?		✓		
	10.1.2	Does the timing of PERT administration in relation to a meal impact PERT efficacy in people with CF?			✓	
	10.1.3	How should PERT be dosed for people with CF to support optimal fat absorption?				
	10.1.4	Is there evidence to support the use of acid suppression medications to improve PERT efficacy for people with CF?			✓	
	10.1.5	What are the risks and long-term health implications associated with phthalate exposure via PERT to Australian and NZ people with CF?				✓
11 Gastrointestinal and Hepatobiliary Considerations	11.1.1	What are the nutrition considerations for the management of gastro- oesophageal reflux (GOR) in CF?			√	
	11.2.1	What are the nutrition considerations for the prevention and management of Distal Intestinal Obstruction Syndrome (DIOS) in Cystic Fibrosis (CF)?		✓		
	11.2.2	What are the nutrition considerations for the prevention and management of constipation in CF?		✓		
	11.3.1	What are the nutrition considerations for colon cancer screening in CF? PICO			✓	
	11.4.1	Should vitamin K supplementation be recommended for all people with CF related liver disease?			✓	
	11.4.2	What are the requirements for effective supplementation in episodes of Vitamin A deficiency in patients with CF related liver disease?			✓	

Chapter	Section	PICO question	Aetiology	Assessment	intervention	Monitoring
12 CF-related diabetes		Nil – narrative review only				
13 CF-related bone disease	13.1	How and when should bone health and disease be assessed for people with CF?			✓	
	13.2	What are the calcium requirements in CF to reduce the risk of low bone mineral density?			✓	
- 	13.3	Does supplementing calcium above the RDI improve bone mineral density in CF?			✓	
14 Special Considerations	14.1.1	What are the nutrition considerations of the management of pregnancy in CF?			✓	
	14.1.2	What recommendations around vitamin A supplementation and monitoring should be provided to females with CF who are pregnant or planning a pregnancy?			✓	
	14.2.1	What are the implications of Ivacaftor on nutritional status in children >2 years and adults with cystic fibrosis who have at least one G551D or other gating mutation allele?	✓			
	14.2.2	Are there any other nutritional considerations (energy, salt intake) that practitioners should take into consideration for people on Ivacaftor therapy?	✓			
	14.2.3	What is role of gastrointestinal and/or other nutritional outcome measures in individuals with CF receiving Ivacaftor therapy?			✓	
15 Complementary Therapies	15.1.1	Does dietary supplementation with probiotic genus Lactobacillus improve nutritional and/or respiratory status in individuals with CF?	~			
	15.1.2	Should routine or targeted use of probiotic supplements be recommended for people with CF?			✓	
	15.2.1	Does antioxidant supplementation with oral glutathione or its precursor N-acetylcysteine improve nutritional and/or respiratory status in individuals with Cystic Fibrosis?			1	
	15.3.1	Is there evidence that dietary supplementation with coconut oil improves nutritional status in pancreatic insufficient individuals with Cystic Fibrosis?			✓	
	15.4.1	Is there evidence that dietary supplementation with specific herbal products or their components improves health outcomes in individuals with CF?			✓	
16 Transplantation		Nil – narrative review only	_			
17 Implementation		N/A				
18 Evidence Matrices		N/A				

Contributors

Dietitian Steering Group (Authorship Group)

A steering group comprised of Australian Accredited Practicing Dietitians' and New Zealand Registered Dietitians, with clinical experience in assessing evidence and in the nutritional management of CF, developed and wrote the '2017 Guidelines'. In some specialist areas, other disciplines assisted with evidence review, critiquing articles and directly contributing to written content. These individuals were also considered to be part of the dietitian steering group. As the dietitian steering group wrote the guidelines, they are also the authorship group.

The dietitian steering group reported to the interdisciplinary clinical expert committee for feedback and consultation on the guidelines.

The dietitian steering group was formed was formed in 2012. Expressions of interest were circulated to all Australian and New Zealand dietitians who specialise in managing CF and to the broader dietetic community through the DAA and DNZ. Acceptance to the dietitian steering group was based on merit.

Table 1: Dietitian Steering Group (authorship group)

Role	Title	Name	Hospital / Affiliation	Profession	State
Co-chair	Ms	Nicole Saxby	Tasmanian Cystic Fibrosis Service	Dietitian	Tasmania
Co-chair	Ms	Catherine Painter	Royal Adelaide Hospital	Dietitian	South Australia
Project facilitator	Ms	Andrea Kench	The Children's Hospital at Westmead	Dietitian	New South Wales
Project facilitator	Mr	Paul O'Neill	Sir Charles Gairdner Hospital	Dietitian	Western Australia
Project facilitator	Ms	Natalie van der Haak	Women's and Children's Hospital	Dietitian	South Australia
Methodological lead	Dr	Susannah King	The Alfred Hospital	Dietitian	Victoria
Methodological expert	Dr	Audrey Tierney	The Alfred Hospital & La Trobe University	Dietitian	Victoria
Methodological expert	Prof	Clare Collins	University of Newcastle	Dietitian	New South Wales
New Zealand lead	Ms	Tory Crowder	Canterbury Cystic Fibrosis Service	Dietitian	New Zealand
Referencing	Ms	Mellissa Carr	John Hunter Hospital	Dietitian	New South Wales
Editor	Prof	Scott Bell	The Prince Charles Hospital	Respiratory Physician	Queensland
SECTION LEADERS					
Vitamins (A, E &K), minerals (Zn), probiotics	Ms	Jacqueline Anderson	The Alfred Hospital/ private practice	Dietitian	Victoria
Macronutrients, appetite stimulants	Ms	Rachael Cavanagh	Royal Children's Hospital	Dietitian	Victoria
Role of nutrition in CF care, assessment, service delivery, overnutrition	Ms	Tory Crowder	Canterbury Cystic Fibrosis Service	Dietitian	New Zealand
Macronutrients	Ms	Kristyn Ford	Royal Children's Hospital	Dietitian	Victoria
Nutrition interventions	Ms	Natalie Forgione	Royal Adelaide Hospital	Dietitian	South Australia
Liver considerations	Ms	Lisa Guest	Auckland City Hospital	Dietitian	New Zealand
Minerals (Fe, Ca)	Ms	Jodi Grunert	Women's and Children's Hospital	Dietitian	South Australia
Pregnancy	Ms	Karen Herd	The Prince Charles Hospital	Dietitian	Queensland
Minerals (Na)	Ms	Jenny Heyward	Starship Child Health	Dietitian	New Zealand
Transplantation	Ms	Donna Hickling	The Prince Charles Hospital	Dietitian	Queensland
Vitamin (D), CF-related diabetes	Ms	Tamarah Katz	Sydney Children's Hospital	Dietitian	New South Wales
Minerals (Ca, Mg, Na), constipation and distal intestinal obstruction syndrome, phthalates	Ms	Andrea Kench	The Children's Hospital at Westmead		New South Wales
Role of nutrition in CF care, assessment	Dr	Susannah King	The Alfred Hospital	Dietitian	Victoria
CF-related diabetes	Ms	Angela Matson	The Prince Charles Hospital	Dietitian	Queensland
Complementary therapies, essential fatty acids	Ms	Caitlin Miles	Monash Children's Hospital	Dietitian	Victoria
Genetic modulators, implementation, Liver considerations	Ms	Catherine Painter	Royal Adelaide Hospital	Dietitian	South Australia
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delivery, behavioural					
modification , genetic					
modulators, bone health, over- nutrition, implementation					
Reflux	Ms	Jenna Stonestreet	The Prince Charles Hospital	Dietitian	Queensland
Pancreatic enzyme replacement therapy	Ms	Natalie van der Haak	Women's and Children's Hospital	Dietitian	South Australia
GROUP MEMBERS					
Transplantation	Ms	Rebecca Baskett	Auckland City Hospital	Dietitian	New Zealand
Various chapters	Ms	Rachel Battersby	Women's and Children's Hospital	Dietitian	South Australia
Various chapters – until end 2015	Ms	Annabel Biven	Lady Cilento Children's Hospital	Dietitian	Queensland
Minerals (Na)	Ms	Joanna Boyle	Nurture Family Allied Health Centre	Dietitian/consumer	Queensland
Various chapters	Ms	Mary Fraser	Tasmanian Health Organisation	Librarian	Tasmania
Various chapters	Ms	Julie Graves	Tauranga Hospital	Dietitian	New Zealand
Transplantation	Ms	Louise Hesketh	Fiona Stanley Hospital	Dietitian	Western Australia
Various chapters – until end 2014	Ms	Kelly Josh	Princess Margret Hospital for Children	Dietitian	Western Australia
Vitamins (D)—until end 2014	Ms	Juliette Mahero	The Prince Charles Hospital	Dietitian	Queensland
Complementary therapies	Mr	Peter Maree	Tasmanian Health Service	Dietitian/consumer	Tasmania
Various chapters – until end 2015	Ms	Sarah McKay	Westmead Hospital	Dietitian	New South Wales
Implementation	Dr	Saravana Kumar	University of South Australia	Academic	South Australia
Transplantation, proof reading	Ms	Maeve O'Driscoll	The Alfred Hospital	Dietitian	Victoria
Gastrointestinal considerations	Dr	Keith Ooi	Sydney Children's Hospital	Gastroenterologist	New South Wales
Transplantation	Ms	Clare Rawcliffe	St Vincent's Hospital	Dietitian	New South Wales
Various chapters	Ms	Nicole Sander	Princess Margret Hospital for Children	Dietitian	Western Australia
Various chapters	Ms	Katie Vardy	Gold Coast University Hospital	Dietitian	Queensland
Appetite stimulants, nutrition intervention	Ms	Evelyn Volders	Monash University	Dietitian	Victoria
Minerals (Fe)	Ms	Kirrilee Waterhouse	Tasmanian Cystic Fibrosis Service	Dietitian	Tasmania
Various chapters	Ms	Linda Williams	Wellington Hospital	Dietitian	New Zealand
Various chapters	Ms	Denise Wong See	John Hunter Hospital	Dietitian	New South Wales

Throughout the project, members of the dietitian authorship took on a variety of roles such as chair-person, project facilitator, section leader and group member (as indicated in table 1 above). Some individuals completed more than one role. The tasks completed at each stage of the project were:

Initiating

Co-chairs

- Initiating the project
- Write project proposal in collaboration with relevant dietitian and interdisciplinary steering group members
- Seeking stakeholder support for the project (TSANZ, DAA, DNZ, CFA, CFNZ)

Planning

Co-chairs, project facilitators, methodological experts and other individuals from the dietitian steering group

- Planning for the project including scope, methodology and reporting
- Coordinate the formation of the interdisciplinary and dietitian steering groups

Executing

Co-chairs

- Chair meetings
- Help to complete systematic literature search strategy for each clinical question
- Notify methodological experts about areas where consensus was unable to be reached

- In collaboration with the methodological experts and project facilitators, help to grade recommendation statements
- Responsible for overarching structure and style of all guideline documents
- Content editing

Project facilitators

- Take minutes for meetings or organise someone else to do this task
- Organise the spreadsheet containing the summaries of the evidence
- Be a resource person for the section leaders
- Assist with creating PICO questions and creating templates for each stage of guideline work
- Content editing

Group members (dietitian and interdisciplinary)

- Provide input into the scope of the project and the clinical questions to be addressed (including key words)
- Help develop practice recommendations
- Provide feedback on drafts of the guidelines and other publications
- Interdisciplinary steering group members to provide expert knowledge and guidance in their specialist areas

Dietitian section leaders

- Ensure each group member of the dietitian sub-working group has completed a declaration of interest form
- Nominate two members to critique each set of articles (e.g. if there were 4 people and 20 articles, 2 would do 10 and the other 2 would do the other 10). These individuals will be known as appraisers (group members).
- Notify project directors if appraisers are unable to reach independent consensus
- Ensure that draft evidence statements are written for each article to be forwarded onto project facilitator
- In conjunction with your dietitian sub-working group, formulate first drafts of the recommendation statements to be forwarded onto project facilitator
- Facilitate the creation of supporting patient handouts for clinical questions in your area (may enlist students to do the work)
- Provide fortnightly updates to the project directors on progress (even in the case where there
 has been no progress)

Appraisers

- Independently critiques articles for designated section (maximum 3 week, 20-40 min each)
- Each appraiser will fill in a 'CF study summary statement template', as well as complete the hank
- Where consensus is not reached, provide a third overriding opinion

Methodological experts

- Provide direction and support to the project co-chairs and guidance regarding the literature review, grading of recommendations guideline format/ other publications, and critical review of the final draft
- Susannah King completed a critical review of the public consultation feedback and integration into final draft. She also provided guidance on internal consistency

Monitoring

Project co-chairs and project facilitators

- Ensure project milestones are met
- Monitor project status on a fortnightly basis

- Provide bi-annual project reports to all relevant organisations
- Communicate progress with all stakeholders fortnightly
- Ensure declarations of interests are kept up to date

Interdisciplinary Clinical Expert Committee

Members of the interdisciplinary clinical expert committee provided expert knowledge and guidance related to cystic fibrosis (CF) nutrition in their specialist areas. This group was established in June 2012 and was comprised of members with clinical leadership, and specific clinical expertise. Members were not a representative of a particular group or organisations, but were members in their own right. Expressions of interest were circulated through TSANZ, as well as through relevant professional associations e.g. the Australian College of Pharmacy. Disciplines sought include: medical, nursing and allied health. CF Australia and CF NZ circulated expressions of interest for consumer representatives.

The interdisciplinary steering group does not have rights of authorship (unless significant contributions were made to the content).

Table 2: Interdisciplinary Clinical Expert Committee Members

Title	Name	Hospital / Affiliation	Profession	State
Ms	Robyn Baird	Canterbury Cystic Fibrosis Service	Nurse Specialist	New Zealand
Prof	Scott Bell	The Prince Charles Hospital	Respiratory Physician	Queensland
Ms	Susan Biggar	Health Issues Centre	Consumer	Victoria
Ms	Stephanie Chen	Monash Medical Centre	Social Worker	Victoria
Prof	Maria Craig	Children's Hospital at Westmead	Endocrinologist	New South Wales
Ms	Mary Fraser	Tasmanian Health Organisation	Librarian	Tasmania
Dr	Shihab Hameed	Sydney Children's Hospital	Endocrinologist	New South Wales
Ms	Karen Haworth	Mater Hospital	Diabetes Educator	Queensland
A/Prof	Jane Holmes-Walker	Westmead Hospital	Endocrinologist	New South Wales
A/Prof	Peter Hopkins	The Prince Charles Hospital	Lung transplant Physician	Queensland
Ms	Kate Luttrell	Launceston General Hospital	Pharmacist	Tasmania
Dr	Karen McKay	Children's Hospital at Westmead	Research fellow	New South Wales
A/Prof	Peter Middleton	Westmead Hospital	Respiratory Physician	New South Wales
Ms	Sue Morey	Sir Charles Gairdner	Nurse Practitioner	Western Australia
Ms	Courtney Munro	Royal Children's Hospital	Pharmacist	Victoria
Ms	Liz Powell	The Prince Charles Hospital	Diabetes Educator	Queensland
Dr	Chee Yee Ooi	Sydney Children's Hospital	Gastroenterologist	New South Wales
Prof	Mark Oliver	Royal Children's Hospital	Gastroenterologist	Victoria
Dr	Bernadette Prentice	Sydney Children's Hospital	Respiratory Fellow	New South Wales
A/Prof	Phil Robinson	Royal Children's Hospital	Respiratory Physician	Victoria
Prof	Kate Steinbeck	Children's Hospital at Westmead	Endocrinologist	New South Wales
Ms	Michelle Wood	The Prince Charles Hospital	Physiotherapist/Research Coordinator	Queensland

Communication Strategy

Timing and frequency of meetings of dietitian steering group and interdisciplinary clinical expert committee were determined by the needs of the project. The full dietitian steering group aimed to meet via teleconference every second month and the interdisciplinary steering group twice yearly (quorum 40% of memberships). If members were unable to attend teleconferences, email correspondence for feedback and consultation was adequate. The agenda and relevant documents for each meeting were circulated via email one-two weeks prior, by the project chair or facilitator. In circumstances of disagreement on an issue, the matter was raised to the relevant group for voting.

Consumer participation in guideline development

The dietitian authorship group contained two consumer members who are also dietitians (i.e. Peter Maree and Joanna Boyle). In addition, expressions of interest for the interdisciplinary committee initially resulted in three consumer representatives however, due to illness (n=1) and resignation of role at consumer organisation (n=1) numbers of consumers participating in guideline development reduced to one (i.e. Susan Biggar). Consumer feedback was also sought via the occasional newsletter, circulated throughout Australia and New Zealand. A one month public consultation was completed in Nov-Dec 2016, advertised through various means including Facebook and Linkedin, and CF consumer networks (i.e. CFA and CFNZ).

The guideline development process did not include any representatives of Aboriginal and Torres Strait Islanders peoples. Cystic fibrosis almost exclusive affects the caucasian population so, it was felt this representation was not necessarily.

Public consultation

The '2016/2017 Guidelines' were released for public consultation for one month in January/December 2016. The public consultation process was advertised to the general public and people with CF (via CFA and CFNZ websites and Facebook pages), and to health professionals (via TSANZ and other professional association webpages including the DAA and DNZ, LinkedIn, as well as via personal email). Individually addressed emails about the public consultation were sent to the director-General, Chief Executive or Secretary of each state, territory and commonwealth health department. A copy of the public consultation notice can be found in Appendix B.

Potential competing interests

None of the individuals involved in the project had any significant declarations of interest (see Appendix C).

Disclosure of interest at commencement of involvement in guideline project

Upon commencement with the guideline project individuals were required to complete a TSANZ declaration of interest form. All members of the dietitian steering group and the interdisciplinary expert committee completed this requirement – as summarized in Appendix C. A copy of all of these documents was forwarded to the TSANZ CCRS.

Disclosure of interest during appointments

It was the responsibility of the project co-chairs to ensure that declaration of interest paperwork remained up-to-date. All project members were required to declare any new potential conflict of interests at the beginning of every meeting. If an individual's circumstances changed in such a way as

there became a direct or indirect pecuniary interest where one didn't previously exist, supplementary actions were taken to manage any perceived risks (as shown in Appendix C).

Procedure at meetings

Conflict of interest was a standing agenda item for all meetings associated with this guideline project. At the beginning of each meeting, the project chairs invited any member to declare an interest in any activity. Any disclosures were recorded in the meeting minutes or, if declaration made outside of a meeting, it was recorded in the next meeting minutes.

Guideline Quality

The guideline and recommendations were assessed by two reviewers, independent of the guideline development process, using the AGREE II tool (see table 3 below). These assessments can be found in appendix D.

The feedback received was largely positive and noted the comprehensive nature of work and its potential to influence and improve nutrition care and outcomes for people with CF. There were some improvements suggested including signposts in the main document for important information found in the administration report including a full list of PICOs as well as funding sources, methods for addressing conflicts of interest and declarations of conflicts of interest for the authorship group. It was also highlighted that potential barriers for implementation of the guidelines had not been explicitly described.

These points have now been addressed, with a full list of PICOs and accompanying recommendations and practice points available in the executive summary, and their inclusion in the administration report signposted in the main document. Information on funding sources, methods for assessing conflicts of interest and declarations of conflicts of interest for the authorship group and interdisciplinary clinical expert committee available in this administration report have also been signposted in the main document. Potential barriers for implementation of the guidelines have been included in the implementation chapter of the main document.

Table 3: Names of guideline quality reviewers

Title	Name	Hospital / Affiliation	Profession	State
Prof	Anne Holland	Thoracic Society of Australia and New Zealand & La Trobe University	Physiotherapy	Victoria
Prof	Judy Bauer	Dietitians Association of Australia	Dietitian	Queensland

Appendix A: Memorandum of Understanding

This memorandum of understanding is made between the **Thoracic Society of Australia and New Zealand, Dietitians Association of Australia, New Zealand Dietitians, Dietitians of Canada, Cystic Fibrosis Australia,** and **Cystic Fibrosis Association New Zealand**. This document is a record of an agreement to contribute towards the revision of Nutrition Guidelines for Cystic Fibrosis in Australia and New Zealand inclusive of a patient resource set.

Thoracic Society of Australia and New Zealand (TSANZ) will provide:

- Advice and support to steering group members regarding creating guidelines via the Clinical Care and Resources Subcommittee
- Teleconference funding for two interdisciplinary steering group year
- Office staff support and access to whole membership to call for expressions of interest (EOI) for the interdisciplinary steering group
- · Access to membership (interdisciplinary) to circulate draft guideline/publications for comment
- Endorsement
- Assistance with preparing documents for publication in the Respirology Journal

Dietitians Association of Australia (DAA) and Dietitians New Zealand (DNZ) will provide:

- Teleconference funding for monthly dietitian steering group meetings (DAA and DNZ members only)
- Advice to the dietitian steering group members around guideline development and Practice-based Evidence in Nutrition pathway (PEN) knowledge pathway development
- Access to the whole membership to call for EOI in being selected for the dietitian steering group
- Access to the whole dietitian membership to circulate draft guidelines for comment

Dietitians of Canada (DC) will provide:

- Specialist advice to the project directors around PEN knowledge pathway development
- Access to international (Canadian) dietitian membership, with relevant topic expertise (i.e. cystic fibrosis), to circulate draft guidelines and resources for comment

Cystic Fibrosis Australia (CFA) and Cystic Fibrosis Association New Zealand (CFANZ) will provide:

- Access to known health professionals' working in the area of cystic fibrosis who have attended recent conferences to enable wider circulation of expression of interest for the interdisciplinary steering committee
- A nomination of a suitable consumer representative for the interdisciplinary steering committee
- Access to the consumer membership for distribution of targeted surveys seeking options of the feasibility of practice recommendations and consumer resources

Additional Important Points

- TSANZ as the primary custodian of these guidelines has first publication rights
- DC gives permission for this project to use, in other guideline documents, the same/similar PICO practice based questions as the DC PEN CF pathway
- TSANZ and DC agree that the information can be re-purposed for inclusion in the Cystic Fibrosis PEN knowledge pathway

- Supplementary dietitian tools and patient handouts, created as part of this guideline review, will be published on the DC PEN CF pathway if they match the evidence in PEN
- The DAA and DNZ name and/or logos will not be used in any relation to the cystic fibrosis nutrition guideline revision
- CFA and CFNZ have permission to publish consumer resources created on their websites
- All individuals involved in developing the guidelines will be acknowledged

Appendix B: Public consultation notice

Public consultation notice





DRAFT GUIDELINES for the NUTRITIONAL MANAGEMENT OF CYSTIC FIBROSIS IN AUSTRALIA AND NEW ZEALAND

The Thoracic Society of Australia and New Zealand has prepared draft guidelines on the nutritional management of cystic fibrosis. These guidelines are proposed for submission to the NHMRC for approval under *section 14A of the National Health and Medical Research Council Act 1992.*

Consultation period

Consultation will be open from Wednesday the 12th of October until 11:59 AEST Sunday the 12th of November, 2016.

How to make a submission

You are invited to make a submission electronically, in writing or as a recorded audio format. Please include your name and an address or telephone number at which you can be contacted. Please send your submission to:

Chair - Cystic Fibrosis Nutrition Guideline Project

Thoracic Society of Australia and New Zealand Suite 405, Level 4, 5 Hunter Street Sydney NSW 2000

Email: Info@thoracic.org.au

Further information

A copy of the draft guidelines can be obtained from: http://www.thoracic.org.au/clinicalpublications/consultations/public OR by phoning (02) 9222 6200

Electronic submissions are preferred and can be completed via the 'provide feedback button' located on the above mentioned website.

Appendix C: **Declarations of interest**

Name	Profession	Role in Project	Relevant Financial Activities	Relevant professional and organizational experience	Other relationships or activities	Conflict of interest identified	Action required
DIETITIAN STEERING	GROUP	T.					
Nicole Saxby	Dietitian	Co-chair	(2012) Attended educational up- skilling events coordinated by CFA, travel funded	Member TSANZ and DAA	(2015) Author of textbook on nutrition care process (2013/14) Vertex multidisciplinary advisory board	None identified	No
Catherine Painter	Dietitian	Co-chair	(2012) Attended educational up- skilling events coordinated by CFA, travel funded	Member DAA	(2006) developed previous CF nutrition guidelines for Australasia	None identified	No
Andrea Kench	Dietitian	Project facilitator	(2012) Attended educational up- skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Nat van der Haak	Dietitian	Project facilitator from June 2016; Section leader 2012 to June 2016	(2010) funding from Abbott medical to conduct research into pancreatic enzyme timing (2012) Attended educational upskilling events coordinated by CFA, travel funded (2012) Abbott partly funded attendance at North American CF conference	Member DAA	No	Potential – research outputs from Abbott funding (2010) were included in this guideline	Project chairs ensured that Natalie had no influence on critiquing her article. PERT section was also reviewed independently
Paul O'Neill	Dietitian	Project facilitator until Dec 2015	(2011) Joint recipient Abbott Scholarship (2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Susannah King	Dietitian	Methodological expert	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded (2015) Nestle Australia supported attendance at Australian and New Zealand CF conference — presentations given by Susannah at this conference were unrelated	Member DAA	(2006) developed previous CF nutrition guidelines for Australasia	None identified	No

			to Nestle products and they had no role in the preparation of material				
Audrey Tierney	Dietitian	Methodological expert	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded (2015) Nestle Australia supported attendance at Australian and New Zealand CF conference — presentations given by Audrey at this conference were unrelated to Nestle products and they had no role in the preparation of material	Member DAA	No	None identified	No
Clare Collins	Professor of Nutrition	Methodological expert	No	Fellow DAA	(2006) developed previous CF nutrition guidelines for Australasia	None identified	No
Tory Crowder	Dietitian	NZ lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DNZ	(2006) developed previous CF nutrition guidelines for Australasia	None identified	No
Melissa Carr	Dietitian	Referencing	No	No	No	None identified	No
Jacqueline Anderson	Dietitian	Section lead	No	Member DAA	No	None identified	No
Rachael Cavanagh	Dietitian	Section lead	No	Member DAA	No	None identified	No
Kristyn Ford	Dietitian	Section lead	No	Member DAA	No	None identified	No
Natalie Forgione	Dietitian	Section lead	No	No	No	None identified	No
Lisa Guest	Dietitian	Section lead	No	Member DNZ	No	None identified	No
Jodi Grunert	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Karen Herd	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Jenny Heyward	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded (2016) Support provided by Nestle for travel to guideline implementation workshop in Melbourne	Member DNZ	No	Potential	Jenny asked to not participate in any voting activities at the implementation workshop
Donna Hickling	Dietitian	Section lead	No	No	No	None identified	No
Tamarah Katz	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by	No	No	None identified	No

			CFA, travel funded				
Angela Matson	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	(2006) developed previous CF nutrition guidelines for Australasia	None identified	No
Caitlin Miles	Dietitian	Section lead	(2012) Attended educational up- skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Jenna Stonestreet	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Aurora Avedillo	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Rebecca Basket	Dietitian	Section lead	No	Member DNZ	No	None identified	No
Rachael Battersby	Dietitian	Section lead	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Catherine Bonifant	Dietitian	Section lead	No	Member DAA	No	None identified	No
Annabel Biven	Dietitian	Group member	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	Member DAA	No	None identified	No
Joanna Boyle	Dietitian	Group member	No	Information not requested	No	None identified	No
Eleanor Capel	Dietitian	Group member	No	Unknown	No	None identified	No
Mary Fraser	Medical librarian	Group member and literature searches	No	Information not requested	No	None identified	No
Julie Graves	Dietitian	Group member	(2012/13) Attended educational up-skilling events coordinated by CFA, travel funded	DNZ member	No	None identified	No
Louise Hesketh	Dietitian	Group member	No	Member DAA	No	None identified	No
Kelly Josh	Dietitian	Group member	No	Unknown	No	None identified	No
Juliette Mahero	Dietitian	Group member	No	Member DAA	No	None identified	No
Peter Maree	Dietitian	Group member	No	Unknown	No	None identified	No
Sarah McKay	Dietitian	Group member	No	Member DAA	No	None identified	No
Saravana Kumar	Academic	Group member	No	Member DAA	No	None identified	No
Maeve O'Driscoll	Dietitian	Group member	No	Member DAA	No	None identified	No
Chee Yee Ooi	Gastroenterologist	Group member and interdisciplinary advisory	No	Member DAA	No	None identified	No
Bhey Orwin	Dietitian	Group member	No	Unknown	No	None identified	No

Clare Rawcliffe	Dietitian	Group member	No	DAA member	No	None identified	No
Nicole Sander	Dietitian	Group member	No	DAA member	No	None identified	No
Indi Swan	Dietitian	Group member	(2012) Attended educational up- skilling events coordinated by CFA, travel funded	DAA member	No	None identified	No
Katie Vardy	Dietitian	Group member	(2012) Attended educational up- skilling events coordinated by CFA, travel funded	DAA member	No	None identified	No
Evelyn Volders	Dietitian and academic	Group member	No	DAA member	No	None identified	No
Kirrilee Waterhouse	Dietitian	Group member	No	DAA member and secretary of the DAA Tasmania branch	No	None identified	No
Linda Williams	Dietitian	Group member	(2016) Support provided by Nestle for travel to guideline implementation workshop in Melbourne	DNZ member	No	Potential	Linda asked to not participate in any voting activities at the implementation workshop
Denise Wong see	Dietitian	Group member	(2012) Attended educational up- skilling events coordinated by CFA, travel funded	DAA member	No	None identified	No
Name	Profession	Role in	Relevant Financial	Relevant	Other	Conflict of	Action
		Project	Activities	professional and	relationships or	interest	required
				organizational	activities	identified	
				experience			
INTERDISCIPLINARY EX							
Robyn Baird	XPERT COMMITTEE			-			
nobyli buliu	XPERT COMMITTEE Nurse specialist	expert advisor	No	Information not requested	No	None identified	No
Scott Bell		expert advisor expert advisor and guideline editor	No No	Information not	No No	None identified None identified	No No
,	Nurse specialist Respiratory physician and professor of	expert advisor and		Information not requested			
Scott Bell	Nurse specialist Respiratory physician and professor of medicine	expert advisor and guideline editor	No	Information not requested TSANZ member	No	None identified	No
Scott Bell Susan Biggar	Respiratory physician and professor of medicine Consumer	expert advisor and guideline editor	No No	Information not requested TSANZ member Health Issues Centre Information not	No No	None identified None identified	No No
Scott Bell Susan Biggar Stephanie Chen	Respiratory physician and professor of medicine Consumer Social worker	expert advisor and guideline editor expert advisor expert advisor	No No No	Information not requested TSANZ member Health Issues Centre Information not requested Information not	No No No	None identified None identified None identified	No No No
Susan Biggar Stephanie Chen Maria Craig	Respiratory physician and professor of medicine Consumer Social worker Endocrinologist	expert advisor and guideline editor expert advisor expert advisor expert advisor	No No No No	Information not requested TSANZ member Health Issues Centre Information not requested Information not requested Information not requested Information not	No No No	None identified None identified None identified None identified	No No No

			education from Metaronic Australia and Novo Noradisk	requested			
Peter Hopkins	Lung transplant	expert advisor	No	Information not requested	No	None identified	No
Karen McKay	Research fellow	expert advisor	No	Information not requested	No	None identified	No
Peter Middleton	Respiratory physician	expert advisor	No	TSANZ member	No	None identified	No
Sue Morey	Nurse practitioner	expert advisor	No	Information not requested	No	None identified	No
Courtney Munro	Pharmacist	expert advisor	No	Information not requested	No	None identified	No
Liz Powell	Diabetes educator	expert advisor	No	Information not requested	No	None identified	No
Mark Oliver	Gastroenterologist	expert advisor	No	Information not requested	No	None identified	No
Bernadette Prentice	Respiratory fellow	expert advisor	No	Information not requested	No	None identified	No
Phil Robinson	Paediatric Respiratory Physician	expert advisor	No	TSANZ member	No	None identified	No
Kate Steinbeck	Endocrinologist	expert advisor	No	Information not requested	No	None identified	No
Michelle Wood	Physiotherapist/res earch coordinator	expert advisor	No	Information not requested	No	None identified	No

Appendix D: Completed AGREE II assessments



A critical appraisal of: Nutrition Guidelines for Cystic Fibrosis in Australia and New Zealand using the AGREE II Instrument

Created with the AGREE II Online Guideline Appraisal Tool.

No endorsement of the content of this document by the AGREE Research Trust should be implied.

Appraiser: Judy Bauer

Date: 16 January 2017

Email: j.bauer1@uq.edu.au

URL of this appraisal: http://www.agreetrust.org/appraisal/40551

Guideline URL

Overall Assessment

Title: Nutrition Guidelines for Cystic Fibrosis in Australia and New Zealand

Overall quality of this guideline: 7/7

AGREE Mounting the science of practice guidelines.

Guideline recommended for use? Yes.

Notes:

This is a very impressive body of work and the authorship team are to be congratulated on this comprehensive work which will influence nutrition care and improve outcomes of individuals with CF internationally.

Domain	Total
1. Scope and Purpose	21
2. Stakeholder Involvement	19
3. Rigour of Development	50
4. Clarity of Presentation	21
5. Applicability	24
6. Editorial Independence	14

1. Scope and Purpose

 The overall objective(s) of the guideline is (are) specifically described.

Rating: 7

The health question(s) covered by the guideline is (are) specifically described.

Rating: 7

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Rating: 7

2. Stakeholder Involvement

The guideline development group includes individuals from all relevant professional groups.

Rating: 7

Dietitian and Interdisciplinary expert committees including consumer representation and peak bodies

The views and preferences of the target population (patients, public, etc.) have been sought.

Rating: 5

Currently being undertaken. Could be more explicit in how this will inform practice points eg patients values and preferences

6. The target users of the guideline are clearly defined.

Rating: 7

3. Rigour of Development

7. Systematic methods were used to search for evidence.

Rating: 6

Full search strategy could be included in the technical document or Appendix

8. The criteria for selecting the evidence are clearly described.

Rating: 7

The strengths and limitations of the body of evidence are clearly described.

Rating: 7

Very well written, appropriate instruments used and transparent process

The methods for formulating the recommendations are clearly described.

Rating: 7

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Rating: 5

There is consideration of health benefits, side effects and risks in formulating recommendations. This could be strengthened by more explicit reporting of balance/tradeoff between benefits and harms/side effects/risks where appropriate and perhaps an overarching statement regarding how the development group considered the benefits and harms equally

12. There is an explicit link between the recommendations and the

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Rating: 7

Very well completed and easy to follow

The guideline has been externally reviewed by experts prior to its publication.

Rating: 5

The purpose and intent of the external review is not explicit and could be improved with also a more comprehensive description of the methods taken apart from AGREE II. It is assumed that the outcomes of the current public consultation will be included

14. A procedure for updating the guideline is provided.

Rating: 6

Methodology for the update is not explcit

4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

Rating: 7

The different options for management of the condition or health issue are clearly presented.

Rating: 7

Key recommendations are easily identifiable.

Rating: 7

Very well done

5. Applicability

18. The guideline describes facilitators and barriers to its application.

Rating: 5

Although implementation is well described, barriers are not currently identified either from this specific group or commonly found barriers.

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Rating: 7

This is a great strength of these guidelines

20. The potential resource implications of applying the recommendations have been considered.

Rating: 5

Resource implications in terms of dietetic staffing are well described. Cost implications was clearly considered in some chapters but was less obvious in others. An overarching statement re cost implications could be added to the methods

21. The guideline presents monitoring and/or auditing criteria.

Rating: 7

6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

Rating: 7

 Competing interests of guideline development group members have been recorded and addressed.

Rating: 7

Created online at www.agreetrust.org 16 January 2017

Nicole Saxby

From:

Anne Holland

Sent:

Monday, 16 January 2017 10:46 AM Nicole Saxby

To:

Cc:

Hayley See RE: CF Nutrition Guidelines - extra technical info for AGREEII assessments AgreeII_TSANZ_Holland.pdf

Subject: Attachments:

Hi Nicole,

Congrats on this amazing piece of work!

My AGREE-II assessment is attached. Most of it looks great, there are just a couple of things missing that we have already discussed and they are easily fixed.

Do you know what the process will be from here with the NHMRC? From our perspective the CCRS will need to see the comments from the public consultation, plus your group's response, prior to sending it to the TSANZ Board for endorsement.

Cheers

Anne

Appraiser: Piof. Anne Holland 16/1/2017 A. Holland@latrobe.edu.

1. The	verall objective(s) of the	guideli	ne is (a	re) spe	cifically	described.
	1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
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DOMAIN 2. STAKEHOLDER INVOLVEMENT

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DOMAIN 3. RIGOUR OF DEVELOPMENT

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DOMAIN 3. RIGOUR OF DEVELOPMENT continued

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page 248				4 - 17		
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Page 248						2 2
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DOMAIN 4. CLARITY OF PRESENTATION

	1 Strongly Disagree	2	3	4	5	6	Strongly Agree
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DOMAIN 5. APPLICABILITY

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Exec summary suggest what will be developed. ("Supplementary projects, page 8) but hasn't yet translating evidence into practice" points are used. O. The potential resource implications of applying the recommendations have been onsidered. Strongly Disagree 2 3 4 5 6 Strongly Agree		Bully market and before the least of the	2	3	4	(5)	6	and the second s
Strongly Disagree 2 3 4 5 6 Strongly Agree	bxec ("S. Tran	plementa, slating evi	Jana	ngest	2 W	hat page actic	8) k	be develope but hasn't yes into one us
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DOMAIN 5. APPLICABILITY continued

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DOMAIN 6. EDITORIAL INDEPENDENCE

Funded by TSAN2, CFA, CFNZ. Competing interests of guideline development group members have been raddressed. Strongly Disagree 2 3 4 5 6 Strongly Agree Therefore a statement in main document. Needs a statement in main document.
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document.

OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible	2	3	4	(5)	6	7 Highest possible
quality	and the same					quality

2. I would recommend this guideline for use

Yes	
Yes, with modifications	
No	

NOTES

Suggest inclusion of 'signiposts' in the main document to important information in the admin report: - full list of Picos
- funding
- methods for addressing Cols
- Col declarations for authorship group